# NONPHARMACOLOGICAL PREVENTION, MINIMISATION AND MANAGEMENT OF AGITATION IN THE ADULT INTENSIVE CARE UNIT

Development of preliminary Danish and Australian patient-centred clinical practice guidelines

By

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|---|---|
| AGREE-II | Appraisal of Guidelines for Research and Evaluation Instrument |
| CAM-ICU | Confusion Assessment Method for the Intensive Care Unit |
| CI | Confidence Interval |
| COI | Conflict of Interest |
| FoC | Fundamentals of Care |
| GRADE | Grading of Recommendations Assessment, Development and Evaluation |
| GIN | Guidelines International Network |
| ICU | Intensive Care Unit |
| IKT | Integrated Knowledge Translation |
| IQR | Interquartile Range |
| JBI | Joanna Briggs Institute |
| LOS | Length of Stay |
| M | Mean |
| MD | Mean Difference |
| Mdn | Median |
| n | Sample size |
| NHMRC | National Health and Medical Research Council |
| NICE | National Institute for Health and Care Excellence |
| NPS | Nonpharmacological Strategy |
| PADIS | Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption |
| PAD | Practice Guidelines for the Management of Pain, Agitation, and Delirium |
| PICS | Post-intensive Care Syndrome |
| PR | Physical Restraints |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| PTSD | Post-traumatic Stress Disorder |
| QE | Quasi-experimental Study |
| RAAS | Richmond Agitation Sedation Scale |
| RCT | Randomised Controlled Trial |
| SAS | Riker Sedation Agitation Scale |
| SD | Standard Deviation |
| SPSS | Statistical Package for Social Science |
| WHO | World Health Organisation |

# GLOSSARY

| | |
|---|---|
| Agitation | Agitation is a psychomotor disturbance characterised by a marked increase in motor activities and emotional tension, accompanied by some or all of the following: a loss of control of action, confusion, resistance or interruption of care, aggression, and change of vital signs. Modified from Chevrolet & Jolliet (2007, p. 1). |
| Barriers | Factors that hinder or make something challenging to achieve |
| Clinical Practice Guidelines | Practice guidelines are statements that include recommendations intended to optimise patient care that is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (Steinberg et al., 2011, p. 4) |
| Facilitators | Factors that help or make something easier to achieve |
| Family | Individuals who have a significant relationship with the patient (e.g., family, friend) |
| Managing agitation | A reactive strategy to stop or manage the behaviours when they occur so that they do not have serious consequences (Brasure et al., 2016). |
| Minimise agitation | A reactive strategy to reduce the severity of agitation. |
| Nonpharmacological Strategies | Any non-chemical intervention or approach that is targeted and replicable and potentially capable of obtaining a relevant benefit. Modified from Herguedas (2020, p. 4). |
| Nordic countries | Denmark, Sweden, Finland, Iceland, Norway, Greenland, and Faroe Islands. |
| Patient-centred care | Patient-centred care is about involving patients and respecting their individual needs and preferences, developing genuine clinician-patient relationships and considering the context in which care is delivered (Kitson et al., 2013b) |
| Physical Restraints | Any manually applied method that reduced a patient's ability to move freely (Arora et al., 2021; Devlin et al., 2018a). |
| Preventing agitation | Preventative strategy to reduce the occurrence, frequency, and severity of future episodes of agitation (Brasure et al., 2016). To investigate if interventions have preventative qualities, long-term effects must be measured. |
| Reducing agitation | In this thesis, this term is used to describe a process which prevents and/or minimises and/or manages agitation. |
| Scandinavia | Denmark, Sweden and Norway |

# THESIS SUMMARY


**Background**

Patient agitation is a common phenomenon in the intensive care unit (ICU) and can be caused by factors related to critical illness, unmet needs and reduced stress tolerance. The behaviours are distressing and can be dangerous for patients and clinicians. Psychoactive pharmacological agents such as sedatives can be effective and sometimes necessary to reduce patient agitation. However, due to the serious side effects of pharmacological agents, clinicians are also encouraged to consider nonpharmacological strategies (NPSs). Yet, no evidence-based guidelines exist for patient-centred nonpharmacological care. Care based on clinicians' personal preferences and experiences rather than on evidence is likely to result in ineffective practices and unnecessary pharmacological management.

**Aim**

The primary aim of this thesis was to develop preliminary patient-centred, evidence-based clinical practice guidelines for the nonpharmacological prevention, minimisation and management of patient agitation in Australian and Danish adult ICUs. A secondary aim was to identify the implications of developing clinical practice guidelines across two countries.

**Methods**

A systematic review of nurses' experiences of caring for agitated patients confirmed the need for the guidelines. A conceptual framework was developed to guide this study. The framework was informed by a concept analysis of agitation, theories on causes of agitated behaviours, the Fundamentals of Care Framework, and the JBI model of Evidence-Based Healthcare. A multiphase mixed methods study was undertaken to address the thesis aims. The first phase used a novel method to consult Danish and Australian patients, family members, ICU clinicians and researchers (n=51) to determine the scope of the guidelines. The second phase consisted of two systematic reviews synthesising and summarising existing evidence. The last phase involved a three-round modified Delphi study aiming to reach consensus on NPSs among Danish and Australian experts (n=114). The first round of the Delphi study was informed by the existing literature and advice from stakeholders. For items to be endorsed in the final guidelines, a consensus of ≥ 75% was required from Danish and Australian participants. Participants also rated the importance and feasibility of each included recommendation and the perceived barriers and facilitators of guideline implementation.

**Main findings**

In the first phase of this study, Danish and Australian stakeholders consulted through workshops, interviews, and written feedback expressed a strong need for clinical practice guidelines. Their advice resulted in significant changes to the final guidelines' scope and, consequently, the design

of the study. The second phase found limited evidence for any NPSs for agitation. The last phase identified a set of 63 clinical practice guidelines and presented these with linked evidence, undesirable effects, feasibility, importance, the certainty of the evidence, the strength of the recommendations and barriers and facilitators to guideline implementation. Together these recommendations form a new understanding of caring for agitated patients in the ICU. Unique to this is the strong focus on establishing trusting staff-patient relationships, optimising staff's caring behaviours, involving family, identifying causes of agitation and supporting staff to provide NPSs. By using NPSs, staff connect with patients, support their individual needs, motivate and give them strength to engage in health recovery activities and rise above discomforts that cannot be easily relieved. This study also discovered potential threats to patient-centred care, including physical restraints (PRs) and discontinuity of care. How ICU clinicians deal with agitation is likely to reflect the broader organisational culture and the value organisations place on nonpharmacological care for agitated patients and care for their staff. Using NPSs requires unique skills and staff who feel safe and empowered to take on the role supported by their leaders with adequate resources, knowledge and training, and emotional support. This thesis found that developing guidelines across countries is possible and advantageous. Developing international guidelines avoids duplication of work and ensures better patient outcomes globally. In addition, bringing knowledge and evidence together from different sources can arguably create more comprehensive guidelines. This study also created an awareness of different cultures and how these affect patient-centred care. Guideline developers need to consider these differences and how they can develop guidance that allows contextualisation of recommendations. While developing guidelines across countries is important, it requires resources and careful planning.

**Conclusion**

This thesis makes several significant original contributions to knowledge. First, it provides a new conceptual understanding of agitation in the ICU. Second, it explores nurses' experiences of caring for agitated patients and finds that agitation management is accompanied by emotional exhaustion. Third, it comprehensively summarises the existing evidence on NPSs for agitation and through a Delphi study identifies a set of clinical practice guidelines. This study also advances guideline development. It provides an example of how a conceptual framework can be used to increase the rigour of guideline development and ensure the development of patient-centred guidelines. It also provides an innovative way of consulting international stakeholders on guidelines’ scope. Overall, it is the hope that the final guidelines will assist clinicians' effective clinical decision-making, promote evidence-based practice and improve patient outcomes.

# DECLARATION

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Signed

Date 25th February 2023

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This thesis was prepared without the use of a professional editor.

# LIST OF PUBLICATIONS, AWARDS AND CONFERENCE PRESENTATIONS

## Publications

Adams, A. M. N., Chamberlain, D., Grønkjær, M., Thorup, C. B., & Conroy, T. (2021). Caring for patients displaying agitated behaviours in the intensive care unit–A mixed-methods systematic review. *Australian Critical Care* 35(4): 454-465. https://doi.org/10.1016/j.aucc.2021.05.011 (Appendix 1).

Adams, A. M. N., Chamberlain, D., Thorup, C. B., Grønkjær, M., & Conroy, T. (2022). Ethical and feasible stakeholder engagement in guideline development. *Collegian*. https://doi.org/10.1016/j.colegn.2022.08.003 (Appendix 2)

Adams, A. M. N., Chamberlain, D., Grønkjær, M., Thorup, C. B., & Conroy, T. (2022). Nonpharmacological interventions for agitation in the adult intensive care unit: A systematic review. Australian Critical Care. https://doi.org/10.1016/j.aucc.2022.02.005 (Appendix 3).

## Awards

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2020: ACCCN Diane Chamberlain Seeding Grant $5000

2021: CNHS HDR Student Publication Award $500

2022: ACCCN members professional fund support to attend a conference in Sydney $250

2022: CNHS HDR Student Publication Award $500

2022: Erik Elgaard Sørensen Travel Grant $ 6850

2020-2022: CNHS Research Student Maintenance (RSM): $6000

**Conference presentations**

**Adams**, AMN D Chamberlain, C Brun Thorup, M Grønkjær, T Conroy (2021) *International consultation of stakeholders to determine the scope of clinical practice guidelines*, Guidelines International Network (GIN) Conference 2021, p. 143 can be found here https://g-i-n.net/wp-content/uploads/2021/10/GIN-Conference-2021-Abstract-Book.pdf

**Adams,** AMN (2021), *Agitating for change*, College of Nursing and Health Sciences, Flinders University, 2021 Asia-Pacific 3MT Competition. This presentation made it to the Flinders University Semi-Final.

**Adams**, AMN Chamberlain, D., Grønkjær, M., Thorup, C. B., & Conroy, T *Are nonpharmacological interventions for patient agitation effective?* Presented at the 2022 ANZiCS/ACCCN conference in Sydney. Abstract published in the *Australian Critical Care*, Vol 35: S22. https://doi.org/10.1016/j.aucc.2022.08.079

**Adams,** AMN (2022) *Udvikling af en klinisk retningslinje for non-farmakologisk håndtering af agitation på intensivafdeling*, Intensive Symposium, Hvide Hus, Aalborg Denmark. Invited international speaker.

**Adams**, AMN (2023) AMN Chamberlain, D., Grønkjær, M., Thorup, C. B., & Conroy, T Recommendations for non-pharmacological management of patient agitation in the adult ICU. Presented at the 2023 ANZiCS/ACCCN conference in Adelaide. To be published later in 2023.

**Interviews**

In 2022 I was interviewed by the Danish critical care journal *Dråbe Nyt*. The publication focusing on my PhD and international research collaboration can be found here: https://draabe-nyt.dk/2022/06/09/et-forskningsprojekt-paa-tvaers-af-kloden/

I have also been interviewed about my PhD project by the college marketing team. The interview can be found here https://www.flinders.edu.au/fearless/global-perspective-sparks-passion-for-change

# THESIS STRUCTURE OVERVIEW

This thesis is structured into ten chapters. While the introduction chapter briefly introduces the research and the literature review identifies a research gap, the conceptual framework provides an in-depth understanding of essential concepts and provides the argument for carrying out the research. It is important to know that developing the conceptual framework was an iterative process that occurred throughout this research. Parts of this thesis have been published. Publications will be referred to at the beginning of the chapter from which they arose. Individual publications are presented in Appendices 1, 2 and 3.

**Chapter 1: introduction** sets the scene for this study and provides the rationale for why I chose to focus on identifying NPSs for agitation in the ICU. It presents the primary aim and objectives and how this study provided significant original contributions to knowledge.

**Chapter 2: literature review** identifies a gap in the existing literature. It consists of two parts. Part one is a systematic review that describes nurses' experiences of caring for agitated patients. Part two searches for existing guidelines on NPSs for agitation.

**Chapter 3: conceptual framework** presents the framework that guided this study. This framework aimed to clarify concepts and how they relate to each other, supported me in making justified choices about the research, and provided a lens through which the findings could be interpreted.

**Chapter 4: philosophical and methodological underpinnings** presents pragmatism as the chosen philosophical paradigm of this study and the chosen multiphase mixed methods methodology.

**Chapter 5: methods** presents the methods employed for the studies in study phase one and phase three. The methods for study phase two are presented together with the results of study phase two in chapter seven. This choice was made to ensure the flow of reading, and since study phase two required less detailed justifications.

**Chapter 6: phase one - stakeholder consultation findings** presents the results from stakeholder consultation and the consequent decisions made related to the scope of the final guidelines.

**Chapter 7: phase two – systematic reviews findings** presents the results from two systematic reviews describing the existing literature on the nonpharmacological management of agitation.

**Chapter 8: phase three - Delphi study findings** presents the results of a modified three-round Delphi study.

**Chapter 9: discussion** integrates and discusses the major findings of the thesis. This chapter also discusses the implications of developing guidelines across countries.

**Chapter 10: conclusion** concludes the thesis by summarising the original contributions of this thesis and the limitations to these. Implications for future practice and research are outlined.

# CHAPTER 1: INTRODUCTION

## 1.1 Introduction

Patient agitation is a major concern in intensive care units (ICUs) globally. Agitated behaviours are distressing and can be dangerous for patients, families and clinicians if not managed effectively. While pharmacological management plays an essential role in keeping patients safe and treating underlying causes of agitation, overuse is associated with severe adverse effects. Consequently, ICU clinicians are encouraged to use nonpharmacological strategies (NPSs) when possible. To date, however, no guidance exists in this area of practice. Therefore, this study aimed to develop preliminary clinical practice guidelines for the nonpharmacological prevention, minimisation and management of agitation in Australian and Danish adult ICUs. This chapter introduces the study by first presenting the background and context, followed by a presentation of the research problem, aim, questions and objectives. It will then describe the original contributions of this thesis and my motivations for carrying out the study.

## 1.2 Background

It is important to know the context of this study to fully understand the challenges experienced by ICU clinicians, the need for clinical practice guidelines, and the need to develop these across two countries.

### 1.2.1 The intensive care unit

ICUs provide specialised care to critically ill patients suffering from life-threatening organ system failure (Marshall et al., 2017). The concept of intensive care is relatively young, originating back in 1953 in Copenhagen, Denmark. It was the anaesthetist Bjørn Ibsen, often called the "father" of intensive care, who set up a unit for polio victims needing positive pressure ventilation (Berthelsen & Cronqvist, 2003; Kelly et al., 2014). It only took a few more years (1961) before an ICU offering mechanical ventilation opened in Sydney, Australia (Judson & Fisher, 2006). Since this time, advanced medication, technology and specialised staff working in multidisciplinary ICU teams have all burgeoned, coinciding with a tremendous increase in ICU survival rates (Marshall et al., 2017). The ICU offers a specialised, complex, dynamic environment that carries out technical and invasive procedures on patients who are severely ill and at a high risk of dying (Backes et al., 2015). Patients are frequently surrounded by mechanical ventilators, monitors, intra-aortic balloon pumps, infusion pumps, renal replacement therapy machines, and other technical equipment. The environment has been described as hostile, noisy and stressful (Alasad et al., 2015; Sanson et al., 2021; Wenham & Pittard, 2009) for patients who feel weak, anxious, isolated, unable to communicate and restricted by equipment (Egerod et al., 2015; Halvorsen et al., 2022).

### 1.2.2 Agitation

Among many distressing neuropsychiatric symptoms in ICU patients, such as psychosis, apathy, depression and anxiety, agitation is perhaps the most challenging and a significant worry for ICU clinicians (Freeman et al., 2022b). Agitation is common (Almeida et al., 2016; Burk et al., 2014a; Mahmood et al., 2018), often disrupts life-saving treatment, and is linked to a number of adverse outcomes such as unintentional extubation (Abbas & Lutfy, 2019; da Silva & Fonseca, 2012), line removal (Jaber et al., 2005), and increased length of stay (LOS) (Woods et al., 2004). Agitation can be upsetting for the person who experiences it (Boehm et al., 2021; Freeman et al., 2022a; Hume, 2020), for the involved ICU clinicians (Lamiani et al., 2020) and for witnessing family members (Boehm et al., 2021; Bohart et al., 2019; Jensen et al., 2017).

Chevrolet & Jolliet (2007) define agitation in ICU as "a psychomotor disturbance characterized by a marked increase in both motor and psychological activities, often accompanied by a loss of control of action and a disorganization of thought" (Chevrolet & Jolliet, 2007, p. 1). Clinicians frequently confuse agitation with delirium (LeBlanc et al., 2018), but it is critical to distinguish between the two conditions. According to Whitehouse et al. (2014), ICU patients can be agitated without being delirious. While delirium is often a cause of agitation (Hickin et al., 2017), there are also a number of other factors that can cause agitation, such as discomfort and unmet needs (Honiden & Siegel, 2010), drug withdrawal (Stewart et al., 2019), poor gas exchange, metabolic disturbances (Honiden & Siegel, 2010) and head trauma (Fraser et al., 2000). Delirium, which presents as hypoactivity (43.5%), hyperactivity (1.6%) or, most frequently, a combination of the two (54.9%) (Hickin et al., 2017), has been defined as a state of abrupt severe confusion or changed level of consciousness (Barr et al., 2013). Agitation is seen in delirious patients who present with hyperactivity. Since there is limited evidence of effective NPSs for delirium (Bannon et al., 2019; Burry et al., 2021), exploring interventions for agitation is likely to offer a more nuanced view of the treatment options for hyperactive delirious patients. Such research would also be beneficial for the many agitated patients who fall outside the delirium spectrum.

Although caring for patients displaying agitated behaviours in ICU is both important and challenging for ICU clinicians, there has been a scarcity of research in this area. Scholars in critical care call for research on what "standard care" in this area should look like (Freeman et al., 2018). Traditionally, pharmacological agents such as antipsychotics, analgesics and sedatives have been used to treat agitation. However, with the increasing expectation and evidence-based recommendation to minimise sedation of ICU patients, clinicians require effective NPSs for managing agitation.

### 1.2.3 The need to keep patients more awake

Traditionally ICU patients have been deeply sedated, as medically-induced coma was seen as a more humane way of keeping patients mechanically ventilated. While sedation continues to be

crucial in the ICU, as it keeps patients safe and facilitates weaning and extubation (Buckley et al., 2021; Devlin et al., 2018a; Ostuzzi et al., 2020), sedatives are now being administered more judiciously. This is due to the recognition of the significant adverse effects sedatives can have, such as worsening of delirium and agitation, haemodynamic and respiratory instability, more days with mechanical ventilation, longer ICU stays, and increased mortality (Daniels et al., 2018; Devlin et al., 2018a; Girard et al., 2008; Strøm et al., 2010; Williamson et al., 2019). Over the last decades, ICU clinicians have thus taken a "less is more" approach, whereby they are accepting less sedation (Kelly et al., 2014; Vincent, 2019).

While caring for more awake and interactive patients has many advantages, it has necessitated a change in nurse-patient interactions. Some scholars have called this a paradigm shift in critical care nursing (Devabhakthuni et al., 2012; Egerod et al., 2015). Moving from caring for heavily sedated patients to lightly sedated patients has been described as rewarding yet demanding (Holm & Dreyer, 2018; Karlsson & Bergbom, 2015; Mortensen et al., 2019). Caring for more awake patients also increases the risk of caring for more agitated patients, an area of critical care nursing that has been described as particularly challenging (Everingham et al., 2014).

Although clinical practice guidelines strongly advise clinicians to keep patients lightly sedated (Devlin et al., 2018a), research indicates that over-sedation of patients continues to be an issue (Dos Santos et al., 2016; Jackson et al., 2009). A multicentre (41 ICUs) study carried out in Australia, and New Zealand found that 10% of mechanically ventilated patients were deeply sedated with a doubtful clinical indication for this and that only two-thirds of patients had their levels of sedation formally assessed (Elliott et al., 2013). In Puerto Rico, 40% of patients were deeply sedated (Arroyo-Novoa et al., 2019). Nordic countries use lighter sedation than other European countries (Egerod et al., 2013a; Nedergaard et al., 2022; Olsen et al., 2020; Strøm et al., 2010), suggesting greater adoption of recent guidelines.

### 1.2.4 Lack of guidelines on NPSs for agitation

There may be many reasons why ICU clinicians continue to opt for pharmacological agents when caring for patients displaying agitated behaviours. Two recent integrative reviews (Freeman et al., 2018; Teece et al., 2020) indicate that the current management of agitation in the ICU is inconsistent and based on personal preferences rather than on evidence. From these reviews, it is clear that there is a paucity of evidence-based guidance or published discussion on how such behaviours should be managed within a patient-centred non-pharmacological framework (Freeman et al., 2018; Pandharipande et al., 2017).

Clinical practice guidelines offer evidence-based recommendations on how to best manage various patient conditions (Steinberg et al., 2011). Research has demonstrated how such guidelines can increase consistency, reduce inefficient practices and improve patient outcomes (Steinberg et al.,

2011). Clinical practice guidelines on NPSs for agitation are crucial to empower clinicians to make informed decisions about any NPS they consider employing. It is also important that these guideline recommendations are patient-centred. Patient-centredness refers to interventions that consider the clinician-patient relationship, the patient's needs and preferences and the context in which care is delivered (Kitson et al., 2013b). In ICU, a highly technological environment primarily focusing on saving patient lives (Kvande et al., 2022; Minton et al., 2018) NPSs may not always be patient-centred. For example, the use of PR may be effective in preventing harm from device removal, but the intervention may inadvertently result in negative patient experiences and lead to posttraumatic stress disorder (PTSD) (Cui et al., 2021b; Franks et al., 2021; Perez et al., 2022; Perez et al., 2019; Smithard & Randhawa, 2022). While ICU patient survival has increased, there is an increased concern related to the quality of survival. For instance, it has been found that 20% of ICU survivors experience symptoms of PTSD affecting their quality of life (Franks et al., 2021).

In the 2013 international guidelines on the management of pain, agitation and delirium (PAD) in the ICU, clinicians are encouraged to use NPSs before administering sedatives (Barr et al., 2013). However, the guidelines provide very few examples of effective NPSs. Experts (Chevrolet & Jolliet, 2007) also suggest using NPSs to prevent agitated behaviours:

> "Nonpharmacological treatment must be considered first, common sense and good clinical practice being the rule to avoid light anxiety in ICU patients, for example, reassurance, a comfortable position in the bed, voiding of a full and painful bladder, and so on" (Chevrolet & Jolliet, 2007, p. 4).

Although preventing and managing agitated behaviours may seem straightforward, the literature reveals that these "common sense" strategies may not be clear and obvious to clinicians (Freeman et al., 2019). Identifying causes of agitated behaviours is challenging when patients are unable to communicate and are critically ill. A lack of knowledge on effective patient-centred NPSs can lead to excessive use of PR (Almomani et al., 2020; Ertuğrul & Özden, 2020; Suliman et al., 2017).

The 2013 guidelines on pain, agitation and delirium were updated in 2019 (Devlin et al., 2018a) to the Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption (PADIS) guidelines. Although clinicians are encouraged to use less PR and pharmacological agents, the guidelines fail to provide any alternative strategies on how to manage agitated behaviours (Devlin et al., 2018a). The guidelines conclude that:

> "The role of nonpharmacologic strategies to reduce agitation, anxiety, and distress in terms of sedative choice and requirements is uncertain, and thus, no recommendations could be made in this regard" (Devlin et al., 2018a, p. 841)

This suggests that guideline developers are unable to provide recommendations on NPSs due to low evidence in the area. The dearth of studies on agitation in the ICU may be related to the complexities that exist around interventions for supporting this group of patients. The plethora of confounding variables makes it difficult, or even impossible, to carry out rigorous controlled trials

(Cohen-Mansfield et al., 2014). Considering how the PADIS guidelines have been implemented worldwide, guiding both practice and education (Zerfas et al., 2022), it is problematic that there are no recommendations for NPSs for agitation in these guidelines.

It is not unusual that in the absence of high-quality evidence, guideline developers decide to provide 'no recommendations' or even withdraw a guideline topic. Several papers argue that we need to test more interventions to identify effective strategies for agitation (Carpenter et al., 2020; Pandharipande et al., 2017). Yet, Loblaw et al. (2012) argue:

> "…it is often the areas of greatest uncertainty in which the evidentiary base is incomplete, and thus, guidelines are needed most" (Loblaw et al., 2012, p. 3136)

These scholars highlight that it is particularly important, as well as feasible, to create guidelines where evidence is limited (Loblaw et al., 2012). Considering the serious consequences of agitation in the ICU and the adverse effect of physical restraints and sedation, it is crucial to find ways of developing clinical practice guidelines.

### 1.2.5 Arguments for developing guidelines across different contexts

There are some important advantages of attempting to develop guidelines on NPSs for agitation across countries. First, as described earlier in this chapter, there is some evidence that the Nordic countries use less sedation and PR. Developing guidelines between a Nordic country and a non-Nordic country that share fairly similar health, social and political systems provides an opportunity to share experiences across borders and, through curiosity and discussions, reach a better understanding of NPSs (Grønkjær & Rasmussen, 2020). Second, collaboration across borders is also about “pooling resources” (Grønkjær & Rasmussen, 2020). Developing guidelines is resource-demanding; therefore, it makes sense to develop guidelines applicable to two countries if possible. Finally, researchers need to consider how health can be improved not just within a country, but also globally (Jordan et al., 2019). Guidelines that are generalisable to two different countries, Denmark and Australia, are likely to also be applicable to multiple countries, thus making an international impact on health.

## 1.3 Problem statement

Patient agitation is a concern in ICUs globally. Agitative behaviours are distressing and can be dangerous for patients, families and clinicians if not managed well. While pharmacological management plays an essential role in keeping patients safe and treating underlying causes of agitation, an overuse is associated with severe adverse effects. Consequently, ICU clinicians are encouraged to use NPSs when possible. However, there are currently no patient-centred, evidence-based clinical practice guidelines on NPSs to prevent, minimise or manage patient agitation in the ICU. Such guidelines are urgently needed to support clinicians in their clinical

decision-making processes and to improve patient care without excessive use of pharmacological agents.

## 1.4 Research aims

The primary aim of this thesis is to develop preliminary patient-centred, evidence-based clinical practice guidelines for the nonpharmacological prevention, minimisation and management of patient agitation in Australian and Danish adult ICUs.

A secondary aim is to identify the implications of developing clinical practice guidelines across two countries.

## 1.5 Research objectives

In order to address the research aims, this thesis has the following objectives:

- To identify how various stakeholders can be consulted to determine the scope of clinical practice guidelines.
- To consult various Danish and Australian stakeholder groups to determine the scope of the clinical practice guidelines.
- To systematically review the evidence on NPSs to prevent, minimise and manage patient agitation.
- To draft tentative recommendations for nonpharmacological prevention, minimisation and management of agitation in the ICU.
- To identify which recommendations reach a high level of statistical consensus among Danish and Australian participants.
- To determine the extent to which experts from different stakeholder groups and in the two countries agree about recommendations and to identify areas of discordance.
- To evaluate the perceived feasibility and importance of included nonpharmacological recommendations.
- To identify potential barriers and facilitators to guideline implementation.

## 1.6 The significant original contribution of this research

ICU scholars call for better ways to care for agitated patients in the ICU (Egerod et al., 2020; Freeman et al., 2018). A key concern is that patient agitation in the ICU can lead to interruption of life-saving treatment, poor patient and family experiences and staff distress and exhaustion. Due to the adverse effects of pharmacological agents, clinicians are encouraged to use NPSs when possible. The issue is that ICU clinicians have no guidance on how to best care for these patients and what NPSs to use.

This study answers this call by being the first to offer a comprehensive set of guidelines on NPSs for patient agitation in the ICU. Identifying effective NPSs will enhance our limited understanding of agitation, and the developed practice guidelines will likely improve patient, family and staff outcomes. This study goes beyond developing guidelines; it also highlights the implications of developing guidelines across two countries. The guideline development process presented here is novel in that it is informed by a uniquely developed conceptual framework and a novel method for consulting various stakeholders to identify the guidelines' scope. These methods are predicted to be valuable for future researchers and guideline developers. This study is also the first to review nurses' experiences of caring for agitated patients and to comprehensively review the existing literature on NPSs for agitation in the ICU.

The findings from this study are likely to inform critical care nursing standards, practice, education and future research internationally. It is also hoped that it will initiate a valuable debate on the limitations of and opportunities for developing clinical practice guidelines across countries.

## 1.7 Researcher's motivation

My years of clinical work experience as a Registered Nurse employed in Norwegian and Australian ICUs have motivated this project. I have observed broad practice variations in the way patient agitation is managed. Approaches differ between countries, institutions and individual clinicians. At times I have observed staff frustrations resulting in the neglect of patients and their needs, the overuse of sedation, the inappropriate application of PR, and the beratement of patients' behaviour. I have found it particularly distressing when patients with pre-existing vulnerabilities, such as those from culturally diverse backgrounds, those with an intellectual disability, and/or those with a history of mental illness or trauma, have been subjected to such actions. At times I have struggled with these experiences and found them profoundly disturbing. I have felt there is, at times, a misunderstanding and even stigmatisation by staff towards the vulnerable and confused agitated patients, whose agitation causes them to act in ways that are not consistent with their usual nature.

I have also observed staff who have been able to reduce agitation without excessive use of pharmacological agents or PRs, and have come to believe that their effective strategies should be first-line strategies for all agitated ICU patients. I believe all nurses want to provide quality patient-centred care for their patients but sometimes lack the framework and guidance to do this. Not being able to provide the best care for our patients can cause moral distress and negatively affect nurses' willingness to work in the ICU (Atashzadeh-Shoorideh et al., 2021). With these experiences in mind, I wonder how other ICU nurses experience caring for agitated patients and what challenges they face, how we can improve patient experiences, what best practices for achieving this would look like, and whether it is feasible to ensure all patients receive the same standard of care.

## 1.8 Conclusion

Chapter 1 has set the scene for this study by describing the contemporary ICU, the challenges of caring for less sedated patients and the need for guidelines on NPSs to reduce patient agitation. Nordic countries appear to use less sedation and PRs in the ICU, providing a solid argument for including both a non-Nordic and a Nordic country in the study. Together these observations form the basis for the overall aim of this thesis: to develop preliminary patient-centred, evidence-based clinical practice guidelines for nonpharmacological prevention, minimisation and management of patient agitation in two countries, Denmark and Australia. A secondary aim was to identify the implications of developing guidelines across countries. This chapter has concluded by describing the expected original contributions to knowledge, and the personal motivations for carrying out this study. Chapter 2 reviews the existing literature on nurses' experiences of caring for agitated patients in the ICU and identifies that no guidelines exist on nonpharmacological strategies to reduce agitation.

# CHAPTER 2: LITERATURE REVIEW

## 2.1 Introduction

Chapter 1 presented the research aims, background and rationale for this research. This chapter presents a mixed methods systematic literature review exploring nurses' experiences of caring for agitated patients in the ICU, and the factors affecting their ability to carry out their role effectively. This review identifies a clear need for clinical guidance on NPSs for agitation in the ICU. This chapter finishes with a search for existing clinical practice guidelines on the nonpharmacological management of agitation.

## 2.2 Caring for patients displaying agitated behaviours in the intensive care unit – a mixed-methods systematic review

A version[1] of this section of the chapter has been published in Australian Critical Care in the article:

> Adams, A. M. N., Chamberlain, D., Grønkjær, M., Thorup, C. B., & Conroy, T. (2021). Caring for patients displaying agitated behaviours in the intensive care unit–A mixed-methods systematic review. *Australian Critical Care* 35(4): 454-465. https://doi.org/10.1016/j.aucc.2021.05.011

The text has been modified to suit this chapter, but the content directly overlaps with the published version (see Appendix 1 for the published version).

## 2.3 Background

Nurses spend more time at the bedside than any other clinician in ICU. Through frequent observations and continuous care, they play a major role in minimising agitated behaviours. However, research indicates that nurses may be using psychoactive pharmacological agents more than necessary (Dos Santos et al., 2016; Elliott et al., 2013; Jackson et al., 2009; Shehabi et al., 2013; Walsh et al., 2016), and lack knowledge on alternative strategies (Freeman et al., 2016; Teece et al., 2020). An integrated review revealed a lack of knowledge of 'standard care' for patients with agitated behaviours in ICU and a dearth of research in this area (Freeman et al., 2018). Furthermore, care for agitated patients in ICU may not be optimal. Freeman et al. (2019) found that 76.3% of 163 UK health professionals believed management of agitation could be improved, and many felt unsure about how to manage agitation in ICU (Freeman et al., 2019). A comprehensive search failed to identify any previous systematic reviews exploring how nurses experience caring for patients with agitation in ICU. Such information is crucial for informing future

[1] I contributed 80% to the research design, 90% to the data collection and analysis and 80% to the writing and editing of the manuscript.

practice and research to ensure high-quality care for patients displaying agitated behaviours in ICU.

## 2.4 Objectives

The aim of the systematic review was to identify and synthesise the best available qualitative and quantitative evidence of nurses' experiences of caring for patients displaying agitated behaviours in the adult ICU. This review also sought to identify strategies nurses use when caring for patients displaying agitated behaviours and the factors affecting this care.

## 2.5 Methodology

A mixed-methods review was chosen as it provides a more comprehensive foundation for decision-making than single-method reviews (Stern et al., 2020). A convergent integrated approach, as described by Joanna Briggs Institute (JBI), was deemed appropriate due to the nature of the research question (Lizarondo et al., 2020). This approach allows reviewers to transform and combine qualitative and quantitative findings. A process of meta-aggregation was followed (Lockwood et al., 2015), integrating qualitative and quantitative research findings across studies to create generalisable statements. Such statements can then be used to guide practice, policies and future research. Meta-aggregation does not attempt to re-interpret data, find new meaning in data or generate theory (Hannes & Lockwood, 2011). The systematic review protocol was registered with PROSPERO international prospective register of systematic reviews, registration number CRD42020191715

### 2.5.1 Data sources and search strategy

This study used the SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) framework to identify key parameters, as it has been suggested to be more effective for mixed methods studies than the traditional PICO (Population, Intervention, Comparison, Outcome) tool (Cooke et al., 2012). Two modifications were made to the framework (Table 1) to ensure the review was inclusive of any relevant literature and focused on the specific context of interest: the last component, "Research type", was removed to avoid missing papers that did not explicitly specify the research type, and "Context" was added due to the importance of the ICU environment. Overall, the search strategy was broad and sensitive to avoid missing relevant articles. An initial search in the Medical Literature Analysis and Retrieval System Online (MEDLINE) was undertaken to identify keywords and subject headings. With support from the supervisory team and a librarian, a search template was created (Appendix 4). The search of MEDLINE, Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsycINFO, Web of Science, Emcare, Scopus, ProQuest and Cochrane Library was completed in July 2020. All identified articles were imported from the databases into Endnote X9 where duplicates were removed. The initial retrieval of papers for appraisal depended on their relevance to the research aim. I reviewed the title and abstracts of

the retrieved articles. A full-text screening was then conducted to ensure that the retrieved articles met the inclusion criteria. Citations and reference lists were also screened for relevant articles. I discussed whether the identified papers met the inclusion criteria with a second reviewer.

**Table 1 SPIDEC (a modified SPIDER framework)**

| S | PI | D | E | R* |
|---|---|---|---|---|
| **S** | PI | D | E | C |
| **Sample Population.** | **Phenomenon of Interest** Interest related to event, activity, process. | **Design** Research methods. | **Evaluation** Attitudes, views, experiences. | **Context** Setting. |
| Critical care nurses. | Caring for an agitated patient. | Interviews, surveys, observations. | Experiences. | Intensive care units. |

*** Research type**

## 2.5.2 Eligibility criteria

### *2.5.2.1 Inclusion criteria*

Studies were eligible for inclusion if they contained descriptions or illustrations related to nurses' experiences or attitudes towards caring for patients displaying agitated behaviours in the adult (18 years or older) ICU. This review sought to include qualitative, quantitative and mixed methods studies. All types of quantitative and qualitative studies were included. Mixed methods studies were considered if the data from the quantitative or qualitative components could be extracted. Only primary, peer-reviewed and published studies were included. Theses and dissertations were included since these have been subjected to a rigorous review process. To carry out a broad exploratory search, no limitation was placed on the age of the data. Studies had to be published in English.

### *2.5.2.2 Exclusion criteria*

Grey literature was excluded as it was less likely to have undergone a rigorous peer-reviewed process.

## 2.5.3 Quality appraisal process

The results of systematic mixed-methods reviews are intended to have immediate applicability to practice (Lizarondo et al., 2020; Stern et al., 2020). Thus, it was important to only include studies of sufficient quality and to provide a transparent report of this quality. All studies that met the inclusion criteria were appraised by two investigators independently (I was involved in this process together with supervisors TC and DC). We used JBI's "Checklist for Qualitative Research" for qualitative studies, and the qualitative component of mixed methods studies (Lockwood et al., 2015) (see Appendix 5), and "Checklist for Analytical Cross-Sectional Studies" for quantitative studies, and the quantitative component of mixed methods studies (Moola et al., 2017) (see Appendix 6). The JBI

organisation confirmed that the ‘Checklist for Analytical Cross-Sectional Studies’ was the correct tool to use for surveys/questionnaires[2]. The questions in the appraisal tool were rated as “yes”, “no”, “unclear” or “not applicable” (NA). NA was rated if a question was not relevant to the method used. For example, NA was rated to the question: "Are the outcomes measured in a valid and reliable way?", when a study did not measure any particular outcomes. An overall appraisal score was calculated by adding all the “yes” ratings and dividing this by the number of applicable ratings. From this scoring system, all studies were ranked as providing weak, adequate, moderate or strong evidence. A study was assessed as weak if up to and including 49% of the critical appraisal items had not been fulfilled, adequate if 50-69% had been fulfilled, moderate if 70-85% had been fulfilled, and strong if 86-100 % had been fulfilled. This classification system is commonly used to grade the quality of outcomes (Gorski et al., 2021; Karran, 2005; Muchtar et al., 2020), and often used to rank studies for their methodological rigour (de Jesus Santos Nascimento et al., 2022; Péculo-Carrasco et al., 2022). It was decided a priori to exclude studies of weak evidence. Where two reviewers were unable to reach a consensus on the inclusion of a paper, a third reviewer was invited to contribute to a final decision.

### 2.5.4 Data Extraction

Qualitative and quantitative data were extracted by one reviewer using JBI’s standardised data extraction tool SUMARI (Lockwood C, 2020). A second reviewer assessed the accuracy of extraction. Data extracted included: 1) characteristics of primary research reports including year, study methods, phenomenon of interest, setting, participant characteristics and sample size, strengths and limitations, and outcomes of relevance to the review question; and 2) findings relevant to the research question. Quantitative data comprised descriptive statistical data, whether statistically significant or not. Qualitative data extraction was conducted to remain as close to the originally reported themes as possible, to prevent re-interpretation (Hannes & Pearson, 2012). As the reported themes were often broad and not always exclusively focussed on nurses’ experiences of agitated behaviours, each theme was screened for emerging concepts or descriptions of experiences of agitation. Verbatim extracts of the authors' analytical interpretations were then labelled as ‘findings’, similar to the way Hannes and Pearson (2012) searched for ‘obstacles’ in their original themes. Data were extracted only when it was evident that the reported experiences related to patient agitation. For instance, studies reporting experiences of delirium were only included if it was clear that the experiences involved agitated behaviours. As per the JBI methodology, all qualitative findings were assigned a level of credibility determined by their associated illustrations (direct quotes or field work observations) from participants’ voices or researcher observations. Findings were unequivocal (U) when their illustration was beyond any reasonable doubt, credible (C) when the association between the illustration was unclear, and nonsupported (NS) if findings were not supported by an illustration (Lockwood C, 2020). All

[2] Janine Margarita Dizon, personal communication, August 13, 2020

extracted data and attributions of credibility were checked for accuracy and agreed upon by a second reviewer.

### 2.5.5 Data transformation and synthesis

Following extraction, quantitative data were converted into textual findings (Lizarondo et al., 2020). All findings, qualitative and quantitative, were aggregated into categories based on the similarity of meaning using the JBI-SUMARI tool. Each category was accompanied by a category description, and an explanatory statement conveying the meaning of the group of findings. These categories were then subjected to synthesis to produce a set of overarching synthesised findings. An example of the process of moving from individual findings, to categories to synthesised findings is illustrated in Table 2. This example also describes the levels of credibility of each finding. Findings were discussed with the supervisory team to ensure rigour in the interpretation of findings.

**Table 2 Example of a synthesised finding**

| Synthesised finding | Categ*ories* | Findings* |
|---|---|---|
| **Synthesised finding 3: uncertainty in how to manage agitated behaviours**<br><br>Nurses described a lack of consensus and guidance on how to manage patients displaying agitated behaviours. The role of pharmacological and NPSs and the factors affecting nurses' decision-making processes around these strategies is poorly understood. | Assessment of agitation | How to identify agitated behaviours (U)<br>Scepticism about assessment (C)<br>Identifying causes of agitation (U)<br>Lack of appropriate assessment tools (U) |
| | The role of sedation when caring for patients displaying agitated behaviours | Uncertainty around when to sedate (U)<br>Sometimes a need for immediate sedation (C)<br>The moral component (U)<br>Questioning optimal sedation (C)<br>Distressing to observe and manage (U)<br>Sedation should be a last resort (C)<br>Chemical and/or PR at times necessary (U)<br>When sedation is necessary (U)<br>Difficult to achieve individual sedation (U)<br>Easier to increase sedation (NS)<br>Lack of time and tolerance (NS) |
| | Nonpharmacological care strategies | Challenging and rewarding (C)<br>Difficult to use NPSs (C)<br>Partnering with family members (C)<br>Knowing when and how to respond (C)<br>A familiar voice or face (C)<br>Family causing patient agitation (C)<br>Difficult families (C)<br>Value of communication (C)<br>Improving sleep patterns (U)<br>The challenging ICU environment (C)<br>Inability to make the patient comfortable (NS) |
| | Lack of training and consensus on how to manage patients displaying agitated behaviours | Lack of guidance and consensus (C)<br>Lack of training (quantitative finding)<br>Unsure about how to manage (NS)<br>Individual preferences (NS) |

*Credibility of findings: U = unequivocal, C = credible, NS = not supported by citations

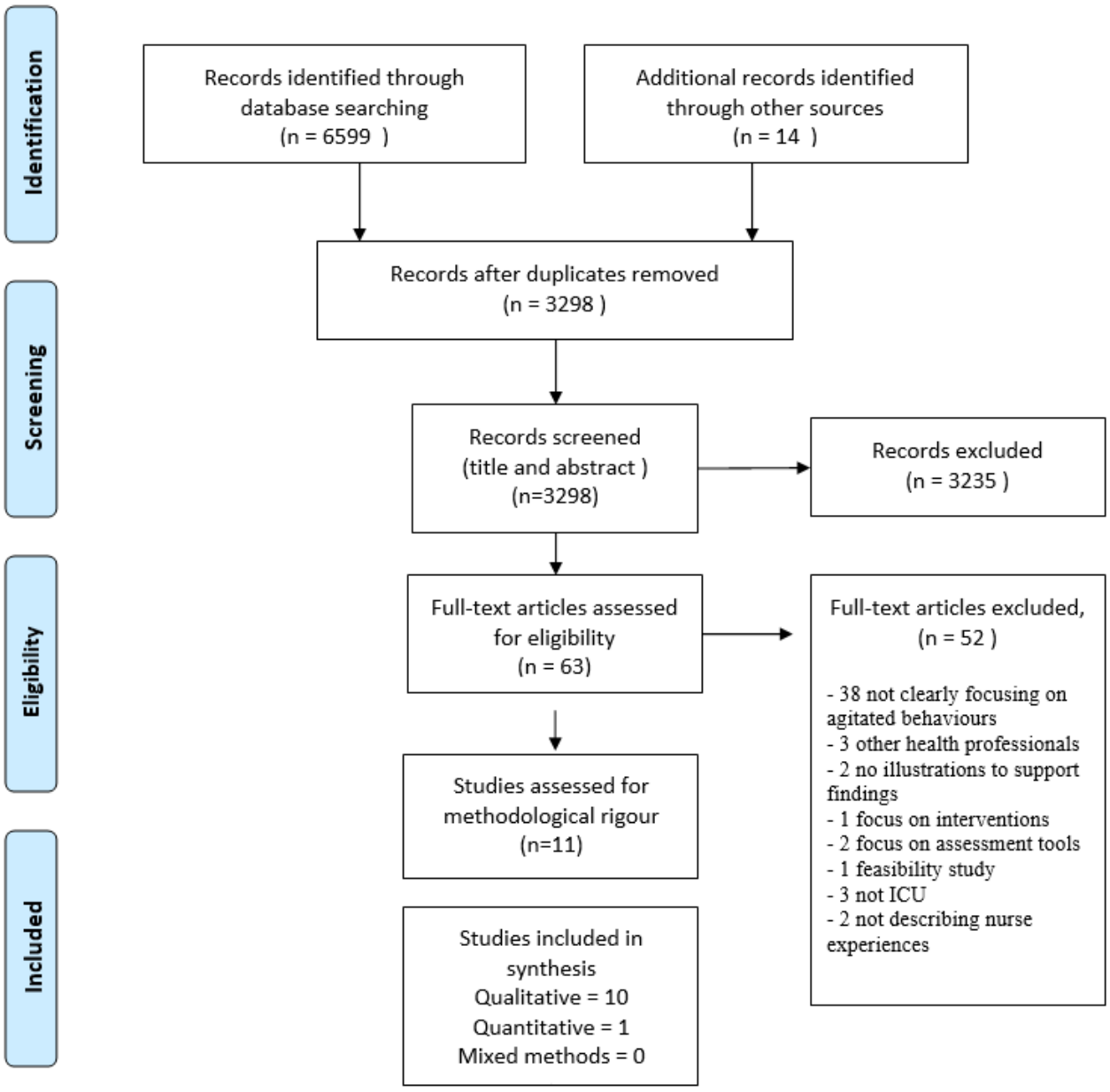



**Figure 1 PRISMA flowchart (Moher et al., 2009)**

## 2.6 Results

A PRISMA flow diagram of the results of the search process and appraisal is illustrated in Figure 1. One quantitative and ten qualitative studies were included in the review. The included studies were published between 2002-2019 and came from Scotland (Everingham, 2012; Kydonaki et al., 2019), Denmark (Collet et al., 2019), Canada (LeBlanc, 2016; Tsang et al., 2019), Norway (Lind et al., 2018), United Kingdom (Freeman et al., 2019; Price, 2004; Zamoscik et al., 2017), USA (Shapira, 2002) and Sweden (Tingsvik et al., 2013). Of the qualitative studies, one study provided a strong level of evidence (Everingham, 2012), seven a moderate level of evidence (Collet et al., 2019; Kydonaki et al., 2019; LeBlanc, 2016; Lind et al., 2018; Shapira, 2002; Tsang et al., 2019; Zamoscik et al., 2017), and two adequate levels of evidence (Price, 2004; Tingsvik et al., 2013) (Table 3). The quantitative study provided a moderate level of evidence (Table 4). None of the studies exclusively aimed to describe how nurses experienced caring for patients displaying agitated behaviours. For an overview of all included studies and their characteristics, see Table 5. From the studies, a total of 50 qualitative and one quantitative findings were organised into nine categories and then grouped into four synthesised findings. The synthesised findings include: 1) The strain of caring for patients displaying agitated behaviours; 2) Attitudes of nurses; 3) Uncertainty around assessment and management of agitated behaviours; and 4) Lack of effective collaboration and communication with medical colleagues. Each synthesised finding is described in detail below.

**Table 3 Critical appraisal using the JBI Checklist for Qualitative Research**

| Citation | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | Q10 | Total[3] | Methodological quality |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Shapira (2002) | U | Y | Y | U | Y | Y | Y | U | Y | Y | 70 | Moderate |
| Price (2004) | U | Y | Y | Y | Y | N | N | U | Y | N | 50 | Adequate |
| Zamoscik et al. (2017) | U | Y | Y | Y | Y | N | N | Y | Y | Y | 70 | Moderate |
| Collet et al. (2019) | Y | Y | Y | Y | Y | N | N | Y | Y | Y | 80 | Moderate |
| Everingham (2012) | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | 90 | Strong |
| LeBlanc (2016) | Y | Y | Y | Y | Y | N | N | Y | Y | Y | 80 | Moderate |
| Tsang et al. (2019) | Y | Y | Y | Y | Y | N | N | Y | Y | Y | 80 | Moderate |
| Lind et al. (2018) | U | Y | Y | Y | Y | N | N | Y | Y | Y | 70 | Moderate |
| Tingsvik et al. (2013) | U | Y | Y | Y | Y | N | N | U | Y | Y | 60 | Adequate |
| Kydonaki et al. (2019) | U | Y | Y | Y | Y | N | N | Y | Y | Y | 70 | Moderate |

Y = yes; N = no; U = Unclear; N/A = not applicable.
0 - 49%: low methodological quality; 50 - 69%: adequate methodological quality; 70 - 85: moderate methodological quality; 86 - 100: strong methodological quality.

Q1 Is there congruity between the stated philosophical perspective and the research methodology?
Q2 Is there congruity between the research methodology and the research question or objectives?
Q3 Is there congruity between the research methodology and the methods used to collect data?
Q4 Is there congruity between the research methodology and the representation and analysis of data?
Q5 Is there congruity between the research methodology and the interpretation of results?
Q6 Is there a statement locating the researcher culturally or theoretically?
Q7 Is the influence of the researcher on the research, and vice-versa, addressed?
Q8 Are participants, and their voices, adequately represented?
Q9 Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?
Q10 Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?

**Table 4 Critical appraisal using the Checklist for Analytical Cross-Sectional Studies**

| Citation | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Total[4] | Appraisal score |
|---|---|---|---|---|---|---|---|---|---|---|
| Freeman et al. (2019) | Y | Y | N/A | N/A | Y | U | N/A | Y | 80 | Moderate |

Y = yes; N = no; U = Unclear; N/A = not applicable.
0 - 49%: low methodological quality; 50 - 69%: adequate methodological quality; 70 - 85: moderate methodological quality; 86 - 100: strong methodological quality.

Q1 Were the criteria for inclusion in the sample clearly defined?
Q2 Were the study subjects and the setting described in detail?
Q3 Was the exposure measured in a valid and reliable way?
Q4 Were objective, standard criteria used for measurement of the condition?
Q5 Were confounding factors identified?
Q6 Were strategies to deal with confounding factors stated?
Q7 Were the outcomes measured in a valid and reliable way?
Q8 Was appropriate statistical analysis used?

[3] Adding all *yes* ratings and dividing this with the number of applicable ratings.
[4] Adding all *yes* ratings and dividing this with the number of applicable ratings.

**Table 5 Characteristics of included studies**

| Study and Year | Methodology, methods for data collection and analysis | Country | Phenomena of interest | Setting | Participant characteristics and sample size | Description of the main results | Strengths and limitations | Quality[5] |
|---|---|---|---|---|---|---|---|---|
| **Qualitative studies** | | | | | | | | |
| Everingham et al. (2012) | Heideggerian, hermeneutic phenomenological approach. Purposive sampling. In-depth interviews, phenomenological analysis. | Scotland | Experience of caring in a technological environment with a focus on sedation and factors influencing decision making in ICU. | One eighteen bed mixed ICU in Edinburgh | 16 nurses | Reduced sedation caused patient agitation and distress affecting patient comfort and safety. Nurses experienced difficulties in simultaneously providing evidence-based, holistic and safe care. Teamwork between doctors and nurses was less than ideal. Consequently, the implementation of changes in sedation practice is failing. | **Strengths**<br>Reflexivity<br><br>Pilot interview<br><br>Investigator triangulation<br><br>**Limitations**<br>Interviews took place in the ICU at the patient's bedside.<br><br>Relationship between researcher and participants not adequately considered | Strong |
| Collet et al. (2019) | Qualitative design, eight focus group interviews, semi-structured interview guide, framework analysis. | Denmark | Experiences and approaches to delirium management | Five mixed ICUs in regional and university hospitals | 24 nurses and 15 physicians | Delirium management lacks clear aims and guidelines.<br><br>When nurses and physicians in ICU do not have clear guidelines they rely on personal experiences and the best evidence they can find. | **Strengths**<br>Interview guide based on previous literature<br>Investigator triangulation<br><br>**Limitations**<br>Methodology not described<br><br>Little information about the settings | Strong |

[5] Critical Appraisal, see breakdown Table 3 and 4

**Table 5 Continued**

| Study and Year | Methodology, methods for data collection and analysis | Country | Phenomena of interest | Setting | Participant characteristics and sample size | Description of the main results | Strengths and limitations | Quality[6] |
|---|---|---|---|---|---|---|---|---|
| Kydonaki et al. (2019). | Qualitative exploratory, purposive sampling, focus groups, combined analytical strategies from thematic analysis and grounded theory | Scotland | Challenges experienced when managing sedation and analgesia | Eight ICUs | 25 nurses, 8 physiotherapists, 11 doctors, 1 pharmacist. | Challenges around new sedation practices included difficulties in managing agitated behaviours and 'difficult to sedate' patients. | **Strengths**<br>Member checking<br><br>Investigator triangulation<br><br>**Limitations**<br>Minimal information about the sample | Moderate |
| LeBlanc (2016). | Interpretive phenomenology, purposive sampling, semi-structured interviews, data analysis with an interpretive phenomenological approach | Canada | Experiences of caring for patients with delirium | Two university hospital mixed ICUs in Ontario | 8 nurses. | Nurses described how they saw their role as helping both families and patients through the experiences of delirium. They saw caring as exhausting, the patient's mental state as important and ensuring patient safety as a big job. | **Strengths**<br>Pilot interview<br><br>Reflexivity<br><br>Investigator triangulation<br><br>**Limitations**<br>Relationship between the researcher and the participants not adequately considered. | Strong |
| Lind et al. (2018). | A qualitative approach, purposive sampling, focus group interviews, thematic analysis. | Norway | Experiences of caring for non-sedated mechanically ventilated patients | 10-bed mixed ICU, University Hospital | 12 nurses | Nurses described both positive and challenging aspects of caring. Themes included excitement and uncertainty; inspiring but demanding nurse-patient relationships; teamwork, and "working against the tide".<br><br>More strategic implementation and improved interprofessional collaboration may improve experiences. | **Strengths**<br>Interview guide builds on previous literature<br><br>**Limitations**<br>Methodology not described<br><br>Relationship between the researcher and the participants not adequately considered. | Moderate |

[6] Critical Appraisal, see breakdown Table 3 and 4

**Table 5 Continued**

| Study and Year | Methodology, methods for data collection and analysis | Country | Phenomena of interest | Setting | Participant characteristics and sample size | Description of the main results | Strengths and limitations | Quality[7] |
|---|---|---|---|---|---|---|---|---|
| Tsang et al. (2019). | Qualitative descriptive study, purposeful sampling, focus group interviews, thematic analysis. | Canada | Experiences, beliefs and perceptions on the management of PAD | A community hospital, 14-bed, mixed ICU | 43 nurses | Many factors contribute to management of PAD including nurse opinion, environmental factors, health care team, patients and families affected pain, agitation and delirium management. A multifaceted and multidisciplinary quality improvement program is needed to optimise management. | **Strengths**<br>Investigator triangulation<br><br>Reflexivity<br><br>Audit trail<br><br>Member checking<br><br>**Limitations**<br>Two of the focus group facilitators also worked in the ICU | Moderate |
| Price (2004). | A qualitative approach, convenience sampling, critical incidence technique, semi-structured interviews, Norman's qualitative data analysis performed. | United Kingdom | Experiences and reflections of recognising, assessing and supporting patients' psychological needs. | Two ICUs in a London Teaching Hospital. | 12 nurses | Six categories require consideration: effects on patients; environmental factors; nurses' education and attitudes; factors affecting psychological assessment and communication; and family effects. Nurses must pay attention to families, improve communication and be aware of current issues. | **Strengths**<br>Pilot interview<br><br>**Limitations**<br>Age of data<br><br>Only one investigator<br><br>Data analysis unclear<br><br>Minimal information about setting and participants<br><br>Relationship between researcher and participants not adequately considered<br><br>No information on the trustworthiness of the study.<br><br>No conclusion of the study. | Adequate |

[7] Critical Appraisal, see breakdown Table 3 and 4

**Table 5 Continued**

| Study and Year | Methodology, methods for data collection and analysis | Country | Phenomena of interest | Setting | Participant characteristics and sample size | Description of the main results | Strengths and limitations | Quality[8] |
|---|---|---|---|---|---|---|---|---|
| Shapira (2002). | Ethnographic fieldwork, qualitative and quantitative methods, analogue scales, observations and interviews. | USA | Process of emotion management by surgical intensive care unit nurses | Surgical ICU, California | 34 nurses working in the surgical intensive care unit, nine nurses participated in interviews, 47 patients included. | Nurses preferred patients who were technologically and behaviourally controlled -this allowed for emotional detachment necessary for their work. The emotional detachment was more difficult to achieve with family members present. | **Strengths**<br>Use of theoretical framework<br><br>Prolonged engagement (17 months of fieldwork)<br><br>**Limitations**<br>Age of data<br><br>Data analysis not described<br><br>Only one investigator<br><br>Trustworthiness and limitations of study not discussed | Moderate |
| Tingsvik et al. (2013). | A qualitative approach, convenience sampling, semi-structured interviews, content analysis | Sweden | Experiences of caring for lightly sedated, mechanically ventilated patients | Three mixed ICUs, one central, two district hospitals. | 9 nurses | Caring for lightly sedated patients is a challenge that requires experience and knowledge. Communication, individualised care, integrity and patient participation are important factors. Nurse satisfaction increases when this is done successfully. | **Strengths**<br>Investigator triangulation<br><br>Reflexivity<br><br>Pilot interviews<br><br>**Limitations**<br>Unclear if all voices have been represented as unclear who said what | Adequate |

[8] Critical Appraisal, see breakdown Table 3 and 4

**Table 5 Continued**

| Study and Year | Methodology, methods for data collection and analysis | Country | Phenomena of interest | Setting | Participant characteristics and sample size | Description of the main results | Strengths and limitations | Quality[9] |
|---|---|---|---|---|---|---|---|---|
| Zamoscik et al. (2017). | A qualitative approach, purposive sampling, focus group interviews, thematic analysis. | United Kingdom | Experiences of delirium, delirium assessment and management . | 20-bed mixed ICU in a large teaching hospital | 12 nurses | Delirium was not prioritised by nurses. Nurses lack confidence in assessing delirium. There was a lack of effective therapies. NPSs must be acknowledged. Psychological support for nurses dealing with delirious patients should be considered. | **Strengths**<br>Pilot interview<br><br>Member checking<br><br>Investigator triangulation<br><br>Audit trail<br><br>**Limitations**<br>Time pressure precluded further data collection<br><br>No male nurses | Moderate |
| **Quantitative studies** | | | | | | | | |
| Freeman et al. (2019). | Web-based questionnaire survey | United Kingdom | Views and opinions on strategies to manage patient agitation | 8 adult critical care units | 114 nurses, 25 doctors, 13 physiotherapists , 6 health care support workers, 5 pharmacists. | 98.5% acknowledged the increased risk of harm for patients who are agitated in the ICU. 76.3% felt that the management of agitation could be improved. Many felt equipped to recognise delirium and agitation but lacked the knowledge to manage agitated behaviours. | **Strengths**<br>Questionnaire is likely to be valid and reliable<br><br>Triangulation of data<br><br>**Limitations**<br>Only unpublished material (email exchange with the author) was included since it was not possible to extract nurses' experiences from the published material.<br><br>Low response rate (18.1%) | Moderate |

[9] Critical Appraisal, see breakdown Table 3 and 4

### 2.6.1 Synthesised finding 1: The strain of caring for patients displaying agitated behaviours

Caring for a patient displaying agitated behaviours was seen as dangerous, stressful and demanding and prevented nurses from performing other duties that were expected of them. This meant that there was a strain applied to nurses when caring for this group of patients. Such strain had emotional consequences affecting nurse well-being and nurses' caring behaviours. This synthesised finding comprises two categories generated from 13 findings. The categories included 1) An exhausting role, and 2) Emotional consequences of caring for patients displaying agitated behaviours

#### *2.6.1.1 An exhausting role*

Five credible findings supported this category. Keeping both patients and health professionals safe was viewed as "a really big job", and nurses had to constantly "be on guard" and close to the bed. The risks involved were significant (Everingham, 2012; LeBlanc, 2016; Lind et al., 2018; Tsang et al., 2019).

> "everything could happen in a minute….always like a time bomb" (LeBlanc, 2016, p. p. 63)

> ''Most of the patients have small margins, and if they remove their endotracheal tube they might not survive. So you have to be much more alert..." (Lind et al., 2018, p. 58)

Everingham (2012). described how nurses felt responsible, even during their breaks. A nurse explained

> ...because you're, you're there, you're in charge of them for 12 hours, I mean whether you're there or not you have to make sure it's a safe environment for them (Everingham, 2012, p. 208)

Caring for patients displaying agitated behaviours required extra resources and support from colleagues (Everingham, 2012).

#### *2.6.1.2 Emotional consequences of caring for patients displaying agitated behaviours*

Eight credible findings supported this category. Caring for patients with agitated behaviours was described as emotionally challenging (LeBlanc, 2016; Shapira, 2002; Zamoscik et al., 2017).. Nurses' perceptions of why patients became agitated adversely affected nurses emotionally. Compounding this emotional adversity was the additional patience required when caring for patients with agitated behaviours. Nurses described how they would be 'soft and sweet' towards patients at the beginning of a shift but feel angry and frustrated by the end (LeBlanc, 2016; Shapira, 2002; Zamoscik et al., 2017). An ethnographic study observed how nurses would become visibly angry and engage in power struggles with patients displaying agitated behaviours.

> One nurse, generally unruffled and empathetic, put her hands on her hips, glared at the patient and said, "Fine, go ahead and get pneumonia. I don't care." (Shapira, 2002, p. 112).

Feelings of guilt, dissatisfaction and failure occurred when nurses felt the need to prioritise patient safety and therefore felt unable to support other patient needs or carry out other duties (Everingham, 2012; LeBlanc, 2016; Shapira, 2002; Tsang et al., 2019).

> "Then [the patient is] all over the place it seems like you have not done your job (...) you did not meet the needs." (LeBlanc, 2016, p. 48)

Such feelings also occurred when an adverse event happened due to patient agitation (Everingham, 2012).

> "...I would feel a failure personally but that's because I am used to the days when you were there all the time, you didn't turn your back on the patient, you didn't leave the patient and so that really was a failure on your part... deep down you think well if I had only done this if I had only done that...it is dangerous for the patient because they potentially then have to be anaesthetised... have their tube put back down maybe, or have a central line put in" (Everingham, 2012, p. 208).

Finally, nurses described feeling vulnerable and scared when caring for patients displaying agitation and aggression. Nurses described how they received minimal emotional support and they questioned if violent situations could have been dealt with better, or if aggression towards nurses had simply become an acceptable part of nursing (Everingham, 2012; Zamoscik et al., 2017). A nurse recalled:

> I do think everyone in the unit has had a bad experience with patients being aggressive and not being allowed to give anything to calm the patient down and seeing as we can't restrain patients. I guess there was that one instance even last week where Staff Nurse T was punched and got concussion. I just wondered what the situation was with that, was there warning signs which I am sure there were because the patient had boxing gloves on, could more have been done to calm that patient down?" (Everingham, 2012, p. 205).

### 2.6.2 Synthesised finding 2: attitudes of nurses

Nurses described a variety of attitudes towards patients displaying agitated behaviours. This synthesised finding comprises one category generated from 6 findings.

#### *2.6.2.1 Attitudes towards patients displaying agitated behaviours*

One unequivocal and five credible findings supported this category. While some nurses empathised with patients displaying agitated behaviours and felt 'professional' and satisfied when able to calm them down (LeBlanc, 2016), others had a different perspective. Patients who rejected or impeded care (Shapira, 2002) and patients with substance use disorders (Everingham, 2012; Shapira, 2002), were held accountable for their agitated behaviour. In these patients, such behaviours were seen as conscious and intentional (Shapira, 2002).

> I think it's more like his personality to be that way (i.e., agitated). You know, as I get to know the family and talk with them, that's how he is in their home. I think a lot of it is his baseline personality (Shapira, 2002, p. 108).

Some nurses described how they were adversely affected by their colleagues' negative attitudes and stigma towards patients with agitation.

> "I find that people are quick to stigmatize them. (...) I would get report that this person is 'crazy'. 'Excuse me!?' You cannot say that. It's almost an ethical thing. I personally have a hard time with that because I think it's not right" (LeBlanc, 2016, p. 49)

Nurses in one study openly admitted that they preferred to care for sedated patients who were cooperative and compliant (Shapira, 2002, p. 101). A nurse explained:

> "To me, the easiest patient is the one on the balloon pump, on the ventilator with 10 different drips. You can control everything about him... Those are the easiest patients. If a behavior is uncontrollable, you know what? It doesn't have to be agitation… they take a lot of time… the majority of your more skilled nurses, prefer the sicker pt, where you don't have to deal with the psychological, or I should say behaviors" (Shapira, 2002, p. 101).

### 2.6.3 Synthesised finding 3: Uncertainty around assessment and management of agitated behaviours

Nurses described a lack of consensus and guidance for how to assess and manage patients displaying agitated behaviours. This synthesised finding comprises four categories generated from 25 findings. The categories included 1) assessment of agitation, 2) the role of sedation when caring for patients displaying agitated behaviours, 3) nonpharmacological care strategies, and 4) lack of training and consensus on how to manage patients displaying agitated behaviours

#### *2.6.3.1 Assessment of agitation.*

Three unequivocal findings and one credible finding supported this category. Shapira (2002) described how some nurses found it easy to identify agitated behaviours.

> …they're moving around, restlessness, pulling at things, thrashes, facial grimaces, thrashes about in the bed. I look at their heart rate, if it is elevated from baseline; BP (blood pressure) is elevated from baseline. If they're on a vent (ventilator), that's the first thing I look at the vent, their breathing, if the respiratory rate is really up. Basically that's it (Shapira, 2002, p. 105).

Meanwhile, clinicians lacked assessment tools to identify the causes of agitation (Kydonaki et al., 2019; Shapira, 2002; Zamoscik et al., 2017). Not being able to identify the causes of agitation lead to uncertainty around management (Kydonaki et al., 2019).

#### *2.6.3.2 The role of sedation when caring for patients displaying agitated behaviours*

Six unequivocal and three credible findings supported this category. A complex issue arose around balancing the risks and benefits of sedation. Some nurses seemed to understand the benefits of keeping patients more awake (Everingham, 2012; Lind et al., 2018; Zamoscik et al., 2017), and that chemical sedation should be a 'last resort' (LeBlanc, 2016). However, nurses also felt frustrated when not being able to comfort the more awake patients displaying agitated behaviours (Tingsvik et al., 2013). They questioned if it was ethical and safe not to sedate these patients (Everingham, 2012; Lind et al., 2018; Zamoscik et al., 2017). Some nurses were concerned about the long-term consequences of experiencing agitation (Everingham, 2012; Tsang et al., 2019).

> "To be totally honest 'I' haven't seen the benefits of it as in…. does it help the patient being woken up every day? I don't know if that's coming back yet. Are we getting to that stage that the

> patients are remembering the wakening periods? I don't know if that is helping them or not..." (Everingham, 2012, p. 240).

Others described how they themselves would have preferred to be deeply sedated to experience complete amnesia to the agitation event (Tsang et al., 2019). Nurses also described how they saw sedation as the only solution when patients became agitated (Collet et al., 2019; Everingham, 2012; Zamoscik et al., 2017) while wishing that other treatment options existed (Zamoscik et al., 2017). A participant explained the problematic situation

> it (. . .) delays weaning off sedation, cause sometimes you find that when the patient is becoming a danger to themselves, sometimes you sedate them a bit more. So, you keep going back and forth (. . .). And sometimes, when you try talking them down, it doesn't work. So, then you go to medications. (. . .) Well, the patient has to be safe, but you also feel like, oh. . . I feel like I'm slowing patient down (Zamoscik et al., 2017, p. 97).

Zamoscik et al. (2017) also described how decisions to increase sedation stemmed from nurses' lack of time and a low tolerance for agitation.

#### *2.6.3.3 Nonpharmacological care strategies*

One unequivocal and nine credible findings supported this category. Few nonpharmacological caring strategies were mentioned in the included studies. Nurses used effective communication (Zamoscik et al., 2017), supported patient sleep (Price, 2004) and partnered with families (LeBlanc, 2016; Lind et al., 2018; Tsang et al., 2019). Although ethical and medical concerns existed around the use of PR, some nurses still believed that they played an important role in controlling patient agitation (LeBlanc, 2016). One study described the importance of knowing when and how to respond to patients with agitated behaviours (LeBlanc, 2016, p. 64). By drawing on previous experience and knowledge, nurses were able to determine if NPSs were appropriate. A nurse reflected:

> "You sort of know what to expect and you know their physiology that they are relatively safe. You know that they can be hypertensive for a while without causing immediate danger. I mean it has to be obviously on your radar. It has to be in the back of your mind that you don't want to get him to be hypertensive for a long time but he's safe. He's still safe to do this" (LeBlanc, 2016, p. 64)

Barriers related to NPSs were mentioned. Interestingly, families were also seen as obstacles to managing patients' agitation by fuelling anxieties and stressors (Shapira, 2002; Tsang et al., 2019), or by requiring nurses' support for themselves in an already stressful and time-critical environment (Shapira, 2002). Another obstacle to patient care was when nurses had to physically distance themselves from a potentially dangerous patient (LeBlanc, 2016, p. p. 49)

> "It's really difficult because we're trying to give care to help the patient but with delirium, it's really hard because they fight with us or be a danger for themselves and to us at the same time. It's time consuming, emotional, and we're always on guard every time that we need to do something. Sometimes the care is not being done and it could be harmful to the patient" (LeBlanc, 2016, pp. 49-50)

The ICU environment was also considered a barrier in providing NPSs, either when patients were too close and disturbing each other, or when the ICU layout hindered appropriate proximity for observing agitated behaviours (Kydonaki et al., 2019). Caring for patients displaying agitated behaviours was seen as both challenging and rewarding when nurses succeeded in calming down a patient (LeBlanc, 2016).

#### *2.6.3.4 Lack of training and consensus on how to manage patients displaying agitated behaviours*

One credible finding and one quantitative finding supported this category. Nurses experienced disagreements and inconsistencies around the management of agitated behaviours, particularly with regards to the use of pharmacological agents and PR (LeBlanc, 2016).

> 'Can we please all try and do that same?' So, we have the consistency there?' You have to sell it to your colleagues. Hopefully, you get someone there with experience as well, and who has a good set of nerves and who (laughing) has a willingness (LeBlanc, 2016, p. p 49).

Participants also described how they felt unsure about how to deal with agitation.

> "I have no idea how to address it (agitation)." (LeBlanc, 2016, p. 49)

Freeman (2019) found that 24 of 39 nurses had not received adequate training in managing patient agitation.

### 2.6.4 Synthesised finding 4: Lack of effective collaboration and communication with medical colleagues

Not feeling understood, recognised or involved in decision-making by the medical team when caring for a patient displaying agitated behaviours caused frustrations and feelings of powerlessness. This synthesised finding comprises two categories generated from seven findings. The categories included 1) medical colleagues' lack understanding of the demanding nature of caring for patients displaying agitated behaviours, and 2) Nurses not feeling recognised and involved in decision-making processes around sedation.

#### *2.6.4.1 Medical colleagues lack understanding of the demanding nature of caring for patients displaying agitated behaviours*

Two credible findings supported this category. There was a feeling that the medical team did not prioritise and take responsibility for the management of agitated behaviours (Zamoscik et al., 2017), and that they simply expected nurses to deal with this part of patient care (Everingham, 2012). Nurses described how the medical team did not understand the demanding nature of caring for this group of patients

> "...they're quite good at saying switch off sedation or no we don't want this, we don't want that, but then they walk off and they're not the ones at the end of the bed for 12.5 hours …(Everingham, 2012, p. 202).

#### *2.6.4.2 Nurses not feeling recognised and involved in decision-making processes around sedation*

One unequivocal and three credible findings supported this category. It was described how the medical team did not recognise or trust nurses' assessment of agitation (LeBlanc, 2016, p. 58). Nurses mentioned different approaches on how to "get through" to the medical staff. One nurse would call the physician to the bedside to 'capture the moment', whereas another used the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) (delirium assessment tool) findings to help describe the agitated behaviours more effectively (LeBlanc, 2016).

Nurses also experienced a lack of involvement and autonomy in decision-making processes around sedation strategies (Everingham, 2012; Kydonaki et al., 2019). The rigidity of implementing care bundles became a tick-box exercise reducing nurses' autonomy. For example, nurses preferred to reduce sedation when they had more time to carry out the intervention and monitor the effect rather than before their break or early morning (Kydonaki et al., 2019). Lack of autonomy also left nurses feeling powerless when witnessing the distress and discomfort patients with agitation seemed to experience (Everingham, 2012).

> "It's a very frustrating thing to have an agitated, uncomfortable patient, just because the doctors decided let's wake them up. That can be really frustrating... bearing in mind that I can't prescribe [sedatives or rescue therapies] ... You know a prescription might allow me to have some autonomy in when and where sedation is used..." (Everingham, 2012, p. 240).

Nurses felt dependent on their medical colleagues, and some wished that they had the authority to at least administer rescue medication (Everingham, 2012).

In summary, this review extracted data from ten qualitative studies and one quantitative study. This data was organised into nine categories and then grouped into four synthesised findings. These four synthesised findings illustrated that caring for agitated patients in the ICU is exhausting, sometimes dangerous, and often associated with feelings of guilt, fear and dissatisfaction. While some nurses felt positive about the challenges of caring for these patients, others exhibited negative attitudes toward agitated patients and openly admitted that they preferred not to look after them. The synthesized findings suggest that nurses often felt unsure about how to best care for this group of patients. This insecurity was related to assessing agitation, particularly identifying causes of agitation, and uncertainties around when to sedate patients. While there was an understanding of the disadvantages of simply sedating agitated patients, participants also felt unsure about when to use NPSs and what NPSs to use. Finally, while some nurses longed for better communication and collaboration with their medical colleagues around the management of agitated patients, others wished they had more autonomy to make independent decisions around care and treatment for this group of patients.

### 2.6.5 Discussion

By systematically synthesising and summarising existing data, this review is the first to provide a comprehensive picture of the challenges nurses face when caring for agitated patients in the ICU. This review shows how managing agitated behaviours in ICU can be exhausting and cause feelings of guilt, dissatisfaction, and failure for nurses. The burden associated with caring for patients displaying agitated behaviours is well known and includes caregiver frustrations and intervention difficulties (Kong, 2005), nurse distress (Hazelhof et al., 2016; Wong et al., 2017; Zwijsen et al., 2014), increased costs and use of resources (Hankin et al., 2011; Kong, 2005), which is increased when patients are aggressive and violent (Blanthorn-Hazell et al., 2018; Wong et al., 2017). Wong et al. (2017) provide one explanation for why caring for agitated patients can be challenging. They call the phenomenon of spending extra effort on caring for someone who is simultaneously vulnerable and threatening the "patient care paradox". This creates ethical and clinical challenges for nurses. The emotional exhaustion and moral distress nurses experience while caring for patients displaying agitated behaviours must be addressed, as such experiences can lead to staff burnout (Friganovic et al., 2019; Fumis et al., 2017). Indeed, agitated patient behaviours have been linked with caregiver burnout and stress within many nursing specialities (Costello et al., 2019; Hazelhof et al., 2016) and have contributed to sub-optimal care, and increases in absenteeism, staff turnover and negative reactions towards patients (Hazelhof et al., 2016). In the current climate of high prevalence of ICU health professional burnout (Chuang et al., 2016) and concerns around adequate staffing (Chen & Nates, 2020), ways to support nurses caring for patients with agitated behaviours must be explored further. Responsibilities lie not only with the individual caregiver but also within the team, the care culture and the organisation. Nurse Managers (NM) in ICU play a major role in supporting the well-being of nurses (Adams et al., 2019a). NMs must strive to create a healthy and trustworthy work environment that acknowledges nurses' experiences when caring for patients with agitated behaviours. Unfortunately, "blaming cultures" - characterised by lack of trust in staff when caring for agitated patients, are common in ICU (Everingham et al., 2014; Kydonaki et al., 2019). Such cultures must be prevented as they create fear in nurses, and nurses may excessively employ PR to avoid being blamed.

The demanding nature of caring for patients displaying agitated behaviours may explain why some nurses possessed negative attitudes towards these patients. Such attitudes were particularly seen towards patients who were known to suffer from a substance use disorder. A recent Swedish study by Wedin et al. (2020) revealed similar findings. ICU nurses described being concerned for their safety, dreaded caring for, and lacked empathy towards the intoxicated, agitated patient, often describing such patients as unreliable, manipulative, aggressive and violent. Aggression and violence are not unusual in ICU (Kumar et al., 2019; Park et al., 2011), and research indicates that nurse lack strategies for dealing with such behaviours (Yoo et al., 2018). In a meta-ethnography of the lived experience of delirium in ICU, Ortega et al. (2020) describe how patients felt they had to

engage in violence to defend themselves, felt helpless, anxious and a strong need for human connection. Since agitation is commonly seen in the “hyperactive” and mixed “hyperactive and hypoactive” delirious patients (Hickin et al., 2017), Ortega et al.'s findings are likely to also apply to the agitated patient. Thus, agitated patients may also feel vulnerable and in need of empathy and personal engagement. Teece (2017) describes how patients displaying agitated behaviours in ICU require a different type of care to patients who are deeply sedated and hence more compliant. She argues that a culture change is necessary because although agitated patients are often ‘unpopular’ and not seen as ‘proper’ ICU patients, they nevertheless require high levels of care (Teece, 2017).

Wedin et al. (2020) found that when nurses were able to create caring environments characterised by empathy and respect, they were more likely to experience positive patient encounters. In this review, nurses felt ‘professional’ and ‘satisfied’ when able to minimise agitation (LeBlanc, 2016). Lind et al. (2018) described the similar finding that caring for non-sedated patients who were sometimes unpredictable and agitated, required a specific skill set. Nurses had to consider how to provide person-centred care and communicate in respectful ways. While this was seen as challenging, nurses also described great advantages, excitement and inspiration that they could gain from the opportunity to communicate with, establish relationships with, and identify the needs of critically ill patients (Lind et al., 2018). More research is needed to explore the role of the nurse-patient relationship during episodes of patient agitation and the factors that can positively support nurses’ motivation to care for this patient group.

The most extensively synthesised finding from this review, supported by the most credible findings, suggests that nurses need support and guidelines on how to manage agitated behaviours. Wedin et al. (2020) confirm this finding in a recent Swedish study describing how ICU nurses felt well-equipped to provide lifesaving interventions in ICU but lacked effective strategies to support agitated behaviours. There is also evidence suggesting that other ICU clinicians, including physiotherapists and physicians, experience similar challenges (Freeman et al., 2019; Kydonaki et al., 2019). While Shapira (2002) found in her early work that nurses easily identified agitated behaviours, more recent scholarship indicates that nurses may struggle with the assessment of agitation, particularly concerning the identification of causes (Kydonaki et al., 2019). It seems intuitive to question whether caring for more awake patients in ICU requires a more nuanced understanding of agitated behaviours. This hypothesis is supported by a more recent ethnographic study (Tate et al., 2012) showing how clinicians struggled to differentiate between agitation, anxiety and patient irritability. Research shows that even experts disagree about what constitutes agitated behaviours and how concepts like aggressive behaviours, restlessness, disturbing behaviours, rejection of care and anxiety (Choi, 2018; Kong, 2005; Volicer et al., 2017) relate to agitation. It is important to recognise agitated behaviours as early as possible, as this will increase treatment options and the success of these (Wilson et al., 2015). However, current agitation assessment tools may not be sufficient. Many assessment tools for agitation in ICU exist. The Richmond

Agitation Scale (Sessler et al., 2002) and the Sedation Agitation Scale (Riker et al., 1999) are recommended in current guidelines (Devlin et al., 2018a), as they are said to be the most reliable and valid tools (Barr et al., 2013). However, these tools were originally designed to determine levels of sedation and may not be sufficient to characterise the nuances of agitation, something which is essential for effective management. Identifying agitation and causes for agitated behaviours, are critical elements of caring for patients displaying agitated behaviours (Chevrolet & Jolliet, 2007; Cohen et al., 2002; Crippen & Ermakov, 1992; Tracy & Chlan, 2011). More research is needed to explore if nurses possess sufficient knowledge to identify agitation and causes of such behaviours, and if they find current assessment tools to be adequate.

Nurses in this review also lacked clarity on the roles of sedation and NPSs. When reporting on their experiences, nurses infrequently referred to NPSs. Some nurses believed sedation was the only solution when patients became agitated (Collet et al., 2019; Everingham, 2012; Zamoscik et al., 2017). This finding is similar to findings in a national multicentre ICU study from China. Wang et al (2017) found that more than half of the clinicians (51%) did not employ NPSs for the management of pain, agitation and delirium (Wang et al., 2017). Mo et al. (2017) found that the majority (97%) of health professionals reported using pharmacologic agents, such as antipsychotics and sedatives, for the treatment of hyperactive delirium.

With a lack of guidance on NPSs and a lack of evidence of such approaches, it is not surprising that health professionals working under time pressures often opt for pharmacological agents. Although pharmacological agents have been the traditional ways of treating agitated behaviours, growing evidence shows that other approaches in ICU may be beneficial, including nature-based sound therapy (Aghaie et al., 2014), music (Trowbridge & Horstman, 2017), touch (Souri et al., 2012) and foot reflexology (Allahbakhhsian et al., 2020). Outside the ICU, person-centred approaches and communication skills training have also proven beneficial (Kim & Park, 2017; Livingston et al., 2014). Further research is needed to explore the effectiveness of nurse-led NPSs to prevent or minimise agitated behaviours and if evidence-based approaches used in other areas of nursing can be applied to the ICU.

Finally, this review highlights that nurses' unmet support needs from their medical colleagues contribute to nuses feeling frustrated and powerless in the context of managing patient agitation. This is consistent with findings from a study exploring delirium care (Palacios-Cena et al., 2016). Nurses described physicians neither trusting their nursing observations nor viewing agitation-related concerns as "urgent". Interestingly, doctors described struggling to find appropriate pharmacological solutions, acknowledging that this issue delayed their communication with nurses (Palacios-Cena et al., 2016). Nurse-physician conflicts in ICUs are common, and causes include poor communication, mistrust, unclear decision-making processes, and inadequate sharing of knowledge (Hartog & Benbenishty, 2015). There are two major concerns when communication

about the care and management of patients with agitated behaviours is dysfunctional. Firstly, nurses may experience that their clinical reasoning is not valued or important, which may negatively affect patient care and lead to feelings of moral distress (Papathanassoglou et al., 2012). Secondly, Wong et al. (2017) identified poor communication and hierarchical challenges between doctors and nurses in the emergency department as threatening the safety of both patients with agitated behaviours and health professionals. This review suggests that nurse-doctor communication about the management of patients with agitated behaviours must be strengthened. Several interventions have been developed to improve ICU nurse-physician communication, including implementation of communication tools and checklists and team training (Wang et al., 2018b) and multidisciplinary ICU rounds (Der, 2009). Studies also suggest that standardised delirium assessment tools can support nurses when communicating their observations to doctors (Eastwood et al., 2012).

In summary, the existing literature reveals that nurses also experience exhaustion and distress when caring for agitated patients in other healthcare settings, such as dementia care and emergency nursing. These challenges must be addressed, as caring for agitated patients can lead to burnout, higher nurse turnover and poor patient care. One way to support nurses is by equipping them with the knowledge and skills to provide high-quality, patient-centred care to agitated patients. It is particularly important that nurses know about alternatives to using sedation and PR. Finally, the existing literature shows that nurses feeling a lack of collaboration with their medical colleagues around the management of agitated patients is not a new phenomenon. However, the literature emphasises how dysfunctional collaboration may negatively affect patients' and staff's safety and well-being.

### 2.6.6 Limitations of the review

Although broad systematic searches were undertaken, there is always a risk that relevant papers may not have been revealed during the searches. As no date limitation was applied, some findings may no longer apply to contemporary ICUs. However, it is believed that while agitation may have become more prevalent, it is unlikely that the experience of caring for patients displaying agitated behaviours has changed. None of the studies exclusively aimed to describe how nurses experienced caring for patients displaying agitated behaviours, revealing the need for more qualitative research on this topic. Furthermore, this review only identified one study with quantitative data (Freeman et al., 2019). Minimal information was extracted from this paper due to the difficulties of separating nurses' experiences from the experiences of other health professionals. Therefore, large-scale quantitative studies providing an empirical picture of nurses' experiences of caring for patients displaying agitated behaviours are needed.

### 2.6.7 Conclusion of systematic review

Caring for patients displaying agitated behaviours in ICU can be both challenging and demanding. While some nurses thrive on the challenges, others struggle – showing negative attitudes and seeking practical and emotional support and guidance on what "best practices" look like. The findings from this systematic review are significant as they provide a better understanding of why suboptimal care, including inconsistencies and excessive use of PR and sedation, may occur. Increased guidance and knowledge for nurses could reduce the perceived burden of care and improve patient care. Therefore, best practices for nurse-led approaches to prevent, minimise and manage agitated behaviours must be identified and inform clinical practice guidelines. Researchers could consider if evidence-based approaches used in other clinical areas of nursing can be transferred to the ICU setting. Multidisciplinary educational programs on best practices to reduce patient agitation should be developed to ensure optimal care and effective collaboration.

It is concerning that our knowledge about treatment for this group of patients is so limited, given the prevalence of agitation and the serious consequences it has on patient outcomes and nurse well-being. Considering nurses' need for guidance on how to provide high-quality person-centred care with minimal use of PR and sedation, the next logical step is to explore if any guidelines existed on the topic. The next section describes a systematic search for existing guidelines on nonpharmacological prevention, minimisation and management of agitation in the ICU.

## 2.7 Searching for existing guidelines

With help from a university librarian, a search for practice guidelines on the nonpharmacological prevention, minimisation and management of agitation in the ICU was conducted. The search was for guidelines published in English, and no date limitations were applied. Databases searched include Google, MEDLINE and a number of international guideline registries (see Table 6). The search was conducted in October 2020.

**Table 6 Clinical Guidelines Searches**

| Source | Search terms | Results |
|---|---|---|
| MEDLINE | Psychomotor Agitation AND (Guidelines OR Practice Guidelines) AND (ICUs OR Critical Care OR Critical Illness) | Results: 6.<br>Only three included NPSs. |
| Google (advanced search) | Combination of words including Guidelines ICU agitation, guidelines intensive care agitation, guideline critical care agitation. | 166.000 results. Looked through the first 1000 publications. No relevant results. |
| Australian Clinical Practice Guidelines (NHMRC) | Agitation or agitated | No results |

**Table 6 Continued**

| Source | Search terms | Results |
|---|---|---|
| National Institute for Health and Care Excellence (NICE) | Agitation or agitated | Two results. Only focusing on pharmacological treatment. |
| Scottish Intercollegiate Guidelines Network<br>https://www.sign.ac.uk/our-guidelines/ | Looked through all developed guidelines | No results |
| Worlds Health Organisation (WHO)<br>https://www.who.int/publications/guidelines/en/ | Looked through all developed guidelines | No results |
| BMJ Best Practice | Agitation AND guidelines AND (ICU OR "intensive care" OR "critical care") | 153 results. No relevant papers. |
| Centre for Kliniske Retningslinjer<br>http://cfkr.dk/retningslinjer | Agiteret | No results |
| Guidelines International Network (GIN) library of guidelines<br>https://guidelines.ebmportal.com/ | Agitation | No results |
| Agency for Healthcare Research and Quality<br>https://www.ahrq.gov/prevention/guidelines/archive.html | All guidelines reviewed | No results |

### 2.7.1 Results

Four clinical practice guidelines were found covering some aspects of nonpharmacological management of agitation in the ICU (Barr et al., 2013; Devlin et al., 2018a; Fonsmark et al., 2015; UHL, 2018). One set of guidelines was an outdated version (Barr et al., 2013) of more recent guidelines (Devlin et al., 2018a) and therefore was excluded. Another set of guidelines did not differentiate between agitation and discomfort, and the relationship between the recommendations and agitation was unclear; consequently, the guidelines were excluded (Fonsmark et al., 2015). Overall, minimal information on NPSs for agitation was found in the remaining two practice guidelines (Devlin et al., 2018a; UHL, 2018). The international guidelines by Devlin et al. (2018a) had a section with the heading Agitation/Sedation. However, this section focused on levels of sedation, sedation interruptions, nurse-protocolised sedation, choice of sedation, sedation monitoring and PR. The section on PR did offer some potentially relevant recommendations. However, it was unclear if the recommendations were specifically related to agitation (Devlin et al., 2018a). Related to NPSs, the authors of the guidelines stated:

> The role of nonpharmacologic strategies to reduce agitation, anxiety, and distress in terms of sedative choice and requirements is uncertain, and thus, no recommendations could be made in this regard (Devlin et al., 2018a, p. e841).

It is unclear what the authors meant with this sentence, as NPSs, per definition, do not include sedatives. However, it seems reasonable to interpret this sentence as the evidence for using NPSs

for agitation, anxiety, and distress is unclear, and therefore the authors were unable to provide any recommendations in this area.

The other guidelines, published by the University Hospitals of Leicester NHS (2018), also strongly focused on the pharmacological management of agitation. The guidelines suggested using the Richmond Agitation Sedation Scale (RASS) for assessing patients for agitation and suggested identifying causes of agitation. Except for these two recommendations, the guidelines did not recommend NPSs for minimising or managing agitation.

## 2.8 Conclusion

Chapter 2 reviewed the existing literature on nurses' experiences of caring for agitated patients in the adult ICU. It shows that caring for agitated patients in the ICU is complex and challenging and that nurses feel unsure about how to best care for this group of patients. An additional literature search confirms that there are currently no guidelines on NPSs to minimise and manage patient agitation in the ICU. It is clear that there is a gap between the need for nonpharmacological recommendations and the establishment of such recommendations.

In response to this gap, developing clinical practice guidelines on nonpharmacological prevention, minimisation and management of agitation in the ICU is essential. Chapter 3 presents the conceptual framework which guided the development of the guidelines and provided a lens from which the results could be interpreted and discussed.

# CHAPTER 3: CONCEPTUAL FRAMEWORK

## 3.1 Introduction

Chapter 2 identified a research gap. While clinicians are encouraged to use NPSs to prevent, minimise and manage agitation in the ICU, they feel unsure about how to do this, and there are no guidelines describing best practices within this area.

This chapter describes the four-stage development of a unique conceptual framework. The conceptual framework's purpose was to clarify relevant concepts and how they relate to each other, support the researcher in making justified choices about the topic and research questions and provide a lens through which the findings can be interpreted and discussed.

## 3.2 Conceptual framework in guideline development

Ravitch and Riggan (2016) claim that conceptual frameworks are necessary to ensure the rigour of a study. However, the use of frameworks within guidelines development is in its infancy. In a systematic review, Davies et al. (2010) found that only 53 of 235 studies disseminating and implementing practice guidelines were guided by a framework (either conceptual or theoretical). While frameworks have been used to implement guidelines and multiple theories exist in implementation science (Nilsen et al., 2020), less is known about the role of conceptual frameworks during guideline development. Conceptual frameworks are unusual during guideline development, but the literature reveals that some guideline developers are using them.

### 3.2.1 Guiding decision-making

When guidelines are not developed based on a conceptual framework, there is a real risk that concepts do not align and that the guideline recommendations lose their purpose. Developing guidelines is a complex process. Guideline developers typically follow manuals developed by committees of experts and published by recognised organisations such as the National Institute for Health and Clinical Excellence (NICE), the Worlds Health Organisation (WHO) or the Australian National Health and Medical Research Council (NHMRC). While these manuals provide essential practical advice, they fail to explain the theories behind the guideline development processes. Such theories can help to understand why specific guidelines matter and how they should be developed. When guideline developers are unclear about this, or their approaches are not supported by existing literature, there is a risk that recommendations are not doing what they aim to. For example, they may not focus on the correct population or the correct end-users, or they may not be patient-centred or based on evidence. When Mathew Mercuri (2020) reviewed the proliferated Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, he found that several recommendations around guideline development lacked roots in the literature and existing theories. As a result of the GRADE authors not being explicit about

terms, he questioned if their approach supported patient-centred care. Mercuri (2020) provided an example where the GRADE working group stated that for clinicians, a strong recommendation means "just do it – spending constrained time individualizing care is unlikely to be productive" (Guyatt et al., 2013, p. 1605). On the other hand, a weak recommendation meant "optimal management will involve considering the patient's particular circumstances and engaging in shared decision-making" (Guyatt et al., 2013, p. 1605). Mercuri (2020) questioned why patient preferences and values should only be considered for weak recommendations. Mercuri's point is that if the GRADE approach had patient-centred theoretical or evidence-based underpinnings, it is likely that they would recommend clinicians always consider patient values and preferences. Based on Mercuri's arguments, it is clear that theoretical or conceptual frameworks can guide decision-making when developing clinical practice guidelines.

### 3.2.2 Underpinning recommendations and providing structure

While not many guideline developers use conceptual frameworks, it was noticed that guideline developers who do, have different reasons for doing so. For example, Rudd et al. (2017) used the Donabedian model and the WHO international classification of functioning, disability and health model as a conceptual framework to underpin their guideline development and form final recommendations. Similarly, Eisenblaetter et al. (2020) used the Nutrition Care Process as a framework to create and structure their clinical practice guideline recommendations. Van Dulmen et al. (2015) developed a framework based on the biopsychosocial model, the international classification of functioning, disability and health, shared decision making and health-related quality of life, to ensure a more person-centred approach to guideline development. Although little information is provided by the authors about how the frameworks were developed and how they affected guideline development, there seems to be a need for guideline developers to lean against conceptual frameworks.

### 3.2.3 Reasons for developing a conceptual framework

Based on the literature on how conceptual frameworks can support research, the conceptual framework has several purposes. First, it helped clarify concepts and their relationships with each other (Miles & Huberman, 1994). These concepts included agitation, patient-centred fundamental care, evidence-based practice, and guideline development. Second, the framework argued for why the topic mattered (Ravitch & Riggan, 2016). Third, it helped make justified choices about the topic, the research questions, and how to best answer these questions (Ravitch & Riggan, 2016). Finally, the framework provided a lens through which the research findings could be interpreted and discussed (Crawford, 2019)

## 3.3 Development of the conceptual framework

In contrast to theoretical frameworks, conceptual frameworks are not ready-made, tested and accepted theories (Crawford, 2019; Osanloo & Grant, 2016; Ravitch & Riggan, 2016). There is no exact recipe for how to develop a conceptual framework. As suggested by scholars in the area (Crawford, 2019; Maxwell, 2012), the conceptual framework in this thesis was developed by synthesising data from multiple sources to fully characterise the breadth and depth of the topic. It is important to mention that the framework evolved over time through continuous engagement and that adjustments occurred throughout the research cycle of this study. For example, it was initially unknown that stakeholders wanted guidelines for the multidisciplinary ICU team, not exclusively for nurses. Nor was it known that there was a paucity of evidence in the area and that the evidence was of low quality. Thus the initial framework needed to accommodate for the probability of requiring multiple changes along the way. Although an iterative process, the framework can be seen as occurring over four stages, each informing the next (see Figure 2). *Stage one* followed Avant and Walkers' (2019) method for concept analysis to better understand agitation in the ICU. Based on the results, there was still a need to better understand why patient agitation occurs, and therefore *Stage two* provided different theories on the causes of agitation. *Stage three* described the importance of NPSs for agitation and explained the role of patient-centred fundamental care when attempting to minimise agitation. Lastly, *Stage four* described the Joanna Briggs Institute (JBI) approach to evidence-based practice, and how this approach provided a map for the development of clinical practice guidelines. Overall, these four stages helped to understand the concepts related to agitation in ICU, guided the research question and design, and the final framework served as a lens through which the findings could be interpreted and discussed.

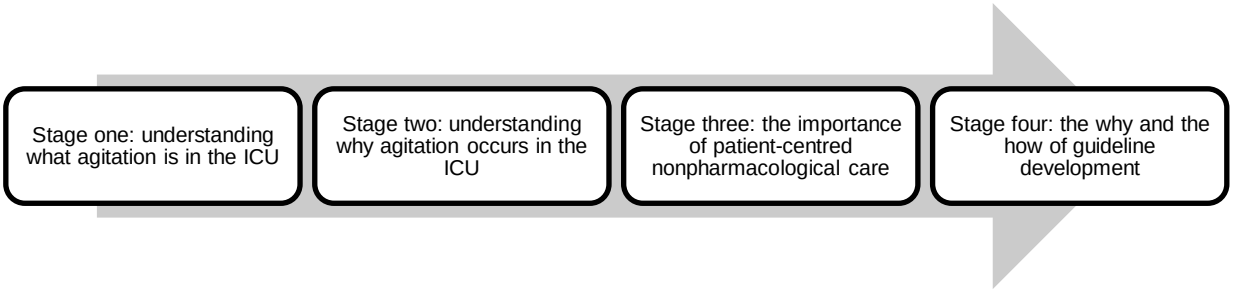



**Figure 2 Stages of the conceptual framework development**

## 3.4 Stage one: understanding what agitation is in the ICU

There is no consensus on what constitutes agitation in the ICU, and there seems to be some confusion in the existing literature. For example, while the popular Riker Sedation Agitation Scale (SAS) indicates that anxiety is a symptom of agitation (Riker et al., 1999) and other scholars in the field claim that restlessness is a symptom of agitation (Burk et al., 2014a) the Richmond Agitation

Sedation Scale (RASS) (Sessler et al., 2002) suggests anxiety and restlessness are something different to agitation. The debate makes the interpretation of research findings using these different scales challenging. There is also evidence suggesting that clinicians struggle to fully understand agitation. For example, LeBlanc et al. (2018) found that clinicians equated agitation with delirium. Due to the lack of conceptual clarity on agitation, this concept analysis aimed to clarify the attributes, antecedents and consequences of agitation in ICU.

### 3.4.1 The method chosen for concept analysis

This concept analysis followed Walker and Avant's (2019) eight-step guide, as it offers a straightforward, pragmatic and recognised guide to concept analysis within nursing (Beecher et al., 2019; Nuopponen, 2010; Walker, 2006). The guide includes: 1) selecting a topic; 2) determining the aim; 3) identifying uses of the concept; 4) determining defining attributes; 5) identifying a model case; 6) identifying borderline cases; 7) identifying antecedents and consequences; and 8) defining empirical references of the concept. Avant and Walker (2019) point out that the steps should not be carried out in a linear way. Instead, concept analysis should be carried out in a dynamic and iterative way where authors continuously move back and forth between steps. Aligning well with pragmatism, Walker and Avant (2019) acknowledge that although their approach is systematic and rigorous, concepts are always tentative and likely to change over time.

### 3.4.2 Data sources

Avant and Walker (2019) suggest carrying out an extensive literature search. Although not directly advised, published concept analyses commonly provide an overview of their data sources (Heslop et al., 2014; Sharifi et al., 2019). For this concept analysis, a comprehensive search was carried out in the databases MEDLINE, PsychINFO and CINAHL. The keywords used were agitation, intensive care, and different synonyms of these terms (Appendix 7 for search strategy). The inclusion criteria were: peer-reviewed primary studies (qualitative, quantitative and mixed-methods), reviews and discussion papers. All papers had to be in English, focus on adults, agitation in ICU and be published at any time up until August 2022[10]. Papers focusing on paediatric or neonatal ICUs or other contexts were excluded. Papers reviewing already included studies were excluded to avoid duplicates of information. A total of 3315 articles were identified and imported to Covidence. From here, 933 copies were removed, leaving 2382 articles for screening. Additional searches were done in an attempt to find a definition for agitation in ICU, as very little research has been done within this context. After screening articles and reading full texts, a total of 36 articles were included.

[10] The original search was done in May 2020. It was then updated in August 2022

### 3.4.3 Step 1: select a concept

The topic selected for the concept analysis was patient agitation in the ICU.

### 3.4.4 Step 2: determine the aims of the analysis

The aim of this analysis was to clarify the concept of patient agitation. In particular, to gain clarity on how agitation can be defined, how the concept is different from other concepts and what antecedents and consequences exist.

### 3.4.5 Step 3: identify uses of the definition

An analysis of the literature indicated that there was no agreement on the definition of agitation in the ICU (Table 7)

**Table 7 Definitions of agitation within the ICU literature**

| Reference | Definition |
|---|---|
| Burk et al. (2014) | Agitation is excessive restlessness, or non-purposeful physical activity (Burk et al., 2014a, p. 1). |
| Chevrolet & Jolliet (2007) | Agitation is a psychomotor disturbance characterized by a marked increase in both motor and psychological activities, often accompanied by a loss of control of action and a disorganization of thought (Chevrolet & Jolliet, 2007, p. 1). |
| Cohen (2002) | Violent motion and strong or tumultuous emotion (Cohen et al., 2002, p. 97). |
| Grippen (1999) | The term 'agitation' describes a syndrome of excessive motor activity, usually nonpurposeful and associated with internal tension (Crippen, 1999, p. 35). |
| Honiden & Siegel (2010) | Physical and psychological distress, commonly characterized as a state of excessive motor activity (Honiden & Siegel, 2010, p. 188). |
| Siegel (2003) | Agitation is characterized by excess motor activity (Siegel, 2003, p. 713). |

The definitions suggest that there are both physical and psychological dimensions of agitation in ICU, although the physical dimensions (restlessness and movements) are particularly emphasised. The definition by Chevrolet & Jolliet (2007) provides the most comprehensive description of agitation in the ICU. Compared with definitions of agitation from outside ICU, it is clear that patient agitation in the ICU context may be different from agitation in other contexts. For example, two semantic scholars in the field of dementia care, Cohen- Mansfield and Billig (1986), define agitation as:

> "inappropriate verbal, vocal, or motor activity that is not explained by needs or confusion *per se*" (Cohen-Mansfield & Billig, 1986, p. 712).

When exploring the antecedents of agitation in the ICU, later in this concept analysis, it is clear that this definition can be misleading, as unmet needs and confusion are often explained as triggering or causing agitation in ICU.

With a strong focus on the pathophysiology of agitation, Lidenmayer (2000) defined agitation as:

> Motor restlessness, a heightened responsivity to external or internal stimuli, irritability, and inappropriate and usually purposeless verbal or motor activity. In addition, vegetative signs exist, such as decreased sleep and an unstable course with symptoms changing very rapidly over time (Lindenmayer, 2000, p. 6).

This definition does not specifically include confusion and emotional tension, which is often seen in agitated ICU patients. However, it describes decreased sleep and fluctuation of symptoms over time, two symptoms that may be present but have received less attention in the literature.

More recently, the International Psychogeriatric Association (IPA) (Cummings et al., 2015) developed a consensus definition of agitation in patients with cognitive disorders. They describe agitation as a syndrome and suggest patients must suffer from a cognitive disorder or dementia syndrome, exhibit excessive motor activity, verbal aggression or physical aggression for at least two weeks, have symptoms severe enough to produce excess disability, and that agitation is not attributable solely to another psychiatric disorder (Cummings et al., 2015). Since patients in the ICU can be agitated without a cognitive disorder and experience agitation over a short period, this definition is irreconcilable with the ICU patient population.

### 3.4.6 Step 4: determine the defining attributes

Defining attributes, or characteristics, are descriptions of the concepts that appear repeatedly (Walker & Avant, 2019). This analysis identified six attributes which are explored below. The first three, excessive motor activity, emotional tension, and interrupting or resisting care, were the most commonly mentioned attributes and may be the core attributes. The last four attributes, including confusion, aggressive behaviours, loss of control and change of vital signs, were mentioned less frequently and may, therefore, not always be present in agitated patients.

#### *3.4.6.1 Excessive motor activity*

Excessive motor activity was described most often in the reviewed literature and covered restless, hyperactive, repetitive, excessive or constant movements (Aitken et al., 2009; Fraser et al., 2000; Sessler et al., 2002; Shapira, 2002). These behaviours were described as having no apparent purpose (Sessler et al., 2002; Tate et al., 2012). Agitation was described as involving either large muscle groups or small muscle groups. Excessive motor activity could involve small muscle groups and be characterised by fidgeting and pulling at dressings or bedsheets (Cohen et al., 2002; Tate et al., 2012). It could also involve large muscle groups and include thrashing, attempts to sit up, banging on the side rails, and rhythmic head movements (Tate et al., 2012).

#### *3.4.6.2 Emotional tension*

Emotional tension refers to a troubled state of mind and includes emotions such as fear, anxiety, distress, paranoia or unease (Burk et al., 2014a; Fraser et al., 2000; Sessler et al., 2002; Tate et al., 2012). Signs of such emotional tensions include grimacing, tensing facial muscles, tensing of

the body, moaning, wincing or shouting (Aitken et al., 2009; Cohen et al., 2002; Shapira, 2002; Tate et al., 2012).

#### *3.4.6.3 Resisting and/or interrupting care*

Resisting and/or interrupting care involves removing or moving away from discomfort. It includes pulling or removing catheters or tubes (Burk et al., 2014b; Cohen et al., 2002; Fraser et al., 2000; Freeman et al., 2022c; Jaber et al., 2005; Riker et al., 2001; Sessler et al., 2002; Tate et al., 2012). Patients may also try to sit up or get out of bed (Fraser et al., 2000; Riker et al., 2001), or resisting care by being uncooperative or protesting loudly (Fraser et al., 2000; Jaber et al., 2005; Shapira, 2002; Tate et al., 2012).

#### *3.4.6.4 Confusion*

Agitation often, but not always, involves confusion and disorganised thinking (Chevrolet & Jolliet, 2007). Irrational thinking, confusion and sometimes delusions result in what was perceived to be inappropriate actions, incoherent speaking and patients not following or understanding commands (Burk et al., 2014a; Cohen et al., 2002; Fraser et al., 2000; Riker et al., 2001; Tate et al., 2012). An example was a patient complaining about pain when the real issue was a need to urinate (Cohen et al., 2002). Previous patients and families described how patients, due to delusions, did not trust staff (Freeman et al., 2022c).

#### *3.4.6.5 Aggressive behaviour*

Aggressive behaviours include hitting, kicking, threatening or striking out at staff (Burk et al., 2014b; Fraser et al., 2000; Riker et al., 2001; Sessler et al., 2002; Tate et al., 2012). These combative and sometimes violent behaviours were described as dangerous for staff (Sessler et al., 2002).

#### *3.4.6.6 Loss of control*

Agitated behaviours have been described as out of patients' control (Chevrolet & Jolliet, 2007) and purposeless (Burk et al., 2014a; Tate et al., 2012). However, there are some indications that patients can perform actions on purpose, as described by clinicians in ICU (Shapira, 2002), and the SAS scale describing how patients strike directly at staff (Riker et al., 1999). Independent of whether an action is purposeless or not, patients are unlikely to have performed the actions if they had not been sick; thus, to a certain extent, patients have lost control of their actions.

#### *3.4.6.7 Change of vital signs*

Vital signs changed during episodes of agitation with increased heart rate, blood pressure and respiratory rate (Aitken et al., 2009; Burk et al., 2014a; Cohen et al., 2002; Sessler et al., 2002; Shapira, 2002; Tate et al., 2012).

Of the existing definitions shown in Table 1, the definition by Chevrolet & Jolliet (2007), which applies to patients in the ICU, includes most of the defining attributes. Chevrolet & Jolliet defined agitation as "a psychomotor disturbance characterized by a marked increase in both motor and psychological activities, often accompanied by a loss of control of action and a disorganization of thought (Chevrolet & Jolliet, 2007, p. 1). However, this study suggests that the definition can be refined to “Agitation is a psychomotor disturbance characterised by a marked increase in motor activities and emotional tension, accompanied by some or all of the following: a loss of control of action, confusion, resistance or interruption of care, aggression, and change of vital signs”.

### 3.4.7 Step 5: identify a model case

A model case gives the reader a perfect example of the concept, and should represent a made-up or real example of the phenomenon of interest (Walker & Avant, 2019). The case in Box 1 is based on the author's previous experiences as a nurse in the ICU.

**Box 1 A model case**

Robert was admitted to the ICU with a severe infection. After a week of critical illness, he was convinced criminals had captured him. He thought people around him were torturing him by restraining him (PR), trying to cut off his penis (when inserting the urinary catheter) and by stabbing him with knives and needles (when changing wound dressings and inserting lines and tubes). He kept looking towards the window and wondered how to escape. Staff experienced a confused, restless and anxious patient who refused to open his mouth to brush his teeth, refused to be turned in bed and who tried to hit, kick or pinch staff during bed wash. Robert often tried to pull in the endotracheal tube and successfully pulled out the nasogastric tube several times. At times Robert was so stressed his blood pressure, heart rate and respiratory rate dangerously increased. Weaning from the mechanical ventilator was complicated by having to continuously increase sedation to keep Robert and the staff safe. Keeping the wound clean was challenging as Robert was 'all over the bed' constantly touching potentially unsanitary sites and pulling off dressings. Over days, staff became exhausted from continually ensuring Robert did not hurt himself or others.

This example includes all defined attributes of agitation, including a marked increase in motor activity, emotional tension, loss of control of action, confusion, resistance and interruption of care, aggression and changes to vital signs.

### 3.4.8 Step 6: identify additional cases

Avant and Walker (2019) suggest identifying borderline cases, related or contrary cases, to get a better picture of what the concept is and what it is not. The case in Box 2 is that of a related case. A related case includes some but not all of the attributes.

**Box 2 A related case**

Mrs Odell was involved in a road traffic accident when riding her push bike to work. The accident caused an intracranial bleed. She had been in ICU for four weeks and was weaned from the ventilator. She showed difficulties following conversations and seemed to withdraw more and more. Staff saw her as being apathetic and lethargic. One day when her husband visited, she told him about how she believed the Russians had taken over, and she begged him to take her home. After this event, staff diagnosed her with delirium.

Mrs Odell displays some attributes of agitation, including emotional tension and confusion. However, she does not display excessive motor activity and therefore should not be classified as agitated. Mrs Odell's delirium diagnosis is likely to be sub-classifiable as hypoactive delirium.

A contrary case would not have any identified attributes of agitation. An example would be an orientated and coherent patient obligingly lifting their arm to facilitate their nurse changing their wound dressing.

#### *3.4.8.1 Additional discussion on terms that are overlapping or related to agitation*

Aggression, anxiety and delirium are often seen in agitated patients, yet they do not equate with agitation. Patients can be delirious, anxious or aggressive without being agitated, and agitated without being either delirious, anxious or aggressive. This will be explained in more detail.

Delirium, which occurs in 4-55% of the ICU population, is a severe condition associated with short and long-term adverse effects and increased mortality (Rood et al., 2018). According to Barr et al. (2013), delirium is "a syndrome characterized by the acute onset of cerebral dysfunction with a change or fluctuation in baseline mental status, inattention, and either disorganized thinking or an altered level of consciousness" (Barr et al., 2013, p. 282). In a systematic review and meta-analysis of 48 studies involving 27342 patients, Krewulak et al. (2018) found that hypoactive delirium had the highest incidence and was the most prevalent type of delirium. While hyperactive delirious patients display agitated behaviours, hypoactive delirious patients have opposite symptoms, including reduced motor activity and drowsiness (Hickin et al., 2017). Agitation in the ICU is also seen without delirium (Whitehouse et al., 2014). Research suggests a higher risk of mortality in agitated patients who are not delirious (Marquis et al., 2007). Therefore, it is crucial to recognise that agitation represents a distinct group of behaviours that deserves separate attention from delirium. Identifying effective interventions specifically for agitation, may eventually provide a more nuanced picture of delirium and effective strategies for patients with hyperactive delirium.

Another term that often overlaps with agitated behaviours is anxiety. Anxiety is defined as "a vague uneasy feeling, the source of which is often non-specific or unknown to the individual" (Mosby, 2006, p. 118). Due to the nature of critical illness, anxiety is often expected to occur in ICU and is

often seen with and without agitation (Shdaifat & Al Qadire, 2020). Patients can also be agitated without being anxious.

Finally, the terminological distinction between agitation and aggression is not always clear. Although the behaviours often occur together, particularly in ICU, they are not identical. Volicer et al. (2017) describe how patients with dementia can be separated into three groups, including those displaying agitated behaviours only, aggression only and both agitated behaviours and aggression. They also explain the principal difference between agitation and aggression:

> "agitation is excessive motor or verbal activity without any focus or intent, whereas aggression is a provoked or unprovoked experience intended to cause harm. Aggression used in self-defence can be called "reactive aggression" (Volicer et al., 2017, p. 2)

It may be particularly challenging to distinguish between these different diagnostic syndromes due to the sedation and mechanical ventilation that is common in ICU. Attempting to make the distinction remains nonetheless important, as management strategies can be diagnosis-specific.

### 3.4.9 Step 7a: Antecedents

Antecedents are events that take place before the concept occurs (Walker & Avant, 2019). For the concept of agitation, researchers and experts have tried to understand its antecedents due to its disruptive and dangerous nature. A comprehensive understanding of what leads to and causes behavioural problems can offer valuable information about treatment and prevention. However, deciphering the exact aetiology of agitation in the ICU can be difficult. For instance, in their study on agitation in ICU, Jaber et al. (2005) could not identify the causes of agitation in one-third of the patients. Agitation is multifactorial, which makes the primary causes complex and often speculative. Communication difficulties and critical illness in agitated patients add to the difficulties of reliably identifying causes of agitation. This analysis identified multiple contributing factors, including critical illness and physical and emotional discomfort. The early antecedent is always patients' critical illness.

#### *3.4.9.1 Critical illness (early antecedent)*

To understand this early antecedent requires the following overview of underlying pathophysiological, pharmacological and other drug processes.

##### 3.4.9.1.1 Pathophysiological

- Gas exchange: hypoxia and hypercapnia (Aitken et al., 2009; Crippen & Ermakov, 1992; Honiden & Siegel, 2010; Siegel, 2003).
- Metabolic: hypoglycemia (Cohen et al., 2002; Honiden & Siegel, 2010; Siegel, 2003), hyperglycemia (Cohen et al., 2002) and metabolic acidosis (Siegel, 2003).
- Infections: central nervous system infections and sepsis (Jaber et al., 2005; Siegel, 2003). Body temperature ≥ 38 $^{O}$C(Jaber et al., 2005)

- Delirium (Almeida et al., 2016; Chevrolet & Jolliet, 2007; O'Connor et al., 2014)
- Dysnatraemia (Jaber et al., 2005),
- Chronic hepatic, renal, pulmonary or cardiac dysfunction (Crippen & Ermakov, 1992).
- Hypotension (Whitehouse et al., 2014). Severe mean arterial pressure reduction before commencing extracorporeal membrane oxygenation (Wang et al., 2018a),
- High severity of illness (Burk et al., 2014b; Gardner et al., 2006; Jaber et al., 2005).
- Brain injury: subarachnoid bleeding (Mahmood et al., 2018; Reimann et al., 2021), severe head injury (Almeida et al., 2016), stroke (Cohen et al., 2002), craniectomy (Huang et al., 2018), intracranial pressure monitor inserted, low Glasgow coma scale (Mahmood et al., 2018).
- Age: two studies showed that younger age was a risk factor (Mahmood et al., 2018; Woods et al., 2004), while other studies found age was not a risk factor (Fraser et al., 2000; Jaber et al., 2005).

#### 3.4.9.1.2 Pharmacological agents and other drugs

- Withdrawal from alcohol or other agents such as opioids, methamphetamines, cocaine, benzodiazepines and other sedatives (Cohen et al., 2002; Jaber et al., 2005; Shapira, 2002; Siegel, 2003; Stewart et al., 2019).
- Nicotine withdrawal (Almeida et al., 2016; Lucidarme et al., 2010).
- Use of sedatives (Jaber et al., 2005) including lorazepam, anticholinergics (Cohen et al., 2002; Siegel, 2003) and propofol (Mahmood et al., 2018). Jaber et al. (2005) found a significant increase in the use of sedatives 48 h before the onset of agitation.
- Drug interactions between antibiotics, muscle relaxants, benzodiazepines, opioids, inhalation agents etc. (Cohen et al., 2002).

### *3.4.9.2 Physical discomfort*

This contributing factor includes a negative physical state causing unpleasant sensations or feelings.

- Difficulties sleeping or resting (Honiden & Siegel, 2010; Malinowski et al., 2020; Shapira, 2002; Siegel, 2003; Whitehouse et al., 2014).
- Dry mouth (Siegel, 2003).
- Discomfort from endotracheal tubes, nasogastric tubes, rectal tubes, intravenous or arterial lines, and urinary catheters (Burk et al., 2014b; Cohen et al., 2002; Freeman et al., 2022c; Tate et al., 2012).
- Full bladder or need to defecate (Aitken et al., 2009; Honiden & Siegel, 2010; Siegel, 2003).

- Mechanical ventilation (Almeida et al., 2016; Burk et al., 2014b; Malinowski et al., 2020), including ventilator dyssynchrony (Cohen et al., 2002; Honiden & Siegel, 2010; Siegel, 2003; Tate et al., 2012).
- Noise (Cohen et al., 2002; Malinowski et al., 2020; Shapira, 2002).
- Light (Cohen et al., 2002).
- Pain (Whitehouse et al., 2014). Multiple causes of pain were described, including pain from procedures, pre-existing diseases, post-operative pain, suctioning, changing dressings, and turning the patient (Aitken et al., 2009; Almeida et al., 2016; Burk et al., 2014b; Cohen et al., 2002; Honiden & Siegel, 2010; Leddy & Wilkinson, 2015).
- Uncomfortable bed position (Siegel, 2003).
- Pruritis (Honiden & Siegel, 2010).
- Nausea (Siegel, 2003; Whitehouse et al., 2014).
- PR, particularly prolonged use of PR (Burk et al., 2014b; Tate et al., 2012). However, Jaber et al. (2005) were unable to confirm that restraints were a risk factor for agitation.

#### *3.4.9.3 Emotional discomfort*

This contributing factor includes a negative emotional state causing unpleasant sensations or feelings. Anxiety, fear, frustrations, and panic play a major role in agitation (Aitken et al., 2009; Chevrolet & Jolliet, 2007; Cohen et al., 2002; Malinowski et al., 2020; Shapira, 2002; Siegel, 2003). Such feelings are often linked to being critically ill, feeling unsafe, alone and unable to communicate. Communication difficulties were described as risk factors for agitation (Aitken et al., 2009; Cohen et al., 2002; Honiden & Siegel, 2010; Malinowski et al., 2020; Siegel, 2003). Patient personality, coping abilities (Shapira, 2002; Tate et al., 2012) and psychiatric history (Burk et al., 2014b; Crippen & Ermakov, 1992; Jaber et al., 2005) were also described as risk factors for agitation. Visiting restrictions during COVID were causing agitation (Hugelius et al., 2021). The family could both reduce and trigger agitated behaviours (Shapira, 2002). Finally, poor communication by staff (Freeman et al., 2022c; Shapira, 2002) and lack of knowledge about how to deal with agitation (Shapira, 2002) were described as contributing to agitated behaviours.

### 3.4.10 Step 7b: Consequences of agitation in ICU

According to Walker and Avant (2019), consequences are events resulting from a concept. Several consequences were described as a result of agitation in the ICU. These included:

- Removal of central venous, superficial venous and arterial catheters (Chevrolet & Jolliet, 2007; Cohen et al., 2002; Jaber et al., 2005).
- Removal of endotracheal tubes (Chevrolet & Jolliet, 2007; da Silva & Fonseca, 2012; Kiekkas et al., 2013; Minda et al., 2022; Woods et al., 2004).
- Frequent urinary catheter insertion (Mahmood et al., 2018).

- Ventilator dys-synchrony causing high airway pressures and inadequate ventilation (Chevrolet & Jolliet, 2007; Cohen et al., 2002).
- Increased metabolism, oxygen consumption and myocardial work precipitating ischemia, arrhythmia and angina (Cohen et al., 2002; Crippen & Ermakov, 1992; Siegel, 2003; Wang et al., 2020).
- High blood glucose levels (Heymann et al., 2007)
- Clouding of the aetiology of underlying diseases (Crippen & Ermakov, 1992)
- Increased drug use, including antipsychotic drugs (O'Connor et al., 2014) and sedatives (Mahmood et al., 2018; Woods et al., 2004).
- Increased use of PR (Luk et al., 2014; O'Connor et al., 2014; Shapira, 2002).
- Post-traumatic stress disorder (PTSD) (Cohen et al., 2002; Samuelson, 2006; Siegel, 2003).
- Pneumonia (Mahmood et al., 2018).
- Nosocomial infections (Jaber et al., 2005)
- Nurse moral distress (Lamiani et al., 2020), stress and exhaustion (Shapira, 2002).
- More ventilator days (Mahmood et al., 2018; Woods et al., 2004), and longer ICU stay (Jaber et al., 2005; Woods et al., 2004).
- Limited mobilisation (Babazadeh et al., 2021; Dafoe et al., 2015).

### 3.4.11 Step 8: define empirical referents

This final step involves describing how the concept has been measured in the real world. This is an important step because it can increase the validity of the concept analysis. Unfortunately, there is no gold standard for measuring agitation in ICU, and as described earlier in this chapter, the existing scales do not agree about what constitutes agitation and often fail to distinguish between anxiety, agitation, aggression, and restlessness. Another limitation to many scales in ICU is that they often attempt to measure both sedation and agitation on a spectrum from heavily sedated to extremely agitated. However, patients can be both sedated and agitated, making accurate measurements of agitation challenging.

### 3.4.12 Summary of the concept analysis

This concept analysis reviewed the existing literature to identify the attributes, antecedents and consequences of agitation. From this analysis, it is clear that agitation is not a specific behavioural problem but a cluster of reactive behaviours, including a marked increase in motor activity and emotional tension. Often these behaviours occur simultaneously with a loss of control of action, confusion, resistance and interruption of care, aggression and change of vital signs.

From the findings of this concept analysis, the early foundation of the conceptual framework was developed. Figure 3 describes patients' critical illness, drugs and pathophysiological processes as the early antecedent. While drugs and pathological changes may directly cause the development

of agitation, there can also be multiple triggering antecedents. Triggering antecedents were related to staff behaviours, physical and emotional discomfort associated with the stressful ICU environment, patients' personalities, coping skills, psychiatric history, and previous experiences. Agitation can have a range of serious consequences, and some of these, such as PR and poor patient experiences, can exacerbate agitation leading the patient to enter a vicious cycle.

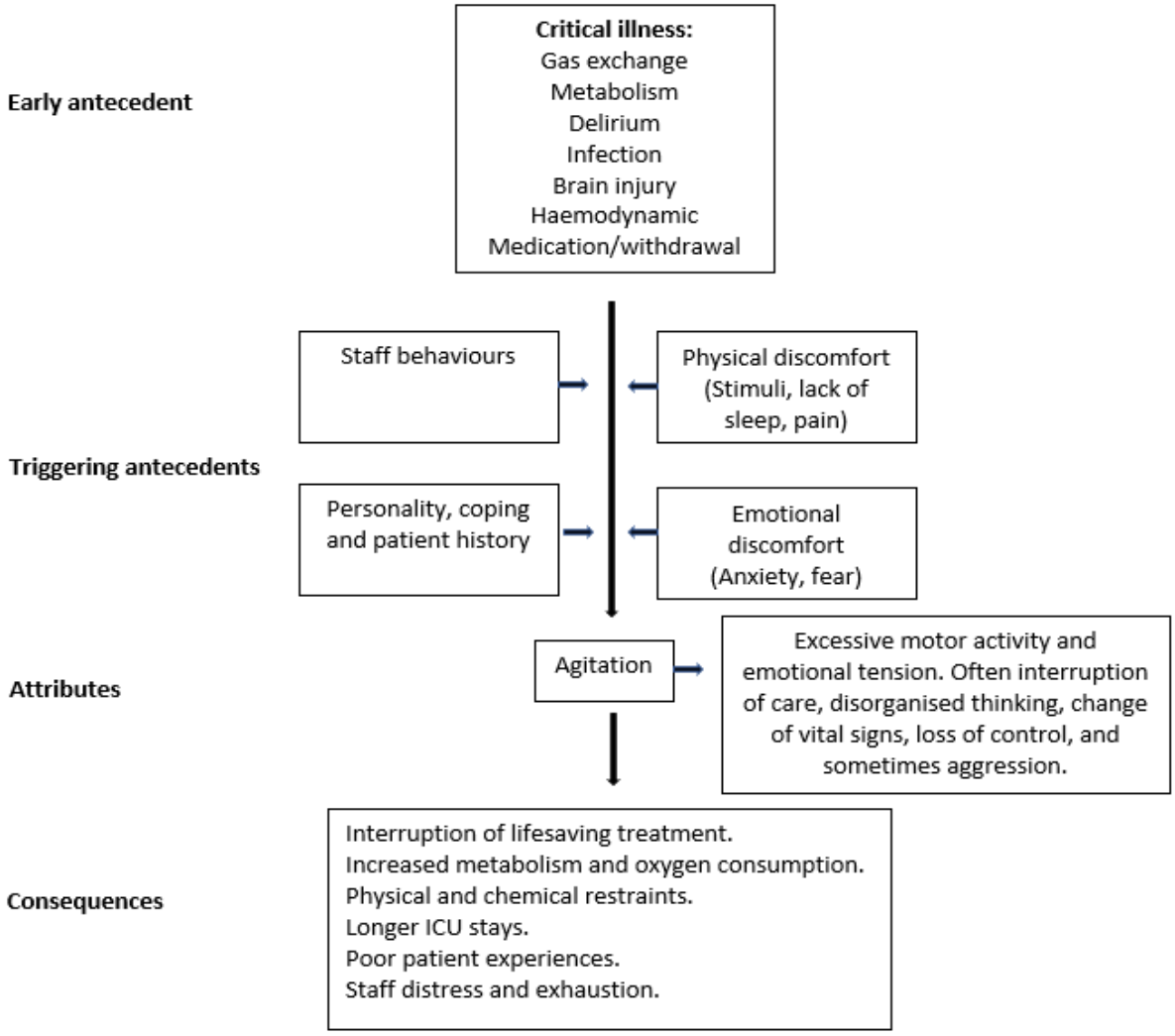



**Figure 3 Stage one conceptual framework: the early foundation**

This analysis has some limitations. Firstly, the literature search focused on agitation in ICU and how it has been defined and described; it was not an exhaustive or systematic review. Furthermore, the analysis included a variety of peer-reviewed literature and did not evaluate the quality of the literature. Despite these limitations, the analysis provides an important contribution to our limited understanding of agitation in the ICU. Risjord (2009) highlights that a variety of evidence can provide a more comprehensive picture of a concept related to nursing. Indeed, including qualitative and quantitative primary research with reviews and discussion papers was a necessity and a strength of this analysis. Since little quantitative research existed, opinions and experiences described by patients, families and expert clinicians were essential to describe

agitation, antecedents and consequences. Finally, it must be acknowledged that our understanding of agitation in the ICU is limited, and it is the hope that the concept analysis will be updated and refined over time.

While this concept analysis provided a clearer understanding of agitation in the ICU and highlighted areas that require more attention, it most importantly described the necessity of effectively reducing agitation. To better understand how agitation can be prevented, minimised and managed in the ICU, it is essential to better understand why agitated behaviours occur. This will be discussed in stage two.

## 3.5 Stage two: understanding why agitation occurs

It is necessary to explore why agitated behaviours in the ICU occur to better understand how the behaviours can be prevented, minimised and managed. The existing literature proposes two types of explanations: biological and social. The biological explanations stem from observational studies of agitated patients, pathology analyses, drug studies and animal models. Most biological explanations stem from psychiatry, but some derive directly from the critical care literature. The social explanations mainly stem from the literature on agitation within dementia care. Although patients with dementia and critically ill patients in the ICU represent vastly different populations, they share important commonalities. In both groups, patients experience difficulties meeting their own needs, difficulties communicating needs and often some level of disorientation or confusion (Baumgarten & Poulsen, 2015; Bridges & Wilkinson, 2011; Egerod et al., 2015). Thus this research is transferable to our population of interest. Based on these observations, stage two of the conceptual framework will present a range of biological theories for why agitation occurs, followed by two explanatory social theories on agitation, including 1) *reduced stress threshold* and 2) *unmet needs*. None of the individual explanations is able to fully explain the causes of agitation, and they overlap each other in several ways. Together they can, however, provide insights that are essential when wanting to identify management strategies.

### 3.5.1 Biological theories

There can be multiple causes of agitation, as evident from the antecedents of agitation in the ICU described earlier in this chapter. The existing literature on agitation outside the ICU support these early findings and describes how causes can be categorised into substances (abuse, use, withdrawal), medical conditions (hypoxia, hypotension, head trauma etc.) and psychiatric conditions (personality, mood- or psychotic disorders) (Zeller et al., 2017). The biological processes producing agitation take place in the central nervous system (CNS). More precisely, the conscious behaviours are associated with activity in the cortex, the unconscious behaviours with activity in the subcortex and limbic system (dorsal striatum, amygdala and hippocampus), and the hyperactivity with activity in the basal ganglia-globus pallidus-substantia nigra circuit (Simpson,

2017). Patients risk becoming agitated when disease processes disrupt the close connections between these regions. Disruption is particularly related to changes in the production or transport of neurotransmitters, hormones and inflammatory markers (Simpson, 2017). The following section will highlight the significant biological mechanisms related to agitation.

Neurotransmitters are essential to the expression of agitated behaviours. One of the most important neurotransmitters for agitation is thought to be serotonin. Scientists are still learning about the multifaceted roles of this neurotransmitter, but a prevailing theory is that serotonin deficiency causes agitation and aggression (da Cunha-Bang & Knudsen, 2021; Jonnakuty & Gragnoli, 2008; Kanen et al., 2022; Simpson, 2017). Serotonin also regulates other behaviours associated with agitation, such as anxiety and fear, mood, sleep, appetite and a myriad of bodily functions outside CNS (Berger et al., 2009). Another important neurotransmitter for the expression of agitation is dopamine (Simpson, 2017). Dopamine plays a major role in decision-making, motivation, reward and higher-order cognition (Rosell & Siever, 2015) and has been shown to protect against aggression (Cupaioli et al., 2021; Schlüter et al., 2013). It is believed that dopamine activity increases through rewards such as food, sex and addictive drugs (Venton & Wightman, 2003). Research also suggests that a lack of acetylcholine activity contributes to the development of agitation (Simpson, 2017). Acetylcholine is the primary neurotransmitter in the parasympathetic nervous system, the part of the nervous system that is responsible for restoring energy and promoting rest and tranquillity. Parasympathetic activity regulates sympathetic activity (also called "fight or flight" or acute stress response) and is characterised by reduced heart rate, decreased pupil size, dilation of blood vessels and increase in digestion (McCance & Huether, 2019). Researchers have described how acetylcholine is essential for upholding a level of cognition that helps solve problems, tolerate environmental stress, and control agitated behaviours (Picciotto et al., 2012; Simpson, 2017). Acetylcholine receptors' activation also improves mood and reduces anxiety, which can be important for regulating irritability and agitation (Picciotto et al., 2015). Finally, agitation has been associated with elevated inflammatory markers, including cytokines and interleukins (Coccaro et al., 2016; Ruthirakuhan et al., 2020; Simpson, 2017). Increased inflammation is seen in multiple psychiatric conditions, including schizophrenia, anxiety and depression (Coccaro et al., 2016), and is described as causing the cognitive and agitated behaviours seen in delirium (Cerejeira et al., 2012; MacLullich et al., 2008). Inflammation, an increased stress response (Dierckx et al., 2021) and neurotransmitter dysfunction (Poulsen et al., 2021) are also factors causing delirium, which may explain why agitation is often seen in delirious patients. Overall, agitation can be explained by complex biological occurrences related to overactivity of the sympathetic nervous system, inflammation and neurotransmitter dysfunction. Due to these explanations, it seems appropriate to consider NPSs that reduce stress and inflammation and regulate neurotransmitter activity.

### 3.5.2 Reduced stress threshold – a social theory

The reduced stress threshold model, also called the environmental vulnerability model, was developed by Cohen-Mansfield (2000). The model suggests that some patients, in particular patients with dementia, struggle to process and respond to environmental stimuli. With this inability to process stimuli, the stress threshold becomes lower. As shown in Figure 4, there is an imbalance between a person's capacity to process stimuli and the number and intensity of those stimuli. When the stimuli exceed a person's ability to process the stimuli, there is a risk the person will become frustrated and agitated. Therefore, people with dementia are more vulnerable to their environment and at higher risk of becoming agitated (Hall, 1987; Smith et al., 2004). Cohen-Mansfield stresses that there has to be a match between a person's capacities and the stimuli of the environment. Patients with dementia progressively lose their coping skills and comprehension. Consequently, they tend to perceive the environment as more stressful, resulting in inappropriate behaviours and anxiety. Environmental stressors may be inappropriate levels of stimulus, inappropriate expectations, and physical stressors. According to this model, the aim should be to ensure sufficient and appropriate levels of stimulation while ensuring that caregiver expectations of the patient are not too high (Cohen-Mansfield, 2000).

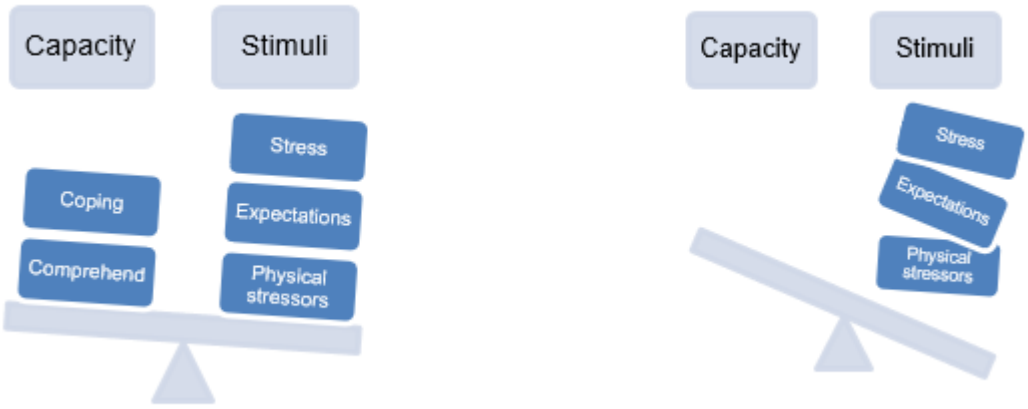



**Figure 4 Balancing capacity and stimuli**

### 3.5.3 Unmet needs – a social theory

The unmet needs model, also called the needs-driven dementia-compromised behaviour model, is possibly the model that has received the most attention within dementia care. This model explains agitated behaviours as resulting from unmet needs (Algase et al., 1996; Cohen-Mansfield, 2000). Unmet needs occur due to a person's inability to meet and express their needs meaningfully to others. Unmet needs may be expressed as physical (e.g. pain, fever, sleep disturbance, fatigue) or

mental discomfort (e.g. feeling lonely) and can be related to unmet physical or psychosocial needs or inadequate levels of stimulation (e.g. too much or not enough stimulation). The theory is that a person with dementia struggles to process stimuli (Cohen-Mansfield et al., 2015). According to this model, agitation can be seen as an expression of unmet needs, a way of fulfilling needs or an outcome of negative emotions such as frustrations. A cornerstone of management is evaluating and supporting patient needs. Caregivers must try to identify which needs result in which behaviours. For example, restlessness may be a sign of toileting needs, and physical aggression may be a sign of pain. This model has formed an essential basis for nonpharmacological management of agitation within dementia care (Cohen-Mansfield et al., 2012; Kolanowski et al., 2011; Williams et al., 2021).

### 3.5.4 Summary of explanatory theories informing the conceptual framework

Stage two of the conceptual framework shows that agitation is complex and cannot be explained by one theory alone. Instead, agitation must be seen on multiple levels, including biological, environmental and psychosocial. Rather than just mentioning the critical illness and triggers of agitation, the second stage of the conceptual framework (Figure 5) provides a more nuanced picture of the causes of agitation in the ICU. These are divided into unmet needs, lowered stress threshold, and biological causes. Together these theories describe how agitation often occurs as a reaction to something. A combination of the different theories can provide essential underpinnings of the management of agitation. This section identified the following three key themes: that clinicians should pay attention to factors that can reduce stress and inflammation and regulate neurotransmitter activity; that clinicians should consider the stressful ICU environment and ensure sufficient and appropriate levels of stimulation; and that a cornerstone of the management of agitation should be to evaluate and support patient needs. Stage three describes why NPSs are likely to support the three conceptual underpinnings and how the Fundamental of Care (FoC) framework was seen as suitable to guide the delivery of patient-centred nonpharmacological care.

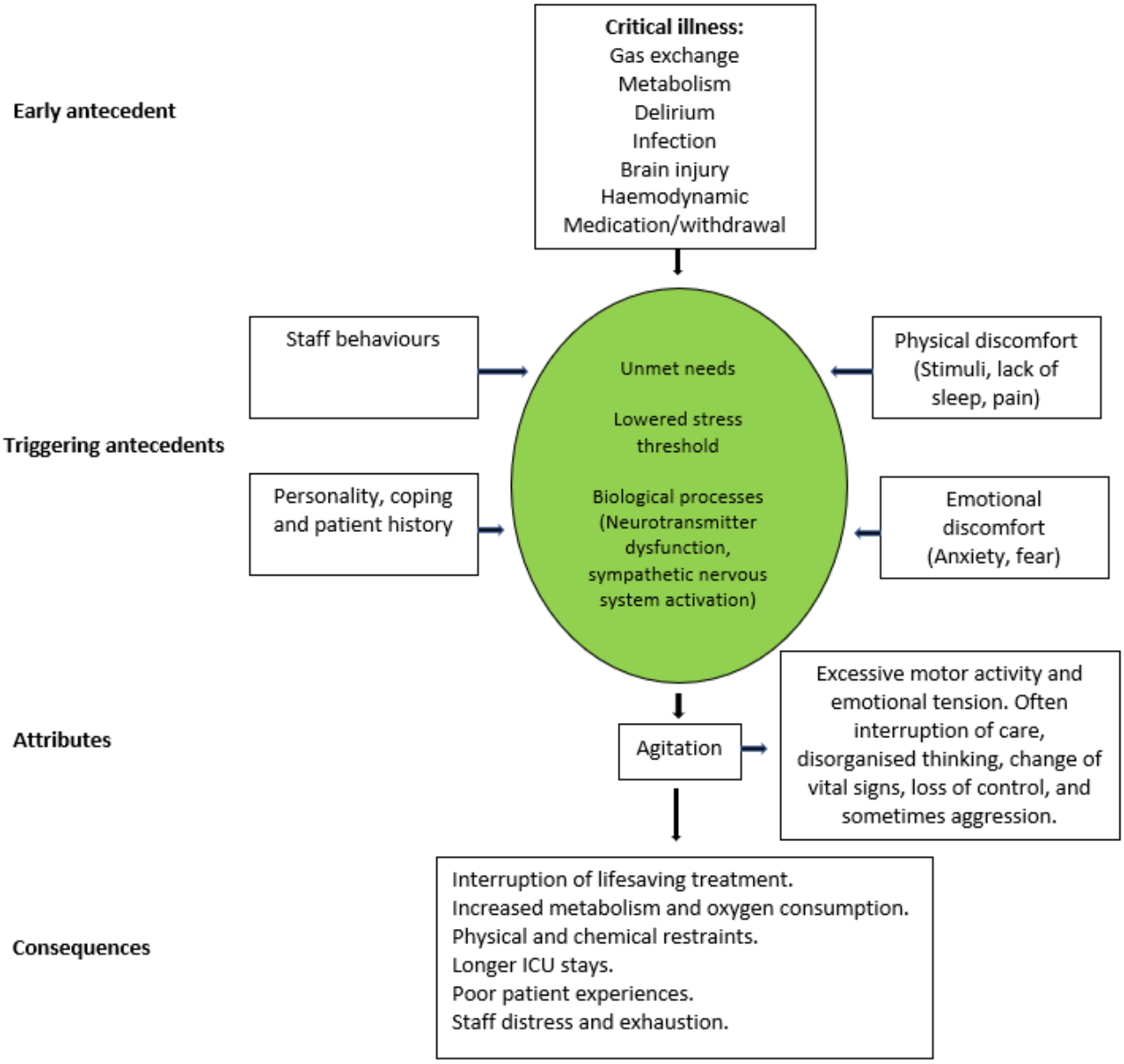



**Figure 5 Stage two conceptual framework: explanations for agitation**

## 3.6 Stage three: the importance of patient-centred nonpharmacological care

So far, the literature has described what agitation is and why it occurs. As part of the development of the conceptual framework, this section will explore in more detail why NPSs can be useful and how such strategies should be provided according to the FoC framework to ensure patient-centred fundamental care.

### 3.6.1 Why use nonpharmacological strategies?

There are issues related to the pharmacological management of agitation in the ICU. Historically, pharmacological agents such as antipsychotic drugs, sedatives and opioids have been used to

treat agitation in the ICU. While these medications continue to be crucial in facilitating weaning and extubation (Buckley et al., 2021; Devlin et al., 2018a; Ostuzzi et al., 2020), they should be used with caution. Excessive use of these pharmacological interventions can cause haemodynamic instability, respiratory depression, prolonged longer ICU stays, more days on mechanical ventilators and worsening of agitation and delirium (Daniels et al., 2018; Devlin et al., 2018a; Strøm et al., 2010; Williamson et al., 2019).

NPSs, on the other hand, may prevent, minimise and manage agitation in the ICU without the adverse consequences of pharmacological management. NPSs have been defined as "any non-chemical intervention, which is theoretically supported, targeted and replicable, performed on a patient or caregiver and potentially capable of obtaining a relevant benefit" (Herguedas, 2020, p. 4). However, in this thesis, consultation with stakeholders suggested that interventions need to be targeted more broadly towards the organisation and leadership, the multidisciplinary team, the family, the environment and the patient (see Section 6.3.3). Also, it was acknowledged that NPSs may not always be based on theory. Based on these considerations, this thesis defined NPSs as any non-chemical intervention or approach that is targeted and replicable and potentially capable of obtaining a relevant benefit. Critically ill patients experience high levels of psychological and physical stress and discomfort (Cuesta & Singer, 2012; Dünser & Hasibeder, 2009; Papathanassoglou & Park, 2016). We have already learnt how stress and discomfort are associated with the progression of agitation. Indeed, while *fight or flight* reactions are important for human survival, excessive stress can lead to organ dysfunction (Cuesta & Singer, 2012), neurotransmitter dysregulation (MacLullich et al., 2008) and poor patient experiences (Papathanassoglou, 2010). Therefore, care in the ICU has always aimed to reduce levels of stress and promote patient comfort (Papathanassoglou & Park, 2016). For years, patients were protected from physical and psychological stressors through heavy sedation, immobilisation and visitor restrictions. However, over time, research has shown multiple adverse effects of these strategies (Papathanassoglou & Park, 2016). Due to the encouragement of keeping patients more awake and using fewer drugs, researchers started to explore NPSs in the ICU and the health benefits of these. For example, a recent systematic review found evidence of the effects of NPSs on delirium (Chen et al., 2022), and a scoping review reported positive effects of a range of therapies (lavender oil, acupuncture, mind-body, garlic) on sleep, blood pressure, heart rate, lung compliance, infections, pain, anxiety and agitation (Mamba et al., 2021). However, the evidence for NPSs is still low, and the exact mechanisms of potential therapeutic efficacy are unclear.

One explanation for why NPSs may work for agitation can be found in Kolcaba's midrange theory on comfort (Kolcaba & Wilson, 2002; Kolcaba, 1994). Kolcaba's comfort theory is often used to design and measure the effect of NPSs (Lin et al., 2022). According to Kolcaba (1994), human

experience occurs in four dimensions, including physical[11], psychospiritual, sociocultural and environmental. When patients' comfort needs are either *relieved, eased* or *transcended* in all of these dimensions, overall comfort will increase. Relieved refers to alleviated or mitigated discomfort, ease to the removal of discomfort, and transcendence to the ability to "rise above" discomfort that cannot be removed. Enhanced comfort also means that patients are more likely to exhibit health-seeking behaviours[12] (Kolcaba & Wilson, 2002). Kolcaba suggests that when comfort in some areas cannot be fully ensured, then the support of comfort in other areas can compensate for this (Kolcaba & Wilson, 2002). Following Kolcaba's theory, it can be hypothesised that by supporting all of a patient's comfort needs, or at least some of them, patient agitation is likely to reduce.

Another explanation of why NPSs may work is that such strategies mobilise mechanisms in the neural reward circuit (Ninot, 2020). Through moments of joy and pleasure, neurotransmitters such as dopamine, serotonin and gamma-aminobutyric acid (GABA) are released, resulting in relaxation and sleep (Ninot, 2020). It is postulated that serotonin can be released through positive mood induction, daylight/bright light, exercise, diet with tryptophan (chickpea, corn) (Young, 2007) and through massage (Field et al., 2005). Potential mechanisms for how reducing levels of dopamine can increase agitated behaviours have been outlined earlier in this chapter. Research suggests that dopamine levels can increase through music (Liao et al., 2015). Certain types of music have also been shown to activate the parasympathetic nervous system, thus reducing sympathetic nervous system activities (Liao et al., 2015; Okada et al., 2009). Another theory is that positive affective states, such as hope and relaxation, can reduce harmful sympathetic nervous system activities (Papathanassoglou, 2010).

### 3.6.2 Patient-centred fundamental care

It is widely advocated that patient care should be patient (person, people, family) - centred (ACSQHC, 2017; WHO, 2018). Carl Rogers (1986) and other influential scholars (Kitson et al., 2013b; Kitwood & Kitwood, 1997; McCormack & McCance, 2011) argue that clinicians should not reduce patients to their disease alone. A patient is a person who has preferences and should be actively involved in their care. Patient-centred care is about developing genuine clinician-patient relationships, involving patients and respecting and supporting their individual needs and preferences while also considering the context in which care is delivered (Kitson et al., 2013b).

[11] Physical discomfort needs include homeostatic and physiological compromised mechanisms, including those needed for optimal oxygenation, fluid and electrolyte balance and thermoregulation (Kolcaba, 2002).

[12] Health-seeking behaviours include internal and external behaviours. Internal behaviours occurs at organ or cellular level. External behaviours are related to the outer world and include self-care activities (Kolcaba, 1994).

Care for patients in the ICU occurs in a highly biomedical and technological environment (Kvande et al., 2022; Minton et al., 2018). In this environment, there is a risk that NPSs for managing patient agitation are not patient-centred but instead focus on facilitating life-saving medical treatment. While this may be critical, it is also necessary to consider patient experiences, preferences and values when using NPSs. Therefore, this thesis argues that NPSs must be patient-centred. In this thesis, the word patient-centred, as opposed to person-centred, is used. The term person-centred is often used to describe all types of care, also care outside a hospital context (Mitchell et al., 2022; Stewart, 2001). However, this focuses on a specific context, namely the ICU. ICU scholars and clinicians commonly refer to a critically ill patient and not a critically ill person (Jakimowicz, 2018). Since this thesis focuses on patients in a unique healthcare setting and not on people in the general population, and due to the intention of promoting knowledge translation for clinicians in the ICU, the term patient-centred care was deemed more appropriate in this thesis.

The Fundamentals of Care (FoC) framework offers a practical way of operationalising patient-centred care. A group of international researchers originally developed it in response to the prevailing biomedical approach to nursing, poor patient experiences, and fundamental care being under appreciated by nurses and the healthcare system (Damsgaard et al., 2021; Kitson et al., 2013a). This particular framework was chosen as it has a strong focus on supporting patients' unmet needs, which correlates well with causes of agitation, as described earlier in this chapter.

Researchers claim that the FoC framework is the only framework that comprehensively describes the importance of the nurse-patient relationship, care integration, and context (Mudd et al., 2020). These elements are essential for patient-centred care delivery (Kitson et al., 2013a), as, without these elements, care is more likely to become task-based and inefficient. For instance, in the agitated patient, care focusing only on supporting the patient's physical needs, for example toileting, is likely to be inadequate, ineffective and result in negative patient experiences.

The FoC framework is different from other models of nursing in that it illuminates how different elements of care are interrelated. The fundamental elements have been illustrated in a model consisting of three concentric circles (see Figure 6). The inner circle represents the nurse-patient relationship. The nurse-patient relationship should always be considered regardless of the type of nursing care nurses provide. The quality of the nurse-patient relationship depends on nurses' ability to focus on the patient, listen, and anticipate any issues. The middle circle describes the actual nursing actions focusing on integrating the patients' physical, psychosocial, and relational needs. The outer circle represents the context in which nursing is being provided and the systems and policies that direct nursing care. This might involve factors such as guidelines, standards, leadership, physical environment, culture, language and regulations (Feo et al., 2016)

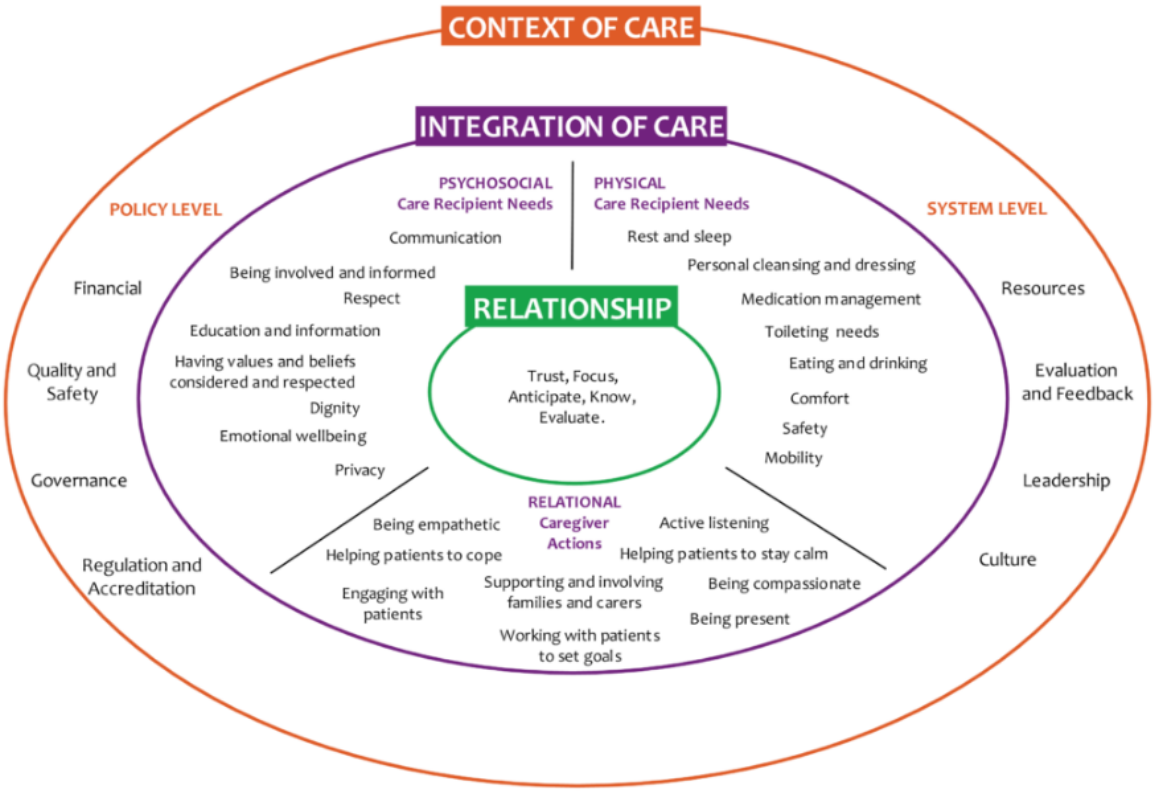



**Figure 6 Fundamentals of Care Framework (ILC, 2022)[13]**

The FoC framework served several purposes in this thesis. First, by stating that all care should be patient-centred (Kitson et al., 2013a), it shaped the primary aim of this study: to develop patient-centred guidelines. Second, the framework also encouraged a patient-centred and holistic approach to guideline development focusing on physical, psychosocial and relational factors that influence health. It was predicted that the FoC framework would facilitate a better understanding of the findings. While the framework seemed to align well with the existing theories and literature on agitation, it was noticed that it emphasised areas not previously identified, such as the importance of establishing a relationship with the patient. While researchers have stated that the FoC framework applies to all areas of nursing (Feo et al., 2016), the framework's applicability to the ICU settings has, from my knowledge, not been empirically evaluated. Therefore, this study may also shine a light on the role of the FoC framework when caring for an agitated patient in the ICU.

### 3.6.3 Summary of the importance of patient-centred nonpharmacological care

Although sedating patients may seem a more comfortable and appealing solution to agitation, there can be significant short and long-term sequelae associated with this approach. Therefore, NPSs should be an essential part of managing agitation in the ICU. NPSs may work in different biological ways, but overall, they are closely linked to reducing physical and psychological stress and increasing patient comfort. In an ICU environment focusing on saving people's lives, it is

[13] Reproduced with permission from the ILC working group.

important that clinicians consider what NPSs are patient-centred and take into account patient experiences, preferences and values. The FoC framework provides a good example of how patient-centred care can operationalised.

Figure 7 describes how patient-centred nonpharmacological care, operationalised through the FoC framework, can support clinicians in providing patient-centred nonpharmacological care. However, providing patient-centred nonpharmacological care does not necessarily result in minimising and managing agitation in the ICU. The fourth and final stage of the conceptual framework will describe the importance of evidence-based practice and guideline development.

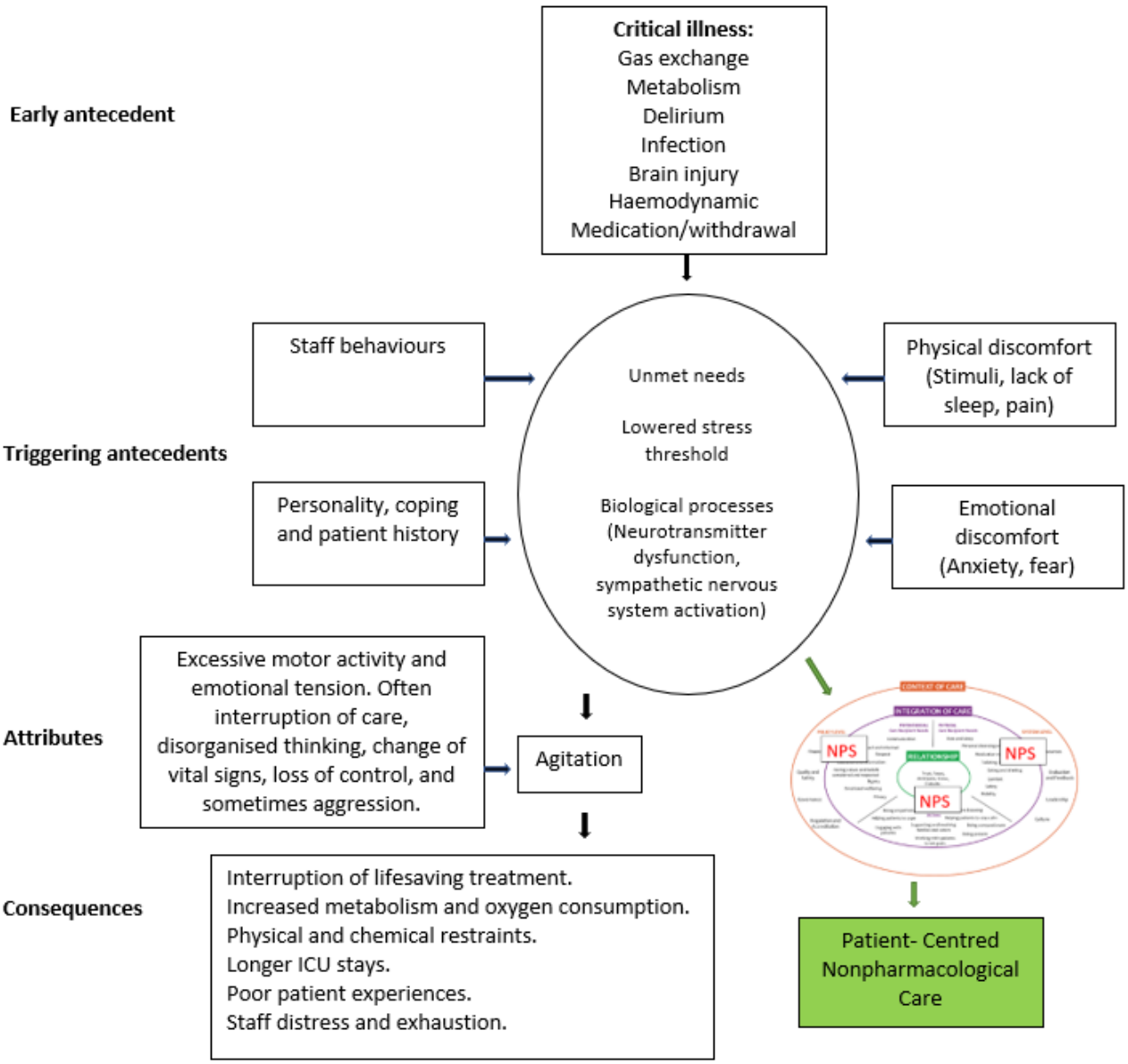



**Figure 7 Stage three conceptual framework: Patient-centred Nonpharmacological Care**

## 3.7 Stage four: the why and how of guideline development

From the reviewed literature and theories, the importance of using patient-centred NPSs to address agitation in the ICU is clear. However, patient-centred NPSs do not automatically produce the desired outcomes. The Australian Nursing and Midwifery Board states that in addition to patient-centred care, practice must also be consistent, safe and evidence-based (NMBA, 2018). Therefore, through the Joanna Briggs Institute's (JBI's) model of evidence-based healthcare, this section describes evidence-based practice (EBP), why guidelines are needed, and the theoretical underpinnings necessary for rigorous guideline development.

### 3.7.1 Evidence-based practice and the role of clinical practice guidelines

Evidence-based practice, the idea that practices should be based on evidence, started to gain significant attention in the 1970s when Professor Archie Cochrane, a British epidemiologist, criticised physicians for not using quality evidence to guide practice (Stavrou et al., 2014). Around this time, health leaders and investigators discovered that medical decisions were often based on personal preferences and choices, resulting in wide practice variation and inappropriate and unnecessary practices among physicians (Steinberg et al., 2011). In today's healthcare services, there is a strong focus on EBP with an increased demand for the delivery of safe, effective and person-centred care at a lower cost (Jamieson et al., 2019).

Despite the importance of EBP, one of the key challenges in today's healthcare systems is evidence not being implemented into practice, creating the so-called evidence-practice gap (Braithwaite et al., 2020). Research shows that it takes up to 20 years for the best available evidence to be accepted and applied to practice (Mohsen et al., 2016). A recent Finnish cross-sectional study of 943 nurses' beliefs about EBP indicates that almost half of clinical nursing practice may not be based on evidence (Saunders & Vehviläinen-Julkunen, 2017). This leads to beneficial therapies not being used (McCormack et al., 2020; Runciman et al., 2012) and potentially an overuse of ineffective or even harmful strategies (Braithwaite et al., 2020; RCACQS, 2019). Many tools and frameworks have been developed in an attempt to form bridges over the evidence-practice gap (Jolley, 2020).

Guidelines are tools developed to close the evidence-to-practice gaps. They were developed to support clinicians who frequently feel overwhelmed by the volume of information available on a topic and the unclear value of the evidence (Pearson et al., 2011). Clinical practice guidelines support clinical decision-making by offering "statements that include recommendations intended to optimize patient care that is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (Steinberg et al., 2011). Research shows that practice guidelines can increase consistency, reduce inefficient practices, improve patient outcomes and guide future research (Steinberg et al., 2011). According to Burgers, Van der

Weijden and Grol (2020), guidelines can provide transparent recommendations for optimal care, reduce practice variations between health professionals, support clinician accountability, provide a foundation for teaching, collaboration and coordination of care and finally, support research and care priorities.

From this, it is clear that clinical practice guidelines on patient-centred NPSs for agitation in ICU are needed to support clinicians in making clinical decisions. However, not all guidelines have been developed in rigorous, transparent and evidence-based ways, and this has resulted in many critiques (Steinberg et al., 2011). In a recent review, Tudrej et al. (2020) assessed the methodological quality of 52 practice guidelines for type 2 diabetes. They found that the guidelines were of poor quality and lacked methodological rigour. Only 50 % had a system of grading the evidence, only 58 % stated that they had carried out a systematic review and 75 % failed to detail their research methods. While guidelines have the potential to optimise patient care and outcomes, poorly developed guidelines may result in ineffective, suboptimal or even harmful practices (Woolf et al., 1999). Evidently, the development of rigorous guidelines is needed; the question is how to do this. While multiple manuals and standards exist on guideline development, it is perhaps the theory behind them that is most important. As emphasised earlier in this chapter, if there are no theoretical underpinnings, guideline developers risk making decisions that are not trustworthy or coherent with their aims. To develop trustworthy evidence-based clinical practice guidelines, this thesis builds on the JBIs model of evidence-based healthcare.

### 3.7.2 The JBI model of Evidence-Based Healthcare

The JBI model of evidence-based healthcare was chosen as it comprehensively describes what EBP is and how it can be operationalised. The model was initially introduced by Pearson et al. (2005) in 2005, and since this time, it has been updated twice (Jordan et al., 2019; Pearson et al., 2011). According to JBI (2019), evidence-based healthcare is "decision-making that considers the feasibility, appropriateness, meaningfulness and effectiveness of healthcare practices" (Jordan et al., 2019, p. 62). This process should be informed by the best available evidence, the context, patient values and preferences and clinicians' professional judgements and expertise (Jordan et al., 2019). What makes this model particularly relevant for guideline development is that it considers all elements in the research cycle. Their model (cycle) consists of five elements (see Figure 8), starting with the development of a question that reflects the global needs of stakeholders (1). These needs are addressed through evidence generation (2). The evidence is then collated, appraised and synthesised (3) and, in appropriate ways, transferred (4) to the clinical setting and to health professionals who implement (5) the evidence (Jordan et al., 2019).


**Figure 8 JBI model of Evidence-Based Healthcare (Jordan et al., 2019)[14].**

The JBI working group defines the first element in their model *global health* as "collaborative transnational research and action that places priority on improving health and achieving health equity for all people worldwide" (Jordan et al., 2019, p. 62). Basically, sustainable global health can only be achieved when research is built on the needs of a community, and a collaborative approach across all stakeholder groups and across countries is needed to identify the appropriate evidence. The strong emphasis on global health encouraged considerations of the audiences of the guidelines more broadly. Often guideline developers develop guidelines applicable to only one country. The NHMRCs guidelines are good examples of this approach (NHMRC, 2022). However, seeing global health as an important endpoint and considering the resources involved in guideline development it seemed appropriate to attempt to develop guidelines across countries. Evidence suggested that Nordic countries use less PR and sedation (Egerod et al., 2013a). Based on the idea that countries could learn from each other through international research (Grønkjær & Rasmussen, 2020), combined with my Erik Elgaard Sørensen Scholarship[15] and ability to communicate in both Danish and English, it was decided to include Australia and Denmark. Finally, it was predicted that guideline users would prefer international guidelines rather than having to choose between multiple versions of guidelines covering the same topic.

Related to Global Health, the JBI model also highlights the importance of collaborating and engaging with stakeholders throughout the research process (Jordan et al., 2019). Inspired by the

[14] Reproduced with permission from Joanna Briggs Institute.
[15] Erik Elgaard Sørensen scholars have supervisors from both Flinders University in Australia and Aalborg University in Denmark. The collaboration, established in 2020, is named after the late Erik Elgaard Sørensen, who was a founder of the International Learning Collaborative (ILC) and a strong advocate for fundamental care.

JBI model, emphasis was thus placed on this aspect of guideline development. Since the JBI model did not provide a detailed justification for why stakeholder collaboration and engagement were particularly important for guideline development, nor did it describe how this could be achieved, these considerations will be discussed in more detail later in Section 3.7.4.

Related to the second element, *evidence generation*, the JBI model has a pluralistic approach to evidence. It states that evidence can take many forms as long as it is developed through rigorous and well-designed research projects (Pearson et al., 2011). The approach recognises that, in general, randomised controlled trials (RCTs) provide the highest levels of evidence. However, due to the limitations of RCTs, observational studies can, in some circumstances, provide higher levels of evidence (Pearson et al., 2011; Schünemann et al., 2013a). Furthermore, the JBI authors emphasise that not all *best available* evidence can be easily quantified and measured and that qualitative data is needed in some cases. For example, they described how practitioners who have expertise in specific clinical areas can be deemed experts, and that the opinions of these experts can represent the best available evidence in areas where research is limited. Pearson et al. (2011) state:

> Expert opinion – whether it is expressed by an individual, a learned body or by a group of experts in the form of a consensus guideline – which draws on the experiences of practitioners; and the experiences of patients/clients and communities are both valuable sources of evidence (Pearson et al., 2011, p. 26).

This aligns with contemporary scholars who believe nursing knowledge is built on multiple ways of "knowing" and requires differing epistemological approaches to be identified (Barker et al., 2016; Merlin et al., 2009). This approach also aligns with the pragmatism paradigm, encouraging researchers to consider what works (qualitative or quantitative) (Creswell & Clark, 2018). The emphasis on experiences and expert opinion as valid sources of evidence encouraged me to consider these sources when limited quantitative evidence existed. How expert opinion was obtained in a Delphi study will be explained later in this chapter under Section 3.7.5.

The third element of the JBI model is *evidence synthesis*, which also can be considered a type of research (Pearson et al., 2011). Synthesising the evidence is not an easy task, and depending on the type of synthesis needed, researchers must follow certain steps to ensure the quality of the synthesis. JBI offers a comprehensive manual for conducting different types of systematic reviews (Aromataris & Munn, 2020). Each of three systematic reviews in this thesis followed a specific JBI methodology. The JBI model suggests that guideline developers consider the effectiveness of interventions and the feasibility, appropriateness and meaningfulness, where possible. Because of this suggestion, this thesis aimed to identify the perceived feasibility of all included recommendations. Due to the potential participant burden it was not practical to ask about the appropriateness and meaningfulness. Instead, participants were asked about the importance of interventions and encouraged them to explain their answers.

The fourth element, *evidence transfer*, refers to the transfer of the evidence into practice, while the fifth element, *evidence implementation*, refers to the engagement of stakeholders to inform decision-making. Although guideline development focuses less on evidence transfer and implementation, the JBI model encouraged me to consider several factors related to these elements of the model. This included the strengths of the evidence, the importance of identifying potential barriers and facilitators to guideline implementation, how to disseminate research in two countries, and finally, how to change practice.

### 3.7.3 Standards for guideline development

In addition to the JBI model's theoretical underpinnings, the guidelines also had to fulfil standards to ultimately enhance patient care and outcomes. The National Health and Medical Research Council (NHMRC) is Australia's principal organisation for supporting health and medical research. The organisation has a long history of developing rigorous guidelines (NHMRC), and their methods align with current international best practices for guideline development (NHMRC, 2020). This project aimed to follow their guidelines for developing guidelines. NHMRC suggests starting with developing the scope of the guidelines, then identifying and appraising the existing literature, developing recommendations, ensuring external review and finally implementing and updating the guidelines (NHMRC, 2020). Although important steps, external review, implementation and updating of the guidelines were outside the scope of this study. As such the guidelines developed in this study can only be viewed as preliminary until they have been reviewed. Table 8 describes all of the NHMRC's standards and how this thesis aimed to fulfil these. Where NHMRC guidance was lacking, other recognised sources were used, including WHO Handbook for Guideline Development (World Health Organization, 2014), Developing NICE guidelines (NICE, 2014), Guidelines International Network (GIN, 2022), GRADE Handbook (Schünemann et al., 2013a) and the guideline appraisal tool AGREE II Checklist (Brouwers et al., 2010).

**Table 8 How this study will fulfil NHMRC's standards for guideline development**

| NHMRC's standards for guidelines | How this study will fulfil the standards |
|---|---|
| Standard 1 - Be relevant and useful for decision-making. | The guidelines will address a significant health issue, specifically an overuse of pharmacology and PR for agitation in the ICU. The purpose is to develop patient-centred, evidence-based clinical practice guidelines for the nonpharmacological prevention, minimisation and management of patient agitation in Australian and Danish adult ICUs. |
| Standard 2 – Be transparent. | To ensure transparency, the guidelines will be publicly available with details of all steps in the guideline development process and the sources of evidence. |
| Standard 3 – Be overseen by a guideline development group. | This study will not have a guideline development group. To compensate for this, a supervisory team consisting of experts within the field and methodology experts will guide all the phases of this study through weekly meetings and discussions. Furthermore, stakeholder views will be included in all study phases. All decision-making processes will be clearly documented to ensure transparency. |
| Standard 4 – Identify and manage COI | As will be documented in all publications, my supervisors and I have no conflicts of interest. All stakeholders and study participants will be encouraged to declare COI |
| Standard 5 – Be focused on health and related outcomes. | The guidelines questions focus on health and related outcomes as identified in the literature and through stakeholder consultation. |
| Standard 6 – Be evidence-informed. | This study will be informed by the best available evidence, including two rigorously conducted systematic reviews and a Delphi study.<br>The final recommendations will be considered in terms of their harms, benefits, importance and feasibility. |
| Standard 7- Make actionable recommendations. | These guidelines will discuss and clearly articulate recommended courses of action, and the recommendations will be linked to evidence and the grading of this evidence using the GRADE approach. |
| Standard 8 – Be up to date. | Recommendations in this study will be based on up-to-date evidence. Given the rapid degree of development occurring in ICUs and the optimistic expectation for higher levels of research evidence, it is recommended that the guidelines are updated within the next five to ten years. |
| Standard 9 – Be accessible. | These guidelines will be published online, preferably in a journal with open access (depending on funding). It will be structured, easy to navigate and in plain English. This thesis will also be publicly available. |

### 3.7.4 Stakeholder consultation

A version[16] of this Section 3.7.4 was published in the Collegian in the article:

> Adams, A. M. N., Chamberlain, D., Thorup, C. B., Grønkjær, M., & Conroy, T. (2022). Ethical and feasible stakeholder engagement in guideline development. *Collegian*. https://doi.org/10.1016/j.colegn.2022.08.003.

The text has been modified to suit this chapter (see Appendix 2 for the published version).
The implementation of evidence-based practice is challenging (Braithwaite et al., 2020). Although guidelines are tools developed to support this process (Steinberg et al., 2011), the lack of guideline uptake is a major concern internationally (Girlanda et al., 2017; Heneghan et al., 2007; Reinecke et al., 2015). Lack of guideline uptake can occur when end-users do not agree with recommendations (Spitaels et al., 2017), when a guideline format is not user-friendly (Cahill et al., 2010), or when the recommendations are not feasible (Perez et al., 2012). Research has explored ways to improve knowledge uptake and to develop guidelines with a form and content that can more easily be implemented (NHMRC, 2020). Evidence shows stakeholder engagement can have an impact on the relevance and usability of the final guideline (Armstrong et al., 2018), thus increasing the likelihood of successful implementation (NICE, 2014; World Health Organization, 2014). This aligns with JBI's emphasis on stakeholder engagement to ensure an evidence-based healthcare system. Within guideline development, stakeholders include those who have a legitimate interest in a guideline and/or who may affect or be affected by it. Stakeholders may include health professionals, patients, those financing, managing or monitoring care, employers, and manufacturers (Cluzeau et al., 2012).

Despite emerging evidence for engaging diverse stakeholder groups when developing practice guidelines, often this is not done or not done well (Armstrong & Bloom, 2017; Wyatt et al., 2014). Facilitating ethical and feasible stakeholder engagement can be challenging, and many attempts at engagement have been criticised for being ineffective or tokenistic in nature (Ocloo & Matthews, 2016). Tokenistic engagement means that projects present a false appearance of inclusiveness. Tokenistic engagement occurs when stakeholders are not holding real influence when their input is underestimated and not taken seriously, and when stakeholders are not allowed to contribute in ways that are meaningful and respectful to them (Romsland et al., 2019).
Determining a meaningful and feasible guideline scope[17] is considered one of the most essential and challenging phases of guideline development (World Health Organization, 2014). The following section describes the philosophical and theoretical lens for stakeholder engagement.

[16] I contributed 85% to the research design, 90% to the data collection and 80% to the writing and editing of the manuscript.
[17] A guideline's scope sets out what it will and will not cover (NICE, 2015).

The integrated knowledge translation (IKT) model was chosen to ensure an implementable practice guideline. Knowledge translation (KT) is the movement of knowledge into practice (Olson & Oudshoorn, 2020). An increasingly popular type of KT is IKT. The IKT framework was chosen to guide the guideline development process. IKT is "a model of collaborative research, where researchers work with knowledge users who identify a problem and have the authority to implement the research recommendations" (Kothari et al., 2017, p. 299). IKT aligns well with pragmatism (Nowell, 2015) and is a promising framework for increasing knowledge uptake (Straus et al., 2013). Traditionally those who produced knowledge and those who used the knowledge were seen as two separate groups, where knowledge got transferred from production in the first group to implementation in the last (Landry et al., 2006). IKT aims to bridge these two groups early in the research process with the purpose of making research relevant and useful to its end-users (Kothari & Wathen, 2013). In IKT, researchers and knowledge users work together in all stages of a research project to solve complex real word problems (Kothari & Wathen, 2013). As explained by Kothari & Wathen (2013), IKT shares many similarities with models such as Engaged Scholarship[18], Participatory Research[19] and Co-production[20]. But in contrast to these models with backgrounds in social science, social justice and education, IKT originates from health research and focuses on increasing knowledge use to improve patient care (Kothari & Wathen, 2017; Nguyen et al., 2020). IKT brings together researchers and stakeholders such as health care providers and policymakers (Kothari & Wathen, 2013). More recently, IKT scholars have started exploring the opportunities to engage patients and the public in their research (Banner et al., 2019; Banner et al., 2020).

IKT encouraged the engagement of various stakeholders from the beginning to the end of guideline development. To ensure feasible and ethical engagement with a broad group of stakeholders, this study was also guided by patient and public engagement scholars, including the International Association for Public Participation (IAP2) and the UK's National Institute for Health Research community engagement program INVOLVE (INVOLVE, 2015). The Delphi method aligns well with stakeholder consultation as it respects individual expertise and knowledge and is based on the belief that collective decisions are more trustworthy than individual decisions (Dalkey, 1969). The next section describes in more depth why a Delphi study was appropriate to identify guideline recommendations.

[18] Engaged scholarship: Participative research process expanding the capabilities of scholars to gather perspectives of key stakeholders (Kothari & Wathen, 2013).
[19] Participatory research: Address community issues in collaborative consultation with people with lived experiences (Kothari & Wathen, 2013).
[20] Co-production/co-creation: Active involvement of consumers in the knowledge production process (Kothari & Wathen, 2013).

### 3.7.5 Delphi as a method to identify guideline recommendations

In ideal circumstances, clinical practice guidelines are based on rigorous scientific research, preferably RCTs. However, in this research, systematic reviews of the existing evidence (see Chapter 7) revealed that such evidence did not exist and could not easily be obtained. It is not unusual that in the absence of high-quality evidence on a topic, guideline developers decide to provide 'no recommendations' or even decide not to develop guidelines on a topic. For example, the 2019 ICU guideline (Devlin et al., 2018a) on nonpharmacological management of agitation decided not to make recommendations due to uncertainties around the topic. However, scholars (Loblaw et al., 2012; Neumann & Schünemann, 2020) emphasise the importance of making recommendations even in those cases where the evidence is considered insufficient. This is because it may take a long time for evidence to occur, it may not be ethical for patients and health professionals to wait for higher levels of evidence, and research shows that health professionals appreciate low evidence recommendations in areas where they are unable to find any other guidance (Neumann & Schünemann, 2020). Due to these arguments it was decided to continue developing recommendations, even when the evidence was of low quality.

Supported by pragmatism, focusing on what works, the JBI model and the need for input from stakeholders in various geographical locations, I decided to carry out a Delphi study to identify guideline recommendations. Delphi research is based on the idea that group decisions are more reliable than decisions made by individuals, or as Dalkey (1969) stated, "two heads are better than one" (Dalkey, 1969, p. v). From a pragmatic point of view, there are many situations within health care where scientific evidence is lacking, and therefore, in practice, collective opinions are often necessary to guide clinicians to provide better care (Steurer, 2011). It must be acknowledged that Delphi research does not produce indisputable facts but rather a snapshot of expert opinion (Hasson & Keeney, 2011). This snapshot can be used to inform practice (Foth et al., 2016; Mustafa et al., 2021) and guideline development (English et al., 2020; Hill et al., 2019; Umay et al., 2021). Schunemann et al. (2019) stated that when guideline developers are unable to identify evidence in the literature, *expert evidence* can be obtained. In their research project, Nasa and colleagues (2021) concluded that the Delphi method provided a rigorous way of synthesising expert evidence in guideline development. Finally, Delphi research allows equal consideration of all comments and ratings (Keeney et al., 2011). These characteristics align well with principles of patient-centred care and ethical stakeholder involvement. Equal consideration was seen as particularly important as all expert opinions, whether from patients, clinicians, or academics, were seen as having equal status.

### 3.7.6 Evidence-based clinical practice guidelines or consensus-based guidelines?

Identifying the nature of guidelines built on evidence from a modified[21] Delphi study is problematic. Djulbegovic and Guyatt (2019) describe how guideline developers tend to call their guidelines consensus-based guidelines when the evidence is of low quality. However, they strongly critique this approach and state that making distinctions between *evidence-based* and *consensus-based* guidelines is wrong and misleading since all practice guidelines should be built on evidence, whether it be high or low, and consensus (Djulbegovic & Guyatt, 2019). Aleksovska et al. (2021) agree with this position. The authors point out that in contrast to consensus statements and position papers, clinical practice guidelines are based on evidence, broad in scope, include multidisciplinary stakeholders, grade the evidence and provide strengths of recommendations (see Table 9). The current study fulfils all of these criteria, which makes it clear that the current study develops evidence-based clinical practice guidelines.

**Table 9 From Aleksovska et al. (2021)[22]**

| Phase | Clinical Practice Guidelines | Clinical Consensus Statement | Position Paper |
|---|---|---|---|
| **Scope** | Broad | Usually narrow | Narrow |
| **Multidisciplinary panel** | Yes | If necessary | If necessary |
| **Clinical question generation (PICO tool)** | Yes | Desirable | If necessary |
| **Outcome importance voting (GRADE method)** | Yes | No | No |
| **Systematic review for each PICO** | Yes | Desirable | No |
| **Grading the quality of studies (various methods)** | Yes | Desirable | No |
| **Grading the quality of the evidence for each outcome and overall (GRADE method))** | Yes | No | No |
| **Direction and strength of a recommendation (GRADE)** | Yes | No | No |
| **Reaching consensus with formal methods** | If necessary | If necessary | Desirable |

Aleksovska et al. (2021) highlight the importance of distinguishing between *good practice recommendations* and recommendations developed from consensus. Good Practice recommendations are based on common-sense, are supported by some indirect evidence and are thought to provide a large net benefit. According to the GRADE working group, these should not be

[21] In this study, a modified Delphi study means having an advanced starting point built on stakeholder consultation and systematic reviews.
[22] Reprinted with permission from John Wiley and Sons

graded (Guyatt et al., 2015). However, as discussed in the supervisory group, it was challenging to determine what constitutes common-sense strategies, and therefore no recommendations were categorised as good practice recommendations.

### 3.7.7 Summary on guideline development

Evidence-based practice guidelines are essential to optimise patient care. The JBI model provided the theoretical underpinnings for guideline development and supported me in developing a map for this study (see Figure 9). Most importantly, it was decided to develop guidelines for clinicians in two countries and to consult stakeholders throughout the study. Such consultation should be done in ethical and feasible ways, focusing on what works and what is important. The study will use systematic review methodology and finally identify guideline recommendations through a modified Delphi study involving the opinions of experts.

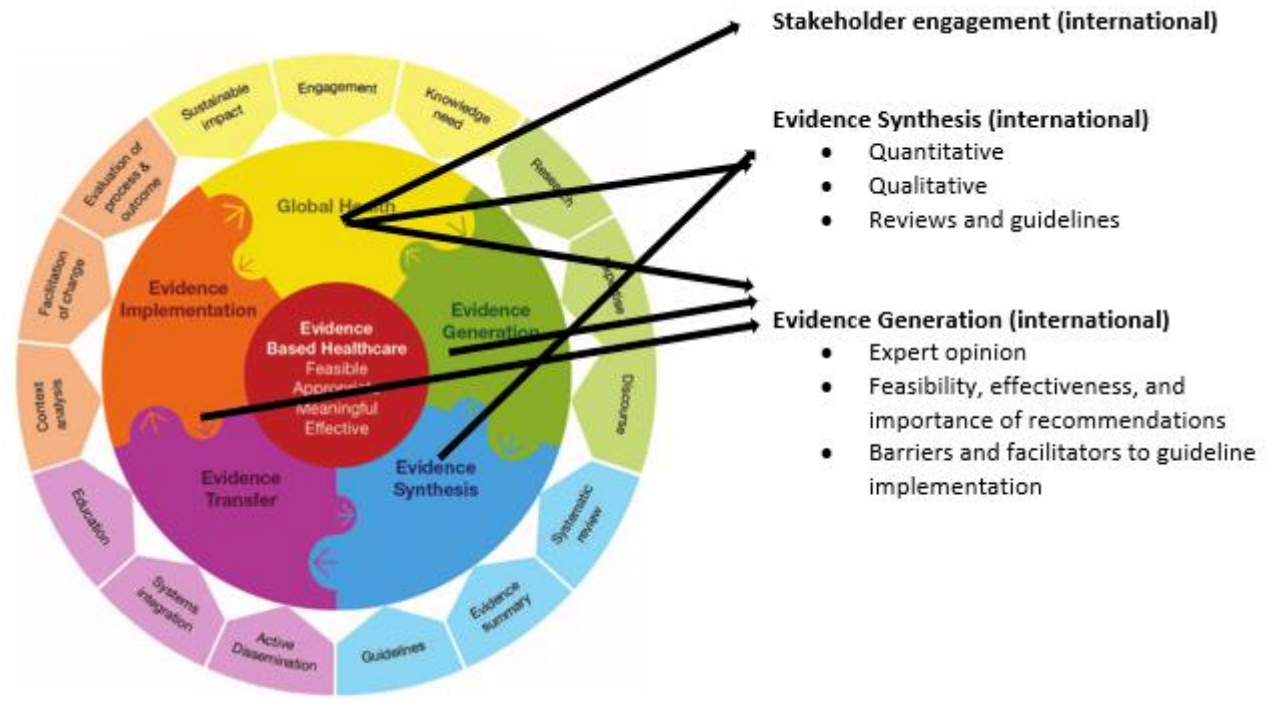



**Figure 9 The JBI model (Jordan et al., 2019)[23] - a map for the study**

### 3.7.8 The final conceptual framework

The final conceptual framework (Figure 10) shows how patient agitation in the ICU must be prevented, minimised, and managed well. Left untreated, the behaviours can have major adverse

[23] The JBI model reproduced with permission from the Joanna Briggs Institute.

outcomes for patients and their caregivers. NPSs are likely to be effective as they have the ability to reverse the causes of agitation, reduce patient stress, increase comfort and relaxation and improve higher-order cognition. NPSs must be provided using a patient-centred approach that considers the staff-patient relationship, integration of care and the influence of the context. However, it is essential that guideline recommendations are implementable and improve patient outcomes. Therefore, the development of evidence-based clinical practice guidelines should involve the needs and knowledge of international stakeholders, synthesis of different types of international evidence, the involvement of experts in a Delphi study, identification of the feasibility and importance of recommendations and the barriers and facilitators to guideline development. Overall, the implementation of evidence-based practice guidelines on nonpharmacological prevention, minimisation and management of agitation is expected to result in a range of positive patient and staff outcomes.

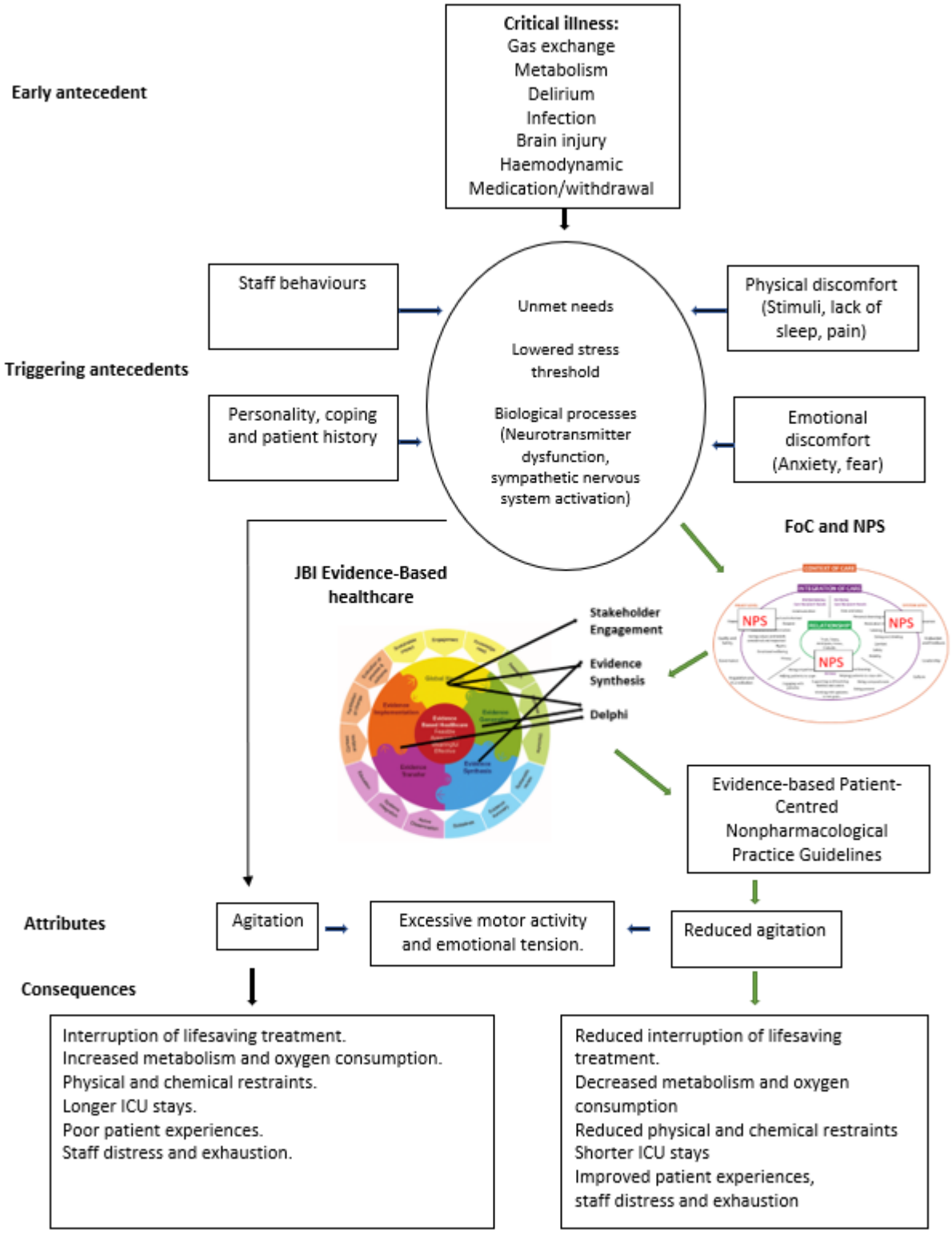



**Figure 10 Final conceptual framework**

There are limitations to this framework that must be acknowledged. The two theories focusing on unmet needs and reduced stress threshold originate from dementia care. Although there are strong arguments for using these, future research may explain agitation in the ICU differently. Furthermore, a broad variety of literature that was not critically appraised is used in the present study. Nevertheless, appraisal of the literature is not the aim of a conceptual framework. Instead,

scholars argue that a variety of literature is likely to produce a more comprehensive picture of concepts (Ravitch & Riggan, 2016; Risjord, 2009). Despite these limitations, the framework provides a new understanding of agitation and a strong argument for identifying NPSs for agitation through guideline development.

## 3.8 Conclusion

This chapter presented a unique conceptual framework. The conceptual framework clarified multiple concepts and how they relate to each other. It provided an argument for the importance of developing evidence-based, patient-centred clinical practice guidelines on nonpharmacological prevention, minimisation, and management of agitation in the ICU. It also provided a map of how such guidelines could be developed in feasible and ethical ways. Overall, the framework informed the study questions and design and provided a lens through which the findings could be interpreted and discussed. Chapter 4 presents the philosophical and methodological underpinnings supporting this research.

# CHAPTER 4: PHILOSOPHICAL AND METHODOLOGICAL UNDERPINNINGS

## 4.1 Introduction

Chapter 3 described the conceptual framework of this study. The conceptual framework guided the choices made about the research topic and questions and provided a lens through which the findings could be interpreted and discussed.

The present chapter provides a detailed justification and explanation of the philosophical and methodological underpinnings of this research. A robust and flexible philosophical and methodological foundation was needed to reflect my perception of knowledge as a researcher and generate trustworthy knowledge that could eventually guide clinical practice.

This chapter is initiated with a presentation of the rationale for choosing pragmatism as the research paradigm and a description of how pragmatism informed guideline development. Based on the previously described conceptual framework, the reasons for choosing a multiphase mixed-methods methodology and the individual methods used in each study phase are described. Finally, researcher positionality and reflexivity are described.

The overall aim for which the philosophical and methodological choices were made was to develop preliminary patient-centred, evidence-based clinical practice guidelines for the nonpharmacological prevention, minimisation and management of patient agitation in Australian and Danish adult ICUs. A secondary aim was to identify the implications of developing clinical practice guidelines across two countries.

## 4.2 Philosophical stance of this study

When commencing a research project, it is essential to consider the overarching philosophical assumptions and beliefs that provide the lens through which the research is conducted and understood. A set of beliefs and assumptions about knowledge is also called a worldview or a paradigm (Creswell & Clark, 2018; Kuhn, 1970). Once the aim and research questions were established for this study, it was clear that multiple methods, including qualitative and quantitative approaches, were needed to comprehensively address the questions. Pragmatism was chosen as the philosophical stance to rigorously guide the use of these different approaches. The next section describes why neither post-positivism nor constructivism were appropriate paradigms for this study. The decision was made to use pragmatism amongst other philosophical approaches because, as explained in this chapter, pragmatism supported the development of clinical practice guidelines.

### 4.2.1 Post-positivism, constructivism and pragmatism

As demonstrated in Figure 11, research paradigms can be understood on a continuum, starting with post-positivism at one end and constructivism at the other (Creswell & Clark, 2018; Johnson & Onwuegbuzie, 2004; Sexton, 2007). The two ends have very different ontological and epistemological beliefs. Ontology is the theory of *being* and focuses on what is real and what exists, while epistemology is the theory of how we gain knowledge (Creswell & Clark, 2018). Related to ontology, post-positivist researchers promote the notion that a singular reality exists independently of the researcher. In terms of epistemology, post-positivists contend that knowledge can only be claimed through the objective collection of data (observations or measurements) (Tashakkori et al., 2020). Post-positivist researchers use deductive reasoning (from theory to hypothesis, to data) to test existing theories and, from this, are able to make generalisations (Creswell & Clark, 2018).

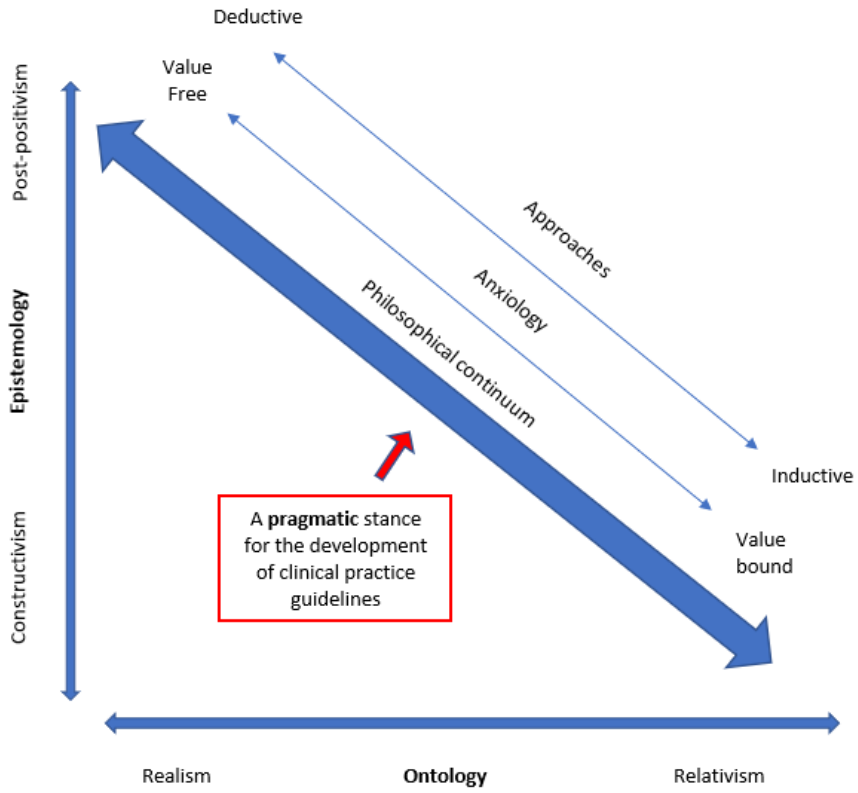



**Figure 11 Overview of paradigms. Modified from Sexton (2007), Aliyu et al. (2015) and Cresswell & Clark (2018.**

In contrast to post-positivism, constructivists believe in relativism, meaning that multiple realities exist. Constructivist researchers believe that knowledge can be gained through social interactions, subjectivity and lived experiences (Denzin & Lincoln, 2018). They use inductive reasoning and interpret qualitative data to find patterns and themes to develop theories (Creswell & Clark, 2018).

Constructivism aims to understand the meanings others have about the world and, therefore, is not interested in making generalisations.

#### *4.2.1.1 Pragmatism – focusing on what works*

For many years the two paradigms, post-positivism and constructivism, were seen as incompatible and contradictory. However, in the 1980s, researchers started to mix qualitative and quantitative methods to address complex research questions (Tashakkori et al., 2020). This resulted in the emergence of new research paradigms combining qualitative and quantitative methods - pragmatism being one of these (Creswell & Clark, 2018). Although pragmatism as a research paradigm did not advance until the 1980s, the philosophical movement began in the United States back in the 1870s by the pragmatists William James, John Dewey and Charles Sanders Peirce (Creswell, 2014). Over the years, pragmatism has been refined by contemporary pragmatists, including Richard Rorty and Susan Haack (Mayumi & Ota, 2022).

Pragmatists argue that researchers should not be forced to choose between post-positivism and constructivism. Instead, the focus should be on finding the most appropriate ways to answer a research question (Creswell & Clark, 2018). Florczak (2014) emphasises that while pragmatism is a move away from rigid principles and absolutes, this does not mean a move away from rigour and logic.

#### *4.2.1.2 Epistemology and ontology of pragmatism*

A central tenet of pragmatist epistemology is the belief that there are several ways of knowing. Therefore, pragmatism allows a plurality of methods when investigating a phenomenon and encourages both induction, valuing subjectivity, context and experiences, and deduction, valuing objectivity, generalisation and testing of theories, in the same study (Creswell, 2014). Some pragmatists prefer the word 'abduction', meaning moving (in one study) between induction and deduction (Morgan, 2007).

Related to ontology, pragmatism argues that the aim of research should not be to accurately represent reality but to produce valuable outcomes (Yvonne Feilzer, 2010). Thus pragmatists are interested in *working truths* or *useful knowledge* that supports action (Tashakkori et al., 2020), solves real work problems (Morgan, 2014), generates helpful products (Biesta, 2015) or provides insights into real-world phenomena (Johnson & Onwuegbuzie, 2004). Pragmatists also emphasise that knowledge is context-bound and may change over time (Kaushik & Walsh, 2019).

### 4.2.2 Pragmatism - an appropriate philosophical approach to guideline development

This thesis builds on the beliefs of John Dewey and classic pragmatism. Dewey embraced a democratic and pluralistic style involving collaboration, discussion and participation (Allemang et al., 2022). He provided an action-orientated framework for research, aiming to use the best methods to address practical issues arising from communities (Dewey, 1941; Morgan, 2013; Yvonne Feilzer, 2010). Dewey argued that knowledge is created between humans and their interactions with the environment (Biesta & Burbules, 2003; Dewey, 1929).

Dewey's pragmatism was seen as an appropriate approach for guideline development for several reasons. Firstly, pragmatism focuses on solving real-world problems and takes into account what is needed, rigorous and feasible (Biesta, 2015; Morgan, 2014). This approach aligns well with guideline development that ultimately aims to solve practical problems by developing practice-based knowledge and optimising patient care (Steinberg, Greenfield, Wolman, Mancher, & Graham, 2011). Having a pragmatic approach to guideline development means that guideline developers will balance scientific rigour, stakeholders' need for guidelines and the affordability of guideline development (Browman et al., 2015). Browman et al. (2015) argue that guidelines can become too rigorous and adhere too much to standards to a point where they are no longer feasible, impactful, generalisable and effective. The PADIS guidelines are an excellent example of this, where no nonpharmacological recommendations were made for agitation due to insufficient high-quality evidence.

Second, pragmatism supports the research methods most suitable for answering a research question (Kaushik & Walsh, 2019). Thus, in the present study, pragmatism supported the use of different methods, including stakeholder consultation, systematic reviews with both quantitative and qualitative data and a Delphi study with both qualitative and quantitative data. These methods are explored and justified in Chapters 5 and 7. Third, pragmatism puts emphasis on asking important research questions that are socially situated and grounded in problems (Kaushik & Walsh, 2019). This philosophical stance encouraged the identification of a research gap and subsequent consultation of stakeholders to better understand their needs in order to develop implementable and impactful guidelines. Finally, pragmatism contends that knowledge cannot be separated from the context in which experiences occur (Morgan, 2013). This belief played a major role in the design of a study carried out over two countries. For example, it encouraged the consideration of the definition of consensus to take into account that participants from two countries could have different views. It also encouraged comparisons of the results between Danish and Australian participants. Other paradigms exist supporting both qualitative and quantitative data collection. These include transformative, dialectics and critical realism (Shannon-Baker, 2016). Table 10 provides an overview of why other mixed methods paradigms were excluded.

**Table 10 Excluded mixed-methods paradigms with rationales**

| Mixed methods approaches | Rationale for exclusion |
|---|---|
| **Transformative paradigm**<br><br>This paradigm provides an emancipatory and participatory perspective in mixed-methods research (Mertens, 2003, 2007). This paradigm focuses on social imbalances and aims to bring about positive social change for marginalised groups (Mertens, 2003), | This research did not aim to seek outcomes exclusively beneficial for marginalised groups. |
| **Critical realism**<br><br>Critical realism is a philosophy that integrates realist ontology (where entities exist independently of being observed) with a constructivist epistemology (where there are multiple ways of understanding reality) (Creswell & Clark, 2018; Maxwell & Mittapalli, 2010). The goal of the research is to understand the 'real world' that is external to experiences (Morgan, 2013). | Critical realism puts more emphasis on philosophical assumptions than pragmatism and is less open towards alternative methods such as those used in the stakeholder consultation phase of this study. In contrast to critical realism, pragmatism focuses on 'what works' rather than making specific choices between postpositivist and constructivist paradigms. |
| **Dialectics**<br><br>Dialectics is particularly appropriate for studies with conflicting data. This approach sees research through both constructivist and postpositivist lenses and offers a technique to reconcile seemingly opposing concepts, theories or datasets. The argument is that when multiple paradigms are in dialogue throughout a study, this contributes to new and different insights (Greene & Hall, 2010). | As conflicting qualitative and quantitative data were not expected, this approach was deemed inappropriate. |

## 4.3 Multiphase Mixed Methods Methodology

This thesis chose a multiphase mixed-methods methodology because the research objectives involved rigorous guideline development requiring both qualitative and quantitative methods (see Figure 12).

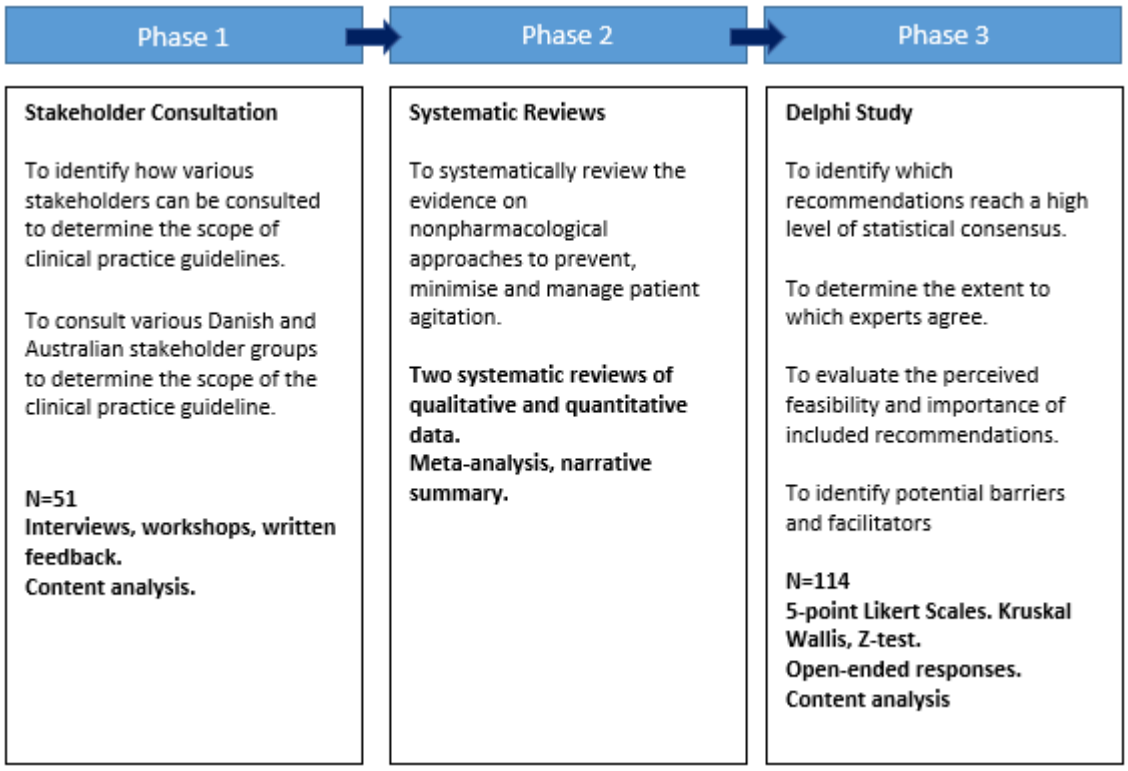



**Figure 12 Study phases, research objectives and qualitative and quantitative methods**

Mixed methods research design is a form of inquiry that encourages the collection of multiple types of data to comprehensively answer a research question. At the core of mixed methods research lies the concept of *integration*, ultimately leading to meta-inferences. Quantitatively this integration is expressed as 1 + 1 = 3 or qualitatively as qualitative + quantitative = more than two individual outcomes (Fetters & Freshwater, 2015). In other words, integrating different types of data leads to a greater understanding of the phenomenon under investigation. To be more precise, this study used a mixed-method approach for *development* and *complementary* reasons.

Development means that one study informs the development of the next to address a central research aim (Greene et al., 1989). This is an important purpose and strength of the study. It was believed that by exploring the needs of stakeholders in the first phase, the results would affect the validity of the systematic reviews in phase two. Similarly, the findings from phases one and two were likely to increase the validity of the tentative recommendations in phase three. The tentative recommendations could then be 'tested' and further explored in phase three.

Complementary means that the results from one study elaborate, enhance, illustrate or clarify results generated by another (Greene et al., 1989). In this study, it was predicted that the qualitative data in the Delphi study would facilitate a more comprehensive understanding of the quantitative data, potentially increasing the validity of the findings in the Delphi study.

Commonly, mixed methods research is categorised into convergent design, explanatory sequential design or exploratory sequential design (Creswell & Clark, 2018). Yet, not all mixed methods studies can be fulfilled with one of these standard approaches. The current study aimed to start with a stakeholder consultation phase collecting qualitative data, continuing with two systematic reviews collecting qualitative and quantitative data and finishing with a convergent Delphi study collecting both qualitative and quantitative data simultaneously (see Figure 13). When researchers decide to combine exploratory, explanatory and convergent approaches through sequentially aligned studies that build on each other's findings to answer an overall research question, a multiphase (Creswell, 2011), or multistage (Fetters et al., 2013), mixed methods approach is appropriate. Based on this argument, a multiphase mixed methods design was chosen for the present study. A multiphase mixed methods design has many advantages, such as the flexibility of the content in the individual phases and multiple research outputs (McBride et al., 2019). This thesis builds on Creswell and Hirose's (2023) six gold-standard quality criteria for mixed-methods research to ensure a rigorous mixed-methods study.

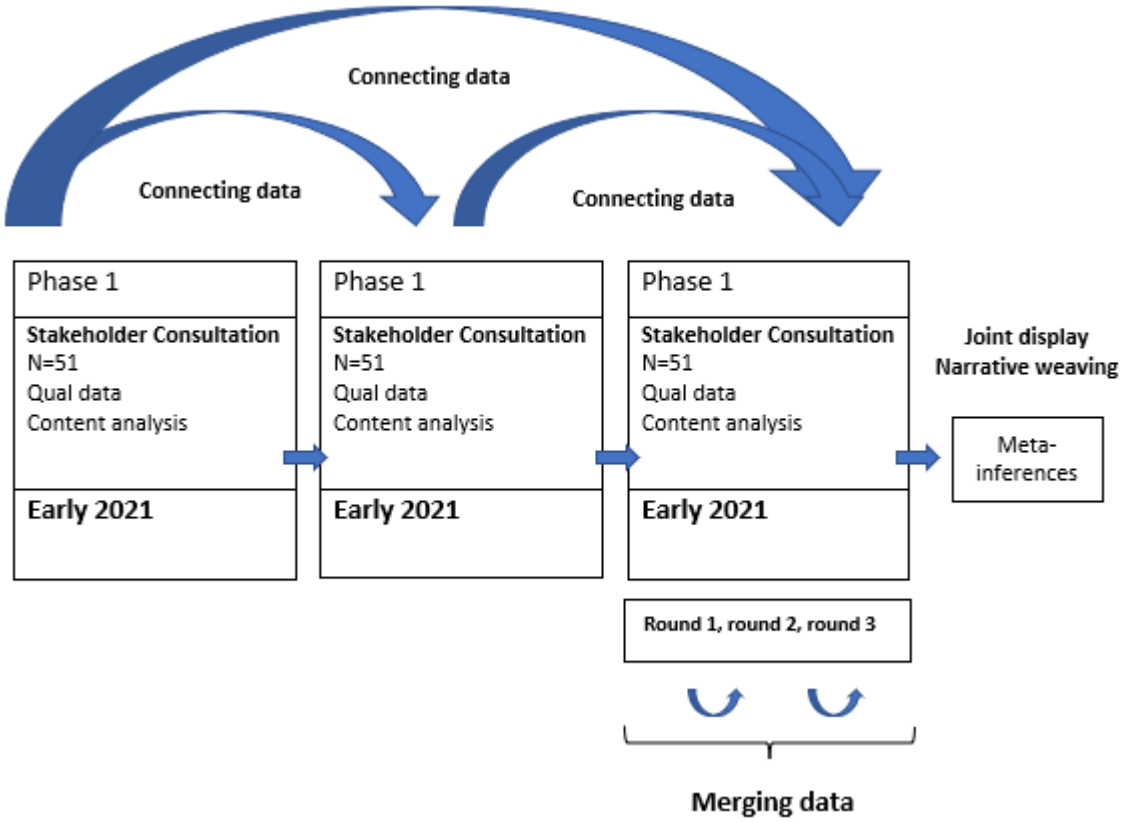



**Figure 13 Multiphase mixed-methods design**

### 4.3.1 Integration of data

Mixed methods research contains more than simply collecting qualitative and quantitative data. A central point of mixed methods research is the integration of data. Data integration has been described as one of the most challenging aspects of mixed methods research, as there are multiple ways (Younas & Durante, 2022) of bringing together words and numbers (McBride et al., 2019). This study integrated data in different ways (see Figure 13). Throughout data collection and analysis, data was connected and merged. After the study phases were complete, data from all study phases were integrated through joint displays and narrative weaving.

Connecting data means that the analysis of one study informs the development of the next, with no direct comparison of results (McBride et al., 2019), a method often used for sequential mixed methods design (Creswell & Clark, 2018). In the present study, data was connected between study phases one and two, study phases two and three, and study phases one and three. Merging data means analysing qualitative and quantitative data separately and then comparing the results from both datasets (Creswell & Clark, 2018, pp. 221-249). This method was used to integrate qualitative and quantitative data in study phase three. After completing the last study of this thesis, the insights gained from all study phases were explored. There are multiple ways in which researchers can integrate data from all study phases in a mixed methods study (2021). For the current study, it was decided to integrate the findings from all three study phases through joint displays and narrative weaving. The intent of this process was to gain new insights that went beyond what had already been learned from individual studies and to make meta-inferences (Fetters et al., 2013; Guetterman et al., 2015). According to Teddlie and Tashakkori (2020), meta-inferences are inferences derived from different types of data sets in a study. Developing meta-inferences has become an essential part of mixed methods research and helps the researcher to make more robust conclusions (Hirose & Creswell, 2023).

## 4.4 Researcher positionality and reflexivity

It has been argued that positionality and reflexivity are essential elements in all types of research to ensure transparency and rigour (Jafar, 2018; Polit & Beck, 2016). Positionality can be described as "the recognition and declaration of one's own position in a piece of academic work" (Jafar, 2018). When researchers place themselves in perspective and critically consider how their values, interests and assumptions may influence data collection and interpretation, this is called reflexivity (Polit & Beck, 2016). I will first describe my positionality to help the reader understand the lens through which this work was analysed. Then I will describe how I used reflexivity as a way to manage bias.

When I commenced this thesis, I had work experience in Danish, Australian and Norwegian healthcare settings, with extensive clinical experience in Norwegian and Australian ICUs. As

described in the introductory chapter of this thesis (see Section 1.7), the broad practice variances between institutions and countries and the suboptimal care for agitated patients motivated me to commence the study. As a clinician, it seemed meaningful to develop a practical tool that could be useful to staff and improve patient care.

Regarding research experience, I had previously used the case study method to explore how nurse managers support the well-being of nurses in the Australian ICUs (Adams et al., 2019b, 2019c). Related to ontology, having worked with critically ill patients and their families in ever-evolving ICU environments, I acknowledge that both multiple perceptions of realities and hard facts such as numbers, volumes and medicine exist concurrently, and are both philosophical approaches essential for keeping patients alive. Regarding epistemology, I contend that truth can be discovered or constructed in different ways, either socially through closeness and subjectivity or sometimes through distance and objectivity. While Danish and Australian participants' viewpoints were likely to diverge at times, fundamentally, I believe that all participants were likely to progress our knowledge of 'what works' for patients in the ICU.

Given my subjective clinical experience background as an ICU nurse as well as the lack of available guidance on guideline development where little evidence exists, I needed to provide robust and ethical arguments for all of my choices, and be aware of factors influencing these choices to avoid researcher bias. To minimise bias and avoid placing preconceived beliefs and opinions into the different stages of the study, I maintained a reflexive journal and often discussed personal, methodological, and contextual factors influencing the study with the international supervisory team. Through critical feedback and discussions, I was able to reflect on how personal experiences and opinions affected the study and, from this, make more informed decisions. I used reflexivity throughout all study phases.

Three stages of this study were particularly challenging. The first occurred after stakeholder consultation in study phase one. I wrote in my reflexive journal:

> "Stakeholders [from study phase one] mention interventions such as active listening, trust, respect, prioritising safety and supporting patient dignity. All of these seem like common sense. I am not sure such suggestions should be in guidelines…."

I decided to include interventions I considered "common sense" and see how people considered them during the cognitive interviews and pilot tests. While a physician expressed a similar concern to my own (see Table 17), I heard a layperson saying those (I considered "common sense") strategies were very important, and an ICU clinician saying, "this is the problem, it seems logical, but it is not being done". We discussed the issue in my supervisory group and considered that amongst a diverse group of Danish and Australian guideline end-users, how could we tell what is common sense and what is not? The recommendations, therefore, stayed within the guidelines.

The next challenge occurred when choosing interventions relevant to the ICU in the umbrella review presented in Section 7.3. I also managed this issue by using my reflexive journal as well as by discussing any interventions I had the slightest doubt about with my supervisors. When doubt still existed after our discussions, I would include the intervention and see how other ICU clinicians considered it during the pilot tests. If doubts still existed after the pilot tests, the interventions would be included.

Another challenging area was when deciding on what items to modify, and what constituted new items between the Delphi rounds. Below is an example of an excerpt from my reflexive journal during data analysis of the first Delphi round:

> One Australian nurse mentioned *Trauma Informed Care* as a useful strategy for agitation. I have never heard of Trauma Informed Care. I am tempted to say this strategy belongs under the category 'knowing about the patient background and preferences' rather than being a strategy in its own right. I do need to be aware of my own pre-existing experiences and ideas and be true to the data rather than forcing the data into pre-existing categories.

With years of clinical experience in critical care nursing, it was tempting to organise data into categories familiar to me. However, there was a risk that important interventions would remain undiscovered. Therefore, I had to set aside my own views and experiences and try to be open to new ideas. Overall, through all study phases, the risk of bias was reduced by actively writing down, reflecting on, and frequently discussing my personal assumptions at supervisory meetings.

## 4.5 Conclusion

This chapter provided an overview of and justifications for this research's philosophical and methodological considerations. Pragmatism offered a flexible and action-orientated paradigm. A multiphase mixed-methods design was chosen to provide depth and breadth to the data and enable the researcher to comprehensively address the research aims. Within the multiphase mixed-method design lay three separate studies, with each phase informing the next.

Chapter 5 reports the research methods used in phase one, consulting stakeholders, and phase three, involving a Delphi study. Phase two methods and results are reported together in chapter 7.

# CHAPTER 5: METHODS

## 5.1 Introduction

Chapter 4 provided an overview of this study's philosophical and methodological considerations. While the methods of this study were introduced in the conceptual framework, this chapter provides a more detailed description of the methods used in study phases one and three. The methods used in study phase two are described in Chapter 7 (see methods for systematic review one in Section 7.2.3 and systematic review two in Section 7.3.3), together with the results of this study phase. This decision was made since the methods for the systematic reviews are widely accepted and did not require the same level of justification as study phases one and three.

## 5.2 Study phase one: stakeholder consultation

### 5.2.1 Introduction

The aim of study phase one was to consult various Danish and Australian stakeholder groups to determine the scope of the clinical practice guidelines. Developing a well-founded guideline scope was challenging due to the lack of literature supporting how to do this. Therefore, based on pragmatism, IKT and guided by patient and public engagement methods, a seven-step framework engaging stakeholders in identifying the scope of the guidelines was created. This section describes the seven steps (see Table 11) undertaken and the learned experiences of using these steps. A version[24] of this Section 5.2 was published in the Collegian in the article:

> Adams, A. M. N., Chamberlain, D., Thorup, C. B., Grønkjær, M. & Conroy, T. (2022). Ethical and feasible stakeholder engagement in guideline development. *Collegian*. https://doi.org/10.1016/j.colegn.2022.08.003

The text has been modified to suit this chapter (see Appendix 2 for the published version).

[24] I contributed 85% to the research design, 90% to the data collection and 80% to the writing and editing of the manuscript.

**Table 11 Steps for stakeholder engagement**

| Steps | Tasks |
|---|---|
| **Step 1** | Clarify the aim of engagement. |
| **Step 2** | Identify relevant stakeholders. |
| **Step 3** | Consider how to find stakeholders. |
| **Step 4** | Consider if your project requires a Human Research Ethics Committee (HREC) review. |
| **Step 5** | Plan how to engage:<br>- Decide on the level of engagement.<br>- Consider what questions to ask the stakeholders.<br>- Offer different forms of engagement.<br>- Decide to engage stakeholder groups separately or simultaneously.<br>- Ensure clear and effective communication.<br>- Maximise benefits and minimise harm.<br>- Allocate sufficient time and resources. |
| **Step 6** | Consider how you will increase trustworthiness and integrity. |
| **Step 7** | Evaluating the project and assessing the impact of engagement. |

### 5.2.2 Step 1: Clarifying the aim of engagement

Guideline developers must articulate a well-defined aim for stakeholder engagement and justify why it is needed (Andrews et al., 2012). By clarifying the aim, clear boundaries and limitations can be set, and appropriate methods chosen. The aim will depend on the stage of guideline development. For example, will stakeholders help select a topic, scope the guideline, identify and synthesise the evidence, develop recommendations and/or disseminate and implement the recommendations? Our project aimed to engage stakeholders to advise on the appropriate scope of clinical practice guidelines. A mixed-methods systematic review carried out in Chapter two indicated the need for guidelines (Adams et al., 2021), and systematic searches suggested that no guidelines existed on the topic.

### 5.2.3 Step 2: Identifying all relevant stakeholders

When identifying relevant stakeholders, it is essential to ask the following questions. Who will be directly and indirectly affected by the guideline? Who would want to be involved? Are there any organisations representing the condition that is the focus of the guidelines? For example, the UK's National Institute for Health Care Excellence (NICE) invites organisations, representatives of service users and registered stakeholders with specific knowledge of or experience with a condition to comment on the scope of their guidelines.

For this project, no relevant organisations or representative groups of service users existed. Therefore, it was necessary to consider who the consumer stakeholders were and how to reach them. The project was reaching ICU survivors who were likely to not have a clear memory of their

ICU stay due to sedation, reduced levels of consciousness and confusion. These previous patients could also have disabilities, including cognitive difficulties and challenges around speech. Due to these factors, it was decided to also involve family members who had experiences with their loved one being agitated in ICU.

Researchers who had published on similar and related topics in peer-reviewed journals (e.g., agitation, sedation, delirium, PR or comfort in the ICU) were also invited, as they were likely to bring a broader picture of agitation in ICU. Consideration was given to whether policymakers and those in hospital leadership positions should be invited. However, in this early phase, it was decided to prioritise those with lived experiences. See Table 12 for an overview of the eligibility criteria for stakeholders.

**Table 12 Eligibility Criteria**

| **Inclusion criteria** |
|---|
| Adult (18 years or older) |
| Can read and understand either English or Danish. |
| Have a computer available and an internet connection. |
| Have experience with agitated behaviours in the adult ICU. For example, have experienced being agitated during an ICU admission, visiting a family member or a friend who was agitated, managing agitation as a clinician or have expertise in agitated behaviours through research |

It is also necessary to consider how many stakeholders to engage. Most commonly, the aim of a scoping project is not to make generalisations; therefore, a large number of stakeholders is not necessary. However, guideline developers should have an inclusive approach and ideally seek various perspectives from individuals with diverse backgrounds (NHMRC, 2020). It was decided to seek a variety of stakeholder groups from different geographical locations.

### 5.2.4 Step 3 Considering how to find stakeholders

It is essential to consider how to find stakeholders. The Guidelines International Network (GIN) Public working group, a broad group of researchers, health professionals and consumers, suggests using either open or targeted invitations or a combination of these (Cowl et al., 2021). Open invitation means publicly publishing a draft guideline scope and asking anyone to provide feedback. The advantage of this method is that anyone can be involved, and since stakeholders are unknown to the guideline development group, they are unlikely to feel pressured to agree with the group, thus reducing bias. The risk is that nobody provides feedback because nobody feels responsible, or too many provide feedback leaving guideline developers overwhelmed with responses (Cowl et al., 2021). Targeted invitations mean sending out invitations directly to relevant stakeholders. This method can be more effective as it takes less time to find stakeholders, and if

they are sufficiently advised, they will know exactly what is required from them. The disadvantage is that important voices may be lost (Cowl et al., 2021). Both open and targeted invitations were used (see Appendix 8, 9 and 10). Danish and Australian researchers were identified through MEDLINE searches and contacted these people directly. The study also reached out broadly through personal networks, already identified stakeholders and relevant professional organisations, including colleges of critical care nurses, intensive care physicians, physiotherapists and occupational therapists. Finally, various patient organisations from different geographical locations in both countries were contacted. Organisations interested in supporting the study reached out to their members via emails and newsletters. Stakeholders could then read more about the study and register their interest online on the project webpage.

### 5.2.5 Step 4: Considering if the project requires a Human Research Ethics Committee (HREC) review.

Stakeholder consultation should be an integral part of all health-focused research. The Australian National Health and Medical Research Council (2016) states consultation activities are more likely to result in ethically conducted patient-centred research. However, the concept of engagement is relatively new, and confusion exists around ethics and the risks involved for stakeholders. Scholars argue that ethics approval is unnecessary when patients and the public are consulted or involved in developing the processes and scope of projects as opposed to being research subjects or participants (Involve, 2009). Consultation in guideline development poses a very low risk of harm to stakeholders. This is because being consulted differs from participating in research where data, such as personal information and experiences, are collected, transcribed, analysed, published and stored. Therefore, consultation of stakeholders rarely causes ethical concerns (Australian Clinical Trials Alliance, 2021). However, regardless of the nature of their engagement in a project, ethical dilemmas can arise (Pandya-Wood et al., 2017; Salerno et al., 2021). Examples of this can be when stakeholders feel pressured to participate; when they provide certain answers due to their relationship with a guideline developer; when stakeholders do not fully understand their role or the aim of a project; or when guideline developers breach confidentiality. Due to these concerns, it is recommended to follow ethical principles for stakeholder engagement as described by Scholars in the field (Pandya-Wood et al., 2017; Salerno et al., 2021), while also contacting a relevant ethics committee for advice on local requirements.

In this thesis, stakeholder consultation was exempted from ethics review. This decision was based on advice from the Flinders University Ethics committee, as the stakeholders were acting as specialist advisors in the planning and designing of a guideline scope, thus not directly participating in research.

### 5.2.6 Step 5 Planning how to engage

Once the *why* stakeholder engagement is needed and the *who* stakeholders are is clear, it is time to identify *how* to engage stakeholders. It is crucial to make a tailored plan that will suit the project's purpose and the characteristics of the involved stakeholders. Guideline developers should work ethically and recognise the limitations of the resources available (Involve, 2015; Pandya-Wood et al., 2017). Below is described the importance of considering the level of engagement, if different stakeholder groups should be engaged separately or simultaneously, what questions to ask the stakeholders, what forms of engagement to use, how to ensure clear and effective communication, how to maximise benefits and minimise harm, and finally, how to allocate sufficient time and resources.

#### *5.2.6.1 Deciding on the level of engagement.*

IKT projects require varying levels of engagement at various times (Andrews et al., 2012). Guideline developers must be clear about the level of engagement required for their project. The IAP2 Public Participation Spectrum can help to define the exact role of the stakeholders (see levels of engagement Figure 14)

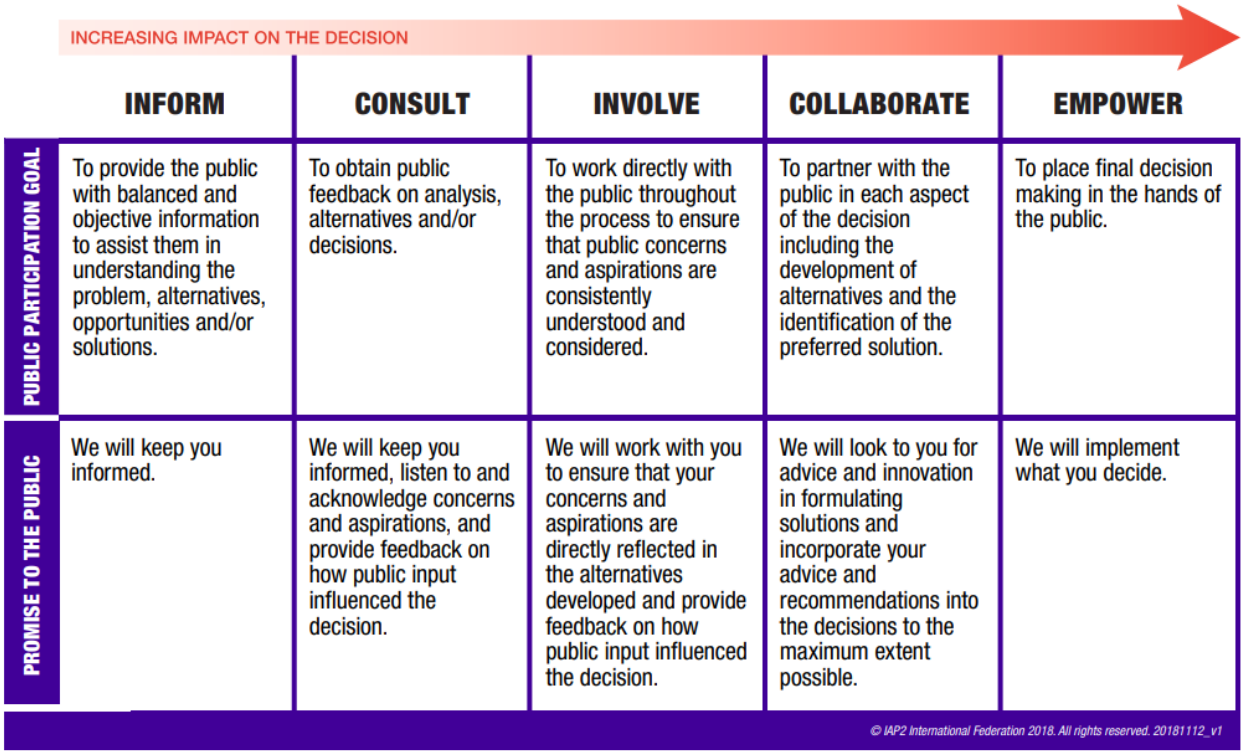



**Figure 14 IAP2 Spectrum of Public Participation (2018)[25]**

The level of engagement ranges along a continuum from *informing* through to *collaborating* and *empowering*. At the lower level of engagement, stakeholders are informed but not able to influence decision-making processes. In contrast, at the higher end, the decisions are fully led by the

[25] Reproduced with permission from the IAP2 working group

stakeholders. Levels of engagement may depend on many factors, such as the aim of the project, the financial resources, and the timeframe. In guideline development, *informing* can be used to inform and raise awareness about guidelines and their updates. *Consultation* can be used in different phases but is commonly used to get advice on the guideline's relevance, scope or review tentative recommendations. *Involvement* and *collaboration* often refer to stakeholders who are members of the guideline development group where they can review evidence or carry out research. Finally, *empower* refer to stakeholders who help implement and disseminate research.

It was decided to consult stakeholders about the guideline scope. While consultation has been criticised for being tokenistic (Arnstein, 2019) and a 'tick box' exercise compared with approaches that collaborate and empower stakeholders, it can be a vital step in international guideline development, allowing a larger group of people to be heard. Consultation suited our aim, and while stakeholders were not able to make final decisions, their advice directly influenced the determination of the final scope. Stakeholders were continuously kept informed about the progress of the guideline development, and those who agreed to be contacted regarding participation in the Delphi study all received an invitation to this study.

#### *5.2.6.2 Considering what questions to ask the stakeholders.*

A proposed guideline scope, built on the existing literature, should be developed before consultation commences (see the draft scope in Appendix 11). Guideline developers can then seek input on the proposed content, such as the population, end-users, setting, interventions, and meaningful outcomes (Cowl et al., 2021; NICE, 2014). Identifying potential barriers to knowledge translation early in a project (Jordan et al., 2019; Kothari & Wathen, 2013) is also important, in particular for rigorous guideline development (Brouwers et al., 2010). Therefore, stakeholders were asked about predicted barriers to guideline implementation. Danish and Australian laypeople and professionals reviewed and pilot-tested all questions. See Table 13 for examples of questions and Appendix 12 for the welcome letter with a complete list of questions.

**Table 13 Examples of questions for stakeholders**

| Examples of questions |
|---|
| Are the guidelines needed? Please explain your answer. |
| Do you think there are other aspects the guideline should cover? Please explain your answer. |
| Who will find the guidelines useful? |
| What strategies do you think work for agitated patient behaviours in the ICU? |
| What kind of results are you hoping for? |
| Do you predict any difficulties when trying to use the guideline? Please explain your answer. |

#### *5.2.6.3 Offering different forms of engagement.*

Engagement can take different forms and occur online or face-to-face through workshops, meetings, open online discussions, or submission of written feedback. Guidelines developers have described how online participation in guideline development facilitates honesty, openness and inclusiveness (Grant et al., 2018). Three different modes of online engagement, including workshops, one-on-one meetings, and the opportunity to provide written feedback, were offered to maximise opportunities for stakeholder input. The opportunity of providing written feedback was offered to allow busy shift workers to participate at a time convenient to them. One-on-one meetings were offered to allow more speaking time to individuals and as an option for those feeling uncomfortable providing writing feedback or raising their voices in workshops. Workshops are often used when consulting stakeholders in research projects (Gutman et al., 2020; Honey-Rosés et al., 2020; Northway et al., 2014; Rapport et al., 2014). They are different from focus groups. While focus groups are helpful research methods to reach an in-depth understanding of a phenomenon (Gawlik, 2018), the aim of workshops is not to develop new knowledge. A workshop is defined by the Cambridge Dictionary as: "a meeting of people to discuss and perform practical work in a subject or activity" (*Cambridge Dictionary*, 2021). Thus, it was hoped that the interactions and negotiations during the workshops would result in more comprehensive answers to the questions asked.

#### *5.2.6.4 Engaging diverse stakeholder groups separately or simultaneously.*

It was decided early on to separate lay people from professionals to promote comfortable group dynamics and avoid power imbalances (Côté-Arsenault & Morrison-Beedy, 2005). It was also predicted that separately engaged groups would facilitate the development of unique and more directly relevant questions for each group. For instance, Tong et al. (2012) successfully invited 30 consumers to participate in two 3-hour workshops to select the topic and outcomes of early-stage chronic kidney disease. While such a method may be effective, it is also resource intensive. Therefore, it was decided to engage diverse professional groups, such as nurses, physicians and researchers, simultaneously. ICU focus groups often involve different professions to encourage discussions of different opinions (Collet et al., 2019; Kvande et al., 2017). Such an approach can also efficiently integrate several views into a project with strict time and resource restrictions. However, it is necessary to have an experienced facilitator present and a strong focus on clinical experiences to avoid potential power struggles (Rabiee, 2004; Wilkinson, 2004).

#### *5.2.6.5 Ensuring clear and effective communication.*

It is essential that stakeholders are fully informed before agreeing to be involved (Andrews et al., 2012; IAP2, 2017; Wright et al., 2010). When stakeholders do not feel clear about what is expected from them, this can hinder engagement (Ocloo & Matthews, 2016). While collaboration across borders has become increasingly popular, it can be challenging to ensure clear and effective communication with people speaking different languages (Dusdal & Powell, 2021). Translation of

documents and other material can be a lengthy process, and researchers, therefore, often restrict themselves to their native language (Alkhaffaf et al., 2021; Berk et al., 2011). Such restrictions can become a significant limitation of a project and can lead to important voices being lost. Therefore, it is advisable that guideline developers working with multinational groups accurately translate all recruitment material and conduct meetings in stakeholders' native language.

A bilingual online platform (click here) for people with different literacy competencies was developed to ensure all stakeholders were fully informed. The platform offered several videos and text describing the purpose of the guideline development and how stakeholders could be involved. Participant information sheets in both languages were developed, including an easy read (Appendix 13) and a standard version (Appendix 14) describing the project's purpose and expectations to stakeholders. The easy-to-read version used plain, inclusive language without medical terminology, jargon, and infographics when possible. The *standard version* contained more detailed background information without infographics. Stakeholders were advised that participation was voluntary and that they could withdraw at any time without consequences (NHMRC, 2007). Participants all provided informed consent. All material was pilot tested on individuals from Denmark and Australia, including health professionals, a researcher specialising in engaging people with disabilities in research, 'lay' people and members of minority groups.

#### *5.2.6.6 Maximising benefits and minimising harm*

Guideline developers should ensure maximum benefits for stakeholders and minimal harm (Salerno et al., 2021). It may be appropriate to reimburse stakeholders for their participation, as resource issues, for example, caring responsibilities, time, money for transport, and limited internet access, can hinder participation (Ocloo & Matthews, 2016). Participants were required to have access to a computer with an internet connection and spend more than one hour reading and answering several questions. Since reimbursing consumers in consultation projects aligns with the principles of patient and public involvement (Hayes et al., 2021), a reimbursement (AU$30/150 DKK voucher) was offered to all participants.

Stakeholders must be able to provide advice without feeling any undue burden (Salerno et al., 2021), and guideline developers must work sensitively to avoid or minimise potentially emotionally upsetting situations (Pandya-Wood et al., 2017). In our project, thinking back to their time in the ICU could be uncomfortable for some stakeholders. To moderate this, questions were developed carefully to focus on the purpose of the project (see Table 13). Participants were not asked to reflect on their own experiences directly. It was anticipated that focusing on the specific questions would minimise the risk of participants finding the involvement emotionally burdening. Although stakeholders were unlikely to become distressed during meetings, there was a backup plan in case it happened. Participants were always able to contact the principal investigator for a debrief and a

list of free online counsellors, as suggested by the literature (Pandya-Wood et al., 2017; Wright et al., 2010).

To align with principles of respect in public involvement, stakeholders must also feel appreciated and respected (Involve, 2015; Pandya-Wood et al., 2017). Researchers and guideline developers are encouraged to provide stakeholders with feedback on how their participation influenced decision-making ("IAP2 Spectrum of Public Participation," 2018). Therefore, all stakeholders in our project received a summary of our findings, a description of how their feedback contributed to the final scoping document, and rationales for why some feedback was not incorporated. Stakeholders were also asked if they would like to be publicly acknowledged for their participation in future publications (see Appendix 15 for an acknowledgement of stakeholders).

Guideline developers must be conscious of how they handle personal and sensitive information (Pandya-Wood et al., 2017). This study followed the General Data Protection Regulation (GDPR) for the European Union (EU) (EU, 2016). Informed consent was obtained according to the GDPR rules. Recording meetings and conversations may be preferable since notetaking can interrupt the flow of discussions. However, the reasons for recording must be clear and permissions obtained. Unless the aim is to carry out research, it is not necessary to transcribe recordings word by word, and personal information, such as names and institutions, should not be written down. All recordings must be destroyed promptly after notetaking, as storing such data involves risks for the stakeholders and may require ethics approval. Due to the nature of the workshops, it was impossible to guarantee confidentiality. However, participants were advised to leave their videos off and leave out their real names if they preferred. They were also reminded to respect the privacy of fellow stakeholders and not repeat sensitive information outside the workshop.

#### *5.2.6.7 Allocating sufficient time and resources*

It is important to allocate sufficient time and resources for an IKT project (Andrews et al., 2012). Guideline developers need to allocate money for reimbursements. They also need to allocate time to develop materials and for stakeholders to read through the material and think about it before giving feedback. Insufficient time may result in inadequate feedback and stress for stakeholders (Pandya-Wood et al., 2017). Stakeholders were given two to three weeks to review the scoping documents, with additional time available to any participant who requested it. A research seeding grant from the Australian College of Critical Care Nurses helped to reimburse all stakeholders for their time commitments.

### 5.2.7 Step 6: Considering how to increase the trustworthiness and integrity of the project

#### *5.2.7.1 Trustworthiness*

Using research methods to analyse data is not necessary for engagement activities (Doria et al., 2018) but can increase the quality and integrity of a study. Dealing with data from multiple

stakeholders from different countries required a systematic and rigorous approach. Content analysis is suitable when dealing with descriptive, focused and narrow questions that do not necessarily require complex interpretation (Elo & Kyngäs, 2008; Graneheim & Lundman, 2004; Liamputtong, 2009). Content analysis is often used for open-ended survey responses and is suitable when aiming to interpret text through a systematic coding process (Hsieh & Shannon, 2005). Directed content analysis is based on previous knowledge while also allowing new knowledge to emerge (Assarroudi et al., 2018; Elo & Kyngäs, 2008; Hsieh & Shannon, 2005). This suited the study as it had an a priori framework, consisting of a draft scoping document, that needed to be explored in more detail (Hsieh & Shannon, 2005). This study followed Assarroudi et al.'s (2018) steps for directed content analysis. The unit of analysis was each individual stakeholder, as stakeholder groups or countries were not compared. Even during the workshops, the responses of each stakeholder were considered individually. Researchers need to consider if they will only focus on manifest content, the text with visual and apparent content, or also on the latent content, including in-depth interpretation of the written work and participants' behaviours when being interviewed (Assarroudi et al., 2018; Elo & Kyngäs, 2008). Due to the nature of the data, including my written notes and participants' written feedback, it was only meaningful and possible to consider the manifest content. Based on the draft scoping document, a categorisation matrix, or a codebook, was developed consisting of categories and subcategories. The categories were the sections in the guidelines scoping document, and the subcategories were each individual question posed to participants. An inductive approach was used to allow new ideas to emerge. When codes did not clearly fit into the codebook's categories and subcategories, new subcategories were developed and grouped into new categories. Due to the amount of data, the software program Nvivo (QSR International, 2021) was used to code and organise data. Initially, codes were counted to identify if any subcategories or categories were more prominent than others. Although it was tempting to assume that the more frequently mentioned categories were more important categories, I realised that with patients and families only representing 6% of the total group, I could not assume this was the case. To ensure that all voices were heard, it was decided to give even weight to all themes independently of how many times they were mentioned. Frequent discussions of the analysis in supervisory meetings, increased the rigour of the qualitative analysis. To ensure transparency, guideline developers are also encouraged to feed back the results to stakeholders with a description of how the final decisions were made.

#### *5.2.7.2 Integrity*

To support the integrity of our project, all stakeholders were encouraged to declare any COI, such as financial or other interests, that could potentially influence considerations on the topic (see Appendix 16). If a significant COI was found, stakeholders would be asked to withdraw from the project. This was important since potential COI among guideline developers can damage people's trust and confidence in the guidelines (NHMRC, 2020).

### 5.2.8 Step 7: Evaluating the project and assessing the impact of engagement.

While stakeholder input is essential to the development of quality guidelines, few studies demonstrate the impact of this engagement. Such evaluation is essential to support future engagement projects and secure funding (Andrews et al., 2012). Evaluating the impact of engagement is also important to stakeholders who want to know if their contribution made a difference (Hardavella et al., 2015). Several tools exist to evaluate the impact of engagement (Boivin & Abelson), yet much evidence in this area has been criticised as being weak and anecdotal (Russell et al., 2020). Due to resource issues, the impact of the project was not assessed. However, I recommend that future guideline developers use robust methods to evaluate their projects and recognise that robust assessment must be planned early on as it is time-consuming and may require ethical approval.

### 5.2.9 Section summary

This section has described a novel seven-step framework for how various stakeholders from two countries can contribute to determining the scope of clinical practice guidelines. Particular attention was placed on the ethical and feasible aspects of stakeholder consultation. By using research methods during the engagement activity, the trustworthiness of the scoping process is increased.

## 5.3 Study phase three: Delphi study

### 5.3.1 Introduction

This Delphi study aimed to draft tentative recommendations, identify recommendations reaching a high level of statistical consensus, determine the extent to which participants agreed about recommendations and evaluate the perceived feasibility and importance of included recommendations. The Delphi method was deemed appropriate to identify final guideline recommendations. As described in Section 3.7.5 Delphi method can be used to inform practice when scientific evidence is lacking.

A modified Delphi study, including a panel of Danish and Australian experts, was carried out over three survey rounds to gain consensus on NPSs for agitation. While the first round in a *classic* Delphi study consists of open-ended questions to facilitate the generation of ideas (Keeney et al., 2001), this modified version had an advanced starting point built on stakeholder consultation and the existing literature. Building the first survey on previous knowledge is commonly done in Delphi research (Keeney et al., 2001).

This Delphi study was seen as a convergent mixed methods study collecting both qualitative and quantitative data. Each type of data was analysed separately using the appropriate qualitative or quantitative methods and then merged to inform the next Delphi round. Although Tashakkori, Johnson and Teddlie (2020, p. 230) argue that developing mixed methods questionnaires with both

qualitative and quantitative questions can be very powerful, Creswell and Clark (2018) describe mixed methods questionnaires as *light mixed methods* since the qualitative questions often play a minor role such as simply validating or explaining the quantitative data. In this Delphi, in addition to providing a better understanding of the quantitative data, the qualitative data could inform new survey items, modify items and suggest the exclusion of items perceived to be harmful or not patient-centred. Therefore, the qualitative data played a major role in the study. By applying mixed methods to the Delphi study, I separately analysed and integrated qualitative and quantitative data, which ultimately resulted in more robust conclusions[26].

The following section will follow the steps of a Delphi study. The section will start by describing the panel composition, size and recruitment of Delphi participants. It will then explain the purposes and practical aspects of the Delphi rounds, including how the surveys were developed. After this, it will explain the qualitative and quantitative data analysis. Finally, it will describe the rigour and ethical considerations of the study.

### 5.3.2 Panel composition

Identifying an appropriate target sample likely to produce high-quality guideline recommendations was seen as essential. As highlighted by Keeney, "the Delphi is only as good as the experts who participate" (Keeney et al., 2011, p. 46). However, there is no agreement about what constitutes an *expert* in a Delphi study. Some scholars have defined experts as "informed individuals" (Niederberger & Spranger, 2020, p. 425), others as those who have "'knowledge and practical experience with the issue under investigation" and a "capacity and willingness to participate" (Keeney et al., 2001, p. 48). In guideline development, an expert has been defined as "a person who is very knowledgeable about or skilful in a particular area" (Schünemann et al., 2019, p. 1). This can be a professional or a patient who has personal insight into a condition (Schünemann et al., 2019). Although some scholars believe the participation of a layperson is inappropriate due to their low levels of expertise (de Meyrick, 2003, p. 10), others argue that it is the broad involvement of both lay and professionals that increases the quality of Delphi findings (Niederberger & Spranger, 2020). Patients and family members were involved based on the recommendation to involve patients in guideline development to ensure patient-centred recommendations (NHMRC, 2020; van Dulmen et al., 2015) and the successful involvement of consumers and professionals in previous Delphi research (Serrano-Aguilar et al., 2015). To increase the robustness and validity of the multidisciplinary guidelines, this study involved a broad group of ICU clinicians and researchers who were required to have knowledge and experience with patient agitation from the ICU.

To participate, all professionals, including ICU clinicians and researchers, needed to have at least three years of clinical experience working in the ICU, hold a postgraduate qualification in intensive

[26] How mixed methods research can result in more robust conclusions is justified in Section 4.3.1

care or be a senior staff member in a managerial position in the ICU. This decision was based on nurse theorist Patricia Benner's (Benner, 2001) description of five stages of clinical competence. The model starts with the novice and then moves to the advanced beginner, the competent, the proficient and finally, the expert clinician. While the novice, advanced beginner and competent nurses lack flexibility and depend on protocols and supervisor support, the proficient nurses, who have more than three years of experience, begin to see the bigger picture and situations as *wholes* rather than parts. Although Benner believes that more than five years of experience is necessary to be an expert, this has been criticised by scholars claiming that experience alone does not necessarily reflect expertise (Baker et al., 2006). Hoffman et al. (2009) explored the differences between novice and expert nurses and, in contrast to Benner, described the expert critical care nurse as someone with more than three years of experience in critical care.

To ensure researchers' knowledge in the field was up-to-date, they were required to have published relevant papers in peer-reviewed journals within the last six years. Their research could focus on either agitation or related concepts such as sedation, delirium, PR or comfort in the ICU. For Delphi participant eligibility criteria, please see Table 14. The online submission form[27] allowed me to assess if each participant fulfilled our inclusion criteria. Participants who did not fulfil the minimum criteria or who had any COI were excluded.

**Table 14 Eligibility Criteria for Participants**

| Inclusion criteria | Rationale |
|---|---|
| **All participants:**<br>• 18 years or older<br>• Able to read and write in either English or Danish<br>• Have access to the internet.<br>• Living in either Denmark or Australia<br>• Do not have any major COI. | Eighteen years is legally required to consent to research.<br>To ensure participants fully understood requirements and to ensure the validity of survey responses.<br>All participation occurred online.<br>To capture the perspectives of Danish and Australian participants.<br>Conflicts of interest are threats to the trustworthiness of guidelines. |
| **ICU clinicians and managers:**<br>This category included all multidisciplinary team members, including nurses, physicians, physiotherapists, occupational therapists, psychologists, social workers, managers, etc.<br>• extensive experience with the management of agitation in the intensive care unit, **and**<br>• have at least three years of clinical experience working in the intensive care unit, **or**<br>• hold a postgraduate qualification in intensive care, **or**<br>• be a senior nurse/physician holding a managerial position in the intensive care unit. | To ensure that participants have insight into what it means to manage patient agitation in the ICU context. |

[27] Online submission form explained in section 5.3.4

**Table 14 Continued**

| Inclusion criteria | Rationale |
|---|---|
| **Researchers:**<br>• Must have published in peer-reviewed journals within the last six years.<br>• Research must focus on agitation, sedation, delirium, PR or comfort in the ICU. | To ensure the input of research knowledge. |
| **Patients:**<br>• Lived experience of being agitated in the ICU. | To ensure that participants have experience with agitation in ICU. |
| **Family members:**<br>• Lived experience of being a next of kin to patients who were agitated in the ICU. | To ensure that participants have experience with agitation in ICU. |

### 5.3.3 Size of the expert panels

There is no agreement on the best panel size required for a Delphi study. Delphi panels have ranged from three to 731 experts (Niederberger & Spranger, 2020). For homogenous groups, smaller samples, such as 10-15, have been considered sufficient (Keeney et al., 2011). Meanwhile, diverse panels, including both professionals and consumers from different countries, will lead to a broader range of perspectives and may require more subjects to reach stable findings (Powell, 2003). Jorm (2015) stated that results would be more stable with larger panels. It has also been suggested that group errors decrease, and the quality of the consensus increases as the sample size grows (Landeta, 2006). Panel attrition must also be taken into account. Delphi studies often suffer from high attrition rates (Keeney et al., 2011), either because the selected participants are unable to participate in the first place or due to the longitudinal nature of a Delphi study consisting of several survey rounds (Keeney et al., 2011).

Ideally, recruitment should reflect the likely ratios of different stakeholders who have experienced agitation in the ICU. Australia has 191 ICUs with 2378 available beds (Litton et al., 2020), while Denmark has 39 ICUs and 441 ICU beds (Bonde et al., 2015), suggesting that the pool of ICU health professionals is much greater in Australia, and thus more participants should be recruited from Australia. It was challenging to identify how many clinicians work in the Danish and Australian ICUs. Knowing that ICU clinicians were under significant pressure due to COVID (see Box 3), this study aimed to recruit as many clinicians as possible.

**Box 3 COVID-19 and its implication for this research**

On March 11, 2020, the WHO declared the COVID-19 virus outbreak a global pandemic and a health emergency of international concern (Cucinotta & Vanelli, 2020). The fast-spreading virus (SARS-CoV-2) lead to lockdowns across the globe. Many people struggled financially, socially and mentally during this time (Onyeaka et al., 2021). ICU clinicians were under tremendous pressure dealing with the sickest COVID patients. They were exposed to an increased death rate, grief, extended separation from their own families and the risk of becoming infected themselves. Research indicated moderate to extreme levels of severe depression, anxiety and stress symptoms in many ICU clinicians (Hammond et al., 2021).

This study recruited participants for stakeholder consultation and the Delphi study when COVID was at its peak in Denmark and Australia (between March 2021 and March 2022). A physician who wanted to help with recruitment stated, "you are literally choosing the worst month of the last 20 years to request this of them". A professional organisation for ICU physicians in Australia cancelled the advertisement in their January 2021 newsletter due to COVID-related "lack of space" in their newsletter. There were visitor restrictions in place for ICU families, and groups for ICU survivors and their family members were closed down (Hart & Taylor, 2021), leading to limited opportunities for face-to-face recruitment.

In terms of ICU survivors and their family members, it was known from the stakeholder consultation study that recruitment could become challenging (see Section 6.9). Based on this knowledge, it was decided to use different recruitment methods and, similar to health professionals, recruit as many as possible. Informed by the stakeholder consultation study and using a stratified purposive sampling strategy, the study aimed for a total of 92 participants, 60% from Australia and 40% from Denmark, including different stakeholder groups to capture variations in responses (Palinkas et al., 2015) (see Table 15 for an overview of the sampling strategy).

**Table 15 Stratified purposive sampling strategy**

| Stakeholders | Recruitment method | Target sample | Minimum group total |
|---|---|---|---|
| **Patient representatives** | Patient (5%) | 3 Australia<br>2 Denmark | 10 |
| | Family members (5%) | 3 Australia<br>2 Denmark | |
| **Health professionals** | Nurses (60%) | 32 Australia<br>22 Denmark | 82 |
| | Physicians (10%) | 5 Australia<br>4 Denmark | |
| | ICU manager or director (nurse or medical) (5%) | 2 Australia<br>2 Denmark | |
| | Physiotherapists (2.5%) | 1 Australia<br>1 Denmark | |
| | Occupational therapists (2.5%) | 1 Australia<br>1 Denmark | |
| | Psychologists, social workers and others from the multidisciplinary ICU team (2.5%) | 1 Denmark<br>1 Australia | |
| | Researchers (10%) | 5 Australia<br>4 Denmark | |
| **Total** | | | **92** |

### 5.3.4 Recruitment and sampling

The purpose of the Delphi panel was not to represent the general population but to seek expert opinion. Therefore, purposive and snowballing sampling techniques were used (Polit & Beck, 2016) (see Appendix 17 for a full overview of recruitment methods). Similar to recruitment of stakeholders in phase one, this study recruited ICU nurses, physicians, researchers, managers, physiotherapists, occupational therapists and other ICU health professionals through professional organisations (see Appendix 18. These organisations were known to my supervisors and me or identified through Google searches. When organisations agreed to support the study, they either forwarded an email to their members or posted an advertisement in their newsletters. Stakeholders from the stakeholder consultation phase who indicated an interest in being contacted again, and the people they nominated were contacted. In addition to the researchers from the stakeholder consultation phase, a few additional researchers identified in database searches were contacted. Since significant challenges were experienced when recruiting patients and family members for the stakeholder consultation phase, I planned to visit ICU survivor groups personally. It was discovered

that only one ICU survivor group existed in Adelaide, and recruitment through this group required local ethics approval. After gaining this approval, the "Survive and Thrive" (S&T) group at the Royal Adelaide Hospital invited me to present the Delphi study and talk about participation in one of their meetings. In Denmark, post-ICU groups were closed due to COVID-19, but in Aalborg, nurses still saw ICU survivors individually four months after discharge. I had the opportunity to talk online with nurses responsible for these patients, and they were happy to mention the study to visiting ICU survivors. Overall, the personal face-to-face contact allowed engagement with potential participants and clinicians and an opportunity to answer their questions directly. Meeting people directly, either in person or online, was time-consuming but considered necessary to enhance recruitment. Recruitment also took place through a broad range of patient organisations (see Appendix 19 and 20).

All interested individuals were encouraged to learn more about the study and express their interest on the study's webpage (Appendix 50). As described in Section 5.2.6.5, this bilingual webpage was built for people with different levels of literacy competency. It offered bi-lingual videos and easy-read information about the study. The webpage had been pilot tested by a variety of people from Denmark and Australia, including academics, health professionals, 'lay people' including people from ethnic minority groups and a researcher experienced in disability research. When potential participants expressed their interest on this webpage, they were screened for eligibility (see Figure 15). Those eligible to participate received a Letter of Invitation (Appendix 21) with a participant information sheet (Appendix 22 patients and family and Appendix 23 professionals) and a link to the first Delphi survey.

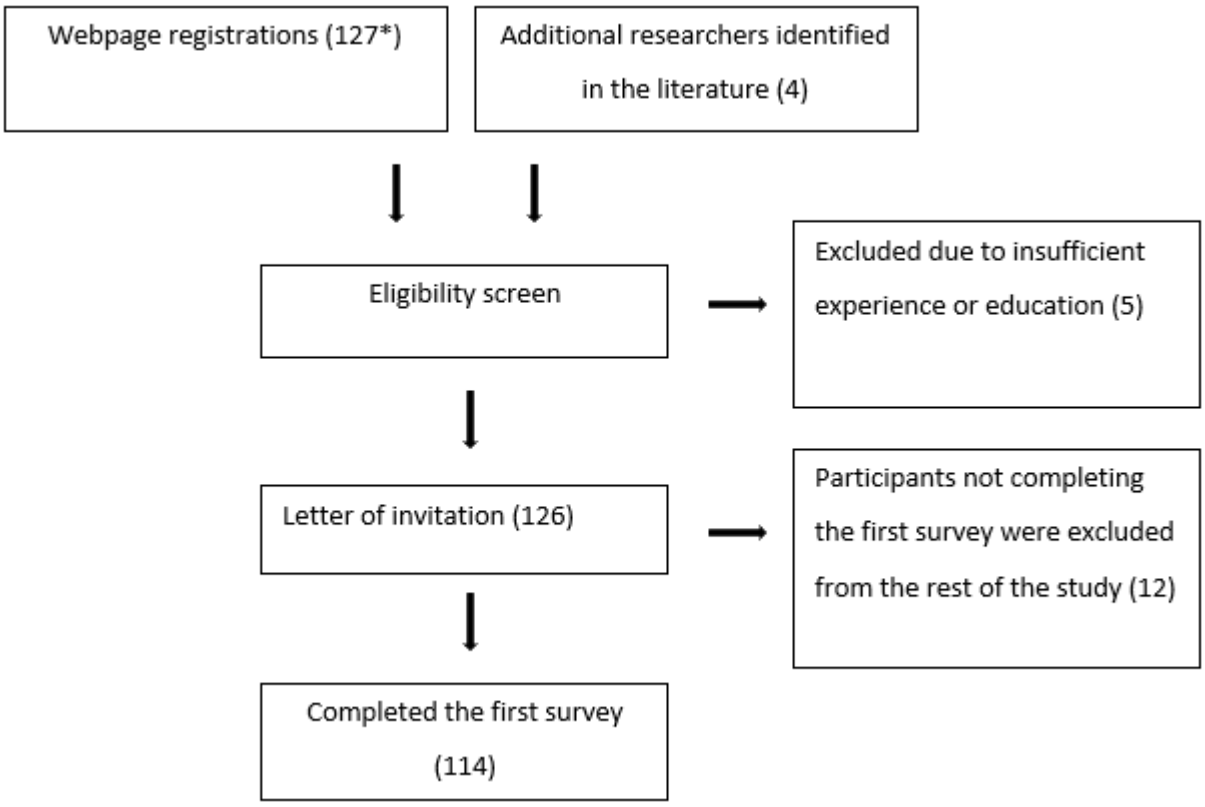



Figure 15 Recruitment process

***** Of these, 15 Australians and 12 Danes also provided advice during the stakeholder consultation phase.

### 5.3.5 Purposes of the Delphi rounds

When guideline developers use the Delphi method, they need to be clear about the purpose of each Delphi round, the type of evidence they are searching for, and thus the type of questions they will ask the participants. Ideally, guideline recommendations should be needed, safe, feasible, acceptable, meaningful and effective, as suggested by the JBI healthcare model and the GRADE working group (Alonso-Coello et al., 2016; Schünemann et al., 2013a).

The first round of the Delphi study was developed based on an amalgamation of the NPSs, the stakeholders identified as working for agitation in the ICU in study phase one, and recommendations on NPSs from the two systematic reviews in study phase two. There were no filters applied to this process, meaning that no data was removed or excluded.

The first round aimed to see which items in the first survey reached consensus and at what level. After each question block of 3-4 closed questions, open-ended questions encouraged participants to justify their choices, to modify or add recommendations or strategies, and finally to describe if recommendations or strategies should not be included in guidelines, either because they were perceived to be harmful, not patient-centred or ineffective. Participants were asked to suggest new

items as a way of discovering new knowledge (Langley et al., 2018) while also increasing participants' engagement and feelings of ownership (Keeney et al., 2011; Langley et al., 2018). To increase the trustworthiness of the evidence, the participants were required to have experience with an intervention before rating it. If participants did not have experience with an intervention, they were encouraged to rate *I don't know*.

The purpose of this first round was also to collect background information about the participants, including status (e.g., previous patient, ICU nurse, ICU physicians), age, gender and geographical location. Professionals were also asked about years of clinical experience in the ICU and their qualifications, while patients and family members were asked how long ago they had experienced agitation in the ICU (See Appendix 24 for the first Delphi survey).

The second Delphi round encouraged participants to re-consider items that reached a high level of consensus in only one country in round one. The second round also aimed to identify the level of consensus for all new items that had been suggested in the first round. Finally, this round aimed to explore the facilitators and barriers to guideline implementation. The questions related to facilitators and barriers were developed based on the advice received during stakeholder consultation in study phase one (See Appendix 25 for the second Delphi survey).

The third and final Delphi round encouraged participants to re-consider items reaching a high level of consensus in only one country in the second round, and to explore each item's level of importance and feasibility (see Appendix 26 for the last Delphi survey). Other scholars have done similar work aiming to develop or implement guide recommendations using the Delphi method (Dunn et al., 2021; Hall et al., 2016; Perry et al., 2017; Temkin-Greener et al., 2015). Importance was defined as the extent to which the panel member believed a recommendation was of value to prevent, minimise and manage agitation in the ICU (Dunn et al., 2021; Evangelou et al., 2021). This round asked about the importance as this would allow ranking of the items and provide guideline implementers with an overview of the hierarchy related to interventions' ability to decrease agitation. It was predicted that such information could help clinicians when prioritising interventions.

Feasibility was defined as the extent to which the panel member believed a recommendation could be successfully carried out within the ICU setting (s) they were familiar with (Pottie et al., 2021). It was decided *a priori* not to exclude items receiving low ratings in terms of feasibility and importance. This stands in contrast to the GRADE handbook, suggesting that the less feasible an intervention is, the less likely it should be recommended (Schünemann et al., 2013a), and Delphi guideline developers' exclusion of items of low importance and low feasibility (Hall et al., 2016; Temkin-Greener et al., 2015). However, good practices may initially be considered not feasible, but in some cases, clinicians decide to prioritise these and ensure that resources are in place.

### 5.3.6 The practical aspect of the survey rounds

There are many practical aspects to consider when planning a Delphi study. These include the number of Delphi rounds, the timeframe, how to distribute the surveys, if and when to send reminders and which participants to include in each round.

Researchers can choose to continue Delphi rounds until consensus is reached or determine the number of rounds *a priori*. Often Delphi researchers decide *a priori* to have between two to four rounds, with three rounds described as optimal (Skinner et al., 2015; Trevelyan & Robinson, 2015). It was decided *a priori* to have three rounds. Three rounds were considered to be sufficient based on other successful guideline Delphi studies (English et al., 2020; Khodyakov et al., 2019; McMaster, Wade, Franklin, & Hart, 2020). Having a pre-determined number of rounds was seen as a respectful way of involving stakeholders, who consequently knew exactly what was expected from them.

Data collection involved three online surveys created using the Qualtrics survey tool (Qualtrics, 2020), a platform facilitating online distribution in two languages. This program allowed participants to skip redundant items for ease of completion and randomisation of questions to avoid contrast effect, that is, answers being influenced by previous questions, and primacy effect, answers being influenced by assigning more time and effort to the initial questions (Skinner et al., 2015). Instructions were provided at the beginning of each survey with a list of defined terms. All survey rounds consisted of closed-ended 5-point Likert scale questions and open-ended questions.

The surveys were distributed to participants via email, asking participants to complete each survey within two weeks. This timeframe was extended by a few days in the second round due to the Easter holiday period and in the last round due to some participants asking for more time. Two weeks has been described as appropriate as it allows enough time for participants to complete the survey while preventing the study from becoming a low priority and, therefore, not being completed (Keeney et al., 2011). Email reminders were sent to non-responders after six days and again after 12 days to maximise the response rate. Reminders are important in Delphi studies and have shown to be acceptable amongst Delphi participants (Turnbull et al., 2018).

Some questions were excluded from the patients' and family members' surveys in order to develop more meaningful and user-friendly surveys. The questions excluded were carefully chosen through discussions within the supervisory team, a health clinician and a layperson. When there were doubts about an item, the item was included. Questions not posed to patients and family members related to the work processes in ICU (e.g., patients should be systematically and regularly assessed for agitation, clinical leaders should support the use of nondrug interventions, staff should be offered debriefing and education, the multidisciplinary team should collaborate), facilitators and barriers to guideline implementation and the feasibility of the included

recommendations. Twelve questions were removed from the first survey, all related to work processes. Twelve were removed from the second round, all related to barriers and facilitators. Seventy-four[28] were removed from the last, all related to work processes and feasibility of implementation.

Researchers must decide if they want to invite participants who have not completed previous Delphi rounds. The advantage is a better representation of the opinions of all of those who were invited to participate. The disadvantage is that the final outcome may not accurately represent the opinions of those who participated (Boel et al., 2021). For example, different participants could be rating the usefulness of an intervention in the first round and the feasibility of the same item in the last round. As commonly done in Delphi research (Keeney et al., 2011), only participants who had completed the first round were included in the rest of the study. It was hoped this would result in a higher level of engagement over rounds, and by only including those completing the first round that was very comprehensive, the results were more likely to represent those who participated accurately. There was also a practical reason for only including those who had completed the first round, namely that the first round allowed me to follow participants over time. For instance, I would know the country and professional backgrounds of the participants without having to ask these questions again.

### 5.3.7 Feedback

An essential feature in Delphi research is the provision of feedback to participants. Feedback allows participants to review group responses and re-consider their own responses and develop a better understanding of an issue before rating in the next round (Keeney et al., 2011; Rowe & Wright, 2001). Keeney et al. (2011) also argue that feedback can increase participant motivation and interest, thus, continued participation. While feedback should be provided carefully, as it is likely to affect opinion change in participants (Barrios et al., 2021), there is no agreement about how and what type of feedback to provide. Within the field of social psychological research, Bolger and Wright (2011) suggest providing rich qualitative feedback, including reasons for judgements, factors to be taken into consideration and even a description of analytical steps. Within health research, scholars have suggested reporting statistical feedback in the form of aggregated percentages, central tendency and a measurement of the spread of data (Trevelyan & Robinson, 2015). In reality, very few (51%) of Delphi studies provide both qualitative and quantitative feedback (Boulkedid et al., 2011).

In this Delphi study, a large amount of qualitative data was received during the first Delphi round. It was necessary to consider how to aggregate feedback and choose what qualitative data to report

[28] The last round consisted of 66 recommendations. I did not ask patients and family members about the feasibility of these 66 recommendations. In addition, they were not asked about the importance of eight recommendations related to work processes in the ICU (a total of 74).

without leading participants. As not everybody provided qualitative comments, there was also a risk that those who provided feedback had strong opinions that were not necessarily shared by the rest of the group. Furthermore, reading large amounts of feedback is cognitively demanding and likely to discourage participants (Belton et al., 2021).

In regards the providing quantitative feedback, this is also not without risks. Researchers (Makkonen et al., 2016; Rowe et al., 2005; Skinner et al., 2015) have also described the risk of the Bandwagon effect, meaning that individuals tend to conform to a majority position, thus rate items similar to most other Delphi participants. Encouraging participants to justify their choices reduced some of the bandwagon effects.

It is important to be clear about the role of providing feedback. The aim of providing feedback in this Delphi was to motivate participants and encourage them to reflect on their answers before rating in the next round. Since scholars in the field have advised researchers to be careful not to bias participants through feedback (Keeney et al., 2011), it was important not to provide feedback that would potentially bias the views of individual participants. To be as objective as possible, two documents with statistical feedback were developed. These included a brief document with graphs and an overview of the items that were to be re-rated in round 2 (see Appendix 27), and a more comprehensive document presenting all of the statistical results without graphs (see Appendix 28). The advantages and disadvantages of the two documents were discussed with my supervisory team. The comprehensive document provided the best overview of the results. Both documents needed to be available in both Danish and English. Together with my supervisors, we considered the broad group of participants and the aim of the feedback. We concluded that meaningful feedback was short feedback, as it was predicted most people would not read a long comprehensive document. The feedback also had to be understood by most people and provide enough information for participants to successfully complete the second Delphi round. Therefore, it was finally decided to develop short videos in Danish and English thanking the participants, providing an overview of the main findings and describing the aim of round two. Click here for the Australian online feedback video and here for the Danish version[29]. Participants interested in a comprehensive description of the statistical results were encouraged to contact me. No participants asked for the statistical feedback.

### 5.3.8 Likert-scales

Delphi study researchers must be aware that the type of rating scales they choose will heavily influence the final consensus (Lange et al., 2020). This study considered using the 9-point interval scale used in the RAM appropriateness method (Khodyakov et al., 2020), the 9-point GRADE scale (Baldwin et al., 2020; Guyatt et al., 2008a) and the 5-point scale (Doley et al., 2017;

[29] For the purpose of thesis publication, the webpage is described in Appendix 50.

McMaster et al., 2020; van der Maaden et al., 2015) to measure levels of agreements, as these have all been used successfully in guideline development. However, as pointed out by Lange et al. (2020), the final decision should depend on what is meaningful and practical considering the aim of a study. Therefore, the final decisions were based on the study's aim, the participants' characteristics, and the nature of NPSs in the ICU.

The labelled five-point Likert scale was chosen for this study as it has been successfully used in other Delphi studies of guideline development involving both specialists and patients (McMaster et al., 2020). The five-point scale has also resulted in better data quality, internal consistency and discriminative validity (Varndell et al., 2021). Studies have found that the 5-point scale is easier to use and understand compared with a 9-point scale (Remus et al., 2021). The 9-point scale has been criticised for being too long and abstract, thus a barrier to the completion of the survey. In contrast, the 5-point scale has been described as being less confusing and increasing the response rate (Bouranta et al., 2009). Furthermore, it has been suggested that no more than five response alternatives should be offered to people with disabilities (Hartley & MacLean Jr, 2006). Since it was important to develop a scale easily understood by previous ICU patients who might have disabilities, it was decided to use a 5-point scale.

The scale aiming to determine if participants agreed to statements asked participants to rate practice recommendations from *strongly disagree, somewhat disagree, neither disagree nor agree, somewhat agree* to *strongly agree*. Delphi studies have often used this scale (Gilbert et al., 2020; Haven et al., 2020; Xu et al., 2020).

The scale aiming to identify if interventions were perceived to work proved to be more challenging, and the scale was changed several times based on multiple pilot tests and discussions with the supervisory team. Through pilot tests in both countries, it was decided to measure perceived usefulness rather than effectiveness or helpfulness. Perceived usefulness was referred to as the degree to which participants believed strategies help reduce patient agitation, thus contributing to the quality of treatment for patients. Perceived usefulness did not consider if it was *easy* or *possible* to use the intervention. Perceived usefulness scores have been used in Danish (Riiskjær et al., 2012) and English (Claudio et al., 2015) research.

In terms of survey anchor points, it was decided to exclude a scale ranging from *never useful* to *always useful*. This was decided as interventions in the pilot tests were rarely seen as *always effective*. It was decided that when dealing with agitated behaviours, interventions rated as *somewhat effective* were very important and should be considered in the guidelines. Therefore, the anchor points included *not useful at all, not very useful, neutral, somewhat useful* and *very useful.* As described below, there was also an *I don't know* option.

Another scale asked participants to rate the extent to which they believed factors could be barriers to guideline implementation in the ICU (s) they knew. The 5-point scale included *definitely a barrier, somewhat a barrier, neutral, somewhat not a barrier,* and *not a barrier.* Participants were also encouraged to explain their responses or add additional barriers in the open-ended response options.

The fourth scale asked participants to rate the extent to which they believed factors could be facilitators and helpful to guideline implementation in the ICU (s) they knew. The 5-point scale included *not helpful at all, somewhat unhelpful, neutral, somewhat helpful and very helpful.*

The fifth scale asked participants to rate included recommendations for importance. This scale was modelled from earlier instruments (Dunn et al., 2021) and included *very important, moderately important, neutral, less important* and *not important*.

The last scale asked participants how feasible they believed the included recommendations were. The study considered using the GRADE EtD frameworks rating 5-point rating scale (Pottie et al., 2021), including *yes, probably yes, probably no, no, varies,* and *I don't know*. However, the scale was not chosen as the anchor points were not on a continuum and did not have a natural mid-point, and as such, it would not be possible to rank the recommendations. Furthermore, the option *varies* could be applicable to all recommendations in an ever-changing ICU environment. Based on these arguments, it was decided to use a modified version of the tool developed by Dunn et al. (2021), including *very feasible, moderately feasible, neutral, less feasible* and *not feasible.*

#### *5.3.8.1 Applicable to all rating scales*

Research indicates a more positive response rate in surveys that use a descending-ordered response scale going from *agree* to *disagree* or from *often effective* to *never effective*, thus creating bias to the results (Chyung et al., 2018). It was, therefore, decided only to use ascending-ordered response scales.

Whether to give participants the option of rating *I don't know* is debated in the literature (Beatty et al., 2019). Denman et al. (2018) studied methodologies to manage the *I don't know* option and concluded that participants use this response when they lack motivation, feel unsure or simply lack knowledge. They suggested researchers consider the participants and the content and carry out pilot tests before including an *I don't know* option (Denman et al., 2018). I decided to include an *I don't know* option in all scales for two main reasons. Firstly, it was anticipated that some participants would not have experience with all the different strategies, and having experience was required to answer questions reliably. Secondly, the pilot test indicated a clear need for the *I don't know* option.

It has also been discussed if the Likert scale should have a midpoint. Some scholars argue that having a mid-point may weaken the reliability and validity of a scale (Trevelyan & Robinson, 2015). Others argue that having a mid-point does not affect the result in a Delphi study where participants are anonymous to each other (Trevelyan & Robinson, 2015). Furthermore, having a mid-point does not negatively influence the quality of the responses; in fact, it avoids forcing participants to choose a direction (Toma & Picioreanu, 2016; Tsang, 2012). Nevertheless, it is important to label the mid-point to avoid misunderstandings and misinterpretations. For instance, some may see the mid-point as *no opinion, I don't know, neither agree nor disagree* or as *not applicable* (Tsang, 2012). In this study, the mid-point was labelled *neutral,* meaning "I don't have an opinion about this".

### 5.3.9 Translation of documents and pilot testing surveys

#### *5.3.9.1 Translation process*

International Delphi studies have become increasingly popular. Since the translation of surveys is a highly complex field requiring a rigorous process to ensure correct translation (Behr, 2018), researchers often restrict themselves to the English language to save time and resources (Alkhaffaf et al., 2021; Berk et al., 2011). When researchers require international experts to demonstrate English proficiency, English-speaking countries often dominate the results (Berk et al., 2011). Having such an approach means that many voices will be lost. Therefore, this study aimed to develop a bilingual Delphi study for both English and Danish-speaking participants.

I translated the Participant Information Sheets, Letters of Invitation, recruitment flyers, web pages and videos and all documents were checked for accuracy by my Danish supervisors. The surveys needed additional considerations as inaccurate translation could affect the validity of the findings. No gold standards exist for how surveys can be accurately translated (Epstein et al., 2015). Alkhaffaf et al. (2021) and Vegsund (2018) have highlighted some necessary steps, including *forward* and *backward* translation processes.

#### *5.3.9.2 Testing surveys*

It is strongly advised to test all surveys through cognitive interviews and pilot tests to ensure reliability and validity and minimise the burden for participants (Clibbens et al., 2012; Keeney et al., 2011; Ryan et al., 2012). Concerningly, research indicates that few Delphi studies pilot-test their survey instruments (Jünger et al., 2017), and often those who do only test the first survey (Clibbens et al., 2012). For the current study, it was decided to test all Delphi surveys in both Denmark and Australia through cognitive interviews and pilot tests. This was seen as important to ensure that the questions were easily understood and interpreted similarly by all participants, that the questions were relevant and necessary, that the Likert scale options were relevant, user-friendly and logical and that the order of the questions did not influence answers. It was also seen as important to assess the amount of time taken to complete the survey to ensure it was not too long, and to report the expected time in the Participant Information Sheet.

The cognitive interviews and pilot tests were performed with people similar to the Delphi participants, including clinicians, researchers and laypeople. These people did not participate in the Delphi study, and the data collected was not included in the data analysis.

#### 5.3.9.2.1 Cognitive interviews

Cognitive interviewing involves participants reading survey items and thinking aloud to report their thoughts as they respond to the survey. (Beatty & Willis, 2007; Ryan et al., 2012; Willis, 2004). The role of the researcher is to listen actively and provide verbal probing such as "what does [term] mean to you" (Beatty & Willis, 2007, p. 299). The first survey was tested in English on three people (one layperson above 60 years of age and two health professionals), and after translation into Danish it was tested in Danish on one person (layperson). The second survey was tested in English on one person (layperson) and in Danish on one person (layperson). Cognitive interviews were not carried out for the last survey, as it did not involve any new items. Testing the surveys on laypeople was chosen due to the importance of ensuring an inclusive language everybody would understand. Overall, the cognitive interviews provided important insight into the interpretation of questions and the identification of potential issues.

#### 5.3.9.2.2 Pilot tests

The literature suggests pilot testing surveys on at least twelve people (Ruel et al., 2015). Therefore, the first Delphi survey was pilot tested by seven people in English and eight people in Danish. The second survey, the shortest of all three surveys, was tested by two people in English and one in Danish. The final survey, which did not involve new items but two new scales, was pilot tested by three people in English and two people in Danish. The pilot participants provided feedback on the ease of understanding the aim, instructions and questions, the structure of the surveys and the time taken to complete it. They were also encouraged to offer additional feedback on how the survey could be improved. Table 16 shows the improvements made to the surveys after cognitive interviews and pilot testing. Table 17 shows examples of the type of feedback received from the pilot tests. The process involved in carrying out an international Delphi study is presented in Table 18.

**Table 16 Improvement to the surveys after cognitive interviews and pilot tests**

| Survey improvements |
|---|
| Vague recommendations were made direct and to the point. |
| The language was changed to accommodate participants who were not health professionals. |
| Ambiguous questions or questions involving more than one topic were changed. |
| All potentially confusing terms were defined at the beginning of each survey. These included agitation, patient-centred care, NPS, usefulness, importance, feasibility etc. |
| Some scales were explained in detail. For instance, there was a need to explain each rating in the usefulness scale. |
| The length of the survey was reduced by removing questions that seemed irrelevant, and by combining similar questions. |
| Clearer instructions were provided. |
| Technical aspects were improved, including reminding participants when they had forgotten to answer a question, adding a timeline in Qualtrics allowing participants to follow their progress, making sure the Danish participants knew exactly how to change the language to Danish etc. |
| The scales went through multiple changes to ensure they measured exactly what I was interested in, to ensure clarity and to make sure they measured the same constructs in both English and Danish. The most significant change was moving from the 9-point semantic differential scales to the 5-point Likert scales with labelled options. |
| Participants needed to be reassured that a later survey would focus on the feasibility of the recommendations, as this was something the pilot participants wanted to discuss early on. |

**Table 17 Examples of pilot test feedback**

| Feedback | Decisions made based on feedback |
|---|---|
| A physician pointed out that some recommendations seemed like common sense and that it was difficult not to agree with these, thus questioning the relevance of the recommendations. | My supervisors and I discussed if such recommendations should be taken out altogether. We noticed some pilot participants saying the same “common sense” interventions were important and often not carried out in the clinical area. We decided that while it was important feedback, how could we justify which recommendations were common sense amongst a diverse group of people? The recommendations, therefore, stayed in the study. |
| A pilot participant described the difficulty of agreeing to recommendations while feeling they were not feasible. An example was provided: "I feel that patients should be regularly and systematically assessed for agitation. But due to the time used on this, it may mean that other patients would not be getting optimal treatment. So how can I agree with the statement?" | From this feedback, we included a statement in the first survey encouraging participants to focus on what works and what is helpful. We also promised that a later survey would ask about the feasibility of each recommendation. |

**Table 18 Process of the international modified Delphi study**

| Steps | Task | Rounds |
|---|---|---|
| **1.** | Identification of the overall aim, objectives and purpose of each Delphi round. | |
| **2.** | Selection of appropriate scales (5-point Likert: strongly disagree – strongly agree, 5-point Likert: not at all useful – very useful). | Round one |
| | Selection of demographic questions. | |
| | Selection of open-ended questions. | |
| **3.** | Development of a tentative survey. | |
| **4.** | Cognitive interviews of the survey in English. | |
| **5.** | Pilot tests English. | |
| **6.** | Forward translation by two independent Danish-speaking translators (professional translator with a master's degree and a health background + author) | |
| **7.** | Comparison of the two translations. Research team (bilingual speaking researchers) discussions of terms, revisions and consensus on a Danish version. | |
| **8.** | Cognitive interviews in Danish | |
| **9.** | Pilot tests of the Danish survey | |
| **10.** | Backwards translation by a native English-speaking health professional proficient at speaking Danish. | |
| **11.** | Final amendments discussed with the research team. | |
| **12.** | First survey sent out to all participants in two countries | |
| **13.** | Data analysis. Data not translated until after analysis. Translated findings discussed with the research team. Decisions made on what items to modify and what to include. | |
| **14.** | Selection of appropriate scales for measuring barriers and facilitators to guideline implementation. | Round two |
| **15.** | Steps 3-11 repeated. Interview and pilot tests focusing on new items and scales. No cognitive interviews. | |
| **16.** | Development of feedback videos in both languages, with emphasis on ensuring that participants from both countries received the same information. | |
| **17.** | Second survey sent out to participants in both countries. | |
| **18.** | Data analysis. Same as step 9. | |
| **19.** | Selection of appropriate scales for measuring importance and feasibility. | Round three |
| **20.** | Steps 3-11 repeated. Pilot tests focusing on new scales, instructions and length of survey. No cognitive interviews. | |
| **21.** | Development of feedback videos. This was done based on a large number of participants who watched the last feedback videos. | |
| **22.** | Third and last survey sent out to participants in both countries. | |
| **23.** | Data analysis. Same as step 13, but this time without focusing on preparing for the next round. | |

### 5.3.10 Qualitative data analysis

In rounds one and two, qualitative data analysis was conducted prior to the quantitative analysis to ensure the data was not influenced by the quantitative ratings and whether an item was likely to be included or excluded.

Similar to the qualitative analysis of stakeholder comments in study phase one, I followed Assarroudi et al.'s (2018) steps for directed content analysis. Directed content analysis is often used to analyse open-ended responses in Delphi research (Hand et al., 2021; Keeney et al., 2011; Topperzer et al., 2020). The unit of analysis was initially each individual participant. However, when comparing data, the unit of analysis changed to stakeholder groups or countries. As suggested by Assarroudi et al. (2018), a formative categorisation matrix was developed based on the items in the first survey (see Appendix 29). The matrix consisted of categories and subcategories. The subcategories were each individual survey item. Grouping subcategories with similar meanings formed the categories. A set of coding rules were developed that could be applied to areas answering the following questions:

- Why did participants rate the way they did?
- Should items be reworded, and if so, in what ways?
- Should a recommendation be excluded from the guidelines, and why?
- Are there any approaches that should be added, and why?

When codes did not clearly fit into the categorisation matrix, new subcategories were developed and grouped into new categories. By the end of the last Delphi survey, the categories and subcategories were refined and divided into larger themes informed by the FoC framework. As Keeney et al. (2011) suggested, the wording was kept as close to the participants' words as possible. Appendix 30 provides examples of how codes were pooled to form subcategories and categories. Due to the volume of qualitative data and to maintain rigour, coding was managed by using the Nvivo software (QSR International, 2021). In the early stages of coding, *intercoder agreement* was established between my supervisors and me to ensure analytical credibility. This is explained in detail later in this chapter (see Section 5.3.13.3). In addition, my supervisory team and I reviewed and discussed the preliminary analysis to ensure that the new or re-worded strategies or recommendations captured the meanings and words of the participants as much as possible.

### 5.3.11 Item generation and modification

One of the important features of a Delphi study is that it allows participants to suggest new items or modifications to items. Such suggestions are then reviewed, edited and included in the next round.

Similar to other Delphi studies (Colucci et al., 2010) and to avoid an overwhelming amount of items, I developed quality criteria for the inclusion of new items (see Table 19). The rules for developing, modifying or removing items were discussed in depth with my supervisors. It was

agreed that the items had to reflect new ideas, be unambiguous, demonstrate an explicit action and not simply be a comment or a statement, fall inside the scope of the study and stem from personal experiences, e.g., statements such as 'I've heard psychiatric nurses use this method, and I think it may be useful' were excluded. I considered applying the criteria 'is supported by existing literature'. However, previous Delphi researchers have emphasised how strategies not reported in the existing literature can be valuable in areas where little knowledge exists (Osika, 2004, p. 46). Based on this, it was not explored if the suggested approaches were known in the existing literature. While some Delphi researchers have decided to exclude infrequently occurring items (Schmajuk et al., 2018), Hasson et al. (2000) suggest that such an approach goes against the basic principles of Delphi research. They argue that a unique feature of the Delphi method is the participants' judgement of the data, not the researchers, and therefore all voices should be given equal consideration. Other scholars support this argument stating that the weight of each individual opinion in a Delphi study should be equal (McPherson et al., 2018). Based on these arguments, it was decided to include all suggested items independently of how many times they were mentioned.

In this study, items that had already reached ≥ 75% consensus were not reworded or added to consecutive rounds for rating. According to Jandhyala (2020), changing items that have already reached consensus and asking participants to rate a modified item in the following round may introduce structural bias and potentially a false consensus. Instead, modifications were only made on items not reaching consensus and where comments suggested alternative wording or actions.

**Table 19 Criteria developing or modifying new items**

| | |
|---|---|
| Developing new items | • A new idea<br>• Unambiguous<br>• An explicit action<br>• Fall inside the scope of the study<br>• Stem from personal experiences |
| Modifying items | • Stem from comments suggesting alternative wording or actions.<br>• Items already reaching ≥ 75% consensus cannot be modified. |

### 5.3.12 Quantitative data analysis

All statistical data were imported to and analysed via the Statistical Package for Social Science (SPSS) statistical software (Corp., 2021) version 28.0.1. The data was then reported as suggested by Lang et al. (2006). The response rate for the first round was calculated by dividing the number of completed survey responses by the number of people who received the survey. The response rates for the second and third surveys were determined by dividing the total number of completed surveys by the total number of participants who had completed the first Delphi round. Demographic data were reported using descriptive statistics, including frequency counts, percentages, means and standard deviations.

Likert scales normally produce ordinal data as they rank data in order and do not have equal intervals between item points like interval data (Chyung et al., 2017; Liddell & Kruschke, 2018). However, authors have argued that parametric tests, assuming a normal distribution, fairly similar sample sizes, and based on *central limit theorem* in studies with reasonably large (>30) sample sizes, can be used and may provide more accurate analysis (Harpe, 2015; Lang et al., 2006; Subedi, 2016). It has also been argued that increasing the number of Likert scale points to 11 will bring scales closer to a normal distribution, thus making parametric tests suitable (Wu & Leung, 2017). While some Delphi studies choose to treat data as interval data (Heiko, 2012), issues such as Type I error and subsequent problems around interpretation can occur when applying ordinal data to statistical analysis that requires interval data (Harwell & Gatti, 2001; Liddell & Kruschke, 2018).

Due to these considerations, and before deciding on which statistical tests to use, the data in the first and the last Delphi rounds were tested for normal distribution in SPSS. In both rounds, the items were highly skewed to the left (>60% had skewness of <-1, and >10% had kurtosis > 3), indicating that the data significantly deviated from normal. It was also noticed that the different groups (countries, stakeholder groups) varied considerably in size (n= 6 - 74) depending on how many people had experience with the individual items. Due to these observations, and the decision to use the five-point Likert scale with ordinal data properties, it was decided to finally analyse all data using non-parametric methods.

All "don't know" responses were treated as missed data and excluded from the group response to ensure that the results reflected the opinions of those who had experience with an approach, a method also used in other Delphi studies (Vogel et al., 2019). The means were used to rank data, as this has been described as appropriate for ordinal data (Morgan et al., 2004).

Consistent with best practices of Delphi research (Jünger et al., 2017; Keeney et al., 2011), this study predefined the criteria for consensus, and the level of consensus needed for an item to be included in the guidelines before the study commenced.

#### *5.3.12.1 Consensus*

Consensus in this study was defined as "collective agreement" (Keeney et al., 2011, p. 14). It is essential to the validity of a Delphi study to be clear about what researchers want consensus on and how it will be established. However, the concept of and criteria for consensus vary. This thesis differentiates between consensus; meaning agreement between participants, and the level of consensus; referring to the most common response. Consensus, or agreement between participants, can be found when there is a narrow spread of data. To measure this spread of data, researchers often look at either the standard deviation (SD), the interquartile range (IQR) or the coefficient of (relative) variation (Gracht, 2008; Trevelyan & Robinson, 2015).

The SD shows the spread of data around a mean, and in normally distributed data allows the reader to visualise 95% of the data falling within about two SDs on either side of the mean (Lang et al., 2006). However, when data is not normally distributed, outliers can pull or skew the mean in unrealistic directions, making it meaningless to measure SDs (Gracht, 2008; Liddell & Kruschke, 2018). The coefficient of variance comes with the same challenge as it is calculated by dividing SD by the mean. This test is particularly useful when comparing results between Delphi rounds, which was not the aim of this study.

This study used the IQR, a dispersion indicator often used when data is not normally distributed. Calculating the IQR has been described as an accurate and robust way of determining consensus without being affected by extreme scores (Gracht, 2008; Heiko, 2012). The IQR measures the dispersion of the median by taking the difference between the 25$^{th}$ and the 75$^{th}$ percentile. A narrow IQR indicates similar opinions amongst participants, whereas a high IQR indicates polarised opinions. Exactly when consensus is reached depends on the length of the scale. Rules established in earlier Delphi studies suggest that an IQR of two or less is suitable when using a ten-point scale, and an IQR of one or less is suitable when using a 5-point scale (Heiko, 2012). In this thesis, it was therefore decided consensus had been reached if the IQR was one or less.

#### *5.3.12.2 Level of consensus*

The level of consensus in this thesis described the percentage of participants rating either *somewhat agree* or *strongly agree* OR *somewhat useful* or *very useful*. When using Likert scales and nominal data, it is particularly meaningful to look at percentages (Gracht, 2008), and the percentage is often used to determine levels of consensus in Delphi research (Diamond et al., 2014; Keeney et al., 2011; Trevelyan & Robinson, 2015). The threshold varies from 20% to 100%, with most studies reporting a cut-off point of 60% or higher (Diamond et al., 2014; Niederberger & Spranger, 2020). In this study, a priori, a high level of consensus was defined as ≥75%, a limit often set by guideline developers to ensure high-quality recommendations (Oladega et al., 2021; Strang et al., 2018; Wopker et al., 2021). Recommendations that received ≥90% were seen as reaching a very high level of consensus.

Keeney et al. suggested using confidence intervals (CIs) to determine the level of consensus (Keeney et al., 2006). CIs indicate how good or precise an estimate is, with wider CIs indicating lesser precision and narrower greater precision (Lang et al., 2006). I decided to calculate the CI (lower 95% CL and upper 95% CL) of the proportions to help understand the certainty of the data. The Wilson method (Wilson, 1927) was used for this purpose, as it is appropriate when sample sizes are relatively small (Brown et al., 2001) and is said to provide more reliable coverage than other methods, such as the Wald and the Clopper Pearsons Exact methods (Brown et al., 2001). The online Epitool (Sergeant, 2018) was used to run the Wilson test.

#### *5.3.12.3 Rules for endorsement in the guidelines*

It was decided that an item was endorsed if it reached consensus (IQR ≤ 1), and the consensus level was ≥ 75% in both countries (Table 20). Items were re-rated if ≥ 75% of participants *somewhat agreed* or *strongly agreed* with an item or rated an intervention to be *somewhat useful* or *very useful* in only one country. Items not reaching these criteria, or items fulfilling these criteria but already re-rated once, were rejected and excluded from the final guideline (see Table 20 for an overview of the rules).

It was considered if individual stakeholder group ratings should have the power to exclude items. For instance, if a particular stakeholder group gave an item a low rating. However, this idea was discarded as it was predicted some stakeholder groups would be very small (<10) and excluding items that otherwise had reached inclusion criteria based on the negative ratings of a few people seemed inappropriate. Nevertheless, the differences of opinions between the stakeholder groups were still seen as important and therefore tabulated to give a more comprehensive understanding of the results.

**Table 20 Rules for inclusion in the guidelines**

| Criteria | Decision |
|---|---|
| Consensus established (IQR ≤ 1) AND consensus level* ≥ 75% in both countries. | Endorsement |
| Consensus of ≥ 75% established in only one country. | To be re-rated |
| Items not fulfilling the criteria above<br>OR<br>Items re-rated once and still not fulfilling the criteria above.<br>**NOTE** If less than 25% of all participants rated an intervention, it would be excluded. | Rejected |

* Percentage of participants rating either *somewhat agree* or *strongly agree* to a recommendation or state that an intervention is *somewhat useful* or *very useful.*

This Delphi study did not measure stability over rounds. Although Delphi researchers often decide not to measure stability (Jünger et al., 2017), this decision was made with caution since it has been argued that the stability of ratings is a more reliable way of establishing consensus (Heiko, 2012). Stability means that participants rate consistently over several rounds. The idea is closely related to the Theory of Errors or, as Bolger and Wright (2011) state, "the closer you are to the truth the less you should change your mind" (Bolger & Wright, 2011, p. 1509). "Instability" suggests that the results are unreliable, and in classic Delphi research, rounds continue until stability has been reached (Becker & Roberts, 2009; Heiko, 2012; Trevelyan & Robinson, 2015). Stability was not measured in this Delphi for two reasons. Firstly, such an approach would have required at least four rounds and the same 74 questions, with any new or modified recommendations being asked repeatedly over the rounds. Thus, measuring stability over rounds posed a risk of participant

fatigue and higher attrition. As Landeta (2006), who evaluated the validity of Delphi research in social sciences, concluded, "Generally, it is necessary to sacrifice questions and rounds in order to guarantee panel participation and continuity" (Landeta, 2006, p. 479). Indeed, research indicates that there is a significant association between the number of Delphi items and dropout rates (Gargon et al., 2019). Secondly, authors have argued that although the measurement of stability over rounds is sound, in theory, it can produce false consensus, as a potential decrease in variance can be caused by attrition over time (Keeney et al., 2011, p. 27). Due to these two reasons, stability over rounds was not measured.

#### *5.3.12.4 Importance, feasibility, barriers and facilitators*

Similar to measuring consensus, data related to importance, feasibility, barriers and facilitators were analysed using descriptive statistics. Percentages were reported to give the reader information about the spread of the data. Means were reported when appropriate to give an indication of the direction of the ratings and to rank individual items from the largest to the smallest. Different colours, as shown below, were used to indicate the levels of reported consensus, feasibility and importance.

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference ($p<0.05$) in ratings between countries AND one country rating below 75%

#### *5.3.12.5 Differences between countries on the excluded items*

One of the advantages of using nonparametric tests when comparing groups is that they may detect differences in distribution. The mode for parametric tests is the mean or standard deviation rather than central tendency. Therefore, if two groups have the same mean ratings, even if one group have several ratings towards the two extremes, this may not be detected in a parametric test such as ANOVA or *t* test (Harpe, 2015). To determine whether consensus between the two countries differed significantly on the excluded items, the nonparametric 2 sample Z test on proportions (2-tailed) was used. This test is appropriate to determine if two proportions are significantly different (Kanji, 2006; Sheskin, 2011). The null hypothesis was that the two proportions were equal (or that there were no significant differences in the ratings between the Australian and the Danish participants). The significant level (*p*) was set as 0.05 or less. Agresti and Franklin (2013, p. 470) define three assumptions that must be in place to use the z test (see Table 21).

**Table 21 Assumptions for Z-test**

| Assumptions | Criteria met |
|---|---|
| Use of categorical data | The dependent variables are ranked on a five-point Likert scale (categorical data) |
| independent random samples | The independent variables consisted of stakeholders from two countries.<br><br>Samples were not random, which was taken into account when reporting the results. |
| Each sample having at least five successes and five failures | Items that did not have at least five successes and five failures were excluded. |

This study fulfilled these criteria, except it did not have a random sample. This must be considered when interpreting the results, where it must be stated that the results do not reflect the opinion of the general population but a group of experts in the area. The Z-test was performed using Epitools (Sergeant, 2018). To facilitate the interpretation of significant results, an estimated effect size of the difference in outcomes between the two groups and its confidence intervals were reported. The interpretation of effect sizes was influenced by Cohen's effect size classification, as described by Morgan et al. (2006). This system suggests that $d = 0.2$ can be considered a *small effect size*, 0.5 a *medium* and 0.8 a *large* effect size.

This study did not measure if there were significant differences in ratings between countries of the included items since this was seen as less clinically important. For example, if a significant difference was found between the Danish and the Australian participants rating "mental stimulation" as either *somewhat useful* or *very useful*, this was unlikely to affect the implementation of the intervention.

#### *5.3.12.6 Differences between stakeholder groups on included items*

To further explore differences between stakeholder groups, groups of people sharing common characteristics were merged to allow enough representation in each group. The grouping of the participants was discussed and agreed upon before the analysis commenced. In total, five groups, perceived to share similar perspectives, were developed, including patients and families, allied health including one ICU chaplain, physicians, nurses including two nurse unit managers and researchers.

To determine whether the stakeholder groups differed significantly (p values < 0.05 considered significant) in their ratings of the included items the Kruskal-Wallis H test, a nonparametric alternative to one-way analysis of variance ANOVA, was chosen. The Kruskal Wallis test is commonly used in Delphi studies that compare the responses of different stakeholder groups (Leuci et al., 2016; Mellett et al., 2020; Thompson et al., 2021; Tolsgaard et al., 2013). In contrast to the ANOVA Kruskal-Wallis test is suitable if the dependent variable is ordinal and does not

depend on the assumption that the sample is normally distributed. The Kruskal-Wallis test compares the ranked means of three or more samples, and the samples do not need to be of equal sizes. In order to use the Kruskal-Wallis test, four assumptions must be met (Chan & Walmsley, 1997; Fowler et al., 2021; Kruskal & Wallis, 1952) (Table 22).

**Table 22 Assumptions for Kruskal-Wallis H test**

| Assumptions | Criteria met |
|---|---|
| The dependent variable must be measured at an ordinal level or interval level. | The dependent variables were ranked on a five-point Likert scale (ordinal data) |
| The independent variables must consist of two or more categorical groups. | The independent variables consisted of five stakeholder groups (nurses, physicians, allied health, patients, and researchers) |
| There must be independence of observations | Participants only belonged to one group |
| Sample sizes ≥ 5 (unless exact p-values are calculated – commonly, the asymptotic p-values are calculated). | All stakeholder groups contained more than 5 participants. |

All assumptions were met in this study. The null hypothesis was that the mean ranks of the stakeholder groups were the same (or that there were no significant differences in rankings between the five stakeholder groups). Similar to the Z test on proportions, the significant level (*p*) was set as 0.05 or less. While the Kruskal-Wallis test indicates if at least two independent variables are significantly different from each other, it does not reveal which groups are different. Bonferroni adjustments to the significance tests for pairwise comparisons were therefore applied. These were explored when p was more than 0.05 to identify which groups were statistically significantly different. The tests were all performed using SPSS (Corp., 2021). Finally, effect sizes, Eta squared, and d-Cohen were calculated using a psychometrika online calculator (Lenhard & Lenhard, 2016). This calculator uses a formula provided by Barry Cohen (Cohen, 2008; Tomczak & Tomczak, 2014). It is important to remember that this method only enables the calculation of nonparametric estimates of eta squared. This study did not calculate the differences amongst stakeholder groups for excluded items, as this was seen as less important for the outcome of the study.

#### *5.3.12.7 Management of missing data*

All surveys were examined for missing data via SPSS. It was found that there was no missing data (0%) in the first two Delphi surveys. In the last Delphi round, two surveys had not been fully completed (55% and 63% completed). In consultation with a statistician and because the questions were randomised, it was decided to include the two responses. Corresponding to the two incomplete surveys, there were between 0.9-2.9% missing answers for the last half of the survey (2-3 respondents for each question). The missed data for the last dataset was checked for their randomness, as suggested by Graham (2009). The little MCAR test (Little, 1988) showed Chi-

Square = 577.324, DF = 706, Sig. = 1.0 indicating that the data was missed at random. It is widely recognised that if small amounts of a dataset are missing at random, it is acceptable to continue analysis without excluding or imputing, meaning substituting with an estimated value (Stewart, 2022).

### 5.3.13 Rigour of the Delphi study

The establishment of methodological rigour is a cornerstone in all research. Although Delphi research is becoming more popular and has shown many benefits, it has also been subject to substantial critique (Hasson & Keeney, 2011; Keeney et al., 2011). Concerningly, a meta-analysis found that many healthcare Delphi studies were poorly reported and, therefore, the results of questionable quality (Diamond et al., 2014). Due to the critique, a discussion of how rigour was established in this study was seen as essential. However, in Delphi research, this process is unclear and contentious, in particular, due to an epistemological and ontological debate about where the Delphi study sits (Keeney et al., 2011). Rigour is evaluated very differently in a postpositivist-informed study valuing objectivity, measurements and control, compared to a constructivist study, valuing subjectivity, context and interpretation. Most scholars believe Delphi studies should focus on ensuring validity and reliability (Keeney et al., 2011), while others argue it is more important to consider the trustworthiness of a Delphi study (McPherson et al., 2018). This Delphi was seen as producing different types of knowledge with an aim to explore and understand on one side and to predict and determine on the other. Therefore, rigour was enhanced using both postpositivist and constructivist criteria. The establishment of rigour was guided by a number of quality parameters on how to improve the quality and reporting of Delphi research (Jünger et al., 2017; Nasa et al., 2021). The section below describes how rigour was enhanced in this study and aims to help the reader to interpret the findings and the level of confidence that can be attributed.

#### *5.3.13.1 Reliability*

Reliability in survey designs is related to "the ability of the scale to provide consistent, stable information across time and respondents" (Liamputtong, 2017, p. 525). Essentially this means that a reliable survey will get the same results from the same person if repeated. One way of ensuring reliability is to reach stability over rounds, as explained earlier (see Section 5.3.12.3). This study did measure stability over rounds. Instead, reliability was ensured by not meeting face-to-face, thus avoiding dominant personalities (2011; Kerr & Tindale, 2011), and by having a large Delphi panel increasing the chances of the findings reflecting the opinions of the population (Jorm, 2015; Keeney et al., 2011).

#### *5.3.13.2 Validity*

Validity refers to "The extent to which an instrument measures what it is intended to measure" (Liamputtong, 2017, p. 529). Face validity is a subjective judgement that evaluates if a tool *looks* like it measures what it is intended to measure (Polit & Beck, 2016). To enhance face validity, this

study ensured that all participants understood the aim and processes of the study. This was supported by the provided participant information sheets and online videos. Through an extended translation process, cognitive interviews and pilot tests, it was ensured that the surveys were easy to read, unambiguous and clear. At the beginning of each survey, a list of important words (e.g., *nonpharmacological intervention, agitation, patient-centred*) and their definitions were provided. The Likert scales were clarified in detail (e.g., the meaning of *usefulness, feasibility and importance*). Finally, the individual items were clarified when necessary (e.g., the meaning of *active listening, fidget toy, trauma informed care*).

Content validity evaluates if the content of the Delhi survey comprehensively reflects the topic explored (Polit & Beck, 2016). The content validity in this Delphi study was enhanced by identifying *group opinions* rather than single people's opinions which can be seen as less valid (Hasson & Keeney, 2011). This study also attempted to capture the opinions of a broad group of *real-world* experts knowledgeable about patient agitation in the ICU (Hasson & Keeney, 2011) and clearly defined the type of expertise required for participation. Content validity was also enhanced by building the first survey on two systematic reviews and advice from an advisory group and then getting verification or endorsement from experts on these items (Hasson & Keeney, 2011). Finally, this study had a very low dropout rate, which also enhanced the validity of the study (Hasson & Keeney, 2011).

#### *5.3.13.3 Trustworthiness*

*Trustworthiness* is the most commonly used criterion for evaluating qualitative research (Lincoln & Guba, 1985). Trustworthy research is "research in which researchers have drawn the correct conclusions about the meaning of an event or phenomenon" (Houser, 2015, p. 146). In qualitative research, credibility, transferability, dependability, confirmability and authenticity, as proposed by Lincoln and Cuba (Lincoln & Guba, 1985), are the criteria often adopted to ensure trustworthiness (Polit & Beck, 2016; Shenton, 2004).

Credibility refers to the extent to which the findings reflect the truth (Polit & Beck, 2016). One way of ensuring the analytical credibility of the qualitative data is by establishing intercoder agreement (Creswell & Clark, 2018; Elo et al., 2014). The idea is that if two or more researchers code the same content similarly, it is more likely that other researchers will be able to replicate the work (Elo et al., 2014). In this study, intercoder reliability was established by two researchers independently coding a random subset of the entire dataset. Two researchers (myself and my principal supervisor) met to discuss the level of agreement, and since a high level of agreement was met, I continued analysing the rest of the dataset. Once coding had finished, the coding results were reviewed by the principal supervisor to ensure the correct interpretation of comments and consistent use of the codebook. Credibility was also enhanced by using anonymity and an iterative process over several months giving participants an opportunity to provide honest and considered

answers. Allowing different stakeholder groups to participate can be seen as a form of triangulation, providing a rich picture of different viewpoints (Shenton, 2004). Three rounds over several months also helped to produce honest and verified results. Finally, credibility was also supported by describing my background and positionality. The researcher is an instrument of data collection and analysis, and therefore the credibility of the researcher is important (Shenton, 2004).

Transferability refers to the degree to which the study results can be applied to a similar context (Polit & Beck, 2016). Transferability was enhanced by including a heterogeneous expert panel from different countries and different organisations (Linstone & Turoff, 1975). Participants were also encouraged to justify their judgements and explain in which circumstances interventions had an effect. Furthermore, they were encouraged to describe the feasibility of interventions together with barriers and facilitators for implementation. Such information can be seen as essential to judge the transferability of the findings.

Dependability equates to reliability and refers to the stability of data over time (Polit & Beck, 2016). Cornick (Cornick, 2006) emphasises that the use of a diverse Delphi panel ensures the stability, thus dependability, of Delphi rounds. Dependability was enhanced by *testing* NPSs over several rounds. In this study, the processes were described in detail to allow future researchers to assess the work and repeat it if necessary (Shenton, 2004).

Confirmability is about objectivity and refers to the extent to which the data represents the ideas of the participants and not the motivations and interests of the inquirer (Polit & Beck, 2016). I enhanced confirmability by using reflexivity as a means to deal with personal influences throughout the study. Confirmability was also enhanced by using by maintaining an audit trail, a transparent and detailed description of all the steps taken and decisions made throughout the study. Since multiple Delphi designs exist, this has been described as a particularly important step in developing a trustworthy Delphi study (Skulmoski et al., 2007). Transparency was enhanced by providing examples of data analysis and by providing quotes to illustrate how conclusions were made from the qualitative data.

Finally, authenticity refers to the extent to which the researcher attempts to show a variety of realities (Polit & Beck, 2016). Lincoln and Cuba (Lincoln & Guba, 1985) included this criterion to deal with power, pluralism, representation and multiple values. I used a range of strategies to ensure fair, authentic and ethical inclusion of a broad group of stakeholders, which is explained throughout the methodology and methods sections of this thesis. I will mention a few of these here, including informed consent, a website with easy read, transparent information and videos to encourage a broad group of people to participate. A disability researcher reviewed this website to make it as inclusive and personal as possible. I also visited a post-ICU group to nurture trusting relationships with participants who may not otherwise have felt confident in participating. Finally, a

small reimbursement was offered to patients and family members to encourage participation from this group. A summary of the methods used to ensure research rigour is presented in Table 23.

**Table 23 Methods used to ensure research rigour**

| Quality criteria | Methods |
|---|---|
| Reliability | Anonymity |
| | Larger Delphi sample |
| Validity | Participants understood the overall aim (participant information sheet and videos) |
| | Clear and unambiguous surveys (definitions provided, pilot tests, cognitive interviews, prolonged translation process) |
| | Group opinion |
| | Surveys build on systematic reviews, advice from stakeholders and verification of these |
| | Low dropout rate |
| Credibility | Intercoder agreement of qualitative data |
| | Anonymity |
| | Background information about the researcher |
| | Background of the researcher |
| Transferability | Including various experts |
| | Encourage participants to explain barriers and facilitators to implementation |
| Dependability | Including various experts |
| | Building the first survey on systematic reviews and advice from an advisory group. |
| Confirmability | Use of reflexivity |
| | Audit trail |
| Authenticity | Informed consent |
| | All materials for participants were *inclusive* to allow a broad group of people to participate |
| | The researcher visited post-ICU groups to recruit participants. |
| | Reimbursement was offered to patients and family members. |

### 5.3.14 Ethical considerations

The ethical considerations for this study were informed by the Australian National Statement on Ethical Conduct in Human Research (NHMRC, 2007), the Declaration of Helsinki (WMA, 2013) and the ethical guidelines published by the Nordic Nurses Federation (NNF, 2003). Respect, research merit and integrity, justice and beneficence were the values that ensured a trustworthy relationship between the research participants and the researcher in this thesis. The Delphi study received ethics approval and Governance from the Central Adelaide Local Health Network (CALHN) (Appendix 31) and cross-institutional approval from Flinders University Social and Behavioural Research Ethics Committee (Appendix 32). In Denmark, research must be carried out in accordance with the Declaration of Helsinki (WMA, 2013) and the ethical guidelines published by the Nordic Nurses Federation (NNF, 2003). However, a more formal ethics approval is not needed for qualitative research and surveys (NVK, 2020).

### 5.3.15 Respect for human dignity

Respect involves recognising the intrinsic value, experiences, opinions and autonomy of participants (NHMRC, 2007). To safeguard the participants, I ensured that participants were fully informed about the research process, the timeframe and their rights within the project so that they could give their informed consent to participate. Each survey asked participants to provide their informed consent. Participants were also reminded that participation was voluntary and that they could withdraw at any time until the commencement of data analysis.

### 5.3.16 Justice

A study must ensure justice which means fairness in the way people are treated (NHMRC, 2007). Online participation ensured that participants from two countries could contribute and that the study was not constrained by the existing COVID restrictions. To ensure fair recruitment and to maximise participation, all written information was provided in both Danish and English. By the end of the study, a written summary of the research findings would be provided to all participants[30].

It was decided to reimburse patients and family members for their time commitment and internet usage ($50 online voucher after the last Delphi round). This aligns with the principles of patient and public involvement (Hayes et al., 2021). Professionals were not reimbursed as they were likely to have a computer and internet available at their workplace. Instead, we offered a professional development certificate to count towards their professional development hours. As an additional incentive to participate, there was a draw of six random names of professionals who received a $50 voucher at the end of the last Delphi. Participants were reminded that confidentiality would be maintained during this process.

### 5.3.17 Confidentiality, data storage and security

Justice is also concerned with ensuring confidentiality. All participants were provided with an identification number that they used for each survey. A map was kept on a password-protected computer that linked identification numbers with panel members, allowing the identification of the panel members. This was necessary to provide feedback to panel members, to send out reminders when necessary and to identify those who were eligible to win a $50 voucher. However, the panel members did not know each other. All panel members were informed that their individual responses would be treated with confidentiality.

### 5.3.18 Merit, integrity and publication of data

For a study to be ethically justifiable, it must have merit, and the researchers must have integrity (NHMRC, 2007). The need for this study was thoroughly justified by systematically reviewing

[30] Pending the peer-reviewed feedback from the examination of this thesis, a final report on the project will be generated and distributed to all Delphi participants.

existing literature and through advice from 51 international stakeholders. The study provided an original contribution to knowledge, and I aim to disseminate the findings through publications and conference presentations and, in this way, support the welfare of future patients and clinicians. The study design was robust, transparent and trustworthy, following a well-recognised Delphi method. The study was conducted under the supervision of experienced Danish and Australian researchers with relevant expertise and qualifications.

### 5.3.19 Beneficence

It was predicted that this study would not cause any harm or discomfort. However, it was acknowledged that it could cause inconvenience in the form of participants having to give up their time and energy to complete surveys over several rounds. To decrease their burden, questions avoided sensitive themes that could potentially evoke traumatic memories, and analysis was conducted as quickly and accurately as possible between rounds. Participants were informed that the Delphi process, involving three surveys, would take no more than five months and that surveys should not take more than 20-50 minutes to complete.

## 5.4 Conclusion

This chapter has described and justified the methods used for study phases one and three of this thesis. To determine the guideline scope, reach a consensus on a range of guideline recommendations and to better understand these recommendations, different datasets and analytical methods were necessary. Particular attention was placed on the ethical aspects of including a broad group of stakeholders in research. It is the hope that the detailed description of the methods will help the reader to understand how the findings can be interpreted and how much confidence to place in the conclusions. The subsequent three chapters will present the results of this study.

# CHAPTER 6: PHASE ONE - STAKEHOLDER CONSULTATION FINDINGS

## 6.1 Introduction

Chapter 5 described the methods chosen for study phases one and three of this research. This chapter reports the findings of the first study phase, consulting stakeholders about the content of the guidelines.

Guideline developers are encouraged to engage stakeholders when determining the scope of clinical practice guidelines. The engagement of people who will eventually use the guidelines, or be affected by them, will increase the likelihood of developing meaningful and implementable guidelines (Armstrong et al., 2018; Kothari & Wathen, 2013). Therefore, this study phase aimed to get advice from various Danish and Australian stakeholders on the appropriate scope of the clinical practice guidelines. Stakeholders included patients, family members, ICU clinicians and researchers. While guideline developers are encouraged to engage stakeholders to determine the guideline scope, little guidance exists on how this can be done. Therefore, this study was also interested in revealing how various stakeholders could be involved and how this involvement affected the final guideline.

This chapter describes the stakeholder contributions, the subsequent decisions made on the final guideline scope and rationales for these decisions, and finally, my reflections on how stakeholders can be involved in ethical and feasible ways. Note that parts of section 6.9 have been published in the Collegian in the article[31]:

> Adams, A. M. N., Chamberlain, D., Thorup, C. B., Grønkjær, M. & Conroy, T. (2022). Ethical and feasible stakeholder engagement in guideline development. *Collegian*. https://doi.org/10.1016/j.colegn.2022.08.003

The text has been modified to suit this chapter, but the content directly overlaps with the published version (see Appendix 3 for the peer-reviewed published version).

## 6.2 Participants and modes of feedback

Researchers were contacted directly, while other stakeholders were invited to participate through professional and patient organisations. Challenges were encountered in finding patients and family members. Several organisations stated they could not help due to COVID-related factors (See Box 3). Due to COVID, many ICU survivors and family members did not spend time in the hospital

[31] I contributed 80% to the research design, 80% to the data collection and 80% to the writing and editing of the manuscript.

environment where they would have heard about the project. To mitigate these barriers and facilitate some personal contact, I developed online videos in two languages explaining what it meant to be involved.

A total of 51 stakeholders offered feedback on the proposed guideline scope. The characteristics of the stakeholders can be found in Table 24. The length of clinical practice of clinicians and researchers ranged from 5 to 30 years, and most had postgraduate qualifications and were involved in education and research.

**Table 24 Characteristics of stakeholders**

| | **Denmark** | **Australia** | **Total** |
|---|---|---|---|
| Nurse | 15 | 21 | 36 |
| Physician | 2 | 3 | 5 |
| Researcher | 2 | 2 | 4 |
| Physiotherapist | 0 | 2 | 2 |
| Occupational therapist | 1 | 0 | 1 |
| Patient | 1 | 0 | 1 |
| Family member | 1 | 1 | 2 |
| Total | 22 | 29 | 51 |

Most stakeholders (n=29) chose to provide written feedback, nine chose interviews, and 13 participated in the country-specific workshops (see Table 25). Seven clinicians and researchers participated in the Danish workshop, while six participated in the Australian. Patients and family members all chose to provide feedback through interviews[32].

**Table 25 Modes of feedback**

| | Denmark | Australia | Total |
|---|---|---|---|
| Written feedback | 10 | 19 | 29 |
| One-on-one interview | 5 | 4 | 9 |
| Workshop | 7 | 6 | 13 |
| Regions/states/territories represented | All | All except Tasmania | |

The following section presents the collected data from workshops, interviews and written feedback from all stakeholders. As described in the methods section, the aim was not to compare different stakeholder groups; therefore, the groups were not differentiated in this study. The section below will first describe stakeholders' advice and thoughts related to the guideline questions, strategies they believed worked for agitation in the ICU and if interventions from healthcare settings should

[32] The questions that were posed to stakeholders are listed in Appendix 12

be considered. It will then present stakeholders' views on end-users, the target population, setting, outcomes and barriers and facilitators to guideline implementation.

## 6.3 The main questions the guidelines are addressing

### 6.3.1 Are the guidelines needed, and why?

One Danish clinician believed the guidelines were less needed, as their unit already had appropriate NPSs in place. All other stakeholders (n=50) expressed a need for the guidelines. Below is a list of rationales for why guidelines were needed. Note that each individual stakeholder was allowed to mention several needs.

- We see an increase in agitation in ICU (n=4) explained by more awake patients (n=2), and an increase in mental health issues (n=2).
- Agitation in ICU is prevalent (n=4).
- Agitation is currently not managed well. This was explained by current practices not being based on evidence (n=4), inconsistent nonpharmacological practices (n=6) and an overreliance on PR and sedation (n=9).
- No guidelines exist on NPSs (n=11). Current guidelines focus on pharmacology (n=2).
- Guidelines will empower staff and increase their confidence and levels of knowledge (n=16). At the moment, they feel exhausted, vulnerable and frustrated due to the lack of guidance (n=9). When no guidance exists, it is easy to feel apprehensive about caring for this group of patients.
- There is a lack of understanding, appreciation and focus on the importance of NPSs (n=3).
- Patients are vulnerable, and we must protect them (n=2),
- Guidelines will support better patient outcomes (n=11).
- Guidelines will reduce sedation and PR (n=6).
- Family members are also suffering due to patient agitation (n=3).
- Guidelines may support us in getting more resources (n=2).
- Guidelines are needed to improve multidisciplinary collaboration around this patient group (n=1).

### 6.3.2 Should the guidelines cover other areas?

When the stakeholders were asked if the guidelines should cover other areas, they provided several suggestions. It was decided to include the following aspects as they were feasible and deemed to be important:

- The interventions should be patient-centred (n=3).
- The interventions must prioritise safety for staff (n=4).
- The interventions must prioritise the safety of patients (n=3).

- Delirium-associated agitation should be included (n=4).
- The difference between delirium and agitation must be clearly described (n=3).
- How family members can be supported to care for their loved one who is displaying agitated behaviours (n=5).
- The guidelines should describe when to use NPSs (n=2).

The stakeholders also suggested areas that could not be covered in the guideline scope. Some of these were beyond the remit of the research, while others referred to areas with already existing literature. The areas that could not be covered included:

- Pharmacological management of the patient (n=3) and what strategies to use when NPSs are ineffective (n=3).
- Safe transfer of agitated patients to the ward and home (n=1).
- How to promote sleep (n=1).
- How nurses can support family members through a difficult time when their loved one is agitated (n=3).
- Risk factors of agitation (2).
- How to best identify agitation (n=3) and agitation assessment tools (n=4).
- When and how to use PR (n=2).

It was decided that risk factors for becoming agitated could be mentioned in the background section of the guidelines. Although assessment tools and PR could not be covered in depth, it was also decided that if these interventions were described while searching the existing literature, they could be briefly described.

### 6.3.3 What strategies do you think work for agitated behaviours in the ICU?

To identify relevant interventions, stakeholders were asked to describe what strategies they believed worked for agitated behaviours in ICU. Three interventions were excluded as they related to pharmacological interventions. One was giving patients as little sedation as possible (n=2)[33], while the other was electroconvulsive therapy (ECT) (n=1).

Based on all other stakeholder advice, interventions were grouped into those targeting the organisation and leadership involving resources, policies and culture; those targeting the multidisciplinary team to ensure they had the skills and knowledge to minimise and manage agitation; those targeting the family to ensure they were well supported to support their loved one;

[33] This was mentioned by two Danish participants. One mentioned it in a workshop. I was surprised and asked if others agreed, and it seemed like the six other stakeholders did. It was described how agitation was better prevented or minimised in patients who were not half sedated, but who were able to understand what was going on and able to collaborate.

those targeting the ICU care environment to reduce factors like noise and stimuli; and finally; those targeting the patient and their individual needs related to their critical illness (see Figure 16).

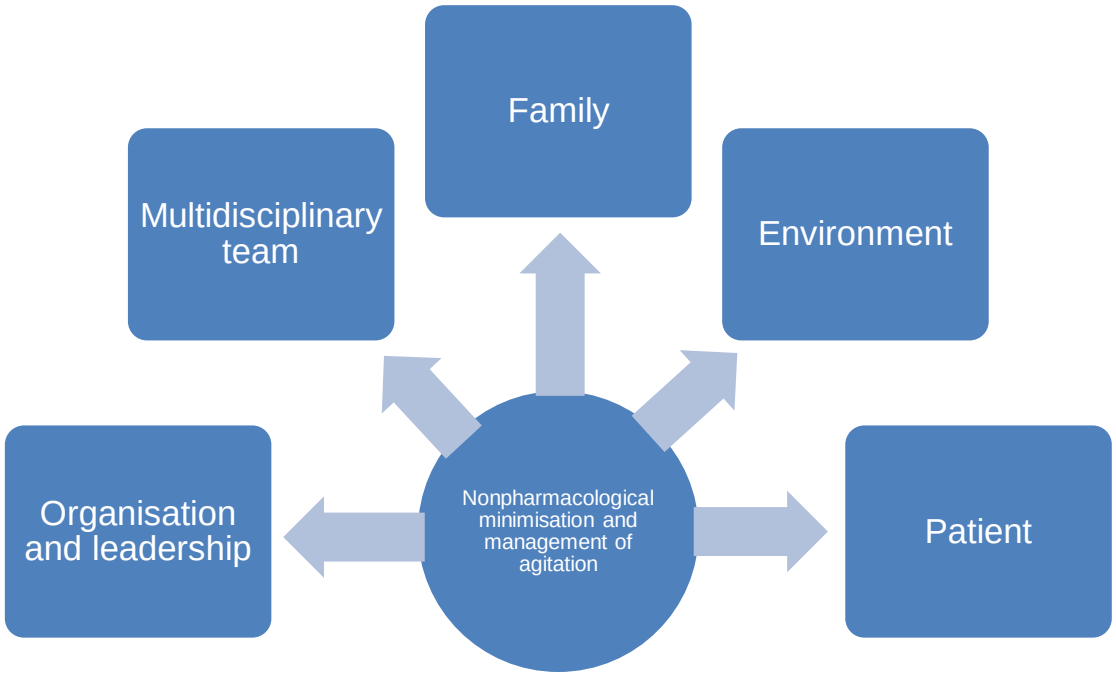



**Figure 16 Targets of NPSs**

#### *6.3.3.1 Organisation and leadership*

Stakeholders described interventions directed toward the organisation and leadership; these included:

- Adequate staffing (n=3) and adequate time (n=4) to support agitated patients. Participants argued that NPSs required more time and more hands, especially to safely de-escalate a situation without using sedation or restraints. Lack of extra hands in a busy large ICU could lead to patient extubation. They described how sometimes there was a need to *just hold a hand* and *just be there*. This often required others to help with medication and documentation.
- Supportive leadership (n=2) encouraging the use of NPSs. It was described as important to have a leadership team encouraging the use of NPSs and acknowledging the challenges nurses face when carrying out this important role. For instance, nurses wanted leaders who acknowledged the importance of "just being with the patient" and leaders who appreciated and prioritised such tasks.
- Having a hospital security team that can be contacted if necessary (n=2).
- Other protocols (n=9), for example, around sedation, PR, delirium, drug withdrawal and pain relief, help nurses choose appropriate approaches.

#### *6.3.3.2 Multidisciplinary ICU team*

Interventions directed towards the multidisciplinary team included both interventions facilitating the team to reduce agitation, such as education on agitation and interventions and approaches the multidisciplinary team could use to reduce agitation.

Interventions and approaches to reduce agitation:

- Using a systematic approach to identify agitation (n=12), causes of agitation and how to treat these causes (n=9).
- Developing a clear management plan (n=2).
- Using effective multidisciplinary team collaboration and communication (n=4).
- Knowing the patient (background, likes and dislikes, culture, fears, history, routines, family, hearing aids etc.). Interventions used included the sunflower tool, a practical tool summarising a patient's background, likes and dislikes (n=12).
- Using approaches to developing trusting clinician-patient relationships. This included active listening, showing respect, using non-threatening and calm behaviours, being present, showing empathy, supporting human dignity and seeing the patient as a person (n=16)
- Using de-escalation strategies (n=1).
- Supporting patients' physical and psychosocial needs (n=1).

Interventions supporting the team to reduce agitation included:

- Ensuring continuity of care by allocating the same nurses/team to care for the patient (n=4). This was closely linked to knowing the patient and their needs, reorientating the patient and supporting the patient to feel safe. Also, acknowledging that sometimes confused patients dislike or fear certain staff members. This required flexibility in how the staff was allocated.
- Educating and training staff in using NPSs (n=6) to support patients who were agitated in the ICU. This could include theory on de-escalation strategies and conflict management.
- Rotating staff to avoid burnout (n=5). Caring for this group of patients was described as challenging both physically and psychologically. It was described how sometimes staff were only able to show empathy, understanding and being present for a few hours at a time.
- Emotional support of staff (debriefing and supervision) (n=2).

#### *6.3.3.3 Family interventions*

Interventions directed toward the family included:

- Family presence and support (n=12). It was argued that family members who knew the patient were often able to calm the patient and make the patient feel safe.
- Family participation in care (n=1). Family members were often seen as a resource and the extra pair of hands needed when preventing agitation or dealing with agitated behaviours.

Family members were able to reorientate the patient, hold a hand, and read a newspaper. Family members could be involved face-to-face or via telephone or video conferences.

- Family information and training of family members (n=4). Family members wanted information about agitation and how they could support the patient. It was described how family members knew the patient and were able to identify their needs.
- Families were also described as hindering the effective management of agitation (n=3). For instance, they could have a need to wake up the patient. It was seen as essential to understand families and their dynamics.
- Family empowerment (n=3). Family members needed information about agitation. Not knowing caused frustrations, trauma and sometimes withdrawal.

#### *6.3.3.4 Care environment interventions*

Interventions directed towards the care environment were used to reduce stimuli, allow sleep and rest and support patient well-being (n=26). Interventions included:

- Noise reduction
    - Earplugs.
    - Adjustment of alarms.
    - Reduce noise from equipment.
    - Reduce staff chatting and talking.
- Lighting control/ therapy
    - Eye masks
    - Adjusting lights (according to day/night, avoid blue light and bright light).
    - Exposure to daylight
- Reduction of stimuli
    - Use of single room
    - Potentially reducing visiting hours if the patient needed rest.
    - Bundling intrusive tasks/clustering activities.
    - 'Hands off'/uninterrupted time.
    - Reducing unnecessary interventions, especially at night-time. Stakeholders suggested asking, "do they need the arterial line, the calf compressors, the IDC etc.? Can we step down from non-invasive mechanical ventilation to nasal prongs?"
    - Remove unnecessary monitoring, in particular, if the patient is hemodynamically stable.
    - Minimise tactile stimulation from lines and other equipment.
    - Clinicians behaving in calm ways.
    - Fewer people in the room.
- Design of ICU
    - Colours of the room, as some colours can trigger agitation (n=2)

- Design, art and creativity (n=2).
- Adequate access in and around the bed spaces and adequate visual monitoring.

#### *6.3.3.5 Patient interventions*

Patient interventions were categorised as physical, psychosocial and sensory interventions.

##### 6.3.3.5.1 Physical needs

- Optimise patient comfort: support elimination (treat constipation, change a dirty nappy, empty a full bladder) (n=4), mouth care (n=1), pain management (n=6), hydration (n=2), nutrition (n=3), hygiene (n=1), change of position (n=1).
- Sleep promotion (n=16).
  - Familiar schedule with day-night routines, exposure to sunlight, for example, by taking patient outdoors, minimisation of disturbance overnight, adjustment of light, stimuli and noise.
- Mobilisation/ exercise/ activation (to increase a sense of meaningfulness and to make patients feel naturally tired) (n=15)
  - As early as possible during their ICU admission.
  - Sitting on the edge of the bed.
  - Short walks
  - Rocking chair.
  - Bed bike.

##### 6.3.3.5.2 Psychosocial needs:

Stakeholders suggested supporting psychosocial needs. They suggested that to minimise or manage agitation, patients needed to feel safe, cared for, empowered and understood. They also had a need for meaning and predictability. Psychosocial interventions included:

- Familiar surroundings (pictures, things from home, using these things to ADL activities) (n=5).
- "See-through" staff masks (n=1), pictures or nametags (n=1).
- Pets in ICU (n=2).
- Patient involvement in care (with meaningful and known activities of daily living (ADL) Felicia Affolter theory was mentioned as useful. Clinicians needed to consider their communication methods by stating one thing at a time, talking slowly, giving patients choices, involving them in conversations and empowering patients (n-3).
- Patient information about agitation (n=1).
- Hearing aids and glasses (n=2).

- Communication tools or devices (n=3)
- Reorientation (clock on wall, calendar, a board with a plan for day, explain what is going on and why) (n=13).
- Predictability by using a fixed daily schedule (n=1).
- Referral to psychiatry (n=1).
- Holding a hand (n=1).

#### 6.3.3.5.3 Sensory stimulation needs

- Basal stimulation (involving touch, positioning, body awareness, and communication) (n=5).
- Therapeutic touch (n=4)
- Cognitive stimulation (Lego, jigsaw, Radio, TV, internet, magazines, pictures) (n=4).
- Fiddle toy/blanket (n=4).
- Heavy blanket (n=1)
- Music therapy (Calming/soft music, adjusted to patient preferences, music specially developed for patients with delirium) (n=11)
- Guided imagery (n=1)
- Nature sounds/bird sounds (n=2).
- Essential oils/ aromatherapy (n=1)
- Massage/muscle relaxation (n=1).
- Reflexology (n=1).
- Acupuncture, acupressure (n=1).

### 6.3.4 Interventions from other areas applicable to the ICU

Most stakeholders thought that the ICU clinicians could learn about NPSs related to agitation from other speciality areas, including mental health (n=9), neurology and neurosurgery (n=9), dementia care (n=7), aged care or geriatric units (n=6), the Emergency Department (n=4), general hospital wards (n=4), palliative care (n=3), recovery/postoperative (n=2), drug and alcohol (n=1), home ventilated patients (n=1), neonatal (n=1) and paediatric ICUs (n=2), delirious patients in general (n=1), police and prison (n=1). Stakeholders also believed there were learnings from physiotherapists (n=1), occupational therapists (n=1) and aboriginal and Torres Strait Islander liaison health workers (n=1). It was also mentioned information could be learned from MET call situations (n=1) and the Hospital Elder Life Program (HELP) (n=1).

## 6.4 Intended end-users.

It was suggested in the guideline scope draft that the intended end-users should be nurses caring for ICU patients. Many stakeholders (n=28) agreed that nurses would find the guidelines useful due to their responsibilities of caring for these patients. Some argued that nurses, in particular,

needed guidance to feel empowered to take on this important role. However, stakeholders also provided strong arguments for including the ICU physicians (n=14) and others from the multidisciplinary team (n=12), including allied health, nurse assistants, social workers, and the leadership team. Arguments for involving a multidisciplinary team included:

- Ensuring meaningful use of the guidelines.
- Ensuring consistency.
- Ensuring collaboration.
- Ensuring implementation.
- All ICU health professionals can affect patient agitation in both negative and positive ways.

Participants provided examples of how individual team members could exacerbate patient agitation if they were not involved in the management plan. There were also examples of how multidisciplinary team collaboration successfully reduced agitation in the ICU. Finally, it was described how the implementation of guidelines could be complicated when team members did not share common goals and approaches.

Several stakeholders also suggested that family members would find the guidelines useful (n=10). The guidelines would support families to better understand the condition and the effective approaches used to reduce agitation. Finally, it was suggested that clinical educators, students, policymakers, indigenous healthcare workers and clinicians from other hospital wards might find the guidelines interesting. It was decided that while the main end-users would be the multidisciplinary ICU team, a broader audience might also find it useful. A patient and family-friendly brochure would also be optimal, but this was outside the scope of the study.

## 6.5 Target population

The draft scope suggested the target population should be critically ill adults (18 years and older). Most stakeholders agreed to this (n=37). A couple of stakeholders mentioned that the age group should be reduced to 16 (n=2). However, as some stakeholders highlighted, 18 is the year people legally become adults (n=1), and many studies define adults as 18 years and older (n=1). One stakeholder believed the guidelines should also cover the management of family members who were agitated in the ICU (n=1). Together with my supervisory team, I decided that the management of agitated family members was outside the scope of the guidelines. Many stakeholders also believed that different groups of patients required different approaches and considerations, including:

- Delirious patients (n=7)
- Patients with language/cultural barriers (n=4)

- Patients admitted due to intoxication or withdrawal from drugs or alcohol (n=4). It was described how these patients often needed pharmacological treatment and were less responsive to NPSs.
- Brain injury patients (n=3)
- Patients with dementia (n=1)
- Frail patients (2)
- Unconscious/confused patients versus conscious, clear and orientated patients (n=3)
- Patients suffering from mental illness (n=1)
- Patients receiving palliative care (n=1)
- Short- and long-term patients (n=2)
- Smokers (n=1)
- Patients suffering from encephalopathy (n=1)
- Young vs elderly patients (n=1)
- Patients in isolation (n=2).

Since 18 years of age is when people legally become adults in both countries, and since most research describes adults as 18 years or older, it was decided to focus the guidelines on adult patients (18 years and older). It was decided to look at all adult patients in ICU, while keeping in mind that some groups could require special considerations within these guidelines. Evidence gathering may dictate if subpopulations unfold, and if the evidence for certain groups is very different, then it would be considered if separate recommendations should be made.

## 6.6 Setting

The guideline scope draft suggested that the guidelines should be relevant in all critical care settings carrying out invasive haemodynamic monitoring and mechanical ventilation, except for recovery wards or post-surgical wards and the emergency department. It was noticed that patients and family members did not have any comments on this section of the guideline scope. Most other stakeholders agreed that the setting should be the ICU (n=35). Arguments included that the ICU is a unique environment due to the acuity, noise, sedation, critical illness and immobile patients posing special challenges when trying to prevent and manage this group of patients (n=3). Including only ICUs in the guidelines would result in tailored guidelines, which could increase the uptake (n=1). There were arguments that the size of the ICU, including mega metro quaternary ICUs vs smaller regional level 2 ICUs and the type of ICU (neuro, long-term, neurosurgery) may require different approaches. Some believed that HDUs or the Danish equivalent 'Intermediær afsnit' should be included (n=8), while others argued they should not be included as these units varied significantly in their setups and patient populations (n=2). Some believed that the Emergency Department (ED) should be included (n=5). The ED is a critical care area, but as argued by some participants (n=3), the environment and patient population vary significantly from

the ICU, mainly due to the ED's short-term management of patients who are often not mechanically ventilated. Many believed that the guidelines should be useful for many settings, including cardiac care units (n=2), recovery (n=3), theatre (n=1), neurology (n=2) and other hospital wards (n=6) (except paediatric and obstetric wards, n=1).

Since most stakeholders suggested the ICU setting and the strong arguments for developing ICU-specific guidelines due to the unique environment and challenges related to this environment, it was decided to direct the guidelines specifically to the ICU setting. It was also decided not to limit the guidelines to specific types of ICUs. It was decided that while exploring the evidence, it would be considered if different types of ICUs required different approaches.

## 6.7 Outcomes

A guideline scope should always describe a list of outcomes that will be considered when reviewing the evidence (Boivin et al., 2015; NICE, 2014). Outcomes in research are defined as:

"…variables that are monitored during a study to document the impact that a given intervention or exposure has on the health of a given population" (Ferreira & Patino, 2017, p. 5).

Primary outcomes describe the variables with the greatest therapeutic benefit. Secondary outcomes are outcomes of secondary importance (Sedgwick, 2010). It was first explored if any core outcome sets already existed on the topic in the COMET database (Williamson et al., n.d.). Core outcome sets are agreed-upon standardised groups of outcomes that should be assessed and reported in all clinical trials (Williamson et al., 2017). Guideline developers should be careful with choosing outcomes described by other researchers. Such outcomes may have been chosen because they are easy to measure and may not be the most important outcomes for stakeholders (NICE, 2014). Because of this, it was seen as essential to determine outcomes important to stakeholders.

Stakeholders in this study were asked what kind of short and long-term outcomes or results they hoped for from the guidelines. Figure 17 was developed to represent the stakeholder responses and the links between outcomes and agitation in the ICU. Overall, it provides an overview of primary, secondary or intermediate outcomes reported by the stakeholders and the roles of these in relation to the prevention, minimisation and management of agitation in the ICU.

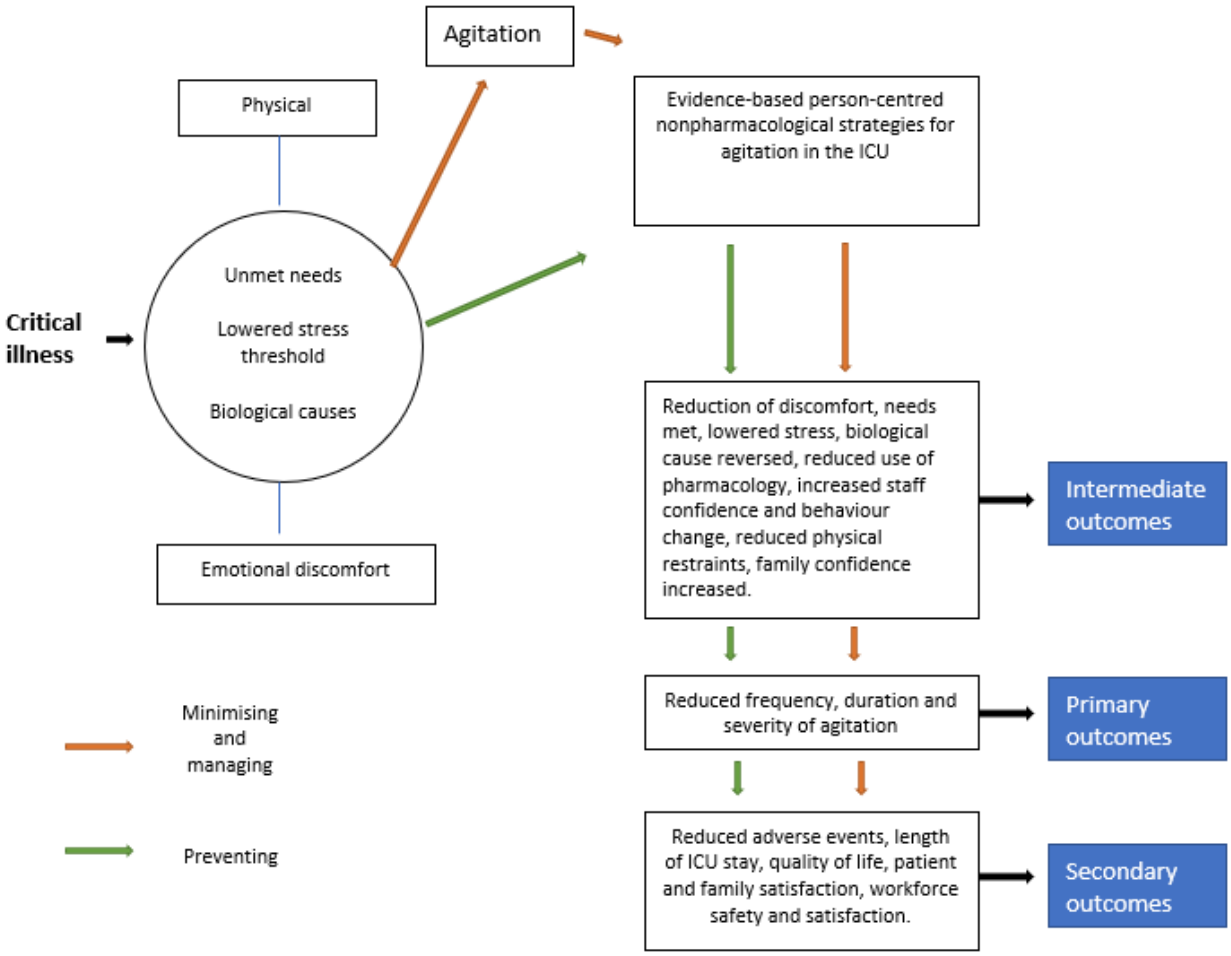



**Figure 17 Relationships between interventions and outcomes**

Table 26 includes stakeholders' suggested outcomes divided into primary, secondary, and intermediate outcomes. The table also includes stakeholder comments related to how outcomes could be measured.

**Table 26 Overview of outcomes**

| Outcomes | Measurement of outcomes as suggested by stakeholders | Decisions made on measurement of outcomes when not described by stakeholders |
|---|---|---|
| Primary outcomes: | | |
| Frequency, severity, and duration of agitation as measured with reliable tools. | Standardised tools or scales | |
| Secondary outcomes: | | |
| Adverse effects such as unplanned extubations, nosocomial infections, device removal. | Incident reports. Documentation in patient's medical record. | |
| Length of ICU stay and ventilator days. | Documentation in patient's medical record. | |
| Patient psychological wellbeing/satisfaction | As measured by interviews or self-reports | |
| Patient injuries | Incident reports. Documentation in patient's medical record. | |
| Patient ability to breathe themselves, and patient-ventilator synchrony | - | Documentation in patient's medical record. |
| Patient mobilisation. | Six-minute walk test | |
| Post-traumatic stress disorder (PTSD) or post-intensive care syndrome (PICS) | - | As reported post ICU |
| Patient mortality | As measured by administrative data | |
| Hospital LOS | Documentation in patient's medical record. | |
| Quality of life | - | As reported post ICU |
| Cognition | - | As reported post ICU |
| Post-Intensive Care Syndrome Family (PICS family) | - | As reported post ICU |
| Family satisfaction | As measured by interviews or self-reports | |
| Staff assaults and injuries | Incidence of Code Black, reported injuries. | |
| Workforce satisfaction/ wellbeing | As measured by sick days, feeling safe at work, satisfaction, and staff turnover. Interviews and self-reports. | |
| Intermediate outcomes (outcomes between the intervention and the final outcomes) | | |
| Reduction of pain, anxiety, distress, stress, and discomfort. Increase of sleep etc. (causes of agitation) | Documentation in patient's medical record. | |
| Reduced use of pharmacological interventions | Documentation in patient's medical record., | |
| Reduced use of PR | Documentation in patient's medical record. | |
| Family confidence in supporting the agitated patient | - | As measured by interviews or self-reports |
| Staff behaviour change | As observed | |
| Staff confidence in managing agitated behaviours | - | As measured by interviews or self-reports |

## 6.8 Barriers and facilitators

Stakeholders were asked if they could see any barriers or facilitators to the implementation of the guidelines. Below are listed the perceived barriers (Table 27) and facilitators (Table 28) to guideline implementation. This information was later used in the second Delphi survey to explore the degree to which Delphi participants agreed or disagreed with the main themes[34]

**Table 27 Barriers to guide implementation**

| Main themes | Explanations |
|---|---|
| Lack of resources | Lack of staff, time, space for mobilisation, equipment, appropriate design (such as light), space, and noise reduction (n=10) |
| Changing existing habits/culture | Difficult to change habits and behaviours (n=1), lack of nurse confidence in the guidelines (n=2), lack of nurse acceptance and knowledge (n=2), fear of using NPSs (n=1), NPSs not a priority/focus/popular (n=2), NPSs require a change of routines in ICU (n=1). |
| A belief that NPSs are resources intensive | NPSs are more demanding (n=3). |
| Lack of confidence in NPSs | Often staff use pharmacological solutions due to safety concerns (n=2). |
| Lack of trust in the guidelines | Lack of evidence (n=1). ICUs pose an ever-changing environment; the guidelines may drown in many other forms and procedures (n=1). |
| | Medical staff may not fully understand the importance and need of guidelines (n=4). |
| | Ethical-legal barriers (n=1) |

**Table 28 Facilitators to guideline implementation**

| Main themes | Explanations (n) |
|---|---|
| Dedicated people to lead change | People leading the change (2). |
| | A good culture in the unit with people supporting each other (2). |
| Multidisciplinary collaboration | The medical team must be involved in guideline development (2). |
| Supportive leadership | The leadership team must be involved and supportive (n=2). |
| Clear outline of the evidence | Outline of advantages and disadvantages. This will make it clear that there are many disadvantages of using drugs. We want the best for the patients, and NPSs pose few risks (1). |
| Clear plan for implementation | A plan for how to implement and follow up (n=2). |
| User-friendly design | The guidelines must be user-friendly (n=4). |
| | A flowchart will be useful (3). |
| | Guidelines with links, short videos with demonstrations, pictures and a forum (n=2). |
| | Personal stories from patients and family members (n=1). |
| | Guidelines that lean closely toward practice and are meaningful will be implemented more easily (1). |

[34] For results of barriers and facilitators to guideline implementation during the Delphi study, see Section 8.15

## 6.9 Reflections on stakeholder consultation

During this study phase, a 7-step framework on stakeholder engagement[35] (Adams et al., 2022b) was developed. It is believed this framework helped to develop a well-founded guideline scope in ethical ways and with limited resources. This section will describe the new insights gained on stakeholder consultation.

Related to the recruitment of health professionals, an overwhelming response was experienced when the Australian College of Critical Care Nurses contacted their members via email. Within three hours, 26 online registrations from nurses who were interested in becoming members of the advisory group were received. This response rate was greater than expected. It was necessary to immediately post a note on our webpage stating:

> "We have received an amazing interest from Australian ICU nurses this morning. All nurses who have registered their interest up until now (25th of February 2021, 12 noon) are eligible for a voucher. Australian ICU nurses are still encouraged to register their interest. However, the voucher allocation for this group is now exhausted" (Adams, 2021b).

Nurses who chose to register after this announcement received a modified Participant Information Sheet highlighting that they would not be eligible for a voucher[36]. Concerns arose that the same issue could happen if the same advertising method was used through other professional organisations in Australia, and since the research project only sought interest in consulting a few people from each discipline in the multidisciplinary ICU team, it was decided to contact occupational therapists and physiotherapists using snowballing methods. From this experience, it is advisable to generally offer incentives carefully, in particular when there is a risk that a large group of stakeholders will register their interest. Guideline developers can state that only a limited number of stakeholders will receive a voucher on a 'first come, first served' basis to avoid exceeding budget limits. This study found that health professionals participating during their working hours were able to claim hours spent on the project as professional development hours. Furthermore, some health professionals described feeling uncomfortable receiving reimbursements. Danish clinicians highlighted that receiving money when participating in a research project in Denmark was unusual. Considering the differences in cultural norms, resource access and reciprocity, it was decided to only reimburse patients and family members.

In contrast to the recruitment of ICU nurses, challenges arose when attempting to recruit patients and family members. Indeed, the engagement of laypeople in projects involving diverse international stakeholder groups has shown to be challenging (Ingoe et al., 2020). Ocloo and Matthews (2016) warn that stakeholders can struggle with a lack of confidence and feel they do not

[35] The 7-step framework is described in detail in Chapter 5
[36] Note that before this message, all stakeholders in the stakeholder consultation phase were eligible to receive a voucher. Also, it was decided to only give patients and family members vouchers in the Delphi study.

have much to contribute. In our project, this was illustrated by one stakeholder who contacted us, writing: "I am just an ordinary person with some experience in this area", and then, unfortunately, withdrew from the project. Similar to other scholars (Pandya-Wood, Elliott, & Barron, 2019). I suggest meeting individuals face-to-face, where researchers can describe the study and engage in conversations. Such engagement may increase stakeholders' trust in the study and potentially their self-confidence, thus increasing participation. Unfortunately, due to COVID physical contact restrictions, accessing post-ICU patient support groups could not be done, which hindered this level of personal contact. Instead, online videos in two languages were developed, which explained what it meant to be involved. The English version can be found here, and the Danish version here[37]. If using a webpage for engagement, guideline developers can also consider developing pages and material specific for patients and family members. A life storyboard allowing all patients and family members to write on in real time may also be helpful.

Related to the webpage, materials were all pilot-tested. This process is recommendable, as it led to several changes related to language and design being made. Overall, patients and family members provided invaluable advice in this project and supporting their involvement in determining the scope of practice for guidelines is recommendable. It is important that guideline developers consider how consumers can be involved in meaningful ways. It is likely that they require different questions to experts and clinicians. For example, it was noticed that patients and family members did not comment on the appropriateness of the setting. This is likely related to not having experiences with related clinical settings; thus, the question may be unnecessary and perhaps even meaningless for this group of stakeholders. The aim of this study was not to get an in-depth understanding of stakeholders' experiences of agitation in the ICU. However, if guideline developers have additional time and resources, it may be worthwhile exploring patient and family members' experiences of a phenomenon in more depth particularly if their experiences are largely unknown to scientific communities. While it was anticipated that clinicians signed up because they had significant experiences with agitation in the ICU, and potentially opportunities to discuss management with colleagues, this was possibly not the case for patients and family members. It was observed that patients and family members did not systematically answer the questions. They moved back and forth, and sometimes I got confused and had to interpret and guess what they were saying. Confirming accurate interpretation of their words was often sought, for example, by saying, "are you saying that…." or "is this what you mean?". To fully understand their needs, exploratory, inductive methods may be more appropriate.

Overall, the different modes of feedback allowed different voices to be heard, at their convenience, regardless of time zones, geographical locations, educational levels, income and ethnic backgrounds. Providing a diversity of methods for input and feedback also offered environments

[37] For the purpose of thesis publication, the links will take the reader to Appendix 50.

where stakeholders could feel safe and comfortable speaking up. The different modes ensured that our strategy was as inclusive and flexible as possible. A summary of the perceived advantages and disadvantages of each engagement method can be found in Table 29.

**Table 29 Advantages and disadvantages of different engagement methods**

| Method | Advantages | Disadvantages | Advice |
|---|---|---|---|
| **Written feedback** | Enable busy shift workers to participate<br>Convenient for both stakeholders and guideline developers.<br>Allows a larger number of people to be engaged. | While some responses were lengthy and detailed with references and explanations, others were brief.<br>Answers from stakeholders may be unclear. | I recommend receiving written feedback before running the workshops and one-on-one meetings. This sequential approach can provide an opportunity to seek clarification on some written feedback. |
| **One-on-one meetings** | Can be carried out at a negotiated time that suits stakeholders.<br>Offers more speaking time, thus an opportunity to provide more detailed feedback. | Can be time-consuming for guideline developers.<br>Require guideline developers to be available outside regular working hours when including stakeholders from other time zones. | Provide questions in advance and encourage stakeholders to come prepared.<br>On average, meetings took between 20-40 minutes.<br>This method can be valuable for groups that are challenging to reach. For instance, I experienced that patients and family members preferred this option. |
| **Workshops** | Allows for discussion of the proposed guideline scope with other stakeholders<br>I experienced passionate and enthusiastic stakeholders who asked both us and each other questions. | Power imbalances can occur.<br>Time-consuming for stakeholders. | To promote comfortable group dynamics and avoid power imbalances, group stakeholders with similar backgrounds.<br>6-8 individuals in each group allow all stakeholders to answer all questions.<br>2.5-3-hour workshops provide enough time to hear everybody's advice and opinions on all questions.<br>I recommend having two facilitators in each workshop, one being an experienced facilitator.<br>Provide questions in advance and encourage stakeholders to come prepared.<br>Have a clear agenda for the workshop and set ground rules, including showing respect and maintaining confidentiality. |

Related to the specific questions presented to stakeholders, it is regrettable that they were not asked to rank outcomes. Such information is essential for conducting relevant systematic reviews that will inform the guideline recommendations, and therefore, it is recommendable to future guideline developers to do this during the scoping phase. Finally, guideline developers must be aware that inclusive multinational consultation of stakeholders requires additional time. Significant time was spent translating all videos, documents and written online texts. All material was pilot

tested on various Danish and Australian laypeople and health professionals. Due to the time differences between the countries involved, scheduling interviews and workshops also needed to be considered to facilitate participation.

## 6.10 Summary

This stakeholder consultation study, involving 51 Danish and Australian stakeholders, revealed several important findings that helped determine the final guideline scope. The vast majority of stakeholders indicated that guidelines were needed. They described how agitation occurred frequently, was not managed well, and how staff lacked guidance on how to best care for this group of patients. The stakeholders felt it was important to ensure NPSs were patient-centred and safe. Some wanted to know when to use NPSs and how to support families to support their loved ones. While it was decided to include these aspects, there were areas that were beyond the remit of the research. The included pharmacological treatment of agitation, transfer out of ICU, promotion of sleep, psychological support of family members, risk factors for agitation, when to use PR, and assessment of agitation. However, it was decided that if recommendations related to assessment tools or PR were mentioned while searching the literature, they could be included in the guidelines.

Stakeholders described a wide array of NPSs to minimise and manage agitation. These were targeted at the organisation and leadership, the multidisciplinary team, the family, the environment and finally, towards the patients. It became clear that NPSs were not simply those directly related to the patient, such as therapeutic touch and sensory stimulation, but they had to be seen in a much broader context. Stakeholders also believed that interventions from other healthcare settings could be useful in the ICU setting.

A major amendment to the guideline scope was on the end-user group. Based on the literature and the fact that nurses often are the first to detect agitation and act upon this, it was assumed the guidelines should be for nurses. However, through consultation, it was found that the guidelines needed to be for the multidisciplinary ICU team. Stakeholders described how the whole team was responsible and involved when patients became agitated. A team member who did not fully understand or accept the principles of NPSs could be a barrier to implementing guidelines and even exacerbate agitation. In the earlier described systematic review on nurses' experiences of caring for patients displaying agitated behaviours[38] , the importance of interdisciplinary collaboration to reduce agitation was emphasised, supporting the argument for including the multidisciplinary team. The decision to develop guidelines for the multidisciplinary team had major implications for the design of the Delphi study, stemming from the need to involve participants from different healthcare disciplines. It was also suggested that a patient-family version of the guidelines

[38] Read more in Chapter two, Section 2.2

should be developed. While the time restraints of this PhD project did not allow for this to occur, this remains an objective for future research.

Based on the stakeholder comments, it was decided that the guidelines needed to be for critically ill patients who were 18 years or older. Stakeholders also suggested that some patients were likely to require slightly different approaches. These included patients with delirium, language and cultural barriers, intoxication, brain injury, dementia, unconscious patients and those receiving palliative care. It was decided that separate recommendations would be made to such groups if the evidence suggested this. Most stakeholders agreed to the study setting, the ICU. Stakeholders argued that the ICU environment and patient population were significantly different from other areas of the healthcare system, and that developing ICU-specific guidelines would therefore be more meaningful. A number of important outcomes were described, including primary, intermediate and secondary outcomes. Finally, the stakeholders described multiple barriers and facilitators to guideline development that helped to determine the scope while also providing important advice for future guideline implementation. Overall, it is believed that the stakeholder consultation phase of this study increased the useability and relevance of the final guidelines.

This study also provided important insights into how stakeholders can be engaged in ethical and feasible ways. Incentives must be offered carefully, particularly if using open invitations through professional or patient organisations. Reimbursement of patients and family members should be prioritised over other stakeholder groups. Personal recruitment of patients and family members is preferred. However, this is often not possible due to physical distances and other logistical challenges. In such cases, it can be helpful to develop informative online videos. All online material should be pilot tested, as this is likely to improve the inclusiveness of the material. If guideline developers have the time and resources available, in-depth interviews with patients and family members may offer additional perspectives. Offering different modes of feedback, including workshops, interviews and the opportunity to provide written feedback, allows for a more inclusive study. Finally, developing an inclusive multinational consultation study requires additional time, which must be taken into account.

## 6.11 Strengths and limitations

A key strength of this study was that it allowed a broad group of international stakeholders to provide honest and open advice independent of geographic location, language or literacy skills. The input was invaluable, and the changes made to the final scope were necessary to ensure the development of implementable and meaningful guidelines. A further strength was the focused approach that supported making informed decisions about the final guideline scope within a certain timeframe and with limited resources.

Limitations to this study phase included not using verbatim transcription to capture the nuances of workshops and interviews. Although such a method would have allowed in-depth analysis, this was not the aim of stakeholder consultation. Furthermore, it would have required additional time and ethical approval and was unlikely to have significantly changed the results of the study.

While online consultation has many advantages related to the inclusiveness of stakeholders and the ability to capture honest advice, there are also limitations associated with this method that must be acknowledged. These relate to the challenges of reaching particular groups of people, such as those suffering from mental or physical illnesses, the homeless, those with lower socioeconomic backgrounds without access to computers and the internet, and those with poor communication, reading, or digital literacy skills. As described in the conceptual framework in chapter two, people with mental illnesses were at higher risk of developing agitation in the ICU – including all types of stakeholders and meeting face-to-care would have been invaluable and may have uncovered inequity issues. Yet, this was not possible due to the geographical distances between stakeholders. Guideline developers must be aware of the drawbacks of online engagement and consider whether and how they can overcome such barriers. Finally, it must also be acknowledged that clinicians participating in this study may have had a special interest in the area and, therefore, may not represent all clinicians.

## 6.12 Conclusion

This study used a 7-step framework to consult various Danish and Australian stakeholders on the scope of clinical guidelines. Subsequent amendments to the draft scope included:

- The aim must be to develop patient-centred guidelines. This was not stated in the draft scope.
- The guidelines should include information about when to use NPSs and how to support families to support their loved ones.
- NPSs must be seen from a broad perspective and target the organisation and leadership, the multidisciplinary team, the family, the environment and the patient.
- The end-users must change from nurses to the multidisciplinary team.
- The age limit for the target population must be 18 years or older.
- The primary outcome should be reduced frequency, duration and severity of agitation.

This consultation phase shows that priorities driven by academics may not always reflect the views and values of those affected by guidelines. Consulting multiple international stakeholders is feasible and can give important information on their needs and issues in the early phase of guideline development. As evident from this chapter, such insights can then be incorporated into the decisions on a final guideline scope in transparent and fair ways.

Despite an increased focus on the importance of engaging various international stakeholders in guideline development, to my knowledge, the 7-step framework presented in Chapter 5, is the first to specifically describe how this can be done in feasible and ethical ways. I suggest that future guideline developers consider what kind of knowledge and experiences consumers bring that can support guideline development. Consulting this stakeholder group may require a different approach than consultation with other stakeholders.

This chapter described, in a transparent way, how the final guideline scope was determined. The next chapter presents two systematic reviews summarising the existing literature on NPSs for agitation in the ICU. These summaries, together with the results from the stakeholder consultation phase, directly informed a list of tentative recommendations used in the first Delphi round.

# CHAPTER 7: PHASE TWO – SYSTEMATIC REVIEWS FINDINGS

## 7.1 Introduction

The previous chapter described how Danish and Australian stakeholders informed the final scope of the guideline. The next step in guideline development is to examine the currently available literature regarding the strategies for preventing, minimising or managing agitation in the ICU. Guidelines should be informed by well-conducted searches that are systematic, transparent and reproducible (NHMRC, 2020, p. 7; NICE, 2014). While the searches must be systematically conducted, it is also important to have a flexible approach that considers different types of evidence (NHMRC, 2020, p. 7; NICE, 2014).

This chapter describes two systematic reviews aiming to summarise the best available evidence. According to the Cochrane handbook, conducting systematic reviews require researchers to "use explicit, systematic methods that are selected with a view aimed at minimizing bias, to produce more reliable findings to inform decision making" (Cochrane). The purpose of the first review was to review studies that evaluated the effectiveness of NPSs for agitation in the ICU. Since this review found very little evidence amongst primary quantitative studies, an additional second review was carried out. This review assessed and summarised systematic reviews of qualitative reviews in the ICU and guidelines from the broader healthcare context.

## 7.2 A systematic review of nonpharmacological interventions for agitation in the adult ICU

An earlier version[39] of this section was published in the Collegian in the article:

> Adams, A. M. N., Chamberlain, D., Grønkjær, M., Thorup, C. B., & Conroy, T. (2022). Nonpharmacological interventions for agitation in the adult intensive care unit: A systematic review. *Australian Critical Care*. https://doi.org/10.1016/j.aucc.2022.02.005.

The text has been modified to suit this chapter, but the content directly overlaps with the published version (see Appendix 3 for the published version).

### 7.2.1 Rationale for conducting a systematic review of interventions

When a guideline scope is determined, it is time to identify guideline questions. Often guideline developers start by asking a question about the effectiveness of an intervention (NHMRC, 2019;

[39] I contributed 85% to the research design, 90% to the data collection and analysis and 80% to the writing and editing of the manuscript.

NICE, 2014). Therefore, this systematic review aimed to evaluate the effectiveness of NPSs designed to prevent, minimise, or manage patient agitation in the adult ICU.

### 7.2.2 Review question and objectives

This review sought to answer the question: what is the effectiveness of nonpharmacological interventions for agitation in ICU?

The objectives were:

- to systematically review studies that evaluate the effectiveness of NPSs designed to prevent, minimise or manage patient agitation in the adult intensive care unit.

- to identify if any harms were reported relating to NPSs

### 7.2.3 Methods

This systematic review followed a priori PROSPERO protocol (CRD42021254918) (Adams, 2021a), the JBIs method for Systematic Reviews of Effectiveness (Tufanaru C et al., 2020) and was registered as per the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Page et al., 2021). Published and unpublished studies in English describing NPSs for agitation in the adult ICU were considered for inclusion. Studies that mixed non-pharmacological and pharmacological components were excluded to enable a more precise indication of the effect of NPSs. Based on advice from the stakeholder consultation phase (see Chapter 6), the primary outcome measure was the effect on prevention, minimisation and management of agitation, which had to be measured with a validated tool. Parameters such as heart rate, stress hormones and antipsychotic or sedative drugs, were not considered exclusively related to agitation as these could be related to other factors in the ICU. Intermediate outcomes considered were the use of pharmacology and PR to reduce agitation and staff and family confidence in managing agitated behaviours. Secondary outcomes included adverse events such as unplanned extubations, nosocomial infections and device removal, length of ICU stay, quality of life, risk of patient post-traumatic stress, patient satisfaction, family satisfaction and workforce injuries. This review considered studies that used comparative designs such as RCTs, quasi-experimental studies and before and after studies with comparators such as usual care (i.e., usual nursing care). Systematic reviews on NPSs for agitation have been criticised for only including RCTs, as this experimental design is often inappropriate or unfeasible for NPSs (Cohen-Mansfield, 2016). Cohen-Mansfield et al. (2014) argue that due to the lack of effective NPSs, any evidence of effect is a step in the right direction. When reviews only include RCTs, there is a risk that meaningful studies are excluded, and clinicians are left with insufficient or untimely treatment options (Cohen-Mansfield et al., 2014). Due to these arguments, this review also considered analytical and descriptive observational studies if there were no higher levels of evidence. No date limitations were applied as the effect of interventions were unlikely to have changed over time.

#### *7.2.3.1 Search strategy*

This review aimed to identify both published and unpublished studies. An initial limited search in MEDLINE was undertaken to identify relevant topic keywords and Subject Headings. A search strategy was developed from the keywords and Subject Headings and checked by an experienced librarian before being adapted for each database. An overview of all search strategies can be found in Appendix 33. Databases included MEDLINE (OVID, 1946-June 2021), EMCARE (OVID 1995 to June 2021), CINAHL (Cumulative Index to Nursing and Allied Health Literature, 1982 to June 2021), Web of Science (1956- June 2021), PsycINFO (1806 to June 2021), Scopus (1788-June 2021). In addition, the following repositories and registers were searched: Cochrane Central Register of Controlled Trials, Australian New Zealand Clinical Trials Register (ANZCTR), EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/ctr-search/search), the World Health Organization International Clinical Trial Registry Platform (www.who.int/ictrp/search/en), US National Library of Medicine Trials Register (www.clinicaltrials.gov), ProQuest Dissertations & Thesis Global and OpenGrey. Reference lists of all relevant studies were also screened.

#### *7.2.3.2 Study selection*

Records identified in the searches were exported into Covidence software, where all duplicates were removed. The principal supervisor and I independently screened a random selection of record titles and abstracts to determine if they appeared to meet the inclusion criteria. After reaching an agreement on these papers, I screened the remaining papers. Relevant articles were retrieved in full text and assessed in detail against the inclusion criteria by two independent reviewers. A third reviewer (an associate supervisor) was invited to provide their view when disagreements occurred between the two independent reviewers. Reasons for excluding full-text articles are provided in Appendix 34.

#### *7.2.3.3 Assessment of methodological quality.*

All studies meeting the inclusion criteria were assessed for external and internal validity by two independent reviewers using the JBIs standardised appraisal tools for RCTs (Appendix 35) and Quasi-experimental studies (Appendix 36) (Tufanaru C et al., 2020). Disagreements were resolved by discussion, and where consensus could not be reached, a third reviewer was involved. When the studies lacked essential information, primary authors were to be contacted. The questions in the appraisal tool were rated 'Yes', 'No', 'Unclear' or 'Not Applicable. 'Not Applicable' was, for example, used when the reviewers believed blinding methods were not possible. The overall methodological quality of each study was then calculated by adding all 'Yes' ratings and dividing them with the number of applicable questions to get a percentage. Studies were rated 'low methodological quality' if rated less than 50%, adequate if rated between 50-69%, moderate if rated between 70-85%, and strong if rated between 86-100%. Since studies of low quality may compromise the quality of systematic review practice recommendations (Aromataris & Pearson, 2014; Porritt et al., 2014), it was decided to exclude all studies with "low methodological quality".

#### *7.2.3.4 Data extraction*

Two independent reviewers extracted data using a purposefully designed data extraction template (Appendix 37). Data included details about the populations, study methods, interventions, and outcomes of significance to the review objective.

#### *7.2.3.5 Data synthesis*

Due to the variability of study characteristics (design, intervention, population) and lack of reported data, meta-analysis was not possible for all included studies. A narrative summary is presented for studies not included in a meta-analysis. Two RCTs describing multi-component non-pharmacological interventions were pooled using the JBI System for the Unified Management, Assessment and Review of Information (SUMARI) tool (Munn et al., 2019). The effect sizes were expressed as standardised mean difference (SMD) for continuous data. Their 95% confidence intervals (CI) were calculated for analysis. Statistical heterogeneity was assessed using the standard chi-squared and I-squared tests. Statistical analyses were performed using the fixed effects model based on guidance by Tufanaru et al. (2015). Publication bias could not be assessed due to the low number of included studies.

#### *7.2.3.6 Assessing certainty in the findings*

Clinicians need to know how trustworthy a body of evidence is before making clinical decisions (Murad et al., 2017). The certainty of the evidence was rated using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach (Schünemann et al., 2013b). Two researchers did the ratings and developed a Summary of Findings table (Table 33) using GRADEpro GDT (GRADEpro GDT, 2020).

### 7.2.4 Results

The results from the search process are presented in Figure 18 (See Appendix 38 for a full list of results). A total of 6000 potentially relevant articles were identified; 2571 duplicates were removed. Titles and abstracts were screened of the remaining 3429 articles, excluding 3394 records. Overall, 35 studies went through a full-text analysis leaving 15 articles for quality appraisal. Four studies were of low methodological quality and were excluded, leaving 8 RCTs and three quasi-experimental studies for inclusion.

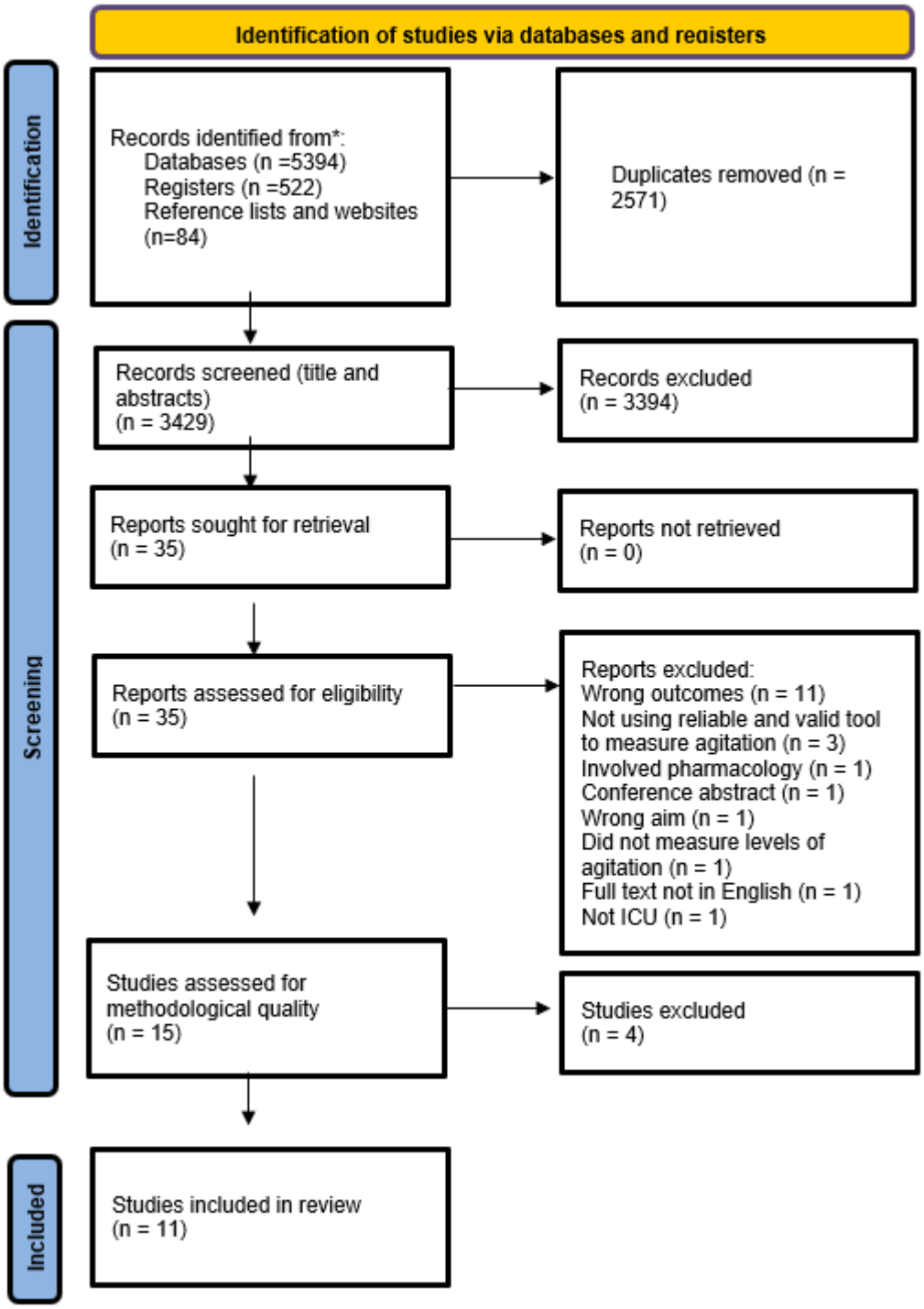



**Figure 18 Prisma Flow (Page et al., 2021).**

*Report of records identified from each database or register searched; see App 38

### 7.2.5 The methodological quality of included studies

An overview of the critical appraisal is provided in Table 30 and Table 31**.** Four studies were excluded due to low methodological quality (Ashlaghi et al., 2018; Khalifezadeh et al., 2011; Korhan et al., 2014; Sedghi et al., 2020) (See Appendix 39 for detailed explanations). Of the included studies, four were of adequate quality (Abbasinia et al., 2021; Dastdadeh et al., 2016; Davis et al., 2020; Mashouf et al., 2017), six of moderate quality (Aghaie et al., 2014; Allahbakhhsian et al., 2020; Guo et al., 2016; Rajora et al., 2019; Saadatmand et al., 2013; To et al., 2013) and one of high quality (Jong Yoen & Soohyun, 2019). Some studies reported using random allocation techniques but did not describe how true randomisation was achieved (Aghaie et al., 2014; To et al., 2013); others did not describe appropriate concealment methods (Dastdadeh et al., 2016; Guo et al., 2016). In some studies, participants were not similar at baseline; this was related to levels of agitation (Aghaie et al., 2014; Dastdadeh et al., 2016; To et al., 2013) and the proportion of males and females (Mashouf et al., 2017; Saadatmand et al., 2013; To et al., 2013). Due to the nature of the interventions, blinding participants and assessors was sometimes impossible or would have little effect on the outcome. For example, knowing if a suction system was open or closed was unlikely to affect levels of agitation (Dastdadeh et al., 2016). Creative methods or placebos were used for blinding in some studies. For example, Aghaie et al. (2020) did not inform participants about the group they were assigned to, the purpose of wearing headphones and the outcome measures until after the experiment. In terms of measurements of outcomes, one study was unclear about when measurements were done (Abbasinia et al., 2021), and many studies did not describe how inter-rater reliability was ensured (Abbasinia et al., 2021; Dastdadeh et al., 2016; Davis et al., 2020; Mashouf et al., 2017; Saadatmand et al., 2013; To et al., 2013). In two studies, the exact differences between the interventions and usual care were unclear (Abbasinia et al., 2021; Guo et al., 2016). The statistical methods used were often unclear, insufficient or results inadequately reported (Aghaie et al., 2014; Jong Yoen & Soohyun, 2019; Mashouf et al., 2017; Rajora et al., 2019; Saadatmand et al., 2013).

**Table 30 Quality assessment using JBI's checklist of randomised controlled trials**

| Study | Q1 | Q2 | Q3 | Q 4 | Q 5 | Q 6 | Q 7 | Q 8 | Q 9 | Q 10 | Q 11 | Q 12 | Q 13 | Total (%) | Methodological quality |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Abbasinia et al. (2021) | Y | Y | Y | Y | NA | N | U | Y | Y | U | U | Y | Y | 67 | Adequate |
| Aghaie et al. (2014) | U | Y | N | Y | NA | Y | Y | Y | Y | Y | Y | N | Y | 75 | Moderate |
| Allahbakhhsian et al. (2020) | Y | Y | Y | NA | NA | N | Y | Y | Y | Y | Y | U | Y | 82 | Moderate |
| Dastdadeh et al. (2016) | Y | U | H | NA | NA | NA | Y | Y | Y | Y | U | U | Y | 60 | Adequate |
| Guo et al. 2016 | Y | U | Y | N | NA | Y | U | Y | Y | Y | Y | Y | Y | 75 | Moderate |
| Rajora et al. (2019) | Y | Y | Y | NA | NA | U | Y | Y | Y | Y | U | N | Y | 73 | Moderate |
| Saadatmand et al. (2013) | Y | Y | N | Y | NA | Y | Y | Y | Y | Y | U | U | Y | 75 | Moderate |
| To et al. (2013) | U | Y | N | Y | Y | Y | Y | Y | Y | Y | U | Y | Y | 77 | Moderate |

Y = yes; N = no; U = Unclear; N/A = not applicable.
0 - 49%: low methodological quality; 50 - 69%: adequate methodological quality; 70 - 85: moderate methodological quality; 86 - 100: strong methodological quality.

Q1 Was true randomization used for assignment of participants to treatment groups?
Q2 Was allocation to treatment groups concealed?
Q3 Were treatment groups similar at baseline?
Q4 Were participants blind to treatment assignment?
Q5 Were those delivering treatment blind to treatment assignment?
Q6 Were outcomes assessors blind to treatment assignment?
Q7 Were treatment groups treated identically other than the intervention of interest?
Q8 Was follow-up complete and, if not, were differences between groups in terms of their follow-up adequately described and analysed?
Q9 Were participants analysed in the groups to which they were randomized?
Q10 Were outcomes measured in the same way for treatment groups?
Q11 Were outcomes measured in a reliable way?
Q12 Was appropriate statistical analysis used?
Q13 Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?

**Table 31 Quality assessment using JBI's checklist of Quasi-experimental studies**

| Study | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | Total (%) | Methodological Quality |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Davies (Davis et al., 2020) | Y | Y | NA | N | Y | U | Y | U | U | 50 | Adequate |
| Jong Yoen Park (Jong Yoen & Soohyun, 2019) | Y | Y | Y | Y | Y | Y | Y | Y | U | 89 | Strong |
| Mashouf (Mashouf et al., 2017) | Y | N | NA | N | Y | Y | Y | U | N | 50 | Adequate |

Y = yes; N = no; U = Unclear; N/A = not applicable.
0 - 49%: low methodological quality; 50 - 69%: adequate methodological quality; 70 - 85: moderate methodological quality; 86 - 100: strong methodological quality.

Q1 Is it clear in the study what is the 'cause' and what is the 'effect' (i.e., there is no confusion about which variable comes first)?
Q2 Were the participants included in any comparisons similar?
Q3 Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?
Q4 Was there a control group?
Q5 Were there multiple measurements of the outcome both pre and post the intervention/exposure?
Q6 Was follow up complete and if not, were differences between groups in terms of their follow-up adequately described and analysed?
Q7 Were the outcomes of participants included in any comparisons measured in the same way?
Q8 Were outcomes measured in a reliable way?
Q9 Was appropriate statistical analysis used?

### 7.2.6 Characteristics of the studies

The characteristics of the 11 included studies are provided in Table 32. Data of publication ranged from 2012 to 2021. Six studies were undertaken in Iran (Abbasinia et al., 2021; Aghaie et al., 2014; Allahbakhhsian et al., 2020; Dastdadeh et al., 2016; Mashouf et al., 2017; Saadatmand et al., 2013), one in Korea (Jong Yoen & Soohyun, 2019), one in China (Guo et al., 2016), one in India (Rajora et al., 2019), one in the USA (Davis et al., 2020) and one in Canada (To et al., 2013). The sample sizes varied from 6 to 160. A total of 882 participants were involved, with the youngest mean age of a group being 41.23 ± 15.31 (Saadatmand et al., 2013) and the oldest 73.7 ± 5.2 (Guo et al., 2016). Although this review included all types of quantitative studies, only RCTs (Abbasinia et al., 2021; Aghaie et al., 2014; Allahbakhhsian et al., 2020; Dastdadeh et al., 2016; Guo et al., 2016; Rajora et al., 2019; Saadatmand et al., 2013; To et al., 2013) and quasi-experimental studies (Davis et al., 2020; Jong Yoen & Soohyun, 2019; Mashouf et al., 2017) were identified. The inclusion criteria varied. Most studies excluded patients with a mental illness (Aghaie et al., 2014; Allahbakhhsian et al., 2020; Dastdadeh et al., 2016; Guo et al., 2016; Jong Yoen & Soohyun, 2019; Rajora et al., 2019; Saadatmand et al., 2013), with drug or alcohol addiction (Aghaie et al., 2014; Allahbakhhsian et al., 2020; Guo et al., 2016; Mashouf et al., 2017; Rajora et al., 2019; Saadatmand et al., 2013) and neurological disorder (Aghaie et al., 2014; Dastdadeh et al., 2016; Guo et al., 2016; Jong Yoen & Soohyun, 2019; Rajora et al., 2019; Saadatmand et al., 2013). Some studies only included conscious participants (Allahbakhhsian et al., 2020; Dastdadeh et al., 2016) or had a Glasgow coma scale score of at least 7 (Mashouf et al.,

2017) or 9 (Rajora et al., 2019; Saadatmand et al., 2013). Some only included patients who were able to communicate (Jong Yoen & Soohyun, 2019; Saadatmand et al., 2013). Most studies did not define criteria for levels of consciousness (Abbasinia et al., 2021; Aghaie et al., 2014; Davis et al., 2020; Guo et al., 2016; To et al., 2013). One study (Mashouf et al., 2017) included patients who were agitated, while another (Davis et al., 2020) excluded patients who were very agitated or combative. Three studies excluded patients receiving sedatives during the intervention (Jong Yoen & Soohyun, 2019; Mashouf et al., 2017; To et al., 2013), one if they received high doses of sedatives (Dastdadeh et al., 2016), and one if participants needed an emergency stat dose of sedatives (Rajora et al., 2019). Most studies did not describe or control for the use of sedation, antipsychotic drugs or analgesia before, during and after the interventions (Abbasinia et al., 2021; Aghaie et al., 2014; Allahbakhhsian et al., 2020; Davis et al., 2020; Guo et al., 2016; Rajora et al., 2019; Saadatmand et al., 2013). All studies used the Richmond Agitation Sedation Scale (RASS) to measure levels of agitation, except one study (To et al., 2013) using the Ramsey Sedation Scale. Apart from two studies measuring the ICU length stay (Abbasinia et al., 2021; Rajora et al., 2019) none of the included studies measured any of the secondary or intermediate outcomes considered for this review.

**Table 32 Characteristics of included studies**

| Study details | Design* | Sample** and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and Measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| **Multi-component Nonpharmacological Care Interventions** | | | | | | | | | |
| Abbasinia (2021).<br><br>Iran | RCT | I:<br>n = 30,<br>mean age 56.46±9.89<br><br>C:<br>n = 30,<br>mean age 58.93±10.57<br><br>Mechanical ventilation unclear.<br><br>Patients recovering from CABG | Cardiac ICU | Multicomponent nonpharmaco-logical intervention<br><br>(Preoperative video and HELP program including reorientation, therapeutic activities, reduced use of psychoactive drugs, promotion of sleep, early mobilisation, adequate hydration/nutrition and provision of vision and hearing adaptions). | Usual care | Until ICU discharge ≈ day 4. | RASS<br><br>Once daily on day 2 and 3 | **Agitation:**<br><br>no significant differences in levels of agitation between I (0.06 ± 0.25) and C (0.36 ± 0.80), p=0.057.<br><br>**Length of ICU stay:** significantly lower in I (3.53 ± 0.57days) compared with C (4.06 ± 1.28 days), p = 0.042. | Staff training required.<br><br>Part of intervention outside ICU<br><br>Short-term follow-up.<br><br>Assessments only done once daily - unclear when.<br><br>Unclear if/how inter-rater reliability was ensured.<br><br>Participants and assessors not blinded<br><br>Differences between intervention and usual care unclear.<br><br>Unclear if patients received psychoactive drugs during the intervention and if they were mechanically ventilated. |
| Guo (2016).<br><br>China | RCT | I:<br>n=81,<br>mean age 73.3 ± 6.1<br><br>C:<br>n=79,<br>mean age 73.7 ± 5.2 | Surgical ICU | Multicomponent nonpharmacological intervention<br><br>(Preoperative visit to ICU, modified HELP program including reorientation, therapeutic activities, promotion of | Usual care | Until ICU discharge ≈ day 4. | RASS<br><br>Twice a day, between 7-8 morning and between 19-20 evening for three days post-surgery. | **Agitation:**<br><br>Levels of agitation were lower in I compared to C all three days after surgery, p < 0.05. Levels of agitation in the last day were 0.5 ± .04 in C compared 0.2 ± | Staff training required.<br><br>Part of interventions outside ICU<br><br>Allocation concealment unclear<br><br>Participants not blinded.<br><br>No arguments for sample size. |

| Study details | Design* | Sample** and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and Measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| | | Mechanical ventilation unclear.<br><br>Patients recovering from oral cancer resection surgery. | | sleep, adequate hydration/nutrition, music etc). | | | | 0.3, in I, p = < 0.001. | Long-term effect not investigated.<br><br>Differences between intervention and usual care unclear.<br><br>Unclear if patients received psychoactive drugs during the intervention |
| **Nature-based Sounds** | | | | | | | | | |
| Rajora et al. (2019).<br><br>India | RCT | I:<br>n=60,<br>mean age 47.07±10.66<br><br>C:<br>n=60,<br>mean age 46.90±10.95<br><br>All patients mechanically ventilated. | Respiratory ICU | Nature-based sounds via headphones. | Placebo:<br><br>Headphones without nature-based sounds | 60 min x 1 | RASS<br><br>Before, then 15, 30, 45 and 60 min after commencing the intervention and 30 min after the intervention. | **Agitation:**<br><br>Significant reduction of agitation in I compared to C at all time points.<br><br>(p =0.003 at 15 minutes, p=0.001 at 30 minutes, p=0.001 at 45 minutes, p=0.001 at 60 minutes and p=0.001 after 30 minutes)<br><br>**Length of stay**<br><br>No significant differences between the groups. | Brief intervention period with short-term follow-up.<br><br>Unclear if assessor was blinded.<br><br>Unclear how inter-rater reliability was ensured.<br><br>Lack of appropriate statistical analysis.<br><br>Unclear if patients received psychoactive drugs during the intervention |
| Aghaie et al. (2014). | RCT | I:<br>n=60,<br>mean age 58.10 ± 6.05 | Cardiac ICU | Nature-based sounds via headphones. | Placebo:<br><br>Headphones without | During weaning from | RASS<br><br>Agitation recorded at | **Agitation:**<br><br>Authors report that I had | Unclear if true randomisation was used. |

| Study details | Design* | Sample** and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and Measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| Iran | | C:<br>n=60,<br>mean age<br>56.66 ± 5.84<br><br>All patients mechanically ventilated.<br><br>Patients recovering from CABG surgery. | | | nature based sounds | mechanical ventilation, unclear for how long. | baseline, and after the first trigger and at 20 min intervals throughout the procedure, immediately after the procedure, and 20 and 30 min after extubation. | significant lower levels of agitation than C. | Data analysis and reporting very unclear.<br><br>Only included patients between 45-65 years of age.<br><br>Different levels of agitation at baseline.<br><br>Brief intervention period with short-term follow-up.<br><br>Unclear if patients received psychoactive drugs during the intervention. |
| Saadatmand (2013).<br><br>Iran | RCT | I:<br>n=30,<br>mean age<br>41.23 ± 15.31<br><br>C:<br>n=30,<br>mean age<br>46.60 ± 16.76<br><br>All patients mechanically ventilated. | General ICU | Nature based sounds via headphones. | Placebo:<br>Headphones without nature based sounds. | 90 min | RASS<br>Before and at the 30th, 60th, 90th minutes and 30 min after the intervention. | **Agitation**<br>A significant difference was found between<br>the agitation scores in the two groups ($p < 0.001$).<br>The odds of having higher<br>scores of agitation in C was ≈ 11.24 times of the same odds in the I. | Control group included 20 males and 10 females.<br><br>Unclear how inter-rater reliability was ensured.<br><br>Brief intervention period with short-term follow-up.<br><br>Unclear if patients received psychoactive drugs during the intervention |
| **Music Therapy** | | | | | | | | | |
| Jong Yoen & Soohyun (2019). | QE Cross-over | I:<br>n=3,<br><br>C:<br>n=3, | Surgical ICU | Music therapy<br><br>(Preferred music first, classical | Music therapy<br>(Classical relaxation music first, | 30 min with classical or preferred music, 60 min washout period, 30 | RASS | **Agitation: S**ignificantly lower levels after both the preferred music intervention | Pilot study (inadequately powered).<br><br>Participants their own controls |

| Study details | Design* | Sample** and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and Measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| Korea | | Overall mean age<br>45.33±16.49<br>All patients mechanically ventilated. | | relaxation music last). | preferred music last). | min with classical or preferred music. | Before and after each music session. | (Z=-2.24, p=.025) and classical relaxation music intervention (Z=-2, p=0.046) compared to before. There was no significant difference in the decrease in median RASS score between the two music interventions (U=15, p= 0.523) | Short "wash our" period<br>Assessors not blinded.<br>Brief intervention period with short-term follow-up. |
| To et al. (2013).<br>Canada | RCT | I:<br>n=25,<br>mean age<br>50.25 + 19.25<br>C:<br>n=25,<br>mean age 50.52 + 17.45<br>All patients mechanically ventilated.<br>Patients undergoing 4-hour sedation vacation. | General ICU | Mozart Piano Sonatas via headphones. | Placebo:<br>Headphones without music. | 4 hours | RAMSEY sedation scale<br>Measurements were obtained at baseline, at every 30 minutes during the intervention and ended at 4 hours. | **Agitation**<br>There was a trend for more successful sedation vacations (meaning no agitation) in the music group (64%) compared to the control group (52%). | Pilot study (inadequately powered).<br>Unclear if true randomisation was used.<br>Higher levels of agitation in music group at baseline<br>Ten females in control group compared to 3 in intervention group.<br>Brief intervention period with short-<br>term follow-up. |

| Study details | Design* | Sample** and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and Measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| **Sensory Interventions** | | | | | | | | | |
| Allahbakhhsian et al. (2020).<br><br>Iran | RCT | I:<br>n=40,<br>mean age 55.90 ± 8.31<br><br>C:<br>n=40,<br>mean age 56.30 ± 7.11<br>P<br>n=40,<br>mean age 57.32 ± 8.62<br><br>Patients not mechanically ventilated.<br><br>Recovering from CABG | Cardiac ICU | Foot reflexology | Control: Usual care<br><br>Placebo: superficial heel touch. | 15 min x 1 | RASS<br><br>Before (T1), after (T2) and 10 min after (T3) the intervention. | **Agitation:**<br><br>Agitation was reduced in all groups from T1 to T3 ($p<0.05$). I showed a significantly higher reduction at T2 ($p<0.001$) and T3 ($p<0.001$). In I agitation levels reduced by 1.844 scores (95% CI -2,768, 0.921), while the reduction was only 0.822 scores (95% CI -1.792, 0.147) for the placebo group. | Researcher trained by a professional reflexologist for one year<br><br>Assessor not blinded.<br><br>Serious indirectness as only men included<br><br>Brief intervention period with short-term follow-up.<br><br>Unclear if patients received psychoactive drugs during the intervention |
| Davis et al., (2020).<br><br>USA | QE | n=87<br><br>mean age = 63.38 ± 16.09<br><br>Mechanical ventilation unclear. | 5 general ICUs | Healing touch (HT) | No comparison | 7-15 min once daily in 1-2 days. | RASS<br><br>Before, after and 5 min after. | **Agitation**<br><br>Significant decreases in agitation scores following HT Pre (-0.59 ± 1.25) to post (-0.86 ± 1.16) first session, $p < 0.01$. Pre (-1.03 ± 1.61) to post (-1.52 ± 1.48) second session, $p < 0.002$. | Staff training required.<br><br>Feasibility study (inadequately powered).<br><br>Mean RASS scores were all below 0.<br><br>No comparisons.<br><br>Unclear how inter-rater reliability was ensured.<br><br>Brief intervention period with short-term follow-up. |

| Study details | Design* | Sample** and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and Measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Unclear if patients received psychoactive drugs during the intervention |
| Mashouf et al. (2017).<br><br>Iran | QE | n=40, mean age 49.36<br><br>Gender (m/f): 26/14<br><br>All patients mechanically ventilated. | General ICUs | Aromatherapy by Lavender Oil | No control | 60 min x 1 | RASS<br><br>Before, every 15 min during the intervention, then every 30 min. until two hours after the intervention. | **Agitation:**<br><br>Levels before and after aromatherapy were significant ($p < 0.001$). The greatest reduction of agitation was seen 180 min after the intervention. | No comparison group<br><br>No arguments for sample size.<br><br>65% males.<br><br>Unclear how inter-rater reliability was ensured.<br><br>Brief intervention period with short-term follow-up. |
| **Suchtion Methods** | | | | | | | | | |
| Dastdadeh et al. (2016).<br><br>Iran | RCT | I:<br>n=30, mean age 65 ±18<br><br>C:<br>n=30, mean age 66(±20)<br><br>All patients mechanically ventilated. | General ICU | Open endotracheal suction | Closed endotracheal suction | One suctioning | Before, during, and immediately after, 5 minutes after, and 15 minutes after the suctioning | **Agitation:**<br><br>The type of suctioning system used had no<br><br>effect on the level agitation ($p < 0.126$). | Allocation concealment unclear.<br><br>Three participants in the "open suction" group were deeply sedated throughout the intervention.<br><br>Brief intervention period with short-term follow-up.<br><br>Unclear if patients received psychoactive drugs during the intervention |

* RCT: randomised controlled trial, QE: quasi-experimental study
** I: intervention group, C: control group, P: placebo group.

### 7.2.7 Effect of interventions

The interventions in this review fell under five categories: multi-component interventions, nature-based sounds, music therapy, sensory interventions, and suction methods. Due to the heterogeneity of the included studies and lack of data pooling for meta-analysis was only possible for two studies. The overall strength of the evidence is summarised in Table 33.

**Table 33 Summary of Findings Table**

| **Nonpharmacological interventions for reducing agitation in the adult ICU** | | | |
|---|---|---|---|
| Bibliography: Adams, AMN; Chamberlain, D; Gronkjaer, M; Brun Thorup, C; Conroy, T. Non-pharmacological interventions for agitation in the adult intensive care unit - a systematic review and meta-analysis | | | |
| Outcomes | Effect | № of participants (studies) | Certainty of the evidence |
| **Multi-component Nonpharmacological Care Interventions compared to usual care** | | | |
| **Agitation**<br>Follow up: day 3 of the intervention. | Meta-analysis showed SMD difference 0.75 lower (95% CI: -1.02—0.47), indicating a large effect size. | 220 (2 RCTs) | ⨁◯◯◯<br>Very low [a, b, c.] |
| **Length of ICU stay** | Meta-analysis was not possible.<br>Significantly lower in I (3.53 ± 0.57days) compared with C (4.06 ± 1.28 days), p = 0.042) | 60 (1 RCT) | ⨁◯◯◯<br>Very Low [a, b, c.] |
| **Nature-Based Sounds compared to placebo** | | | |
| **Agitation**<br>Follow up: immediately after the intervention. | Meta-analysis was not possible.<br>Studies found a significant reduction of agitation in the intervention group. | 300 (3 RCTs) | ⨁◯◯◯<br>Very Low [b, c, d, e.] |
| **Length of ICU stay** | No significant differences of length of stay between the groups | 120 (RCT) | ⨁⨁◯◯<br>Low [b, c.] |
| **Music Therapy** | | | |
| **Agitation**<br>Follow up: immediately after the intervention. | Meta-analysis was not possible.<br>One RCT with 25 patients showed a trend toward lower levels of agitation. A pilot study with 6 participants showed a significant decrease of agitation. | 56 (one RCT and one quasi-experimental study) | ⨁◯◯◯<br>Very Low [c, f, g, h.] |

**Table 33 Continued**

| **Nonpharmacological interventions for reducing agitation in the adult ICU** | | | |
|---|---|---|---|
| Bibliography: Adams, AMN; Chamberlain, D; Gronkjaer, M; Brun Thorup, C; Conroy, T. Non-pharmacological interventions for agitation in the adult intensive care unit - a systematic review and meta-analysis | | | |
| Outcomes | Effect | № of participants (studies) | Certainty of the evidence |
| **Sensory Interventions** | | | |
| **Agitation**<br>Follow up: immediately after the intervention. | Meta-analysis was not possible.<br>One RCT and three quasi-experimental studies showed a significant effect. | 327 (one RCT and three QEs) | ⨁◯◯◯<br>Very Low [b, c, f, i.] |
| **Suction Methods - closed compared to open suction systems** | | | |
| **Agitation**<br>Follow up: immediately after the intervention. | Meta-analysis was not possible.<br>The type of suction system used had no effect on the level of patient agitation. | 60 (one RCT) | ⨁◯◯◯<br>Very Low [b, c, j.] |
| CI: confidence intervals; MD: mean difference; RCT: randomised controlled trial | | | |
| **GRADE Working Group grades of evidence**<br>High certainty: We are very confident that the true effect lies close to that of the estimate of the effect<br>Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different<br>Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect<br>Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect | | | |
| **Explanations**<br>[a]: serious risk of bias (differences between intervention and usual care unclear).<br>[b]: serious indirectness (psychoactive drugs received before/during the intervention is unclear).<br>[c]: serious imprecision (related to small sample size/ short intervention/ short term follow-up).<br>[d]: serious risk of bias (lack of inter-rater reliability).<br>[e]: serious risk of bias (data analysis and reporting unclear).<br>[f]: serious indirectness (different intervention components between studies).<br>[g]: serious risk of bias (unclear if true randomization was used).<br>[h]: Serious risk of bias (control and intervention groups not similar at baseline).<br>[i]: serious indirectness (mostly men included).<br>[j]: serious risk of bias (three patients were deeply sedated throughout the study). | | | |

The GRADE ratings show our confidence that the observed effect of the interventions reflects a true effect of the intervention. Although seven individual interventions (Aghaie et al., 2014; Allahbakhhsian et al., 2020; Davis et al., 2020; Jong Yoen & Soohyun, 2019; Mashouf et al., 2017; Rajora et al., 2019; Saadatmand et al., 2013) and a meta-analysis of two studies (Abbasinia et al.,

2021; Guo et al., 2016) demonstrated a statistically significant effect on agitation and one study showed some effect (To et al., 2013), the overall certainty of this evidence was very low. Two studies examined the effect on length of ICU stay, one found a significant effect (Abbasinia et al., 2021), and another did not find any differences between the intervention and control groups (Rajora et al., 2019). The certainty of the evidence for this outcome was also very low. The studies were grouped into five categories, as described in the following section.

#### *7.2.7.1 Multi-component non-pharmacological interventions*

Two RCTs (Abbasinia et al., 2021; Guo et al., 2016) investigated the effectiveness of multi-component non-pharmacological interventions to reduce agitation. The studies included patients undergoing oral tumour resection (Guo et al., 2016) and coronary artery bypass graft (Abbasinia et al., 2021), and provided a pre-operative video (Abbasinia et al., 2021) or a visit to the ICU (Guo et al., 2016). Both studies were built on Hospital Elder Life Program (HELP) for the prevention of delirium. They involved reorientation, therapeutic activities, promotion of sleep, adequate hydration and nutrition, provision of vision and hearing aids and staff training. Abbasinia et al. (2021) also included reduction of psychoactive drugs and early mobilisation, while the study by Guo et al. (2016) added music therapy. Both interventions lasted for approximately three days. Abbasinia et al. (2021) only measured RASS once a day, and it is unclear when this was done. Levels of agitation may vary depending on the time of the day and procedures carried out around the patient; therefore, not stating when agitation was measured and whether it was measured consistently poses a threat to internal validity. Both studies lacked information on how the interventions differed from usual care and if patients received psychoactive drugs before or after the interventions.

The study by Abbasinia et al. (2021) saw lower levels of agitation in the intervention group (0.06 ± 0.25) compared to the control group (0.36 ± 0.80) on the last day; however, these differences were not statistically significant ($p = 0.057$). Guo et al. (Guo et al., 2016) saw a significantly lower level of agitation in the intervention group (0.2 ± 0.3) compared to the control group (0.5 ± 0.4) on the last day, $p = < 0.001$. The two studies were pooled in a meta-analysis, including 220 participants. The pooled analysis showed that multi-component non-pharmacological interventions significantly reduce levels of agitation (see Figure 19).

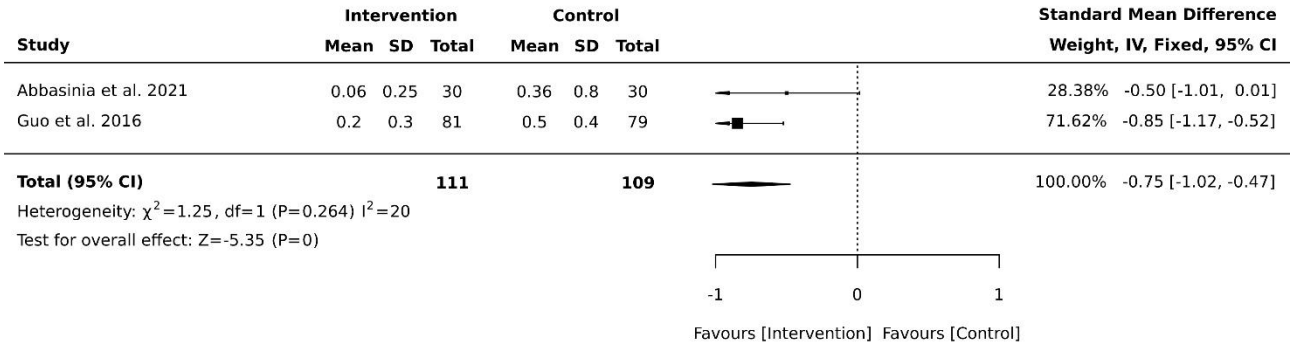



**Figure 19 Meta analysis of multicomponent nonpharmacological interventions**

#### *7.2.7.2 Nature-based sounds*

Three RCTs (Aghaie et al., 2014; Rajora et al., 2019; Saadatmand et al., 2013) investigated the effect of nature-based sounds versus placebo. In all three studies, the nature-based sounds consisted of birds' songs, soothing rain sounds, river streams and waterfall sounds. The sounds were played once in the intervention groups using a media player and headphones for between 60 min (Rajora et al., 2019) and 90 min (Saadatmand et al., 2013). In the study by Aghaie et al. (Aghaie et al., 2014), the duration of the intervention was unclear. The placebo groups wore headphones without sound. Meta-analysis was not possible due to inadequate data reporting. The study by Saadatmand et al. (Saadatmand et al., 2013) found that the intervention group had significantly lower levels of agitation ($p \leq 0.01$). Aghaie et al. (Aghaie et al., 2014) replicated the study by Saadatmand et al. except that their intervention was carried out during weaning from mechanical ventilation. Nevertheless, the authors found similar results to Aghaie et al. A more recent study by Rajora et al. (Rajora et al., 2019) on 120 patients from the respiratory ICU found a significant reduction of agitation from baseline among the intervention group. This study also found no significant differences in ICU LOS between the groups.

#### *7.2.7.3 Music therapy*

Two pilot studies, one RCT (To et al., 2013) and one cross over quasi-experimental study (Jong Yoen & Soohyun, 2019), investigated the effect of music therapy. The designs, content and frequency of interventions varied across the two studies and therefore pooled effect sizes could not be calculated. The RCT by To et al. (To et al., 2013) took place in the General ICU during a 4-hour sedation vacation (interrupting sedation infusions). Twenty-five patients (intervention group) listened to Mozart piano sonatas via headphones, and 25 patients (placebo group) used headphones without music. If patients became restless and agitated at any time, sedation infusion was commenced, and the 'sedation vacation' was seen as unsuccessful. While patients in the music group were more likely to remain off sedation infusions compared to the control group (64% vs 52% success), a major limitation is that the control group had higher levels of agitation at baseline (Ramsey 4 vs 3 in music group). Statistical significance is not reported. In the cross over

quasi-experimental study by Jong Yoen et al. (Jong Yoen & Soohyun, 2019), six mechanically ventilated patients listened to either preferred music or classical relaxation music for 30 min, and after a 60 break, they would swap to the other music option (either preferred or classical relaxation music). This study found no significant difference in agitation between the two music interventions, but a significant decrease in agitation after both preferred music (p=0.025) and classical music (p =0.046)), suggesting that both classical music and preferred music were effective in reducing levels of agitation. A significant limitation of this study was the inclusion of only 6 participants.

#### *7.2.7.4 Sensory interventions*

One RCT (Allahbakhhsian et al., 2020) and two quasi-experimental studies (Davis et al., 2020; Mashouf et al., 2017) evaluated the effect of sensory interventions. The RCT focused on foot reflexology (Allahbakhhsian et al., 2020) and the others on healing touch (Davis et al., 2020) and aromatherapy (Mashouf et al., 2017). Due to these studies' different designs and interventions, the results could not be statistically pooled.

A three-armed RCT examined the effect of foot reflexology on male patients in the cardiac ICU (Allahbakhhsian et al., 2020). This study included an intervention group (n=40) receiving 15 min of foot reflexology, a control group (n=40) receiving usual care and a placebo group (n=40) group receiving 15 min of superficial heel touch. The intervention was carried out by the researcher, who had received training for one year from a professional reflexologist. The study found that agitation reduced significantly in all three groups. However, the intervention group showed a significantly higher reduction immediately after ($p<0.01$) and ten minutes after the intervention ($p<0.001$).

In a quasi-experimental feasibility study, Davies et al. (Davis et al., 2020) aimed to identify the effect of healing touch on 87 patients from 5 general ICUs. A caring relationship between the nurse and the critically ill patient provided a foundation of this healing touch intervention. All nurses involved had received at least one of four healing touch courses. The study found a significant reduction of agitation after both the first healing touch session (before -0.59 ± 1.25, after -0.86±1.16, $p<0.01$) and the second healing touch session (before -1.03 ± 1.61, after -1.52 ± 1.48, $p<0.02$). A major limitation of this study was the low RASS scores, making it challenging to interpret the findings.

A quasi-experimental study with 40 participants examined the effect of lavender oil aromatherapy (Mashouf et al., 2017). According to the authors, aromatherapy with lavender oil has proven effective on a range of conditions such as inflammation, pain, stress, depression and muscle spasm. This study found a significant reduction of agitation after aromatherapy with lavender ($p< 0.001$) and that the greatest reduction of agitation was seen 180 minutes after the intervention commenced.

#### *7.2.7.5 Suction methods*

In an RCT, Dastdadeh et al. (2016) compared the effectiveness of open and closed endotracheal suction tube systems on 60 mechanically ventilated patients. Patients were randomly allocated to closed suction or open suction systems. The intervention was done once per patient. They found that the type of suction system used did not affect the level of patient agitation ($p < 0.126$).

### 7.2.8 Discussion

This systematic review aimed to synthesise the best available evidence to identify effective NPSs for agitation in ICU. An exhaustive search found 11 studies of sufficient quality to be included in this review, five published within the last three years (Abbasinia et al., 2021; Allahbakhhsian et al., 2020; Davis et al., 2020; Jong Yoen & Soohyun, 2019; Rajora et al., 2019). Meta-analyses of two studies demonstrated a significant effect of multi-component non-pharmacological interventions. Several individual studies showed a significant effect, including nature-based sounds, music, foot reflexology, healing touch and aromatherapy.

The included studies had several limitations to their designs and were often inadequately described. Issues included allocation concealment, blinding of assessors, groups not being similar at baseline, not clearly outlining the differences between usual care and intervention and finally not ensuring that outcomes were measured in similar ways. Harms, feasibility and acceptability by patients and staff were also poorly reported. Overall, sample sizes were small, interventions were short in length, carried out once only and measured immediately after the intervention. Other systematic reviews on agitation have faced similar issues. Brasure et al. (Brasure et al., 2016) reviewed 125 RCTs on agitation within dementia care and were unable to make conclusions due to the variety of comparisons and low quality of methodological designs. Similarly, a 2019 meta-synthesis (Richardson et al., 2019) of 15 systematic reviews on NPSs for aggressive patients in the emergency department concluded that little and poor quality evidence existed on effective strategies. The complex nature of agitation combined with the characteristics of NPSs challenges rigorous studies in this area.

Despite missing data and low methodological quality, the included studies may still provide important insight into what may be working. This argument is supported by Cohen Mansfield et al. (2014), scholars with extensive knowledge on agitation within dementia care. They highlight that while methodological quality is important, researchers must also consider what is meaningful and practically possible. They argue that NPSs are often low-cost, low-risk interventions that, even when they are small or prove little effect, may be extremely valuable for clinicians and patients for whom the alternative, e.g., PR and pharmacological agents, is associated with much higher risks. It is clear that research on NPSs for agitation in ICU is in its early stages. While RCTs are ideal, they may not be feasible and ethical and are designs with a higher potential for bias. Researchers may consider observational studies, including prospective and retrospective cohort studies, case-control

series, and realist evaluation. Since multiple factors often cause agitation, a multi-component approach may be most effective, preferably with a complex intervention approach (MRC, 2000; Skivington et al., 2021) involving iterative cycles with continuous stakeholder engagement (O'Cathain et al., 2019). Other outcomes related to agitation must also be considered, such as the use of PR, use of pharmacological agents, adverse events, length of mechanical ventilation, patient and staff experiences, workforce injuries etc. We have developed a list for future researchers to consider when developing studies in this field; please see Table 34.

**Table 34 Suggestions for future research**

| Limitations of included studies | Suggestions for future researchers |
|---|---|
| Lack of reporting. | Report how several steps are taken to ensure a rigorous study: randomisation, allocation concealment, characteristics of the groups including GCS, levels of sedation, mechanical ventilation etc. Information on follow up and detailed information on statistical analysis. |
| Only RCTs and quasi-experimental studies were identified. | It is challenging to develop rigorous RCTs or quasi-experimental studies on NPSs for agitation in ICU. Therefore, researchers may want to consider other research designs informed by complex interventions frameworks. |
| Lack of clear definitions of agitation. | Authors must report how they define agitation. Consensus on what constitute agitated behaviours in the intensive care unit is needed. Such an agreement will ensure consistent observations, measurements, interpretation and understanding of what may work. |
| The role of theory in intervention design and evaluation is unclear. | Researchers must be clear about the theoretical framework used to design and evaluate a study. |
| Limitations to the tools measuring agitation. | Provide solid arguments for the tools used to measure agitation.<br><br>Identification and verification of tools to measure agitation in ICU are needed. |
| Only a few outcomes were considered. | Other outcomes worth exploring:<br>- Drug use.<br>- Use of PR.<br>- Adverse events such as unplanned extubations, nosocomial infections and device removal.<br>- Post-traumatic stress.<br>- Patient experiences and satisfaction.<br>- Family experiences and satisfaction.<br>- Workforce wellbeing and injuries.<br>- Length of mechanical ventilation. |
| Authors do not state if they aim to prevent, minimise or manage agitation. | Authors must describe if interventions aim to prevent, minimise or manage agitation, and interventions must be designed to fulfil the specific aims.<br><br>Research may need to explore if prevention, minimisation and management require the same or different approaches. |
| Short duration of studies. | Studies that carry out interventions over long periods and follow patients over more extended periods would provide more insight into the short- and long-term effects of interventions. |

**Table 34 Continued**

| Limitations of included studies | Suggestions for future researchers |
|---|---|
| Blinding issues. | Creative blinding methods may be used. For instance, participants may not need to know the precise aim of interventions and when and what outcomes are measured. Researchers can use sham interventions without the active ingredient. |
| Inter-rater reliability is not ensured. | Ensure that all outcome assessors measure agitation in accurate and consistent ways. |
| No information about psychoactive medication. | Interventions must describe the type of psychoactive drugs patients receive hours before, during and after an intervention. |
| Lack of information about the circumstances and expected active ingredient (who was involved, what was done, when, how often, and in what circumstances were the interventions applied).<br>*This information helps the reader understand when and why an intervention may be effective and assist future researchers in developing similar interventions.* | Describe the circumstances of an intervention. What could potentially cause agitation in this patient group? Were patients weaning from mechanical ventilation? From drugs? Was the intervention carried out in the morning or evening? After mobilisation? In a quiet room? Etc.<br>Ensure that other causes of agitated behaviours are dealt with before an intervention starts, for instance, discomfort due to pain, thirst or a full bladder. |
| No studies explored if different sub-groups required different types of treatment. | ICU patient sup-groups may require different NPSs. More research is needed to explore this. |
| Harms, feasibility and acceptability by patients, family members and staff were not reported, making it difficult for clinicians and guideline developers to know if interventions should be recommended. | Interviews and observations may provide valuable insight into the feasibility and acceptability of interventions. |

Based on the findings in this review, a diverse range of interventions, including multi-component interventions, music, nature-based sounds and sensory interventions, seem promising. The perhaps most promising intervention is the multi-component non-pharmacological intervention. Systematic reviews on delirium in ICU have also demonstrated the impact of multi-component non-pharmacological interventions (Deng et al., 2020; Liang et al., 2020). One explanation is that delirium, as with agitation, has multiple causes and, therefore, multi-component interventions are more likely to target several risk factors (Hughes et al., 2020). In this review, the multi-component interventions were built on the Hospital Elder Life Program (HELP), a complex intervention focusing on mobilisation, fluids, nutrition, sensory aids, orientation and therapeutic activities. Originating from the US with a goal to preserve physical and cognitive functioning (Inouye et al., 1999), this program has successfully reduced the incidences of delirium among elderly patients worldwide (Hshieh et al., 2018). However, translation of research can be challenging, and implementation of HELP in the UK National Health Service was not achievable due to a lack of resources (Godfrey et al., 2013). More research is needed to explore the effects of multi-component interventions on agitation in the ICU and the feasibility of carrying out such

interventions. Furthermore, while such interventions may be effective for agitation, it is still unclear what elements of the NPSs contribute to improvements in clinical outcomes.

Nature-based sounds also showed some effects on agitation. The sounds of nature have shown to have a positive effect on the health and well-being of people in general (Buxton et al., 2021). The theories of why nature-based sounds create such a powerful reaction in individuals stem back to the theory of evolution. Like mindfulness, one explanation is that nature sounds do not require direct attention, and therefore increase our awareness through unconscious and cognitive processes (Buxton et al., 2021). Another explanation describes how nature is perceived as less threatening and less arousing, thus reducing stress (Buxton et al., 2021). While Buxton and colleagues (Buxton et al., 2021) describe how nature sounds can be helpful in reducing stress in noisy urban areas, Minton and Batten (Minton & Batten, 2016) explored how such interventions could minimise patient stress and delirium in a hectic ICU environment. They concluded that many nature-based interventions could be implemented, including sounds, views, light, pictures and posters. Changing patients' physical position changes their views of the environment, and watching nature reminds patients that they are alive and that there is a life beyond the ICU (Minton & Batten, 2016).

Music may be beneficial for agitation, both classical (Jong Yoen & Soohyun, 2019; To et al., 2013) and patients' preferred music (Jong Yoen & Soohyun, 2019). Robust literature supports this statement. Music has been used for decades in health. A recent meta-analysis of 12 RCTs showed strong evidence that music can reduce agitation in persons who have dementia (Pedersen et al., 2017). Another systematic review states that music effectively reduces stress (de Witte et al., 2020a). Scholars have described how music decreases physiological arousal and affects stress-related emotional states, including anxiety, worry and restlessness, by modulating activities in our brain structures (de Witte et al., 2020b). Music, in particular classical music, has been described as effective in reducing pain and levels of stress in the ICU (Richard-Lalonde et al., 2020). However, clinicians must be aware that since music evokes feelings, playing heavy metal or techno may be ineffective or even harmful (Richard-Lalonde et al., 2020).

Lavender aromatherapy may also reduce agitation, although the evidence in this area is sparse. Lavender is said to have anti-pain, anti-anxiety, and anti-depressant effects similar functions to increased benzodiazepines and GABA (gamma-aminobutyric acid) in the amygdala (Jafari et al., 2020). A meta-analysis including 15 studies showed some evidence that aromatherapy, including smearing and inhalation, can reduce agitation and aggression in patients suffering from cognitive impairment. A non-randomised study showed that aromatherapy alleviated stress and improved sleep in the intensive care unit (Cho et al., 2017), and an RCT showed a reduction of anxiety, lower heart rate and blood pressure after exposure to lavender aromatherapy. These studies

support that lavender can possibly be used as a lost cost and inexpensive method to prevent or reduce low levels of agitation.

Foot reflexology may reduce agitation in the ICU (Allahbakhhsian et al., 2020). The researcher providing this intervention was trained by a professional reflexologist for one year prior to the study, which poses a major limitation to the feasibility of this intervention. However, some studies have described how the intervention is easy to learn and apply (Song et al., 2015). A systematic review and meta-analysis reviewing ten studies of reflexology for anxiety found that reflexology had some positive effect on anxiety among patients undergoing cardiac procedures (Chandrababu et al., 2019).

Healing touch also showed some effects in this review. Healing touch is believed to reduce stress and promote relaxation work through body-mind communication between the autonomic, endocrine and immune systems (Davis et al., 2020). Limited research has been carried out on the ICU population, but similar to the study by Davies et al. (2020), a pilot study within dementia care also found an effect of healing touch on agitation (Anderson & Taylor, 2011). An RCT found an effect of healing touch on anxiety and LOS in coronary artery bypass patients (MacIntyre et al., 2008). A qualitative Swedish study from the emergency department (Airosa et al., 2013) explored patients' experiences of "caring touch" (a combination of healing touch and tactile massage) and found that the intervention provided trust and consolidation for most acutely ill patients. However, some patients expressed ambivalence toward the "caring touch" (Airosa et al., 2013). When researchers interviewed US nurses about "healing touch", they expressed a desire to provide the intervention. Still, barriers such as lack of time, patient acceptability and lack of training were common concerns (Anderson et al., 2016).

45% of the included studies were published within the last three years, suggesting an increased awareness and need for effective NPSs. While waiting for rigorous evidence, it may be worthwhile to explore how interventions and recommendations from other areas of health may apply to the intensive care unit. For instance, a large body of work has been done on agitation and aggression within psychiatry, and different working groups have developed guideline recommendations (Garriga et al., 2016; NICE, 2017; Richmond et al., 2012). It may also be that interventions proven to be effective in other areas of health can be helpful in the ICU context. For instance, a recent network meta-analysis within dementia care, including 65 RCTs, found that massage therapy, animal-assisted intervention, personally tailored activities and pet robot interventions were the most effective NPSs for agitation (Leng et al., 2020). A recent scoping review on the management of the agitated psychiatric patient found that de-escalation techniques, risk assessment and programs involving staff training, patient involvement and leadership were the most effective interventions and alternatives to PR (Fernández-Costa et al., 2020). We suggest that future

research involve relevant stakeholders when developing interventions or guidelines to fully understand what is feasible and acceptable in the ICU context.

### 7.2.9 Limitations to the RASS scale when measuring levels of agitation.

All studies, except one, used the RASS scale, a scale that has been said to be valid and reliable (Ely et al., 2003), and that has been used in several studies measuring the effectiveness of pharmacology on agitation (Ng et al., 2019). However, there are several limitations to this scale that was originally developed to measure levels of sedation. Firstly, on the scale, -4 to -1 describes levels of sedation, not levels of agitation. If RASS scores increase in sedated patients, it is an indication of a more awake patient rather than increased levels of agitation. This makes it challenging to ensure accurate analysis and interpretation of research results. For example, in the study by Davis et al. (Davis et al., 2020) the authors claim that levels of agitation decreased from a mean of -0.59 ± 1.25 to a mean of -0.86 ± 1.16. One could argue that patients were simply more awake after the HT sessions. Secondly, issues arise with the RASS scale when patients are sedated/unconscious and agitated. Other scholars have pointed out the difficulties of rating two constructs, sedation and agitation, on one scale (Newton et al., 2013). We recommend that authors pay special attention to inter-rater reliability and scales that more precisely measure agitation and are able to capture the breadth of these behaviours. Multiple and more nuanced scales, such as the Overt Agitation Severity Scale (Yudofsky et al., 1997) and the Cohen-Mansfield agitation inventory (Cohen-Mansfield, 1997), exist outside the ICU setting that can potentially be modified and tested to suit the ICU environment. Related to levels of agitation, the included studies did not provide information about the frequency and duration of agitation, and no authors discussed what constitutes clinically meaningful changes in levels of agitation, making it difficult to fully understand the reported statistically significant differences.

### 7.2.10 Strengths and limitations of the review

We conducted an exhaustive search and rigorously evaluated studies to ensure reliability in study inclusion and quality ratings. We reduced bias by excluding studies of low quality and by only including studies that used validated tools to measure agitation. However, there are limitations to this review. Only studies in English were included, which may have excluded some relevant studies. Although we followed the GRADE approach for grading the certainty of the evidence, this assessment is a subjective process, and even though the reviewers in this article agreed about the ratings, others may not. However, we have attempted to provide transparent and explicit explanations for our judgements throughout this review.

### 7.2.11 Conclusion

Despite an urgent need to identify effective interventions, this review found insufficient evidence to draw firm conclusions on ways to reduce agitation in the ICU. Multi-component non-pharmacological interventions, nature-based sounds, music, foot reflexology, healing touch and

aromatherapy may offer some benefits but need to be further studied. While this paper calls for rigorous research designs, it also encourages researchers to consider alternative methodological research approaches. RCTs are at the top of the evidence hierarchy but may not be meaningful, feasible and ethical when researching agitation in a complex and ever-changing critical care environment. In addition to the effect on agitation, future research should also consider other important patient-, family- and clinician outcomes.

It is a concern that no consensus exists on what NPSs should be recommended for agitation in the ICU. As a result, agitation is more likely to be managed pharmacologically or with methods that may not be effective or person-centred. While waiting for rigorous evidence, clinicians and researchers need to continuously discuss the role of NPSs while also considering how high-quality care for this vulnerable population can be ensured internationally.

## 7.3 An umbrella review of systematic reviews and guidelines on non-pharmacological management of agitation

### 7.3.1 Rationale for conducting an umbrella review

The primary aim of this thesis was to develop patient-centred, evidence-based clinical practice guidelines for the nonpharmacological prevention, minimisation and management of patient agitation in Australian and Danish ICUs. As reported in the first part of this chapter, a systematic review of primary studies found little evidence of effective NPSs (Adams et al., 2022a). Sometimes guideline developers need to conduct additional searches to capture all relevant evidence (NHMRC, 2019; NICE, 2014). Qualitative evidence exploring patient and family experiences can be an important source of evidence in guideline development (NHMRC, 2020; NICE, 2014). Such perspectives can provide insights into factors not readily identified in quantitative research. The manual for developing NICE guidelines also states that indirect evidence, involving other populations or settings, can help to identify good practices when little direct evidence can be found (NICE, 2014). Considering evidence from other areas of nursing was also encouraged by stakeholders engaged in the first phase of this project.

Based on these arguments, an additional systematic review was carried out on systematic reviews on patient perspectives of agitation in the ICU and guideline recommendations for managing agitation in all healthcare settings. Rather than reviewing primary research, reviewing existing reviews and guidelines can save guideline developers time and resources (NHMRC, 2019). Stakeholders involved in phase one of this study suggested looking at evidence of effective NPSs from other settings. The NICE manual also suggests using such an approach when little evidence exists (NICE, 2014). Yet, it warns guideline developers that such 'indirect evidence' must be considered carefully before being implemented into guidelines (NICE, 2014). Therefore, this review

was carried out to identify tentative recommendations that could be further explored for appropriateness, importance and feasibility in phase three of this study.

### 7.3.2 Review questions and objectives

The overarching aim of this review was to examine qualitative systematic reviews from the ICU context and guidelines from all healthcare settings for evidence on NPSs to reduce agitation. See Table 35 for the research questions and objectives of this review.

**Table 35 Research questions and objectives**

| Research Questions | Research Objectives |
|---|---|
| How do ICU patients experience agitation and nonpharmacological treatment of agitation? | To review qualitative systematic reviews of ICU patient experiences of agitation and NPSs |
| What NPSs are important for reducing agitation? | To review guidelines containing recommendations for nonpharmacological prevention, minimisation or management of agitation in all healthcare settings. |

### 7.3.3 Methods

Although reviews sometimes include both systematic reviews and guidelines (Feyissa et al., 2018; Tran et al., 2022), no official methods exist for how to review these different types of documents in rigorous way. Therefore, I used a modified JBI umbrella review method (Aromataris et al., 2020). An umbrella review offers a method for reviewing existing reviews and research syntheses. Although the JBI method does not officially include both review and guidelines, the method was deemed appropriate as it allowed me to investigate already synthesised or reviewed evidence of a broad topic (Aromataris et al., 2020). The study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Page et al., 2021). This review did not pre-register a protocol, as this is not commonly done for reviews of guidelines (Mian et al., 2019; Stout et al., 2021). However, the search criteria were defined a priori.

#### *7.3.3.1 Inclusion criteria*

Two separate searches were carried out following the PICO elements (see Table 36).

##### 7.3.3.1.1 Types of participants

The first search considered adult patients in the ICU, while the second for guidelines considered adult patients from all healthcare settings.

#### 7.3.3.1.2 Interventions/phenomena of interest

The interventions of interest were nonpharmacological interventions. The phenomena of interest were experiences of agitation and NPSs for agitation. Systematic reviews on patients' experiences of delirium were included if the findings indicated patients had experienced symptoms including excessive motor activity, emotional tension, confusion or aggression. This decision was made since agitation is commonly seen in delirious patients in ICU (Hickin et al., 2017), and it was expected that little evidence would describe experiences of agitation in ICU separately.

#### 7.3.3.1.3 Outcomes

The outcome was prevention, minimisation and management of agitation.

#### 7.3.3.1.4 Types of studies

The first search included qualitative systematic reviews, and the second included guidelines, consensus statements and practice recommendations. Only the most recent guideline version was included when several versions existed. This review considered published and unpublished papers in English, from any country, and published between 2011 and September 2021 to ensure the relevance and currency of the literature. Papers describing care for children, papers only focusing on causes of agitation and reviews using theoretical papers or opinion papers as their primary source of evidence were excluded.

**Table 36 Inclusion criteria**

| | Inclusion criteria | |
|---|---|---|
| | **Search 1** | **Search 2** |
| **Patient** | Adult patients in the ICU | Adult patients in all healthcare institutions |
| **Interventions/ phenomena of interest** | Experiences of agitation and NPSs<br>or<br>NPSs for agitation | NPSs for agitation |
| **outcome** | Agitation | Agitation |
| **Study design** | Systematic reviews | Guidelines, consensus statements, best practices. |

### *7.3.3.2 Search strategies*

Two separate systematic literature searches were carried out: one for qualitative reviews within the ICU and one for guidelines in all healthcare settings. The search strategies can be found in Appendix 40, and an overview of searches, sources and results can be found in Appendix 41. The searches were carried out in the databases Medline (OVID, 1946-September 2021), CINAHL (Cumulative Index to Nursing and Allied Health Literature, 1982 to September 2021) and PsychInfo (1806 to September 2021). In addition guidelines were searched for in the following registers: NHMRC Australian Clinical Practice Guidelines (https://www.nhmrc.gov.au/about-us/publications), National Institute for Health and Clinical Excellence (https://www.nice.org.uk/guidance), US

National Guideline Clearinghouse (https://www.sign.ac.uk/our-guidelines/), Scottish Intercollegiate Guidelines Network (https://www.sign.ac.uk/our-guidelines/), Worlds Health Organisation (https://www.who.int/publications/guidelines/en/ BMJ Best Practice (https://bestpractice.bmj.com/info/) Guidelines International Network (GIN) library of guidelines (https://guidelines.ebmportal.com/), Agency for Healthcare Research and Quality (https://www.ahrq.gov/prevention/guidelines/archive.html), Canadian Medical Association CPG InfoBase, Canada (https://joulecma.ca/cpg/homepage),Turning research into practice (TRIP) database (https://www.tripdatabase.com/), New Zealand Guidelines Group, New Zealand (https://www.nzgp-webdirectory.co.nz/WEB+DIRECTORY/CLINICAL+INFORMATION/GUIDELINES+NEW+ZEALAND.html), Centre for Kliniske Retningslinjer (https://cfkr.dk/retningslinier/). Reference lists of all relevant papers were also screened. All citations were exported into the Covidence software file. From this platform, duplicates were removed. Titles and abstracts were screened against the inclusion criteria. Full texts were retrieved from relevant papers and assessed by two independent reviewers. See Figures 20 and 21 for PRISMA diagrams.

#### *7.3.3.3 Assessment of quality*

The included reviews were critically appraised using the JBI critical appraisal tool for systematic reviews (Aromataris et al., 2015) (see Appendix 42). The guidelines were critically appraised using the Appraisal of Guidelines for Research and Evaluation (Agree II) checklist (Brouwers et al., 2010)[40] This tool consists of six domains, including 1) scope and purpose, 2) stakeholder involvement, 3) rigour of development, 4) clarity of presentation, 5) applicability and 6) editorial independence.

It was decided not to exclude guidelines based on their quality, as it was anticipated that the quality would vary depending on the evidence and resources available for guideline developers. Guidelines based on consensus were included as they are valuable in areas where little guidance exists (Nasa et al., 2021).

#### *7.3.3.4 Data extraction*

Key information from each study was extracted by the primary author using the Nvivo software (QSR International, 2021). This data included type of paper, year, authors, aim, study population, interventions, methods to evaluate evidence and formulate recommendations, recommendations including statements or explanations related to these, and finally, patient experiences related to agitation and NPSs. When guideline recommendations were clearly not relevant to the ICU population, data were not extracted. Such data included: 'transfer the patients to a seclusion room', 'the waiting room should have an exit door', 'minimise the time in the waiting room', 'use electronic

[40] The AGREE II tool is not provided in the Appendices as it is a 57 pages long document. The tool can be located following this link

bracelets' and 'prevent wandering'. How researcher bias was avoided during this process is described in Section 4.4.

#### *7.3.3.5 Data synthesis*

The extracted data were evaluated for similarities and grouped into categories. As a higher level of categorisation started to form, the FoC framework[41] was deemed suitable to organise categories into themes. The 'relationship' dimension included recommendations for developing a staff-patient relationship. The 'psychosocial needs' and 'physical needs' included recommendations related to patients' physical and psychosocial needs. The 'relational' included recommendations related to staff-patient interactions, as originally described by Kitson et al. (2013c). The 'context' dimension included information about factors indirectly affecting care, such as policies, staff support, safety and leadership. Additional themes were developed when appropriate.

### 7.3.4 Results

The search for systematic reviews resulted in 2323 articles, of which 380 duplicates were removed. After screening 1943 titles and abstracts against the inclusion criteria, a total of 164 full-text articles were retrieved and assessed. From these, three systematic reviews were identified. The search for guidelines resulted in 2125 reports, of which 439 duplicates were removed. After screening 1686 titles and abstracts, 93 full-text reports were retrieved. From these, ten guidelines were included. Table 37 provides an overview of the included guidelines. Table 38 provides an overview of the included qualitative systematic reviews.

[41] The FoC framework is described in detail in Section 3.6.2

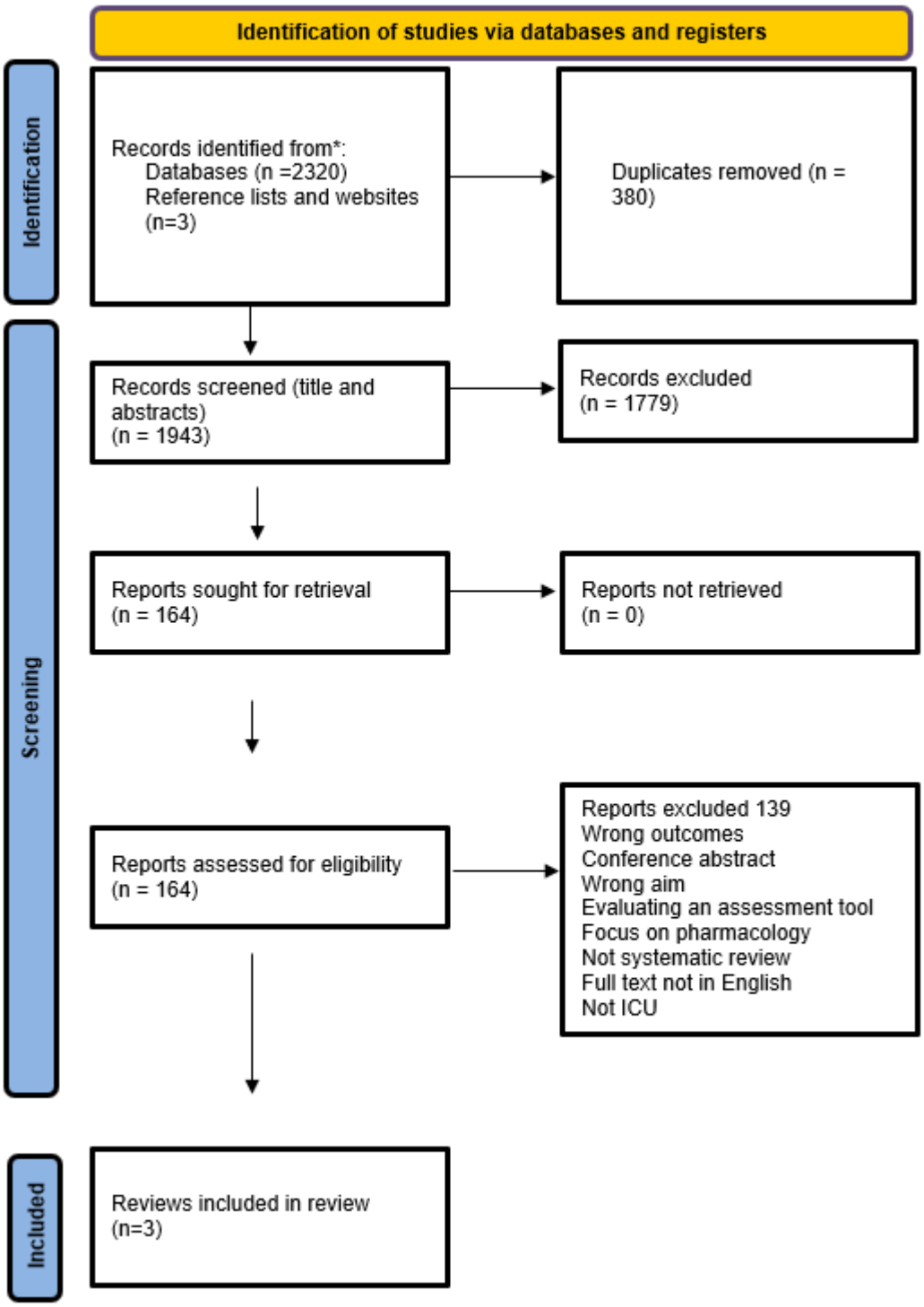



**Figure 20 PRISMA Search one: qualitative systematic reviews (Page et al., 2021).**

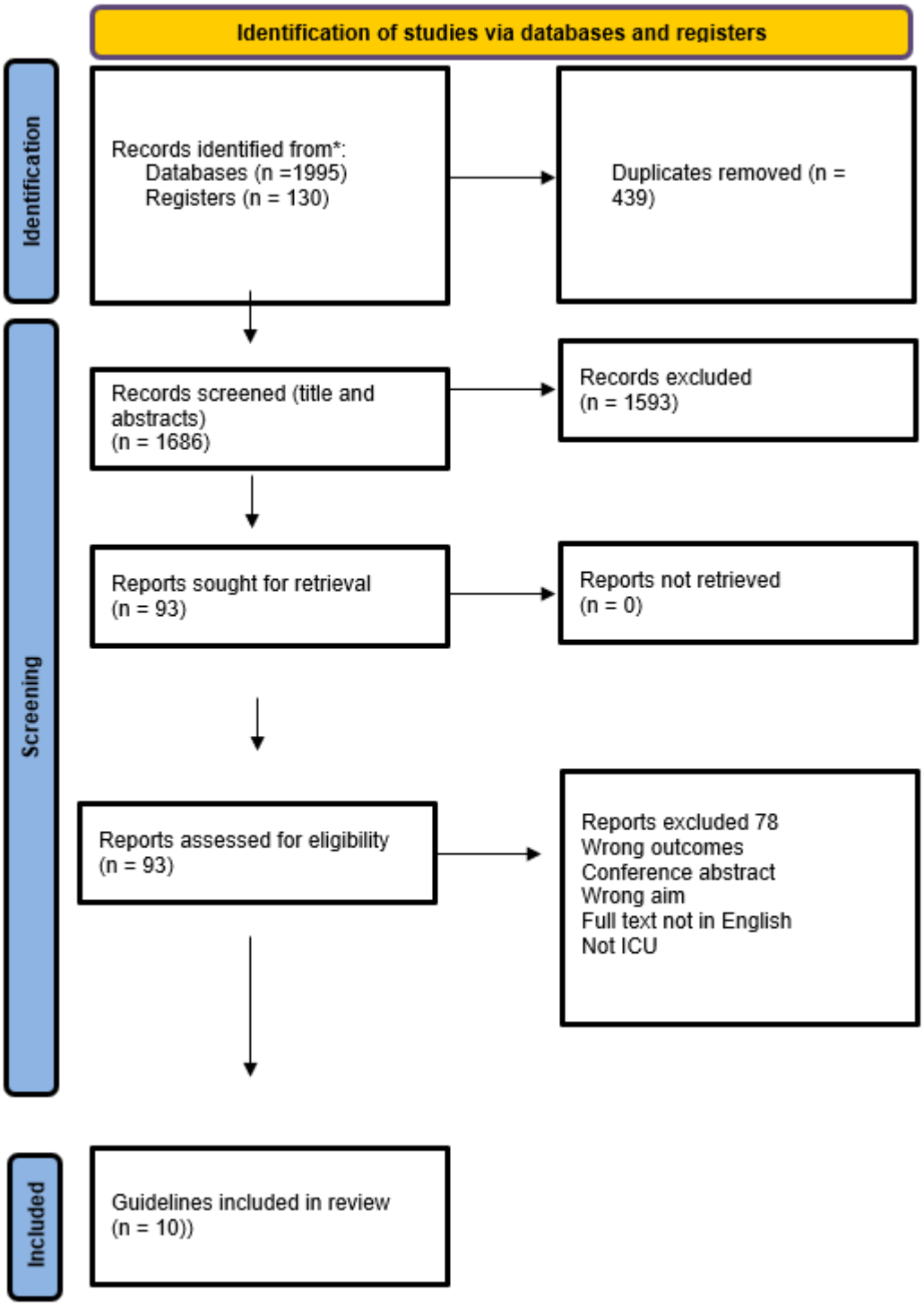



**Figure 21 Search two: guidelines (Page et al., 2021).**

**Table 37 Characteristics of included guidelines on the management of agitation**

| Study details (year/country) | Organisation responsible for development | Aim | Contexts | Patient population | End-users | Method used to evaluate evidence and formulate recommendations | AGREE II score [42] |
|---|---|---|---|---|---|---|---|
| **Guidelines in ICU** | | | | | | | |
| Devlin et al. (2018a) | Society of Critical Care Medicine.<br><br>Thirty-two international experts, four methodologists, and four critical illness survivors formed the guideline development group. | Prevention and management of pain, agitation, sedation, sleep, delirium, immobility and sleep | ICU | Adults | ICU clinicians | Systematic reviews, GRADE approach. Formal consensus. | 94% |
| Donato et al. (2021)<br><br>Argentina | Sociedad Argentina de Terapia<br><br>Intensiva | Propose strategies for optimal management of analgesia, sedation and delirium | ICU | Adult patients with acute respiratory distress syndrome due to COVID 19 | Unclear | Systematically reviewing the literature. Formal consensus. | 39% |
| Hospitals of Leicester NHS (2018)<br><br>UK | Hospitals of Leicester NHS. Unclear who developed the guidelines | Describe the management of pain, agitation and delirium in critical care | ICU | Unclear | Intensivists, Advanced Critical Care Practitioners, Nurses, Pharmacists, Anaesthetists and other physicians in the critical care units within University Hospitals of Leicester. | Unclear | 40% |

[42] For more information about calculated AGREE II rating see Appendix 43

| Study details (year/country) | Organisation responsible for development | Aim | Contexts | Patient population | End-users | Method used to evaluate evidence and formulate recommendations | AGREE II score [42] |
|---|---|---|---|---|---|---|---|
| **Guidelines outside ICU (8)** | | | | | | | |
| Baldacara et al. (2018)<br><br>Brazil | Brazilian psychiatric association. Eleven Brazilian psychiatrists involved | Management of agitation in Brazil. | Emergency settings | Adults | Physicians. | Systematic review, consensus.<br><br>Oxford Centre for Evidence-based medicine and critical appraisal tools to determine levels of evidence. | 41% |
| Garriga et al. (2016)<br><br>Spain | Not linked to any association.<br><br>24 international experts | Management of agitation | Emergency | Patients with a psychiatric condition. Excluded delirium and dementia | Not stated | Systematic reviews, formal expert consensus (Delphi). Jadad scale for appraisal. NHMRC grading of evidence. | 63% |
| Gillings et al. (2016)<br><br>UK | Royal College of Emergency Medicine, UK | Management of excited delirium/ Acute Behavioural Disturbance | Emergency settings | Patients in the Emergency Department | Emergency physicians.<br><br>Strong focus on restraints and sedation. | High quality evidence was not always available. Recommendations based on consensus of senior emergency physicians and invited experts. | 38% |
| Luaute et al. (2016)<br><br>France | French society of physical and rehabilitation medicine working group<br><br>Developed by 23 physicians, psychiatrists, psychologists, physical education, social worker, lawyer, medical director, physical education professor and two persons representing patients | Agitation and aggression in TBI patients | Not stated | TBI patients | Not stated | Followed the guideline methodology suggested by the French Authority for Health. This included a systematic review, consensus amongst a group of professionals and patient representatives. Guidelines reviewed by a separate group. | 53% |

| Study details (year/country) | Organisation responsible for development | Aim | Contexts | Patient population | End-users | Method used to evaluate evidence and formulate recommendations | AGREE II score [42] |
|---|---|---|---|---|---|---|---|
| | and families of TBI patients. | | | | | | |
| Patel et al. (2018)<br><br>UK | British association for psychopharmacology and national association of Psychiatric intensive care and Low Secure Units. | Clinical Management of acute disturbance (agitation, aggression, violence). | Mostly related to emergency psychiatric care or acute psychiatric adult inpatient care, but may also apply to other settings. | Adults | Health professionals | Review of existing systematic reviews, RCTs, observational studies, published NICE guidelines and Standards. Expert consensus. Strengths of recommendations applied. | 58% |
| Richmond et al. (2012)<br><br>USA | American Association for Emergency Psychiatry (AAEP)<br><br>Developed by psychiatrists, emergency physicians and other health professionals. | Verbal de-escalation | Psychiatric emergency | Agitated patients | Not stated | Part of Project BETA. Best available research (method unclear) and expert consensus (method unclear). | 45% |
| Vieta et al. (2017)<br><br>Spain | Endorsed by the Catalan Society of Psychiatry and Mental Health, the Spanish Society of Biological Psychiatry (SEPB) and the Spanish Network Centre for Research in Mental Health Involved psychiatrists, nurses and psychologists. | Protocol on how to best manage psychomotor agitation | Psychiatric emergency | Adult psychiatric patients | Health professionals. | Protocol based on an international guideline, systematic review, interviews, formal consensus using Delphi. | 38% |

**Table 38 Characteristics of included systematic reviews of experiences of agitation**

| Author/date/ country | Type of study | Phenomenon of interest | Study population (number of studies included) | Inclusion criteria | Conclusion | Critical Appraisal[43] |
|---|---|---|---|---|---|---|
| **Systematic reviews in ICU** | | | | | | |
| Boehm et al. (2021)<br><br>USA | Qualitative meta-synthesis | Patient and family experiences of delirium in ICU | 14 papers | Adult patients, 1980-2021 (four papers before 1999 and three papers 2019-2021) | Patients experience fear, anger and shame. Patients and families value compassion, communication and connectedness. | 11/11 |
| Freeman et al. (2022a)<br><br>UK | Meta-synthesis | Patients' experiences of agitation in ICU | 8 papers | Adult, 2010-2019 | Staff interactions and communications skills and the ICU environment affect patient agitation. | 10/11 |
| Ortega et al. (2020)<br><br>Canada | Meta-ethnography | Patients' experiences of delirium in ICU | 9 papers | Adult, no year limitations up until 2017 | Delirious patients in ICU experience existential issues. Patients report talking about their memories would be useful. | 10/11 |

[43] For detailed information, see Table 39

### 7.3.5 Characteristics and appraisal of identified systematic reviews

The three qualitative systematic reviews were published between 2020 to 2021[44]. None of these explicitly examined experiences of NPSs for agitation. However, they all provided insights into patients' experiences of agitation and NPSs while providing a range of recommendations to improve patient experiences. Many of the themes described in the systematic reviews were pertinent across all studies, including an overarching focus on physical, psychological and mental suffering. Overall, the three qualitative systematic reviews were of high quality (see Table 39).

**Table 39 JBI critical appraisal tool for systematic reviews**

| Study | Q1 | Q2 | Q3 | Q 4 | Q 5 | Q 6 | Q 7 | Q 8 | Q 9 | Q 10 | Q 11 | Total (%) | Methodological quality |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Boehm et al. (2021) | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | 100 | Strong |
| Freeman et al. (2022a) | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | 91% | Strong |
| Ortega et al. (2020) | Y | Y | Y | Y | Y | Y | U | Y | Y | Y | Y | 91% | Strong |

Y = yes; N = no; U = Unclear; N/A = not applicable.
0 - 49%: low methodological quality; 50 - 69%: adequate methodological quality; 70 - 85: moderate methodological quality; 86 - 100: high methodological quality.

Q1 Is the review question clearly and explicitly stated?
Q2 Were the inclusion criteria appropriate for the review question?
Q3 Was the search strategy appropriate?
Q4 Were the sources and resources used to search for studies adequate?
Q5 Were the criteria for appraising studies appropriate?
Q6 Was critical appraisal conducted by two or more reviewers independently?
Q7 Were there methods to minimize errors in data extraction?
Q8 Were the methods used to combine studies appropriate?
Q9 Was the likelihood of publication bias assessed?
Q10 Were recommendations for policy and/or practice supported by the reported data?
Q11 Were the specific directives for new research appropriate?

### 7.3.6 Characteristics and appraisal of identified guidelines

This review included ten guidelines published between 2011 and 2021. Three guidelines were from the ICU (Devlin et al., 2018a; Donato et al., 2021; 2018), six from the emergency setting including psychiatry (Baldaçara et al., 2018; Garriga et al., 2016; Gillings et al., 2016; Patel et al., 2018; Richmond et al., 2012; Vieta et al., 2017) and one paper did not describe a specific setting (Luauté et al., 2016). The ICU guidelines aimed to describe the management of delirium, sedation and pain and none of them specifically focused on nonpharmacological management of agitation. The guidelines outside ICU all aimed to describe the management of agitation, both pharmacological

[44] The article by Freeman et al. was updated from 2021 to 2022 as the paper changed from being *in press* to being *published*.

and nonpharmacological. Overall, the guidelines were developed in Argentina (Donato et al., 2021), Brazil (Baldaçara et al., 2018), Spain (Garriga et al., 2016; Vieta et al., 2017), France (Luauté et al., 2016), the UK (Gillings et al., 2016; Patel et al., 2018; 2018), the USA (Richmond et al., 2012) and one was developed across multiple countries (Devlin et al., 2018a).

The quality was low for the majority of the guidelines, with six guidelines receiving an overall AGREE II score below 50% (Baldaçara et al., 2018; Donato et al., 2021; Gillings et al., 2016; Richmond et al., 2012; 2018; Vieta et al., 2017), three guidelines receiving a score between 50-65% (Garriga et al., 2016; Luauté et al., 2016; Patel et al., 2018) and one receiving a score of 94% (Devlin et al., 2018a). For a full overview, see Appendix 43[45]. Low rigour was a major reason for the low scores and can partly be explained by little existing evidence available and, therefore, the need to use consensus methods. However, there were multiple other reasons for the low scores, including objectives and questions not being clearly described, systematic searches not carried out, appraisal of evidence not performed, the strength of the evidence not described, recommendations being ambiguous and unclear, guidelines not being externally reviewed, resources not being considered and lack of information around funding bodies and how they influenced the content. A pharmaceutical company sponsored one guideline (Vieta et al., 2017), and across the guidelines, multiple guideline developers had worked for or collaborated with pharmaceutical companies without describing how such COI were managed. Guideline developers seldom described potential barriers and facilitators to guideline development and how these could be overcome (domain five, AGREE II). Finally, only four guidelines (Devlin et al., 2018a; Luauté et al., 2016; Patel et al., 2018; Vieta et al., 2017) included a broad group of stakeholders in guideline development (Domain two, AGREE II). Two were international guidelines inviting 21 international experts from three countries (Patel et al., 2018) and 32 experts from six countries (Devlin et al., 2018a). The majority of people in guideline development groups were psychiatrists and physicians, which may explain the strong pharmacological focus in some guidelines. Only one set of guidelines sought the views and preferences of the target population (Devlin et al., 2018a). It is unclear what countries the target population came from.

### 7.3.7 Recommendations

Below is a narrative synthesis of the recommendations extracted from the included guidelines and qualitative systematic reviews. The recommendations were aggregated into categories based on the similarity of meanings. Categories were then organised into eight major themes, including assessment, identification and treatment of underlying causes, NPSs first, a caring and trusting relationship, supporting psychosocial needs, supporting relational needs, supporting physical needs, PR and context of care. Some overlaps can be found between supporting psychosocial and relational needs.

[45] The AGREE II critical appraisal results were not included here due to its length

#### *7.3.7.1 Assessment*

Four guidelines outside the ICU emphasised the importance of timely recognition of agitated behaviours (Baldaçara et al., 2018; Garriga et al., 2016; Richmond et al., 2012; Vieta et al., 2017). Multiple objective agitation assessment tools to measure the presence and severity of agitation were suggested by guidelines both inside and outside the ICU (Table 40) (Baldaçara et al., 2018; Donato et al., 2021; Garriga et al., 2016; Vieta et al., 2017). Within the ICU, these tools measured both sedation and agitation.

**Table 40 Assessment tools for agitation**

| | |
|---|---|
| Agitation Assessment tools | • The Historical, Clinical, Risk Management-20 (HCR-20) (Webster et al. 1997).<br>• Agitation Severity Scale (ASS) (Strout 2014).<br>• Violence Screening Checklist (McNiel, 2003).<br>• Richmond Agitation Sedation Scale (RASS) (Sessler et al. 2002).<br>• Sedation Agitation Scale (Nassar et al. 2008).<br>• Brief Agitation Measure (BAM) (Ribeiro et al. 2011).<br>• Clinical Global Impression Scale for Aggression (CGI-A) (Huber et al. 2008).<br>• Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield et al. 1989).<br>• Broset Violence Checklist (BVC) (Linaker and Busch-Iversen 1995).<br>• Overt Aggression Scale (OAS) (Silver and Yudofsky 1991).<br>• The McNiel-Binder Violence Screening Checklist (VSC) (McNiel and Binder 1994).<br>• Staff Observation Aggression Tool (Hvidhjelm et al., 2014; Nijman al al., 1999)<br>• Behavioural Activity Rating Scale (BARS) (Swift et al. 1998).<br>• Overt Agitation Severity Scale (OASS) (Yudofsky et al. 1997).<br>• Positive and Negative Syndrome Scale Excited Component (PANSS-EC) (Kay et al. 1987).<br>• Sedation Assessment Tool (Calver, 2011).<br>• Staff Observation Aggression Scale (SOAS) (Palmstierna and Wistedt 1987). |

As described by Baldacara et al. (2018), Devlin et al. (2019), Donato et al. (2021), Carriga et al. (2016) and Vieta et al. (2017).

#### *7.3.7.2 Identification and correction of underlying causes of agitation.*

Five guidelines, one from the ICU and four outside the ICU, emphasised the importance of identifying and treating the underlying causes of agitation (Baldaçara et al., 2018; Garriga et al., 2016; Luauté et al., 2016; 2018; Vieta et al., 2017). Multiple factors were described that could cause agitation, including medical (hypoxia, inadequate cerebral perfusion), psychiatric causes, drug-related causes, discomfort (pain, nausea), anxiety and unmet needs (hunger, thirst, constipation, full bladder) (Garriga et al., 2016; 2018). Three guidelines described how management plans should be built on patients' preferences, backgrounds (medical, social and psychiatric) and needs (Garriga et al., 2016; Patel et al., 2018; Vieta et al., 2017).

#### *7.3.7.3 Nonpharmacological strategies first*

Before resorting to other means such as pharmacological agents and PR, clinicians should use verbal-de-escalation, empathetic dialogue, support of the patient's well-being and modifications of the environment. This was pointed out by non-ICU guidelines (Baldaçara et al., 2018; Garriga et al., 2016; Luauté et al., 2016). It was also noted that in the previous version of the Clinical Practice

Guidelines for the management of pain, agitation and delirium, clinicians were encouraged to use NPSs (including providing adequate analgesia) before administering sedatives (Barr et al., 2013). It is unclear why this recommendation was excluded from the updated guidelines (Devlin et al., 2018a).

#### *7.3.7.4 Developing a therapeutic relationship*

Developing a therapeutic relationship was recommended by three of the guidelines outside the ICU (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017). Baldacara et al. (2018) stated, "the goal is to establish a good relationship between staff and patient, based on trust and respect, so the patient will feel welcome and believe his/her suffering is recognized" (Baldaçara et al., 2018, p. 162). Vieta et al. (2017) suggested achieving a therapeutic alliance with the patient based on trust to be able to evaluate the patient and identify their needs (Vieta et al., 2017, p. 3). Finally, Richmond et al. (2012) highlighted the importance of developing a collaborative and therapeutic relationship with the patient that allows patients to 'help themselves' and be active partners in the de-escalation process.

While no guidelines from the ICU described the staff-patient relationship, three qualitative systematic reviews emphasised the importance of a caring and trusting nurse-patient relationship in the ICU (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020). Patients longed for human connection and needed someone they could trust, who understood and who cared for them (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020). Nurses were seen as supportive when they were compassionate, present, kind and caring (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020). Freeman et al. (2022a) explained how the relationship also mitigated patient anxiety and helped them through a frightening time of their life. This review also emphasised the importance of having the same staff to care for the patient to maintain the relationship and ensure consistency in care delivery (Freeman et al., 2022a).

#### *7.3.7.5 Supporting psychosocial needs*

##### 7.3.7.5.1 Psychological support and debriefing

Three guidelines from outside the ICU context described the importance of debriefing patients after an episode of agitation (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017). This was seen as particularly necessary after an episode of involuntary intervention, such as using PR, to restore a therapeutic relationship and alleviate potential traumatic experiences (Richmond et al., 2012). Debriefing involved letting the patient explain their experiences and explore how agitation could be managed better if the behaviours occurred again (Richmond et al., 2012; Vieta et al., 2017). One guideline suggested organising a consultation with a psychiatrist to shed another light on management strategies (Luauté et al., 2016). Another set of guidelines explained how shame could trigger agitation and the importance of seeking solutions that allowed patients to retain their dignity (Patel et al., 2018).

All three qualitative reviews (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020) described how patients could feel ashamed and guilty about their "bad" behaviours, which could include, for instance, hitting a staff member. One qualitative review advised talking to patients about their episodes of agitation and how educating patients about delirium could alleviate feelings of guilt, shame, and humiliation (Boehm et al., 2021). Ortega et al. (2020) also described the potential benefits of debriefing patients and acknowledging their distressing ICU experiences.

#### 7.3.7.5.2 Re-orientation

Related to re-orientation, one non-ICU guideline recommended introducing oneself and explaining what to expect (Richmond et al., 2012), while another suggested orientating the patient by using suitable lighting, clocks, calendars, and nametags (Baldaçara et al., 2018).

The three qualitative reviews (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020) explained how patients could feel frustrated and anxious for not understanding or misunderstanding what was happening around them and having a "disturbed' sense of time. Being disorientated could lead to anxiety and feelings of vulnerability (Gaete Ortega et al., 2020).

#### 7.3.7.5.3 Involving the patient

Involving and empowering patients as much as possible was recommended by four guidelines outside the ICU (Garriga et al., 2017; Patel et al., 2018; Richmond et al., 2012; Vieta et al., 2017). Patients should be involved in their own care, and management plans should be built on patient preferences and choices (Garriga et al., 2017; Patel et al., 2018; Richmond et al., 2012; Vieta et al., 2017). Involving patients could empower them and give them a sense of control (Richmond et al., 2012).

All three qualitative reviews illustrated how patients felt an overwhelming sense of dependence, powerlessness and loss of control and how being involved in care and decision may benefit the agitated patient (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020).

#### 7.3.7.5.4 Therapeutic touch

Patients in one qualitative review described how holding a hand helped reduce agitation (Freeman et al., 2022a). Two qualitative reviews (Freeman et al., 2022a; Gaete Ortega et al., 2020) described the importance of therapeutic touch to help delirious and agitated patients feel connected to other humans.

#### 7.3.7.5.5 Family involvement

One ICU guideline supported family visitation (Donato et al., 2021), but did not provide any information about how this could be done or how it would reduce agitation. One ICU guideline

highlighted that the role of families in reducing patient stress and delirium required further research (Devlin et al., 2018a). One set of guidelines (Luauté et al., 2016) from outside the ICU context, recommended informing the family about agitation and effective strategies, so that they could be supportive in reducing the agitated behaviours.

All three qualitative reviews described the importance of involving the family who could provide protection, comfort, guidance and orientate the patient (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020). Family members could engage patients in a meaningful way, for instance, by bringing in familiar items, newspapers, cards or books (Boehm et al., 2021). Nurses could also encourage family members to be involved in personal hygiene, such as brushing the patient's hair or performing oral care (Boehm et al., 2021). Involving family members in clinical rounds and decision-making was seen as important (Boehm et al., 2021).

#### *7.3.7.6 Supporting relational needs*

This category included descriptions of how staff should interact with patients to prevent, minimise or manage agitation.

##### 7.3.7.6.1 Respect personal space

Four guidelines from outside the ICU recommended respecting patients' space (Baldaçara et al., 2018; Garriga et al., 2016; Patel et al., 2018; Richmond et al., 2012). This was described as decreasing potentially perceived threats. Richmond et al. (Richmond et al., 2012) provided examples of how a homeless person could be particularly sensitive about protecting their belongings, or a person who had been sexually abused could be particularly worried about being uncovered. Such situations may increase feelings of vulnerability and humiliation.

##### 7.3.7.6.2 Effective communication/de-escalation

Four guidelines from beyond the ICU (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017) focussed on how clinicians should communicate with agitated patients. This involved active listening and using clear and concise language with short sentences (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017). Actively listening involved paraphrasing, for example, by saying, "tell me if I have this right.. (Richmond et al., 2012, p. 21). It also involved being empathetic, using open-ended questions (what helps you at times like this?), being patient and showing this through body language and verbal acknowledgements (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017). Richmond et al. (2012) suggested putting oneself in the patient's shoes and imagining that delusions are real. Addressing patients with a non-judgmental and compassionate approach tends to de-escalate patients' agitated behaviours (Richmond et al., 2012). Staff should speak slowly and repeat when necessary (Richmond et al., 2012). The tone should be gentle but confident (Vieta et al., 2017).

All of the qualitative reviews (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020) highlighted the importance of using effective communication strategies. Patients struggled to communicate due to being mechanically ventilated, weak and confused. It was explained how patients' inability to communicate effectively induced feelings of anxiety, anger and frustration. While Freeman et al. (2022a) mentioned alternative communication methods such as communication boards, pads and lip reading, they acknowledged how patient anxiety reduced the effectiveness of these methods. However, precisely what effective communication strategies should be used was not explicitly described in any of the reviews. None of the guidelines explained the importance of supporting patient communication.

#### 7.3.7.6.3 Set clear limits

Three guidelines from outside the ICU recommended being clear about acceptable behaviours (Patel et al., 2018; Richmond et al., 2012; Vieta et al., 2017). This should be done in a respectful, reasonable, non-confrontational and non-threatening way. Richmond et al. (2012) explained that if clinicians felt uncomfortable or threatened, they should tell this to their patients in an empathetic, caring and respectful way, allowing patients to regain control.

#### 7.3.7.6.4 Reassurance

Guidelines from outside the ICU described the importance of reassurance. Reassurance involved being empathetic and caring and telling patients they were looked after and safe and that staff were there to help (Patel et al., 2018; Richmond et al., 2012). Staff should avoid exhibiting threatening, provocative or judgemental behaviours (e.g., crossed arms, prolonged or intense eye contact, clenched hands) (Baldaçara et al., 2018; Garriga et al., 2016; Patel et al., 2018; Richmond et al., 2012).

ICU patients' feelings of fear and anxiety dominated all three qualitative reviews (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020). Such feelings were related to perceptions of helplessness, the real possibility of death, surreal experiences and delusions. All three qualitative reviews emphasised the importance of reassuring patients that they were not alone, that potential stressful delusions were temporary, and that people cared for them (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020).

### *7.3.7.7 Physical needs*

#### 7.3.7.7.1 Promotion of sleep

One guideline from outside the ICU suggested restoring a proper sleep-wake cycle, as often agitated patients lacked sleep (Luauté et al., 2016). The three qualitative reviews emphasised the importance of supporting patients' sleep as a way of managing delirium and agitation (Boehm et al., 2021; Gaete Ortega et al., 2020). Ortega et al. (2020) described how patients entered a vicious

cycle starting with disrupted sleep due to critical illness and the environment. Disrupted sleep would lead to sleep deprivation, leading to confusion and restlessness [agitation, delirium], leading to difficulties sleeping. The authors suggested modifying the ICU environment, for example by reducing noise at night and promoting natural light (Boehm et al., 2021).

#### 7.3.7.7.2 Ensuring physical comfort

Three guidelines from outside the ICU advocated for ensuring comfortable physical surroundings, including appropriate temperature, light, noise, ventilation and colours (Baldaçara et al., 2018; Garriga et al., 2016; Richmond et al., 2012).

### *7.3.7.8 Physical constraints and restraints*

One guideline from outside the ICU (Luauté et al., 2016) proposed discarding all non-essential physical constraints such as urinary catheters, nasogastric tubes, and intravenous perfusions. Another guideline outside the ICU (Garriga et al., 2016) recommended choosing non-invasive treatment strategies rather than invasive whenever possible.

An ICU guideline explained how PR did not prevent adverse events, were traumatic for patients and potentially aggravated delirium and, therefore, should only be used under exceptional circumstances (Donato et al., 2021). Another ICU guideline highlighted the lack of evidence around PR (Devlin et al., 2018a). The guideline developers described how the intervention, paradoxically, increased self-extubation, exacerbated agitation, resulted in longer ICU LOS, increased use of benzodiazepines, antipsychotic drugs and opioids, increased the risk of disorientation and delirium and finally provoked strong emotional feelings in ICU patients (Devlin et al., 2018a). Due to these considerations, clinicians were advised to carefully consider the benefits and risks when using restraints (Devlin et al., 2018a).

Five guidelines from outside ICU advocated for only using PR in emergency situations and as a last resort when other strategies have failed (Baldaçara et al., 2018; Garriga et al., 2016; Gillings et al., 2016; Patel et al., 2018; Vieta et al., 2017). Reasons included the uncertainty around the therapeutic effect of using PR, the evidence of multiple negative outcomes, including negative patient experiences, negative effects on therapeutic relationships, inappropriate use of restraints (Baldaçara et al., 2018; Garriga et al., 2016), patient injuries and death (Gillings et al., 2016). Guidelines from outside ICU suggested using local guidelines as multiple considerations had to be taken into account when using PR. Such considerations included monitoring, contraindications, the type of PR used and available (material and types), limitations for how long time patients should be restrained, staff training, patient communication and identification of appropriate authority to initiate treatment (Baldaçara et al., 2018; Garriga et al., 2016). One qualitative review (Boehm et al., 2021) suggested minimising PR, as it likely worsened patients' experiences.

#### *7.3.7.9 Context of care*

##### 7.3.7.9.1 Supporting staff

Three guidelines from outside the ICU proposed debriefing with staff after an episode of patient agitation (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017). Debrief was seen as an opportunity for the care team to discuss aspects of the care provided and analyse what went well, what did not, and how care could be improved (Richmond et al., 2012; Vieta et al., 2017). Adequate staff was crucial for successfully de-escalating agitated behaviours outside the ICU (Luauté et al., 2016; Richmond et al., 2012).

Four guidelines outside the ICU explained the importance of training staff to reduce and manage agitated behaviours (Baldaçara et al., 2018; Garriga et al., 2016; Luauté et al., 2016; Richmond et al., 2012). Part of this included self-awareness, attitudes toward patients, and understanding own vulnerabilities when dealing with agitated behaviours. One qualitative review highlighted the importance of teaching staff about the experiences of agitated patients (Freeman et al., 2022a).

Four guidelines from outside the ICU emphasised how professionals working with agitated patients should work in partnership and be trained in how to support each other (Baldaçara et al., 2018; Luauté et al., 2016; Patel et al., 2018; Richmond et al., 2012)

##### 7.3.7.9.2 Safety as a high priority

Guidelines from outside the ICU context urged how the safety of patients, staff and others had to be of high priority (Baldaçara et al., 2018; Garriga et al., 2016). It was described how the layout of the unit had to facilitate close observations (Baldaçara et al., 2018).

##### 7.3.7.9.3 Keeping a safe distance

Two guidelines from outside the ICU recommended keeping a safe distance from an agitated patient (Baldaçara et al., 2018; Garriga et al., 2016). A safe distance ensured staff safety while also supporting psychotic patients who saw physical contact as a threat (Baldaçara et al., 2018).

### 7.3.8 Lack of high-quality guidelines for agitation

This review aimed to identify NPSs for reducing agitation. While the included qualitative systematic reviews were of high quality, the overall quality of the included guidelines was poor, with only four guidelines (Garriga et al., 2016; Luauté et al., 2016; Patel et al., 2018) scoring more than 50% using the AGREE tool.

Most existing guidelines did not prioritise stakeholder involvement (AGREE II domain 2). More precisely, they did not involve individuals from all professional groups, did not seek the views and preferences of patients and family members, and when several countries were involved, they did

not seek the views of stakeholders from all countries. When a broad group of stakeholders are not engaged, guidelines are more likely to fail the implementation process. This is because stakeholder engagement makes guidelines more implementable (Armstrong et al., 2018; Gagliardi et al., 2011). Despite the increased knowledge of the importance of involving a broad group of stakeholders, guideline developers still fail to do this (Armstrong & Bloom, 2017). Guideline developers may feel that stakeholder engagement is not feasible, and perhaps they feel unsure about how stakeholders can be involved. The novel guidance on how to consult various stakeholders may help change practices (Adams et al., 2022b).

The guidelines also received low scores in terms of the rigour of the development (AGREE II domain 3). Rigour in guideline development is perhaps the most important indicator of the quality of guidelines (Armstrong et al., 2017). The lack of rigour was due to not carrying out systematic searches, describing the criteria for selecting the evidence, appraising the evidence, describing the methods for formulating the recommendations, making explicit links between the evidence and the recommendations, receiving external approval of the guidelines, and finally, not having a procedure for updating the guidelines. Due to little existing evidence, most guidelines employed expert consensus but minimal information about how consensus was reached. The AGREE II tool (Brouwers et al., 2010) does not downgrade guideline development involving consensus as long as rigorous methods are used and guideline developers are transparent about these. Yet, one could argue that in order to contribute to a low knowledge base, consensus methods must produce reliable and credible evidence. To do this, guideline developers need to use rigorous consensus methods. The CREDES guide is an excellent example of how Delphi methods can be appraised by those developing, reviewing or publishing a consensus guideline (Jünger et al., 2017).

There were also issues related to COI, with one guideline (Vieta et al., 2017) being sponsored by a pharmaceutical company and several guideline developers declaring COI related to medical companies without describing how these were managed. In general, COI, where secondary interests may influence the judgements of an individual, can have profound implications for patient outcomes and the trustworthiness of guidelines (Traversy et al., 2021). Norris et al. (Norris et al., 2011) carried out a systematic review of the prevalence of COI and its effect on guideline recommendations. They found that of the 12 included US guidelines, all acknowledged that guideline developers had financial relationships with pharmaceutical companies. They also found that guideline developers with financial ties appeared to profit from the recommendations in the guidelines, and some guideline developers believed that their conflicts of interest influenced their recommendations (Norris et al., 2011). Although there has been an increased awareness of the importance of managing COI issues since this time, issues still occur related to incomplete disclosures and inadequate management (Bauchner et al., 2018). Bauchner et al. (2018) predict that COI will become more challenging in the years to come due to the popularity of collaboration between academia and industry partners. Fortunately, a range of tools exists for guideline

developers on how to manage COI (Traversy et al., 2021). Such approaches will ultimately protect the integrity and rigour of guidelines.

Finally, related to applicability (AGREE II domain 5), none of the guidelines described the barriers and facilitators to guideline application, and very few described the resources needed for guideline implementation. Although clinical health guidelines have improved over time, poor applicability seems to be a persistent problem (Armstrong et al., 2017). Authors argue that increasing the applicability of guidelines will increase their usage and impact (Armstrong et al., 2017). One explanation for why applicability is less prioritised by guideline developers may be that guideline development, and guideline implementation, is perceived to be two separate procedures (Alonso-Coello et al., 2010). However, it can be argued that knowledge translation starts when commencing guideline development, and therefore, guideline developers need to consider barriers and facilitators to implementation already when scoping the guidelines (Adams et al., 2022b).

Due to the low quality of the included guidelines, the low levels of evidence (qualitative and consensus) and the indirectness of the evidence (from other healthcare settings than the ICU), this review was unable to provide any definitive recommendations. Nevertheless, the review provides an essential understanding of patient experiences and strategies that may work, thus providing tentative recommendations and directions for the development of a rigorous guideline.

Certain principles and approaches were mentioned repeatedly across the guidelines and reviews, suggesting that there may be some general principles for managing agitation. Overall, the themes included developing a therapeutic relationship with the patient, identifying and correcting underlying causes, including medical causes, discomfort and unmet needs, use NPSs first, supporting physical, psychosocial and relational needs and supporting staff. Finally, PR should be used cautiously and as a last resort to keep patients and staff safe. Developing a therapeutic relationship was described by all qualitative reviews (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020) and three guidelines outside the ICU (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017), but was not mentioned by any ICU guidelines. It was also noticed that there seemed to be slightly different aims of the relationships recommended. In the ICU, the relationship was related to trust and a need for human connection. It was described how a trusting and caring relationship was vital for supporting the patient through a challenging and frightening time. Outside the ICU, however, the relationship, also called therapeutic alliance or collaborative relationship, seemed to play a slightly different role. It helped clinicians to identify patient needs and partner with patients, allowing them to support themselves. More research is needed to better understand the exact role of the relationship in reducing patient agitation in the ICU.

A range of individual strategies to reduce agitation was only described outside the ICU context, and whether these apply to ICU is unknown. These strategies included respecting personal space,

setting clear limits, ensuring physical comfort, reducing non-essential physical constraints, keeping a safe distance, debriefing staff, and safety should be of high priority (see Table 41).

**Table 41 Differences in topics inside and outside the ICU context**

| | |
|---|---|
| Topics across included papers (non-ICU guidelines, ICU guidelines and qualitative reviews) | Assessment for agitation<br>Identifying causes<br>Developing a therapeutic relationship<br>Psychological support and debrief<br>Reorientation<br>Reassurance<br>Involve patient<br>Family involvement<br>Effective communication<br>Promotion of sleep<br>Reducing non-essential PR<br>Teaching staff<br>Adequate staff |
| Topics only described outside ICU (non-ICU guidelines) | Respect personal space<br>Set clear limits<br>Ensuring physical comfort<br>Using non-invasive and discarding non-essential physical constraints.<br>Keep safe distance<br>Debrief staff<br>Safety a priority |
| Topics only described in ICU (qualitative reviews) | Therapeutic touch<br>Communication methods/tools |

Guidelines are important tools for promoting patient care and therefore have become increasingly popular over the last decades (Burgers et al., 2020). Although hundreds of guidelines are developed each year, the quality varies substantially, with many guideline developers not following basic criteria (Qaseem et al., 2012). The overall quality of the existing guidelines for agitation was poor. Poorly developed practice guidelines contribute to suboptimal treatment, wasted effort and resources during guideline development and poor guideline uptake (Lin et al., 2018). Overall, not only did this review reveal the low level of rigour associated with existing guidelines for agitation, it also highlighted multiple opportunities for improvements in this area.

### 7.3.9 Strengths and limitations of this review

The strength of this review was the comprehensive search and evaluation of existing reviews and guidelines on nonpharmacological management of agitation. This evidence, which has never been comprehensively gathered before, can inform future guideline development.

Nevertheless, there are also several limitations of this review that must be considered. All recommendations stem from expert opinions often supported by some type of literature. As described earlier, most authors did not grade the evidence and did not describe the strength of recommendations as suggested by the GRADE working group (Guyatt et al., 2008b). This review did not attempt to evaluate all the literature used by guideline developers. As a result, all

recommendations were seen as providing a very low level of evidence, although higher levels of evidence may have supported some recommendations.

Furthermore, some recommendations were not extracted as they were judged to be less relevant to the ICU context. It is possible that other scholars would have judged differently. Also, this review did not consider primary research. Such a review could have provided more up-to-date knowledge. However, systematic reviews and guidelines are higher in the evidence pyramid (Merlin et al., 2009) and were therefore prioritised. Guideline developers with more resources and time could consider conducting additional systematic reviews. The included qualitative reviews only described delirious and agitated patients in ICU. Agitated patients in ICU are not all delirious; therefore, this review gives a skewed picture which must be acknowledged. More research is clearly needed on patients' experiences of agitation. Finally, this review included guidelines from different healthcare settings. Most guideline recommendations came from non-ICU settings, including psychiatry and emergency. Although patients may be critically ill in the emergency department, they are only seen for a short period, and they are not sedated or mechanically ventilated, which patients often are in the ICU. Due to these limitations, the findings may not directly apply to or be feasible in the Danish and Australian ICUs.

### 7.3.10 Conclusion

This review aimed to review qualitative systematic reviews from the ICU context and guidelines from all healthcare settings for evidence on NPSs to reduce agitation. However, the findings from this review suggest that the evidence base of NPSs for agitation remains problematic with a low certainty of existing evidence and recommendations. While the qualitative reviews were of high quality, appraisal with the AGREE II tool indicated that most existing guidelines were of poor quality. To improve the quality of future guidelines, guideline developers must consider how to involve a broad group of stakeholders, how to ensure rigour during guideline development in particular when using consensus methods, how to manage COIs, how to describe the feasibility of included recommendations and finally how to consult stakeholders around barriers and facilitators to guideline development

On a more positive note, the included literature provided a range of similar recommendations suggesting that there may be some universal or fundamental principles for managing agitation. The review also found differences in recommendations. Whether approaches recommended outside the ICU are applicable to the ICU context is largely unknown. Due to the lack of evidence on effective NPSs in the ICU, such approaches deserve considerably more attention.

### 7.3.11 Changes to the review protocol

Initially, it was decided to include systematic reviews looking at NPSs for agitation and similar constructs, including delirium, anxiety and aggression. This decision was made based on the

knowledge that little evidence of agitation existed. However, a large amount of evidence was identified of varying quality. It was challenging to decide what to include and exclude. For example, many of the papers described interventions related to pain, discomfort and sleep; and the exact role of these interventions was unclear. Secondly, when attempting to synthesise the evidence, the author realised that interventions for different constructs could not easily be merged. For example, how could one claim that ice packs (for pain) or objective tools for measuring delirium or anxiety would be useful for agitation? Based on these challenges, it was decided only to include NPSs for agitation and patients' experiences of agitation. It was also decided that experiences of delirium could be included as long as these involved agitated behaviours.

## 7.4 Conclusion

This chapter identified the best available evidence on NPSs for agitation in the ICU. The first part of this chapter systematically reviewed studies that evaluated the effectiveness of NPSs for agitation in the ICU. Since very little evidence was found in these primary studies, an additional second review was carried out. This review systematically reviewed qualitative systematic reviews of patient experiences of agitation in the ICU and guidelines on NPSs for agitation from all healthcare settings. Multiple strategies were mentioned, providing important guidance and directions for future research.

It is challenging to develop recommendations on NPSs for agitation in ICU. There is a paucity of evidence, and the identified literature is affected by low methodological rigour, patient heterogeneity and a myriad of other confounding factors, which makes it challenging to reach firm conclusions. Due to the low quality and indirectness of the existing evidence, the reviews can only inform tentative recommendations. Such recommendations must then be tested in a Delphi study before being implemented into a practice guideline for agitation in ICU. It is likely that a Delphi study, including both qualitative and quantitative data, can provide the type of evidence required to optimise care.

Chapter 8 describes a modified Delphi study aiming to reach consensus amongst a panel of experts on nonpharmacological recommendations.

# CHAPTER 8: PHASE THREE - DELPHI STUDY FINDINGS

## 8.1 Introduction

Chapter 7 identified and summarised the existing evidence on the nonpharmacological prevention, minimisation and management of agitation in the ICU. When little evidence was found within the ICU context, an additional search was carried out to identify recommendations from the broader healthcare context. Although several NPSs were identified, the low quality of these and their indirectness[46] meant they could not go directly into the guidelines. Therefore, a Delphi study was deemed necessary to verify recommendations.

This chapter presents the results from a three-round modified Delphi study, aiming to reach consensus amongst Danish and Australian participants on NPSs for preventing, minimising, and managing agitation in the ICU. To better understand the non-pharmacological practices, this study also sought to explore the qualitative comments linked to the ratings, evaluate the perceived importance and feasibility of each included recommendation, determine the extent to which the different countries and stakeholder groups agreed with the recommendations, and finally to examine the perceived barriers and facilitators to guidelines implementation.

This chapter starts with presenting the demographic data to describe the representativeness and characteristics of the participants involved. It will then present the recommendations that reached a high level of consensus in both countries together with their perceived level of importance and feasibility. Then the recommendations that did not reach a high level of consensus, and the perceived barriers and facilitators to guideline implementation will be described. Finally, this chapter will discuss the strengths and limitations of this study.

## 8.2 Demographics

A total of 126 participants were invited to participate in the Delphi study. The majority had registered their interest on the project webpage, 27 were stakeholders who had provided advice in the first phase of our study, and four were invited directly due to their research expertise in the area. The first survey was sent out on the 17th of January 2022, and the last on the 19th of May 2022.

There was a high retention rate throughout the study (see Figure 22). Of the 126 invited participants, 114 (90%) completed the first survey, 106 (93% of included participants) the second, and 103 (90% of included participants) the last. The number of participants in each stakeholder group remained constant, except for the nursing group declining with a total of 11 between the first

[46] Indirectness refers to the guideline recommendations from outside the ICU setting

and the last Delphi round. An overview of the different stakeholder groups can be found in Figure 23.

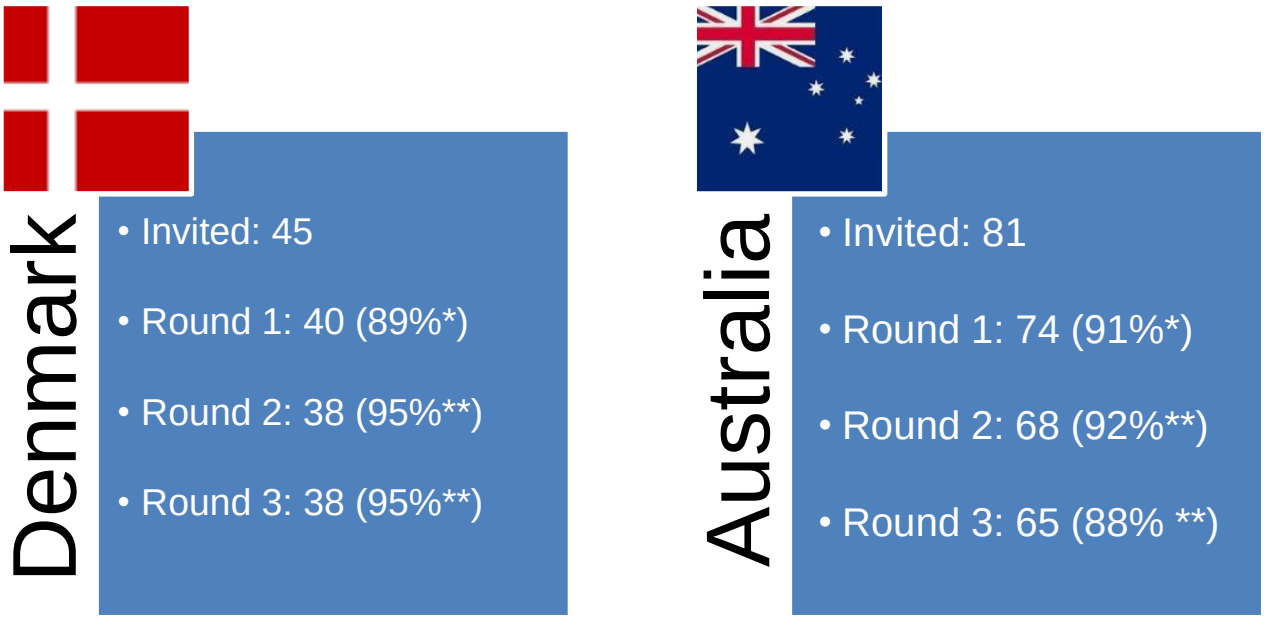



**Figure 22 Flow of participation across rounds**

* % of invited.

** % of included participants (round one).

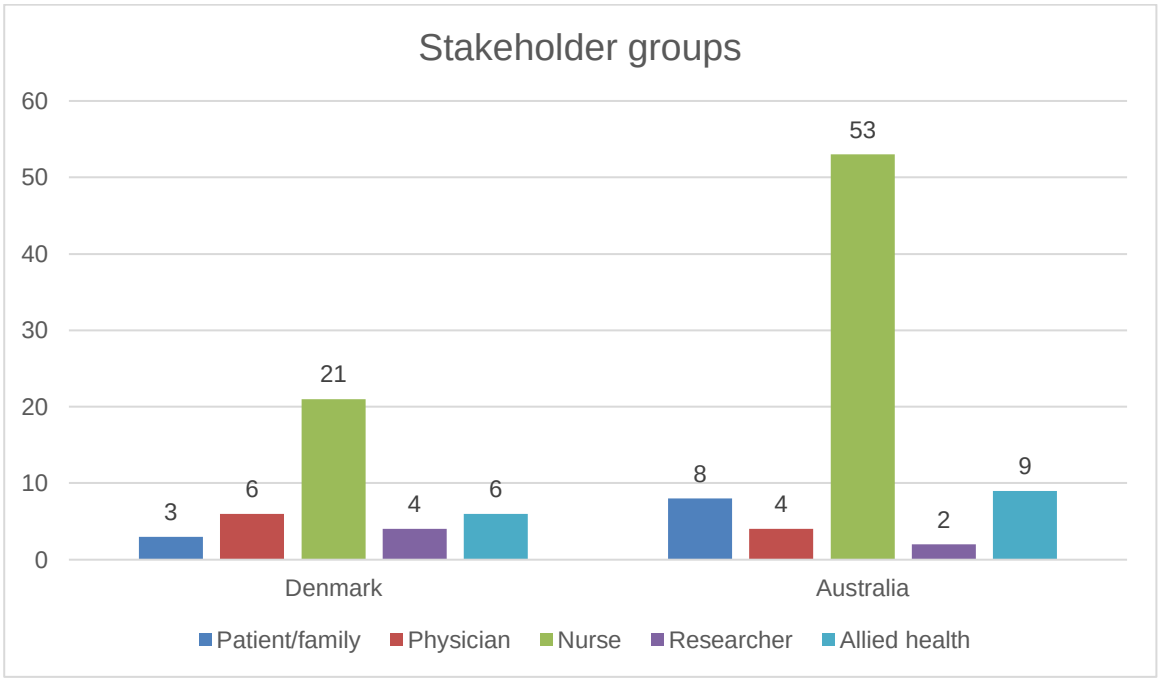



**Figure 23 Stakeholder groups**

Overall, there was a good representation of participants from all regions of Denmark (see Figure 24). All States and Territories in Australia were represented except the Northern Territory (see Figure 25). The mean age of all participants was 44.53 (±11.95), and 86% were females.

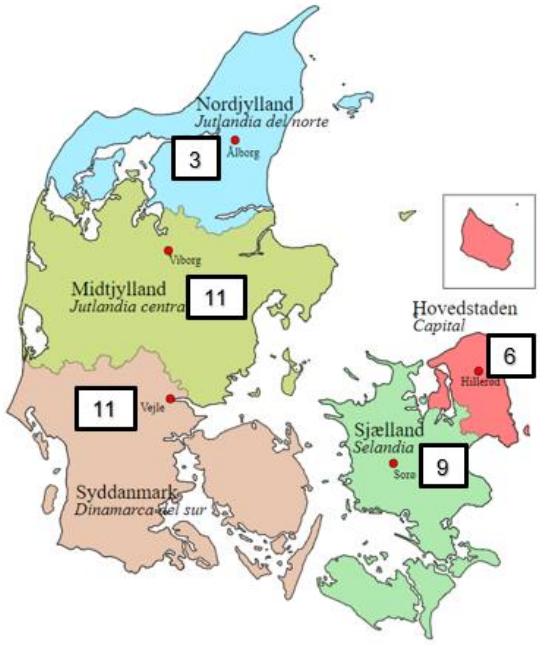



**Figure 24 Danish participants location**[47]

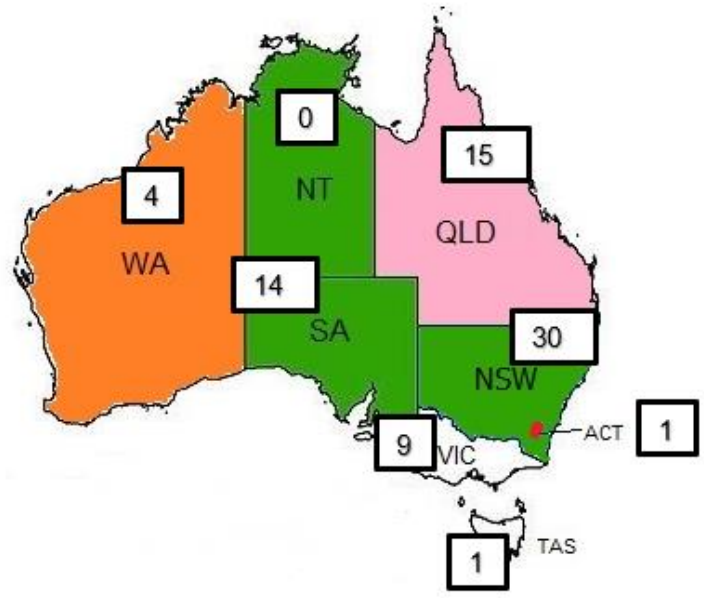



**Figure 25 Australian participants location**[48]

[47] Regions of Denmark by Jarke is shared with permission, licensed under CC BY-SA 2.5

[48] Australian States and Territories by Cpc Chine is shared with permission, licensed under CC BY-SA 3.0

A substantial number of clinicians (63%) had more than ten years of clinical experience in the ICU, and 87% indicated that they held a postgraduate qualification (see Table 42). The high level of expertise and experience amongst clinicians is important in Delphi research (Keeney et al., 2011) and increases the credibility of this study's findings. Three patients and two family members had experienced agitation in the ICU within the last three years, and six family members more than three years ago (see Table 43). The fact that six family members did not have recent experiences of agitation in the ICU, may have affected the quality of their responses.

**Table 42 Characteristics of clinicians**

| Clinicians | Denmark | Australia | Total |
|---|---|---|---|
| Years working in ICU | | | |
| 2-4 years | 5 | 3 | 8 |
| 5-7 years | 5 | 14 | 19 |
| 8-10 years | 1 | 10 | 11 |
| 11-20 years | 13 | 26 | 39 |
| 20+ | 13 | 13 | 26 |
| **Total** | 37 | 66 | 103 |
| Highest level of education | | | |
| Bachelor | 8 | 5 | 13 |
| Graduate Certificate | | 21 | 21 |
| Graduate Diploma | | 8 | 8 |
| Danish Intensive Care Nursing (2 years full-time) | 9 | | 9 |
| Master | 5 | 24 | 29 |
| Danish Kandidat | 5 | 0 | 5 |
| PhD | 5 | 5 | 10 |
| Fellowship | 3 | 3 | 6 |
| Other * | 2 | 0 | 2 |

*Clinical Nurse Facilitator Degree, EDIC, SSAI

**Table 43 Characteristics of patients/family members**

| Patients and family members | Denmark | Australia | Total |
|---|---|---|---|
| Time since experience | | | |
| 3-6 months ago (one family member) | 1 | 0 | 1 |
| 6-12 months ago (one patient) | 0 | 1 | 1 |
| 1-2 years ago (one patient) | 1 | 0 | 1 |
| 2-3 years ago (one patient, one family member) | 0 | 2 | 2 |
| More than three years ago (six family members) | 1 | 5 | 6 |
| **Total** | 3 | 8 | 11 |

## 8.3 Overview of the three Delphi rounds

A total of 89 recommendations were tested in the Delphi study; 71 were derived from the systematic reviews and stakeholder consultation and were presented in round one, and 18 were 'new' and developed during the Delphi study. Three of the 'new' recommendations were

modifications of existing recommendations from round one. Consensus was defined *a priori* as recommendations reaching IQR ≤ 1. For recommendations to be included in the guidelines, they needed to reach a consensus of ≥ 75% in both countries. Twelve recommendations reached ≥ 75% consensus in only one country and were re-rated in either round two or three. Overall, 63 recommendations reached at least 75% consensus in both countries and were endorsed in the final guidelines. The full set of endorsed recommendations and their linked evidence can be found in Appendix 44. Among the endorsed recommendations, one was a modified recommendation, and two were re-rated. A total of 26 recommendations were excluded. See Table 44 for a flow of the recommendations across rounds.

**Table 44 Flow of recommendations across rounds**

| Rounds | Number of recommendations * | Recommendations excluded | Recommendations endorsed | Recommendations continuing | New recommendations developed |
|---|---|---|---|---|---|
| **1** | 71 (59) | 13 | 52 | 6 | 18 |
| **2** | 24 (24) | 10 | 11 | 3 | 0 |
| **3** | 3 (3) | 3 | 0 | 0 | 0 |
| **Total** | | 26 | 63 | 9 | 18 |

* Recommendations presented for patients and families in brackets

The following section first describes the endorsed recommendations, and then the excluded recommendations.

## 8.4 Endorsed recommendations

The 63 endorsed recommendations were grouped into nine themes, including 1) care principles; 2) assess for agitation; 3) treat causes including unmet needs; 4) caregiver behaviours and developing trusting relationships; 5) family involvement; 6) psychosocial needs; 7) physical needs; 8) provide individualised care; and 9) interventions relating to the context. The following section presents each theme, including their categories and recommendations. For each recommendation, the level of consensus and any statistically significant differences between stakeholder groups are described (Appendix 46 provides and overview of all recommendations and their levels of consensus, IQR, Medians, Means and SD). A table for each theme provides a visual overview of the recommendations and their corresponding level of consensus, feasibility and importance (see Appendix 45 for an overview of all tables combined). In the tables, green indicates a very high level, yellow a high level and red a medium level of consensus, feasibility or importance. The red circles indicate areas where a significant difference ($p<0.05$) in ratings between countries was found, and one country rated below 75%. In the survey, importance was defined as the extent to which a recommendation was seen as valuable for reducing or managing agitation in the ICU (All recommendations ranked for importance can be found in Appendix 47). Feasibility was defined as the extent to which a recommendation was seen as practical or possible, including cost-effective,

in the ICUs the participants were familiar with (feasibility of all recommendations can be found in Appendix 48).

The qualitative data supporting the ratings, including any concerns and explanations, will also be presented. Not all participants had experiences with all recommendations. Participants who did not have experience with a recommendation were advised to rate *don't know*, and these ratings were excluded from the analysis. The total number of people rating a recommendation was indicated. For example, related to feasibility, n=105/110 meant that 105 rated *somewhat feasible* or *very feasible* out of a total of 110 who rated the recommendation.

## 8.5 Theme 1: care principles

This theme consisted of four categories and twelve recommendations (see Table 45). Together the included recommendations describe the care principles that should guide all nonpharmacological care interventions aiming to reduce patient agitation.

**Table 45 Theme 1: care principles**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Safety should be a high priority | 1.1.1 | The safety of patients, staff and family/next of kin should be given high priority when managing agitation. | 97 | 93 | 94 (14) |
| | 1.1.2 | Clinicians caring for and treating agitated patients should always have access to immediate practical support[b]. | 99 | 82 | 99 (10) |
| | 1.1.3 | Clinical staff should check that aggressive and violent agitated patients do not have access to objects that can be used to injure others (e.g. sharp objects, weapons, hard objects that can be thrown)[b] | 99 | 94 | 98 (8) |
| | 1.1.4 | Clinicians should consider keeping a safe physical distance from a violent patient. | 88 | 78 | 98 (30) |
| | 1.1.5 | The intensive care unit should be laid out in a way that makes observing agitated patients easier. | 85 | 64 | 96 (26) |
| Always consider NPSs | 1.2.1 | Non-drug approaches should be considered first when managing agitation | 89 | 92 | 90 (5) |
| | 1.2.2 | Non-drug approaches for the prevention of agitation should be an integrated part of standard care[b] | 100 | 98 | 97 (2) |
| Use multiple NPSs | 1.3.1 | Clinicians should consider using several non-drug strategies for agitated patients simultaneously. | 89 | 89 | 91 (43) |
| Physical restraints should be a last resort | 1.4.1 | Clinicians should use physical restraints only as a last resort to ensure patient and staff safety. | 85 | 85 | 91 (45) |
| | 1.4.2 | Physical restraints should not be used as a substitute for direct observation[c]. | 93 | 89 | 94 (22) |
| | 1.4.3 | Intensive care units should have clear guidelines for the use of physical restraints. | 95 | 93 | 98 (9) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible or very feasible*
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference ($p<0.05$) in ratings between countries AND one country rating below 75%

### 8.5.1 Category 1.1: safety should be a high priority

#### *8.5.1.1 Recommendation 1.1.1: the safety of patients, staff and family/next of kin should be given high priority when managing agitation.*

The recommendation *The safety of patients, staff, and family/next of kin should be given high priority when managing agitation* reached a consensus level of 97.4% (n=114/114, 95% CI: 0.93 – 0.99, Mdn 5, M 4.89, IQR 1). A significant difference was presented in the data in the rating between stakeholder groups (H (4) = 11.07, p=0.026, $\eta^2$ 0.065, d=0.527). When explored further, the difference existed between researchers and nurses (p=0.046), with 97.3% (n=72/74) of nurses strongly agreeing with this recommendation compared with 66.7% (n=4/6) of researchers. Clinicians described how safety was not always prioritised. For instance, Australian nurses described how they felt encouraged to use NPSs in situations when it was no longer safe, and drugs were required.

> Sometimes bedside staff are just kept told you just need to manage even though the patient's behaviour is escalating to an unsafe point (Australian nurse, ID 1019).

Another Australian nurse stated

> I had this experience where a patient was about to hit me in my face before the medical team charted medications to calm him down. Non-pharmacological measures are important, but nurses must be felt heard because they are the ones at the bedspace and are at constant risk (Australian nurse, ID 1033).

Overall, 94.2% (n=97/103, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 93% (n=78/89, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. Some participants described how although the recommendation was important, it may not always be easy to carry out.

> The safety of staff can be difficult to prioritise, as staff often prioritise the safety of their patients higher than their own safety (Danish nurse, ID 2012).

One Australian nurse manager described how the ICUs were not built to manage severely agitated patients like mental health facilitates (Australian nurse manager, ID 1081).

In summary, the recommendation to prioritise safety reached a very high level of consensus. Participants emphasised the importance of recognising when drugs were necessary to keep patients safe. The recommendation also reached a very high level of importance and feasibility in both countries.

#### *8.5.1.2 Recommendation 1.1.2: clinicians caring for and treating agitated patients should always have access to immediate practical support*

This recommendation reached a consensus level of 99.1 % (n=105/106, 95% CI: 0.95- 0.1, Mdn 5, M 4.91, IQR 0) in the second Delphi round. The recommendation was developed based on several comments from Australian participants in the first round:

> …and also have a team of trained staff who are familiar with lines etc, to assist with immediate de-escalation of agitation - 24 /7 (Australian Nurse, ID 1013).

Both Danish and Australian nurses described how handheld alarm devices might be useful to indicate the need for immediate help. Several Australian participants described how those providing immediate support, whether it be security guards, ICU staff or ward support officers, should be trained to de-escalate a situation as otherwise they risked intimidating the patient (and family), thus escalating agitation.

> Code blacks (calling security and ward support officers) are necessary at times but can definitely inflame the situation (Nurse manager, ID 1081).

Overall, 99% (n=100/101, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 82% (n=73/89, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. One Australian nurse (ID 1054) expressed that although immediate practical support was a good idea in theory, this was often not available in practice.

In summary, the recommendation of ensuring immediate practical support for staff caring for agitated patients reached a very high level of consensus in both countries. The recommendation was also rated very highly in terms of importance and highly in terms of feasibility. The qualitative comments suggest that those providing immediate support should be trained to deal with agitated behaviours in a person-centred way.

#### *8.5.1.3 Recommendation 1.1.3: clinical staff should check that aggressive and violent agitated patients do not have access to objects that can be used to injure others (e.g. sharp objects, weapons, hard objects that can be thrown)*

This recommendation reached a consensus level of 99% (n=103/104, 95% CI: 0.95 -1, Mdn 5, M 4.93, IQR 0). This recommendation was developed based on suggestions in round one and agreed upon in round two. Ratings between stakeholder groups differed significantly (H (4) = 12.38, p=0.015, $\eta^2$ 0.085, d=0.608). More specifically, significant differences were seen between researchers and all other groups, including nurses (p=0.020), patients-families (p=0.020), physicians (0.024) and Allied Health (p=0.013). Only 60% (n=3/5) of researchers strongly agreed with this recommendation, compared with 94% (n=63/67) of nurses, 100% (n=10/10) of patients/families, 100% (n=9/9) of physicians and 100% of people from the Allied Health group (n=13/13). Participants expressed some concerns related to this recommendation. While a Danish researcher (ID 2031) alluded to the fact that the recommendation was not relevant in Danish ICUs where weapons were typically not seen, a Danish nurse (ID 2021) described how a patient stole a pair of scissors and lunged toward a colleague. An Australian nurse believed the recommendation was very useful; he explained:

> I have had a patient wake from cardiac surgery. We did not know the past history. The patient ripped drains from themself. Attacked staff and other patients with a carving knife. Then escaped the unit (Australian nurse, ID 1027).

Another Australian nurse (ID 1067) highlighted how staff needed to be aware that family could also bring in potentially sharp or dangerous objects, such as knives or razors.

Overall, 98% (n=98/100, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important. A total of 94% (n=83/88, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible. A Danish nurse pointed out that staff might not have the legal authority to check patients' personal belongings.

In summary, the recommendation on checking that aggressive and violent patients did not have access to dangerous objects reached a very high level of agreement in both countries. However, researchers rated this recommendation lower than other stakeholder groups. Overall, the recommendation was rated highly both in terms of importance and feasibility. Before a recommendation like this can be implemented, it is necessary to determine the legal obligations of staff as they may not have the authority to look through patient belongings.

#### *8.5.1.4 Recommendation 1.1.4: Clinicians should consider keeping a safe physical distance from a violent patient*

This recommendation reached a consensus level of 88.4% (n=99/112, 95% CI: 0.81 – 0.93, Mdn 5, M 4.54, IQR 1). A significant difference was seen in rating between stakeholder groups ($H(4) = 19.48$, $p<0.001$, $\eta^2$ 0.142, $d=0.814$). More specifically, significant differences were seen between physicians and nurses (p=0.002) and between physicians and the Allied Health group (p=0.027). While 78.4% (n 58/74) of nurses and 76.9% (n=10-13) of people from the allied health group strongly agreed with this recommendation, only 20% (n=2/10) of physicians strongly agreed. A Danish physician (ID 2033) stated that such patients were rarely seen in the Danish ICUs, thus suggesting differences in the characteristics of the patient populations between the two countries. Nevertheless, participants from both countries described how a safe physical distance could be beneficial not only for the staff but also for the patient. While most participants agreed with the statement, several concerns were also mentioned. Clinicians explained how they often needed to be close to an agitated patient to avoid extubation, give medication, provide care, and finally calm down an agitated patient. A Danish nurse explained:

> Staff must pay attention to their safety when caring for the patient. But in some instances, it is the physical contact, care and basal stimulation that can calm down a patient (Danish nurse, ID 2022).

Participants described the importance of having a team approach, considering risks of harm (e.g. patient characteristics), and finally ensuring that physical distance was only used for short periods.

Overall, 98% (n=100/102, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 78% (n=73/89, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. A significant difference was seen between the ratings of the two countries (U=1201.5, p=0.003), with only 67.7% (n=21/31) of the Danish participants rating the

recommendation as somewhat or very feasible, compared with 84.2% (n= 48/57) of the Australian participants.

In summary, the recommendation for keeping a safe distance reached a high level of consensus in both countries, although physicians rated the recommendation slightly lower. The recommendation was rated very highly in terms of importance. However, while the recommendation was rated highly in terms of feasibility in Australia, it was perceived to be less (<75%) feasible by Danish participants. Qualitative comments from both Danish and Australian participants suggested that close proximity to an agitated patient was often necessary to keep the patient safe and reduce agitation. There is clearly an ethical challenge related to this recommendation where staff need to decide if they should keep a safe distance and protect themselves, or stay close to someone who is vulnerable and needs protection but who simultaneously poses a risk to staff safety.

#### *8.5.1.5 Recommendation 1.1.5: the intensive care unit should be laid out in a way that makes observing agitated patients easier*

This recommendation reached a consensus level of 85.4% (n=88/103, 95% CI: 0.77- 0.91, Mdn 5, M 4.47, IQR 1). Some participants questioned how ICUs could be laid out to facilitate observations. Could this be done through 'open plan' designs, video surveillance, windows to patient rooms or more staffing? Some of the concerns related to this recommendation involved balancing the need for observations with patients' need for privacy, sleep and reduced stimulation.

Overall, 96% (n=97/81, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while only 64% (n=58/90, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. Participants described how changing the physical layout of an established ICU was challenging.

In summary, the recommendation for ensuring a layout that facilitates observations of agitated patients reached a high level of consensus in both countries. The recommendation was rated as very important but less feasible. The qualitative comments suggested that participants had different perceptions of what was meant by 'layout', that the need for observations had to be balanced with patients' needs for privacy and reduced stimuli and finally, that the physical layout was challenging to change.

### 8.5.2 Category 1.2: always consider NPSs

This category described how NPSs should be a part of standard care and clinicians should always think NPSs first before giving drugs.

#### *8.5.2.1 Recommendation 1.2.1 Non-drug approaches should be considered first when managing agitation*

This recommendation reached 88.5% (n=100/113) 95% CI: 0.81 – 0.93, Mdn 5, M 4.75, Mdn 5, M 4.46, IQR 1) consensus. Clinicians, patients and family members described how clinicians often relied too much on drug therapy. A Danish physician highlighted:

> I believe that it is absolutely crucial that NPSs come before the medication of agitated patients. After all, there is a reason why they are agitated, and that reason must be found and dealt with, not just medicated. Medication may definitely be necessary, but it should be the last in the line of options. Otherwise, the agitation will most likely just occur again when you stop sedating - and it will keep happening, at least until the patient has become so weak that he does not have the strength to be agitated anymore (Danish physician, ID 2033).

Clinicians from both countries expressed concerns about using NPSs as a first-line treatment. The concerns related to severely agitated, threatening and violent patients who posed a danger to themselves and others. An Australian physician stated:

> "Non-drug approaches should always be considered, but may need to be considered simultaneously to other approaches depending on the level of agitation. They should always form a part of a management strategy (Australian physician, ID 1052).

An Australian nurse described the importance of staff knowing when NPIs were no longer safe

> I've experienced delayed pharmacological measures because the staff is too engrossed at doing non-pharmacological measures to the point where the staff becomes assaulted (Australian nurse, ID 1033).

There were also comments suggesting that some patient categories responded less to NPSs, including patients undergoing drug withdrawal.

Overall, 90.3% (n=93/103, Mdn 5, IQR 1) of participants rated this recommendation as somewhat or very important, and 92% (n=81/88, Mdn 5, IQR 1) rated the recommendation to be *somewhat* or *very feasible*.

In summary, there was a high level of consensus that NPSs should be considered first when managing patient agitation. This recommendation also reached a high level of importance and feasibility. It must be noted that according to the qualitative comments, some situations require prompt pharmacological treatment to keep patients and staff safe. To ensure safe practices, the recommendation should therefore be provided conditionally.

#### *8.5.2.2 Recommendation 1.2.2: non-drug approaches for the prevention of agitation should be an integrated part of standard care*

This recommendation reached 100% (n=105/105, 95% CI: 0.97- 1, Mdn 5, M 4.89, IQR 1) consensus. This statement was developed based on a direct quote from a Danish physiotherapist (ID 2043) and was supported by several other comments emphasising the importance of

prevention since NPI were challenging to use when patients were already agitated. There were no coded comments on this statement in the second round.

This recommendation was the second highest rated recommendation of all, with 97.1% (n=91/102, Mdn 5, IQR 0) of participants rating this recommendation as being somewhat or very important. A Danish nurse stated:

> I believe that if we can integrate nonpharmacological interventions into our standard care to prevent and minimise agitation, then we have come a long way (Danish nurse, ID 2018)I

A total of 98% (n=86/88, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible. An Australian nurse stated:

> Many non-drug approaches can be incorporated into systems approaches and standard care, e.g. visiting hours, support staff for Aboriginal and non-English speaking patients, and timely and unhurried patient review and explanations (Australian nurse, ID 1067).

In summary, the recommendation of having NPSs as an integrated part of standard care reached a very high level of consensus, importance, and feasibility in both countries.

### 8.5.3 Category 1.3: use multiple NPSs

#### *8.5.3.1 Recommendation 1.3.1: clinicians should consider using several non-drug strategies for agitated patients simultaneously.*

This recommendation reached 88.6% (n=101/114, 95% CI: 0.81- 0.93, Mdn 5, M 4.52, IQR 1) consensus. There was a suggestion of changing the sentence to *Clinicians should use a multi-component nonpharmacological approach to reduce or manage agitation* (Danish researcher, ID 2031). However, since the recommendation reached a high level of consensus, the rule was, that the recommendation could not be changed. Furthermore, testing of the survey had shown that lay people struggle to understand the term "multi-component". The other qualitative comments suggested that using several NPSs could be useful. One concern about this approach related to the difficulty of understanding the effect of one method when using several simultaneously.

Overall, 91% (n=91/100, Mdn 5, IQR 1) of participants rated this recommendation as being somewhat or very important, while 89% (n=80/90, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for using several non-drug strategies reached a high level of consensus, a very high level of importance and a high level of feasibility in both countries.

### 8.5.4 Category 1.4: physical restraints should be a last resort

This category includes three recommendations and describes how PR should be used as a last resort and never as a substitute for direct observation. This category also describes how ICUs should have clear guidelines for the use of PR.

#### *8.5.4.1 Recommendation 1.4.1: clinicians should use physical restraints only as a last resort to ensure patient and staff safety.*

This recommendation reached a consensus level of 85.1% (n=97/114, 95% CI:0.77- 0.90, Mdn 5, M 4.38, IQR 1). The survey defined PR as any manually applied method that reduces a patient's ability to move freely (Arora et al., 2021; Devlin et al., 2018a). Participants described how they saw the "last resort" as an option only when everything else had failed, and the patient and/or staff were at risk of physical harm. An Australian family member explained:

> For many patients, periods of agitation are short-lived and do not warrant harsh measures. Physically restraining patients will only further feed their paranoia and should only be used when all else has failed, and patient/staff are at risk of physical harm (Australian family, 1004).

Similarly, a Danish nurse stated:

> Physical restraints should be a last resort, where psychiatrists are involved and where both pharmacological and nonpharmacological interventions are insufficient, and there is a risk of harm towards staff" (Danish nurse, ID 1022)

In terms of importance, a total of 91% (n=91/100, Mdn 5, IQR 1) of all participants rated the recommendation to be somewhat or very important. A total of 85% (n=75/88, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. This recommendation received similar comments as the recommendation "physical restraints should not be used as a substitute for direct observation".

In summary, the recommendation only to use PR as a last resort reached a high level of consensus in both countries and received very high scores in terms of importance and feasibility.

#### *8.5.4.2 Recommendation 1.4.2: physical restraints should not be used as a substitute for direct observation*

This recommendation reached a consensus level of 93.3% (n=97/104, 95% CI: 0.87 – 0.97, Mdn 5, M 4.64, IQR 0). This recommendation was a modification of the original recommendation, "Physical restraints should never be used to enable staff to leave the patient", which only reached above 75% consensus in Denmark (described in section 8.14.1.4). Danish participants described how it was not legal in Denmark to use PR as a substitute for observation. They explained how PR were only used in exceptional circumstances and required specific approval. In contrast, some Australian participants described how PR were used too frequently and often as a convenience. Danish and Australian participants, including patients, families, and clinicians, explained how PR could increase anxiety levels, exacerbate agitation, and worsen post-traumatic stress disorder (PTSD). A Danish physician explained:

> "In Denmark, we do not use PR, which I think is really good. The more the patient "gets stuck", the more delirious they become. This also applies to cannulas, catheters and the like, so they should only be there if they are really needed" (Danish physician 1033).

An Australian researcher explained:

> Over my many years of clinical work I came to realise that PR gave an illusion of safety for the clinical team while actually making the critically ill person even more agitated. Additionally, most agitated people are reacting to threats and are profoundly frightened… Therefore agitated people should be treated with kindness, NOT restraints (Australian researcher, ID 1006).

A family member noted:

> Wrist restraints were very upsetting for my mother, who had had a stroke and was very confused (Australian family member, ID 1065).

Participants also described how PR could result in dangerous behaviours:

> The expectation that the staff will physically restrain the patient is harmful to the patient and the staff member. It leaves open the opportunity for physical harm to the staff and they are not legally covered if the patient is harmed due to not being trained in such techniques (Australian nurse, ID 1011).

Finally, it was described how using PR could negatively affect the development of a trusting relationship

> From my experience, they [PR] increase agitation and prevent the development of trust between clinicians and patients (Australian nurse, ID 1048).

Although many Danish comments described how PR were not used and did more harm than good, one participant suggested increasing the use of PR in order to reduce the use of sedation:

> Again, I often experience prolonged polypharmacy and prolonged sedation because patients are agitated. Here, PR that prevents auto-extubation can help shorten the ICU stay. It should only be the difficult cases, but it is being used too little in our department (Danish physician, ID 2035).

Some Danish allied health staff described how they used mild PR to protect agitated and confused patients and that these methods allowed clinicians to focus on other tasks. Examples were when staff placed a table in front of a patient, placed a patient bed against a wall, allowed patients to sit in a hoist sling in a chair, or used heavy blankets.

While some Australian participants agreed with the recommendation, multiple participants disagreed. It was described how PR were necessary to facilitate breaks, check medication and help other staff members:

> Sometimes due to staff breaks or needing two staff to check medications you may need [physical] restraints for safety (Australian nurse, ID 1054).

> There are times when PR are required to allow for the nurse to assist with other patients (Australian nurse, ID 1012).

To protect staff from being assaulted

> Depending on the case, some patients swiftly turn from being friendly to throwing objects in half a minute. Physical restraint has to be used for those patients (Australian nurse, ID 1072).

And to protect the patient from harm

> PR are there to protect patients from themselves, and it protects them from more painful procedures (Australian nurse, ID 1025).

> My father was in intensive care after a stroke. Unfortunately, he was not [physically] restrained and would, in agitation and disorientation, pull his feeding tube out. Every time it would be hours, sometimes an entire day, before they could coordinate a time to re-insert the tube (Australian family member, ID 1063).

Since the question was changed from "Physical restraints should never be used to enable staff to leave the patient" to "physical restraints should not be a substitute for direct observation", there was also a question around what this meant. An Australian nurse suggested this meant PR was reasonable to use, to provide a "sense of safety", as long as a clinician was present.

> I do agree with the notion that the restraints provide a greater sense of patient safety so that I do not have to feel fear or worry that my patient has pulled something out, or have to have a constant eye on my patient so that I can get things done (ID 1029).

In contrast, a Danish nurse described how PR should never be used just to make staff feel safe

> Physical restraints should only be used on a correct legal basis, and not just because staff feel unsafe (Danish nurse, ID 2014).

Overall, 94.1% (n=96/102, Mdn 5, IQR 0) of all participants rated this recommendation as ‘somewhat’ or ‘very important’. A total of 89% (n=78/88, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible. Some Australian participants described how in *the ideal world,* PR should not be used. However, under the current circumstances, it was seen as necessary to keep patients and staff safe.

In summary, there was a high level of consensus on the recommendation 'physical restraints should not be used as a substitute for direct observation'. Overall, the recommendation was also highly rated in terms of importance and feasibility. Following the qualitative comments, it is important to consider if the recommendation is culturally appropriate in a Danish context. Although qualitative comments suggested, there might be some disagreements around what constitutes PR in the Danish ICU. In an Australian context, it may be necessary to consider whether the recommendation can be implemented while keeping patients safe.

#### *8.5.4.3 Recommendation 1.4.3: intensive care units should have clear guidelines for the use of physical restraints.*

This recommendation reached a consensus level of 95.1% (n=97/102, 95% CI: 0.89 – 0.98, Mdn 5, M 4.78, IQR 1).

Overall, 91%% (n=91/100, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. A Danish researcher (ID 2026) pointed out that guidelines were of less importance since there was already a national law on restrictive practices that clinicians had to

comply with. A total of 93% (n=80/86, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation of having clear guidelines on the use of PR reached a very high level of consensus, importance and feasibility in both countries.

## 8.6 Theme 2: assess for agitation

This theme consisted of only one category and one recommendation (see Table 46).

**Table 46 Theme 2: assess for agitation**

| Category | | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Assessment | 2.1.1 | ICU patients should be regularly and systematically assessed for agitation. | 97 | 100 | 96 (20) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference (p<0.05) in ratings between countries AND one country rating below 75%

### 8.6.1 Category 2.1: assessment

#### *8.6.1.1 Recommendation 2.1.1: ICU patients should be regularly and systematically assessed for agitation*

This recommendation reached a consensus level of 97.1% (n=100/103, 95% CI: 0.92- 0.99, Mdn 5, M 7.78, IQR 0). Participants described how assessments needed to be consistent and accurate. Early assessments allowed clinicians to put strategies into place before agitated behaviours escalated.

> Agitation is one of the conditions that is often easily identified in contrast to, for instance, hypo-active delirium. But sometimes, milder forms of agitation, like restlessness and unease, are not identified and then lead to an escalation of behaviours (Danish researcher, ID 2026).
>
> Also, missing the early signs of agitation and letting it build makes it much more difficult to manage (Australian nurse, ID 1057).

Participants also described how assessments over several days could show patterns in behaviours, thus helping to identify causes of agitation (e.g. time of the day, visiting hours) and the effect of NPSs.

There were some concerns related to the assessment of agitation. These included patients already being assessed for delirium and/or sedation - making the assessment for agitation redundant,

constant assessments could exacerbate agitated behaviours, not having evidence-based assessment tools available and feeling unsure about the signs and symptoms of agitation.

> Staff members still get punched & kicked by agitated patients. It would be useful to be aware of the signs to look for…(Australian nurse, ID 1053).

Related to importance, 95.6% (n=87/91, Mdn 5, M 4.78, IQR 0) rated this recommendation as *somewhat* or *very important*. All participants rated this recommendation (n=88/88, Mdn 5, M 4.78, IQR 0) as somewhat or very feasible.

In summary, there was a very high level of consensus that clinicians should do regular and systematic assessments of agitation. The recommendation was also very highly rated in terms of importance and feasibility. However, future research may need to focus on the early signs and symptoms of agitation and potentially the development of appropriate assessment tools. Finally, clinicians must consider how assessments can be done without disturbing patients.

## 8.7 Theme 3: treat causes, including unmet needs

This theme consisted of one category and two recommendations (see Table 47)

**Table 47 Theme 3: Treat causes including unmet needs**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Treat causes, including unmet needs | 3.1.1 | Clinicians should support patients' fundamental care needs to reduce and manage agitation. | 99 | 95 | 100 (13) |
| | 3.1.2 | Clinicians should identify and, when possible, treat causes of agitation. | 100 | 89 | 99 (20) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference (p<0.05) in ratings between countries AND one country rating below 75%

### 8.7.1 Category 3.1: treat causes, including unmet needs

#### *8.7.1.1 Recommendation 3.1.1: clinicians should support patients' fundamental care needs to reduce and manage agitation.*

This recommendation reached a 99% (n=102/103, 95% CI:0.95 -1, Mdn 5, M 4.93, IQR 0) consensus level. Fundamental care needs were defined in the survey as physical, psychosocial and relational needs. While participants described how unmet needs could cause agitation, it was

also explained how it could be challenging to identify patient needs. An occupational therapist explained:

> Patients' needs should be met before using drugs. Often patients are intubated and unable to communicate their needs which can cause agitation. Strategies aren't always used by the nursing staff to help patients express their needs (Australian occupational therapist, ID 1075).

A Danish researcher described ways to support psychosocial and relational needs:

> For me, it means that we need to manage the patient's need for safety, feeling safe and feeling informed. Help them to be together with their closest relatives and other people who are important to the them, for instance a spiritual adviser or a priest (Danish researcher, ID 2031).

There was some confusion about what constituted fundamental care needs and how to prioritise these. A nurse manager alluded to the notion that fundamental care needs meant physical care needs and that staff sometimes neglected these.

> The third recommendation is so important. Fundamental care provision in the confused patient is so often avoided because staff don't want to wake or rouse the patient because it means more work for them (Australian manager, ID 1040).

A Danish nurse seemed to have the same perceptions about fundamental care needs being physical needs, but in contrast, this person seemed to suggest prioritising patients' need for rest and less stimulation.

> Fundamental care needs include brushing teeth. Should this be done if it irritates the patient and thus increases agitation? (Danish nurse, ID 2027).

A couple of participants described how they struggled to differentiate between psychosocial and relational needs. Finally, some participants suggested adding spiritual, pastoral and cultural needs.

Overall, 100% (n=92/92, Mdn 5, IQR 0) of participants rated this recommendation as being somewhat or very important, while 95% (n=84/88, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible. An Australian nurse (ID 1073) mentioned how COVID had made it particularly challenging to support patients' psychosocial and relational needs.

In summary, *supporting patients' fundamental care needs* reached a very high level of consensus in both countries. The recommendation was also very rated highly in terms of both importance and feasibility. The qualitative comments suggest that participants had slightly different perceptions of what constitutes fundamental care needs and how these should be prioritised.

#### *8.7.1.2 Recommendation 3.1.2: clinicians should identify and, when possible, treat causes of agitation*

This recommendation reached a consensus level of 100% (n=103/103, 95% CI: .0.96-1, Mdn 5, M 4.97, IQR 0). Participants described this recommendation as essential and provided examples of how the identification of causes and understanding of these causes led to tailored treatment and a reduction of agitation. One example came from a previous ICU patient:

> They [nurses] thought I purposely tried to annoy them or that I wouldn't collaborate, but I was lying uncomfortably with my right leg, and I couldn't talk…they gave me a drug to make me relax. They didn't consider that perhaps there was another reason for my agitation…I struggled with pain in my leg for a long time after the incident (Danish patient, ID 2003).

Participants mentioned emotional, spiritual, psychosocial and physical causes of agitation, including anxiety, withdrawal of drugs/alcohol, a full bladder, hunger, thirst, pain, infection, and low oxygen levels. Clinicians from both countries also explained how sedation could disguise the causes of agitation making assessment challenging. This recommendation was the highest rated recommendation in terms of importance, with most participants seeing the recommendation as somewhat or very important (98.9%, n=90/91, Mdn 5, IQR 0). When ranking recommendations of importance, this recommendation was seen as the single most important recommendation of all. The majority of participants rated this recommendation as somewhat or very feasible (98%, n=87/89, Mdn 5, IQR 1).

In summary, the recommendation for identifying and treating causes of agitation reached a very high level of consensus, feasibility and importance in both countries.

## 8.8 Theme 4: caregiver behaviours and developing trusting relationships

This theme included two categories and six recommendations describing the importance of developing a trusting relationship with the patient, knowing the patient and considering one's communication style in order to support patients' relational needs (see Table 48).

**Table 48 Theme 4: caregiver behaviours and developing trusting relationships**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Relationships | 4.1.1 | Develop a relationship with the patient based on empathy, respect and trust. | 95 | 98 | 99 (12) |
| | 4.1.2 | Become familiar with the patient's background (e.g., likes, dislikes, culture, history, values, fears and routines). | 99 | 94 | 98 (35) |
| Caregiver behaviours | 4.2.1 | Clinicians should be trained to use de-escalation techniques[b]. | 99 | 92 | 97 (15) |
| | 4.2.2 | Use clear and concise language. | 96 | 99 | 98 (11) |
| | 4.2.3 | Use "active listening". | 93 | 96 | 96 (25) |
| | 4.2.4 | Use alternative communication methods. | 95 | 93 | 94 (34) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference (p<0.05) in ratings between countries AND one country rating below 75%

### 8.8.1 Category 4.1: relationships

#### *8.8.1.1 Recommendation 4.1.1: develop a relationship with the patient based on empathy, respect and trust*

This recommendation reached a consensus level of 94.7% of participants (108/114, 95% CI: 0.89 – 0.98, Mdn 5, M 4.73, IQR 0). Participants described how NPSs were more likely to work if patients trusted staff.

> These NPSs are only effective when people trust you (Australian nurse, ID 1048).

Trust was particularly important when dealing with patients with poor previous experiences with institutions.

> We see a lot of young people, young men in particular who have been involved in MVAs or suicide attempts, with issues of drug dependence, particularly amphetamine use. Their previous experiences of institutions, such as prison or inpatient psych units, may impact their feelings of safety and trust when in ICU... Building a rapport and a relationship based on trust, respect and kindness is absolutely fundamental to my role" (Australian nurse, ID 1082).

A trusting relationship involved seeing and understanding the patient and acknowledging their suffering.

> Staff need to try and understand the patient. I know that first of all, they need to save the patient, but they also need to remember that you are dealing with a person, with a human being (Danish patient, ID 2003).

> This [developing a relationship of trust] is the most important activity health care providers can do. Treating patients as humans and provide care in a holistic manner. At the moment, patients are treated as if they are specimens from a laboratory (Australian patient, ID 1005).

Respecting patients also meant being non-judgemental and understanding that the agitated patient did not do things on purpose to be naughty or disobedient. An Australian ICU chaplain described how having judgemental attitudes and seeing patients as the "troubled patient" or "a challenge" was a barrier to reducing agitation, and how a caring and non-judgemental approach could calm down a patient (Australian ICU chaplain, ID 1058). This was supported by an Australian nurse:

> Consistent attempts to establish trust, safety and rapport are really important. I think patients can sense when they are being patronised or judged for their lifestyle choices by nurses and doctors. Clinicians that are not able or willing to provide respectful, non-judgemental care should be discouraged from being involved with the patient (Australian nurse, ID 1082).

A significant difference was seen in ratings between stakeholder groups (H (4) = 17.10, p=0.002, $\eta^2$ 0.12, d=0.739). There were significant differences between physicians and all other groups. While only 30% (3/10) of physicians rated the recommendation as very useful, 81.8% (n=9/11, p=0.034) of patients/families, 92.3% (n=12/13, p=0.003) of people from the Allied Health group, 79.7% (n=59/74, p=0.004) of nurses and 100% (n=6, p=0.011) of researchers rated the

recommendation as very useful. Physicians explained how adding a trustworthy relationship when a patient was already agitated had little effect. Meanwhile, it was acknowledged that removing empathy and respect was likely to excavate agitated behaviours.

Overall, 99% (n=101/102, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 98% (n=87/89, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for building trusting relationships with patients reached a very high level of consensus in both countries. The recommendation was also very highly rated in terms of importance and feasibility.

#### *8.8.1.2 Recommendation 4.1.2: become familiar with the patient's background (e.g., likes, dislikes, culture, history, values, fears and routines).*

This recommendation reached 99.1% (n=112/113, 95% CI:0.95 -1, Mdn 5, M 4.86, IQR 0) consensus. Participants described how knowing the patient and their history helped clinicians to understand patient needs and triggers of agitation better. An Australian nurse explained:

> Yes, I think often our patients have had bad or traumatic experiences in institutions (inpatient psych, prison), and they experience significant challenges being in ICU, connected to a monitor and restricted in what they can do (Australian nurse, ID 1082).

Participants from both countries mentioned the importance of respecting and understanding patients' cultures and norms to reduce and manage agitation.

> Muslim women must be covered below, just like the hair should be covered if there is a male carer present. It is important for patient dignity and a part of her culture (Danish Nurse, ID 2027).

Overall, 98% (n=100/102, Mdn 5, IQR 1) of all participants found that this recommendation was somewhat or very important, while 94% (n=84/89, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation reached a high level of consensus and was rated highly in terms of importance and feasibility.

### 8.8.2 Category 4.2: caregiver behaviours

#### *8.8.2.1 Recommendation 4.2.1: clinicians should be trained to use de-escalation techniques*

This recommendation reached a consensus level of 99.1 % of participants (n=105/106, 95% CI: 0.96 – 1, Mdn 5, M 4.89, IQR 0). In the survey, de-escalation was described as a technique involving verbal and non-verbal techniques to calm down a patient. This recommendation was developed based on several participant comments in round one and was agreed upon in round two. In round one, a Danish nurse explained:

> We can benefit from thinking about our communication style to these patients. I find that we don't always do this well. We have good experiences with the exchange of ideas with psychiatry. They are experts in de-escalation, and we have learned an incredible amount from their knowledge (Danish nurse, ID 2013).

Several participants, including patients, families and clinicians, described how staff sometimes triggered agitated behaviours in patients rather than de-escalating behaviours. They did this by talking over the head of patients in a non-confidential manner, arguing with patients, being 'bossy', shouting at patients, ignoring patients, not listening or involving patients, standing over them and telling them off and matching patients' agitated behaviours. A family member explained:

> Sadly, some staff seem only to be clinical and abrupt, and this can, in fact, escalate distress and agitation in patients (Australian family member, ID 1063).

Another Australian family member provided a similar statement:

> She [mum] was trying to pull the tube from her nose, and one of the nurses was very rough with her when she tried to stop mum. Quiet and calm is really important for restless and agitated patients (Australian family members, ID 1065).

Overall, 96.9% (n=95/98, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important. Participants explained how all staff would benefit from training in de-escalation strategies, in particular the novice staff members. However, a nurse manager was concerned about the quality of the training:

> Our hospital has just started providing occupational violence training – it is just not very good and not very relevant to our cohort of patients (Nurse manager, ID 1081).

A total of 92% (n=81/88, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible. It was described how de-escalation training required regular training and focus.

In summary, the recommendation for training staff to use de-escalation strategies reached a very high level of consensus in both countries. It also was very highly rated in terms of both importance and feasibility. Qualitative comments suggest that the training has to be directly relevant to clinicians in the intensive care unit.

#### *8.8.2.2 Recommendation 4.2.2: use clear and concise language*

This recommendation reached a consensus level of 95.6 % (n=109/114, 95% CI: 0.90 - 0.98, Mdn 5, M 4.65, IQR 1). A Danish physician explains why clear and concise language was important:

> Most patients have reduced consciousness. They are not able to concentrate for longer periods of time, and they quickly forget. Information must be relevant, short and clear. Otherwise, it will become unnecessary noise. The most essential information must be repeated as needed (Danish physician, ID 2033).

Danish participants described how it was helpful when clinicians only used a few unambiguous words (5-7 words), presented one topic at a time, used closed-ended questions, avoided jokes and

repeated important messages when necessary. It was described that although patients were often so confused that they forgot the message again, it still provided a sense of reassurance.

Overall, 98.1% (n=101/103, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important. A total of 99% (n=85/89, Mdn 5, IQR 0.25) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation of clear and concise language reached a high level of consensus in both countries. This recommendation was also rated very highly both in term of importance and feasibility.

#### *8.8.2.3 Recommendation 4.2.3: use active listening*

Active listening was described in the survey as listening carefully and demonstrating an interest in what a person has to say. This recommendation reached a consensus level of 92.9% (n=105/113, 95% CI: 0.87- 0.96, Mdn 5, M 4.61, IQR 1). Participants explained how active listening was important to make patients feel understood and help clinicians to understand patient needs better. It was explained how listening also meant listening to body language, as often patients in ICU were unable to talk. A couple of participants described how active listening was not always helpful, mainly if a patient continuously repeated themselves. An Australian patient (ID 1005) described how often staff were too busy to listen.

Overall, 96.1% (n=98/102, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 86% (n=85/89, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for active listening reached a very high level of consensus in both countries. The recommendation was also highly very rated in terms of importance and highly rated in term of feasibility.

#### *8.8.2.4 Recommendation 4.2.4: use alternative communication methods*

Alternative communication methods were described in the survey as methods such as pen and paper, boards with icons and pictures, alphabet boards, computer communication systems. The recommendation reached 95% (n=103/109, 95% CI: 0.89 – 0.97, Mdn 5, M 4.47, IQR 1) consensus. A significant difference was seen in rating between stakeholder groups ($H(4) = 17.98$, $p=0.001$, $\eta^2$ 0.134, $d=0.788$). When explored further, the difference was found between physicians and Allied Health ($p=0.004$), and physicians and patients/families ($n=0.007$). While only 10% (n=1/9) of physicians rated this recommendation as very useful, 89% (n=8/9) of patients/families and 85% (n=11/13) of people from the Allied Health group rated the recommendation as very useful.

Using alternative communication methods was seen as particularly useful when struggled to express needs and make themselves understood, situations that could lead to agitation. An Australian family member explained how alternative communication methods worked for her mum, but how staff did not prioritise this:

> My mother could not communicate effectively verbally for a period, and the hospital had written her off as unable to communicate at all. The family had implemented other strategies for communicating such as pen and paper and an alphabet block, but the hospital staff seemed unaware of this and continued to not attempt any form of communication with her (Australian family member, ID 1066).

Other participants supported the idea of using simple tools like pen, paper and pictures. Some participants described how it could be challenging to use alternative communication methods when patients were agitated and confused.

Overall, 94.1% (n=96/102, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important, while 93% (n=82/88, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for using alternative communication methods reached a very high level of consensus in both countries. The recommendation was also very highly rated in terms of importance and feasibility.

## 8.9 Theme 5: family involvement

This theme included two categories and five recommendations (see Table 49). It describes the importance of partnering with family and other carers to determine how much they could and should be involved in care. Participants from both countries described how family and next of kin helped patients through their ICU stay by providing critical information about patient preferences and needs and by making patients feel safer.

**Table 49 Theme 5: family Involvement**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Communication with families | 5.1.1 | Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation | 89 | 95 | 97 (32) |
| | 5.1.2 | Clinicians should offer family members information about agitation | 98 | 99 | 95 (31) |
| Family in care | 5.2.1 | Teach family members/next of kin to use non-drug strategies. | 91 | 80 | 92 (52) |
| | 5.2.2 | Involve family members/next of kin in care. | 90 | 77 | 86 (55) |
| | 5.2.3 | Use telephone and/or video conferencing when family members/next of kin are unable to visit the patient in person. | 83 | 89 | 94 (50) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*

[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference (p<0.05) in ratings between countries AND one country rating below 75%

### 8.9.1 Category 5.1: communication with families

#### *8.9.1.1 Recommendation 5.1.1: clinicians should establish how much the family would like to and are able to be involved in managing patient agitation*

This recommendation reached a consensus level of 88.5% (n=100/113, 95% CI: 0.81 – 0.93, Mdn 5, M 4.52, IQR 1). Participants described how the findings of such inquiry should be documented in patient care plans. Family needs should be established on admission and throughout the patient's ICU stay, as their abilities and capacities to be involved were likely to change over time.

Overall, 97.1% (n=99/102, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 95% (n=84/88, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on establishing how much the family were able to and would like to be involved reached a high level of consensus in both countries. The recommendation received very high ratings in terms of importance, and high rating in terms of feasibility.

#### *8.9.1.2 Recommendation 5.1.2: clinicians should offer family members information about agitation*

This recommendation reached a consensus level of 98.2% (n=112/114, 95% CI: 0.94 – 1, Mdn 5, M 4.85, IQR 0). Offering information was seen as important to help the family understand that agitation is normal and expected in the critically ill patient and usually occurs for a shorter period. An Australian nurse explained:

> Families can be incredibly traumatised by patient agitation. Offering education and information about it would help. Especially in written form, so they can take it home and read about it. I believe they should also be offered debriefing if needed (Australian nurse, ID 1048).

Overall, 95.1% (n=97/102, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important. A total of 99% (n=88/89, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on offering family information reached a very high level of consensus in both countries. The recommendation received very high ratings in terms of importance and feasibility.

### 8.9.2 Category 5.2: family in care

#### *8.9.2.1 Recommendation 5.2.1: teach family members/next of kin to use non-drug strategies*

This recommendation reached a consensus level of 90.4% (n=99/109, 95% CI: 0.84 – 0.95, Mdn 5, M 4.48, IQR 1).

Overall, 92.1% (n=93/101, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. A total of 80% (n=70/88, Mdn 4, IQR 0) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for teaching family non-drug strategies reached a very high level of consensus in both countries. The recommendation received very high ratings in terms of importance, and feasibility.

#### *8.9.2.2 Recommendation 5.2.2: involve family members/next of kin in care*

This recommendation reached a consensus level of 90.4% (n-103/114, 95% CI 0.84 – 0.95, Mdn 5, M 4.39, IQR 1).

Participants from both countries described different levels of involvement. Families could be involved by sharing information about the patient, being present during patient care, and being actively involved in caring for the patient.

The importance of listening to family was emphasised by clinicians, patients and family members. An Australian family member explained:

> Instead of dismissing the family of patients, increased involvement and communication with family can assist the patient, doctors and staff. They can provide valuable feedback that is often dismissed, as they are with the patient for long periods and have observed things staff may have missed in the limited amount of time they spend with them or has been omitted in staff handovers (Australian family member, ID 1066).

This particular family member described a situation where staff dismissed crucial information provided by the family. It was not until staff listened to the family and changed their care, that the patient's agitated behaviours improved. A Danish patient explains a similar experience:

> But if they had talked to my husband and asked what I was like as a person, then they would have known that I have difficulties with such things (Danish patient, ID 2003).

Clinicians also described the importance of involving family members in care. At times, family involvement almost seemed like an underutilised resource that could relieve staff when they needed it the most. An Australian physician explained:

> Use of family members is an extremely high-yield intervention, and most family members are keen to be involved even in the early hours (Australian physician, ID 1052).

Aligning with this finding, there were multiple concerns related to involving family and next of kin in care, and their level of involvement. Several participants pointed out that family should only be involved if they had the energy and desire to be involved. A nurse manager explained:

> It’s not always appropriate for families to be involved or see their family members so agitated. When helpful with a good outcome, I definitely agree. However, not if there is an emotional risk to the family (Nurse Manager, ID 1057).

Seeing patient agitation could be confronting and, in some cases, make family members feel unnecessarily responsible and guilty. An Australian nurse illustrated:

> It is easy to put undue stress on the family, who may feel that they are 'letting the patient down' if they feel they can't do what is asked. This sort of guilt may resonate for a long time after the admission if not managed properly (Australian nurse, ID 1012).

It was clear from quotes from family members that sometimes they felt overly responsible for the care of the patient and guilty for letting the patient down. An Australian family member explained

> The family needed to be hyper-vigilant, present 24/7 and ready to physically prevent my mother from tearing out her IV central line and feeding tubes or injuring herself. She was then treated with annoyance after having removed her feeding tube repeatedly and was left without it reinserted for a period. If the family were not present 24/7, then my mother would have suffered serious injury, and she would certainly have needed to be restrained (Australian family member, 1066).

Another Australian family member had a similar experience:

> Unfortunately, he [father] was not restrained and would, in agitation and disorientation, pull his tube out. Every time it would be hours, sometimes an entire day, before they would be able to coordinate a time to re-insert the tube. The distress of frequently having to have his feeding tube re-inserted impacted significantly on my father's state of mind and health. In desperation, the family tried to be at his side at every possible allowable moment (Australian family member, ID 1063).

A Danish physiotherapist pointed out that family members should not take over the role as carers, and that their role as "family" consisted of something different.

> Generally, I would recommend that relatives are not included in the care, but have the primary purpose of being relatives when they are visiting (Danish physiotherapist, ID 2043).

Multiple participants from both countries, both patients, family members and clinicians, described how family or next of kin could escalate or cause agitated behaviours and that in such cases, clinicians had to prioritise patient needs and involve family less.

Overall, 86% (n=86/100, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. A total of 77% (n=67/87, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. A significant difference was seen between the ratings of the two countries (U=1154.5, p=0.004), with only 60% (n=18/30) of the Danish participants rating the recommendation as somewhat or very feasible, compared with 86% (n= 49/57) of the Australian participants. Two Australian participants described how it would be easy to include family members

to calm down a patient. A Danish participant described how it was important to involve family members in care, but not in personal care activities

> Culturally, we in Denmark do not have a tradition for involving relatives in personal care. This is related to the patient's dignity and integrity in the long term (Danish physiotherapist, ID 2029).

In summary, the recommendation on involving the family in care reached a high level of consensus in both countries. The recommendation also received high ratings in terms of importance. However, while the recommendation reached high ratings in terms of feasibility in Australia, it was seen as less feasible in the Danish context. It is unclear why the recommendation was less feasible to carry out in the Danish context, but it may be related to cultural barriers and the belief that family members should be family members and not carers. The qualitative comments suggested clinicians should be very careful when involving families in care to ensure they have the capacity to be involved and to safeguard them from feeling guilty or responsible for patient care. Furthermore, the family of adult patients should not be involved in intimate care activities to support the dignity and integrity of both patient and family members.

#### *8.9.2.3 Recommendation 5.2.3: use telephone and/or video conferencing when family members/next of kin are unable to visit the patient in person*

This recommendation reached a consensus level of 83.3% (n=80/96, 95% CI: 0.75 – 0.89, Mdn 4, M 4.19, IQR 1). Participants described how telephone conversations and/or video conferences had become good alternatives to face-to-face meetings, although physical contact was seen as much more useful in calming down a restless and agitated patient. A Danish patient explained:

> It is a good idea with telephone or video meetings with relatives. I experienced an episode where I was very sad and confused. I missed my husband and our children. It helped me to hear my husband's voice, even though it was just a few minutes. It was difficult for me to speak, but I just needed to hear his voice. It helped me a lot (Danish patient, ID 2003).

Clinicians described how phone and video calls had to be managed well to avoid patients getting overly exhausted or agitated. Clinicians explained how it was an advantage when patients and family members were familiar with the methods used.

Overall, 93.8% (n=91/97, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. A total of 89% (n=77/87, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for using telephone and video conferences reached a very high level of consensus in both countries. The recommendation also received very high ratings in terms of importance, and high rating in terms of feasibility.

## 8.10 Theme 6: psychosocial needs

This large theme comprised four categories and included 22 recommendations related to reorientating patients and helping them feel safe, comfortable, relaxed and empowered (see Table 50).

**Table 50 Theme 6: psychosocial needs**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Help patients to feel safe | 6.1.1 | Reassure the patient that they are safe. | 94 | 99 | 96 (28) |
| | 6.1.2 | Hold a patient's hand. | 89 | 94 | 83 (58) |
| Empower the patient | 6.2.1 | Involve patients in personal care activities. | 92 | 91 | 95 (44) |
| | 6.2.2 | Debrief the capable patient after an episode of agitation. | 88 | 85 | 89 (51) |
| | 6.2.3 | Use neuropaedagogy[b]. | 82 | 72 | 69 (62) |
| | 6.2.4 | Involve a psychologist or psychiatrist in the treatment plan. | 77 | 51 | 70 (63) |
| | 6.2.5 | Respect patients' need for personal space. | 94 | 85 | 95 (39) |
| | 6.2.6 | Ensure patient dignity. | 99 | 97 | 99 (6) |
| Comfort and relaxation | 6.3.1 | Ensure comfortable surroundings (i.e. by optimising room temperature, ventilation and/or design). | 84 | 73 | 94 (36) |
| | 6.3.2 | Offer a fidget toy. | 83 | 73 | 74 (61) |
| | 6.3.3 | Play classical or relaxing music, preferably adjusted to patient preferences. | 89 | 85 | 84 (59) |
| | 6.3.4 | Take the patient outdoors. | 92 | 70 | 86 (53) |
| | 6.3.5 | Use pet therapy. | 86 | 42 | 78 (60) |
| | 6.3.6 | Use therapeutic touch. | 82 | 89 | 81 (56) |
| Re-orientation | 6.4.1 | Inform the patient about the plan for the day. | 88 | 95 | 95 (42) |
| | 6.4.2 | Use a personalised fixed daily schedule with familiar activities. | 89 | 82 | 87 (57) |
| | 6.4.3 | Irrespective of how much the patient appears to understand, explain to them their circumstances. | 95 | 96 | 94 (40) |
| | 6.4.4 | Use hearing aids in the hearing-impaired patient. | 100 | 98 | 99 (3) |
| | 6.4.5 | Use visual aids in the vision-impaired patient. | 97 | 100 | 98 (7) |
| | 6.4.6 | Use appropriate lighting adjusted according to the time of the day. | 97 | 93 | 98 (29) |
| | 6.4.7 | Create familiar surroundings (e.g. with pictures or other items from the patient's home). | 94 | 94 | 93 (48) |
| | 6.4.8 | Have a clock and calendar visible to the patient. | 93 | 94 | 98 (33) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference (p<0.05) in ratings between countries AND one country rating below 75%

### 8.10.1 Category 6.1: help patients to feel safe

#### *8.10.1.1 Recommendation 6.1.1: reassure the patient that they are safe*

This recommendation reached a consensus level of 93.9% (n=107/114, 95% CI: 0.88 – 0.87, IQR 0). Participants described how reassuring patients that they were safe and cared for decreased anxiety, stress and agitation. Two participants described how reassurance only worked if patients trusted the staff.

Overall, 96.1% (n=99/103, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 99% (n=88/89, Mdn 5, IQR 0) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on reassuring patients that they are safe reached a very high level of consensus in both countries. The recommendation was also very highly rated in terms of importance and feasibility.

#### *8.10.1.2 Recommendation 6.1.2: hold a patient's hand*

This recommendation reached a consensus level of 88.6 % (n=101/114, 95% CI: 0.81 – 0.93, Mdn 4, M 4.30, IQR 1). Participants explained how holding a hand signalised that someone cared for, looked after and wanted to connect with the patient. Several, both Danish and Australian, clinicians described how this was about being present, "just being there" with the patient. An Australian patient (ID 1005) described how not seeing anybody made her feel alone, anxious and scared. Clinicians also described how patients felt scared and afraid of dying if they felt alone. A Danish physician explained:

> We often experience agitated patients, if they are intubated, calm down and accept treatment if there is a person present with them all the time. Someone to hold their hand, calm them and explain what is going on (Danish physician ID 2033).

While being present could be done in silence, another Danish nurse (ID 2019) described how it could also be doing things together, like watching TV together. Similar to therapeutic touch, it was described how holding a hand could be useful in some patients, but not in all, and perhaps even provoke agitation. One Australian nurse (ID 1027) stated that staff needed to be trained in how to hold a patient's hand to avoid a violent situation, while another Australian nurse (ID 1039) claimed that patient consent should always be sought before holding a hand.

Overall, 82.5% (n=85/103, Mdn 4, IQR 1) of all participants rated this recommendation as somewhat or very important, while 94% (n=84/89, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on holding a patient's hand reached a high level of consensus in both countries. The recommendation was also highly rated in terms of importance and feasibility.

### 8.10.2 Category 6.2: empower the patient

#### *8.10.2.1 Recommendation 6.2.1: involve patients in personal care activities.*

This recommendation reached a consensus level of 91.9 % (102/111, 95% CI: 0.85 – 0.96, Mdn 5, M 4.49, IQR 0). Australian and Danish patients commented on the importance of involving the patient in care to make care more meaningful and support patient confidence. Clinicians described some barriers, such as patients' ability to be involved and some patients being reluctant to or refusing to be involved. A Danish nurse (ID 2012) highlighted that while it was a useful approach, it was important to not constantly be correcting and criticising patients.

Overall, 95% (n=96/101, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. A total of 91% (n=81/89, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for involving patients in care activities reached a very high level of consensus in both countries. The recommendation was also very highly rated in terms of importance and feasibility.

#### *8.10.2.2 Recommendation 6.2.2: debrief the capable patient after an episode of agitation.*

This recommendation reached a consensus level of 88.2 % (n=75/85, 95% CI: 0.80 – 0.93, Mdn 5, M 4.46, IQR 0). From the few comments on this recommendation, it was clear that participants had slightly different understandings of debriefing and when it should be done. A Danish patient (ID 2003) seemed to think debriefing involved explaining to the patient their situation, which she believed helped her significantly. A Danish researcher (ID 2008) described how they debriefed patients one year after ICU discharge but questioned how useful it would be to debrief an agitated patient. A Danish nurse (ID 2020) described how nobody talked to patients about their episodes of agitation unless the patient started the conversation. A Danish physician stated that debriefing could be useful, but it really depended on what was meant by debriefing:

> I find that patients who are delirious, and thus sometimes agitated, do not always remember what they have done. And if they do, they are very sad and ashamed. I don't know exactly what is meant by 'debriefing'. If it just means talking to the patient about what happened, that's fine – that is what we do - but if there's something more systematic about it, then I don't know how useful it is (Danish physician, ID 2033).

Overall, 89% (n=81/91, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important, while 85% (n=71/84, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for debriefing a patient after an episode of agitation reached a high level of consensus in both countries. The recommendation was also highly rated in terms of importance and feasibility. From the qualitative comments, there seem to be come uncertainties around how this recommendation should be carried out.

#### *8.10.2.3 Recommendation 6.2.3: use neuropaedagogy*

Neuropaedagogy is as a method building on knowledge of how the brain works, the patient's specific brain damage and knowledge about the individual patient (Thybo, 2013). The method focuses on getting a holistic picture of the patient and their strengths rather than focusing on their weaknesses (Fredens, 2012). The recommendation was developed based on a comment from a Danish physiotherapist (ID 2043) in round one, stating that neuropaedagogy was very useful. In round two, the recommendation reached a consensus level of 82 % (n=37/45, 95% CI: 0. 69 – 0.91, Mdn 4, M 4.21, IQR 1). There was a statistically significant difference seen between stakeholder groups (H (3) =14.06, p=0.003, $\eta^2$ 0.252, d=1.159. More precisely, the difference was seen between physicians and patients/families (p=0.017) and physicians and allied health (p=0.001), with no physicians (n=0/4) findings the recommendation very useful, compared with 83.3% (n=5/6) of patients/families and 87.5% (n=7/8) of allied health. The only comment on the recommendation came from a Danish patient:

> Neuropaedagogy is very relevant. It provides insight into why the patient responds the way he does. What lies behind the actions and behaviours? In my opinion and experience, the holistic and humanistic approach is missing. Of course, it is difficult to prioritise this in the acute stages of admission. But except for this, it is important to look at the whole person, and unfortunately, from my experiences, this does not happen (Danish patient, ID 2003).

Overall, only 68.9% (n=42/61, Mdn 4, IQR 2) of all participants rated this recommendation as somewhat or very important. However, a significant difference was seen between the two countries (U=306.5, p=0.031), with 75% of the Danish participants (n=15/24) rating the recommendation as somewhat or very important, compared with 64.9% (n=24/37) of the Australian participants. Overall, only 72% (n=26/36, Mdn 4, IQR 2) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation of using neuropaedagogy reached a high level of consensus in both countries. However, the recommendation was seen overall as less (<75%) feasible, and the Australian cohort saw the intervention as less (<75%) important.

#### *8.10.2.4 Recommendation 6.2.4: involve a psychologist or psychiatrist in the treatment plan*

This recommendation reached a consensus level of 76.9 % (n=70/91, 95% CI: 0.67 – 0.84, Mdn 4, M 4.13, IQR 1). The lower 95% CI is below 75, indicating that the true value may be less than 75%. Participants described how psychiatrists or psychiatric nurses were seen as helpful advisors around medication and the use of de-escalation strategies, in particular, in patients with a psychiatric background. It was also described how psychologists provided patients with an opportunity to talk to someone who was not directly involved in care and could help patients with long-term issues such as PTSD. An Australian nurse explained:

> Ideally, we should have psychology services available to these patients because, very often, we see untreated mental illness or poorly supported neurodiversity as being a key reason for their situation in ICU. Psychology services could help to provide these patients with key tools to get them through their stay in ICU and hospital without escalating agitation and the consequences of these incidents (physically restraining the patient, forcibly injecting them) and related trauma (Australian nurse, ID 1082).

Participants also mentioned some concerns related to this recommendation, including psychiatrists not fully understanding agitation and delirium in an ICU (Danish physician, ID 2033), psychologists only visiting people who are able to communicate verbally (Australian nurse, ID 1053), and finally there were concerns related to lack of resources in individual units.

Overall, 69.6% (n=64/92, Mdn 4, IQR 2) of all participants rated this recommendation as somewhat or very important. A total of 51% (n=40/79, Mdn 4, IQR 2) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation of involving a psychiatrist or psychologist in the treatment plan reached a high level of consensus in both countries. However, the recommendation was seen as less (<75%) important and not very (≤50%) feasible.

#### *8.10.2.5 Recommendation 6.2.5: respect patients' need for personal space.*

This recommendation reached a consensus level of 93.8% (n= 105/112, 95% CI: 0.88 – 0.97, Mdn 5, M 4.69, IQR 0). Participants described the importance of maintaining a physical and psychological distance that felt comfortable for the patient. Meanwhile, it was also noted that this could be challenging in the ICU, in particular when dealing with an agitated patient who needed several life-saving interventions and/or who was at risk of removing equipment.

Overall, 95% (n=96/101, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important, while 85% (n=76/89, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on respecting patients' needs for personal space reached a very high level of consensus in both countries. In addition, it received very high ratings in terms of importance and feasibility.

#### *8.10.2.6 Recommendation 6.2.6: ensure patient dignity*

This recommendation reached a consensus level of 99.1 % (n=112/113, 95% CI: 0.95 – 1, Mdn 5, M 4.83, IQR 0). An Australian nurse provided an example of how ensuring dignity played a role in managing agitation:

> I recently witnessed a patient become extremely agitated over a twelve-hour (or so) period. The patient was sedated with Precedex. Once the chemical sedation was removed, and the patient was awake enough, he expressed that he wanted to be taken to the bathroom to have his bowels open (the patient had been given a pan overnight several times). After some hesitation, the physio and nurse took the patient to the bathroom, where he had his bowels open. After this the patient returned, and his level of agitation had significantly lowered, indicating to me that ensuring the patient's dignity is extremely useful (Australian Nurse, ID 1035).

An Australian nurse (ID 1016) explained how it could be difficult to maintain patient dignity when patients were confused and displayed behaviours which they would not do under normal circumstances.

Overall, 99% (n=101/102, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 97% (n=85/88, Mdn 5, IQR 0) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on ensuring patient dignity reached a very high level of consensus in both countries. The recommendation was also very highly rated in terms of importance and feasibility.

### 8.10.3 Category 6.3: comfort and relaxation

#### *8.10.3.1 Recommendation 6.3.1: ensure comfortable surroundings (i.e. by optimising room temperature, ventilation and/or design)*

This recommendation reached a consensus level of 84% (n=89/106, 95% CI:0.76- 0.90, Mdn 5, M 4.41, IQR 1), agreed that it was useful to ensure comfortable surroundings (i.e. by optimising room temperature, ventilation and/or design). A significant difference was seen in rating between stakeholder groups ($H(4) = 21.06$, $p<0.001$, $\eta^2$ 0.169, d=0.902). The significant differences were seen between patients/families and researchers (p=0.027), physicians (p=0.019) and nurses (p=0.032). There were also significant differences between Allied health and researchers (0.045) and physicians (0.019). While 92.3% (n=12/13) of the Allied health group and 100% (n=11) of patients/families rated comfortable surroundings to be very useful, only 28.6% (n=2/7) of physicians, 20% (n=1/5) of researchers and 51.4% (n=36/70) rated the recommendation as very useful. Participants suggested how in addition to room temperature, ventilation and design, it was important to think of light and being able to look out a window. Participants also mentioned the challenges of changing the physical space in the ICU, light, noise, ventilation and room temperature.

Overall, 93.9% (n=93/99, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important, while only 73% (n=65/89, Mdn 4, IQR 2) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for ensuring comfortable surroundings reached a high level of consensus in both countries. The recommendation was very highly rated in terms of importance but was perceived to be less feasible.

#### *8.10.3.2 Recommendation 6.3.2: offer a fidget toy*

A fidget toy was described in the survey as an object designed to be touched, squeezed or pulled to keep restless hands occupied. The recommendation reached a consensus level of 82.5% (n=66/80, 95% CI:0.73 – 0.89, IQR 1). While participants explained how they had good experiences with using fidget toys, which could also just be normal children's toys or even a magazine, other participants described how they were concerned about infection control, the need for staff supervision and the risk of patients throwing the toy.

Overall, only 74.4% (n=67/90, Mdn 4, IQR 2) of all participants rated this recommendation as somewhat or very important. Overall, 73% (n=58/79, Mdn 4, IQR 2) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for using a fidget toy reached a high level of consensus in both countries. However, it was noticed that the lower confidence interval was 0.73, suggesting that the true value might be below 75%. Furthermore, the recommendation was seen as less important and less feasible in both countries.

#### *8.10.3.3 Recommendation 6.3.3: play classical or relaxing music, preferably adjusted to patient preferences.*

This recommendation reached a consensus level of 88.9%, n=88/99, 95% CI: 0.81 – 0.94, Mdn 4, M 4.23, IQR 1). Participants explained how the music had to be monitored with a time limitation and assessment of the effect on the patient. It was described how, for some patients, the music might be perceived as noise.

Overall, 83.8% (n=83/99, Mdn 4, IQR 1) of all participants rated this recommendation as somewhat or very important. However, a significant difference was seen between the ratings of the two countries (U=1434, p=0.018), with only 72.2% (n=26/36) of Danish participants rating the recommendation as somewhat or very important, compared with 90.5% (n=57/63) of Australian participants. A total of 85% (n=74/87, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. It is unclear why this recommendation was seen as less important by the Danish participants.

In summary, the recommendation for playing relaxing or classical music reached a high level of consensus in both countries. However, Danish participants rated the recommendation less important (<75%). The recommendation received high ratings in terms of feasibility in both countries.

#### *8.10.3.4 Recommendation 6.3.4: take the patient outdoors*

This recommendation reached a consensus of 92.4% (97/105, 95% CI: 0.86 – 0.96, Mdn 5, M 4.52, IQR 1). An Australian nurse explains why taking the patient outdoors was seen as useful:

> Taking them out to an open space and getting some sun exposure during the morning will help improve their mood and somehow calm patients down and improve their behaviours (Australian nurse, ID 1044).

While participants described the importance of taking patients outdoors, there were also some concerns. Clinicians described how patients needed to be haemodynamically stable, not require too much monitoring and equipment, and finally, not exhibit behaviours posing a risk to staff safety.

One Australian nurse (ID 1067) was apprehensive about the idea, claiming patients would love it so much they would become agitated if not supported to do it again:

> Taking patients outdoors can provoke ongoing agitation for repetition of the outdoor activity which might not be possible to achieve (Australian nurse ID 1067).

An Australian nurse (ID 1033) claimed that patients who were able to be taken outside were not sick enough to be in ICU. Finally, three Australian participants described how their ICUs did not offer an outdoor area for patients.

Overall, 85.9% (n=85/99, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important, while only 70% (n=62/88, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation of taking the patient outdoors reached a very high level of consensus in both countries. While the recommendation was also highly rated in terms of importance, it was overall seen as less feasible.

#### *8.10.3.5 Recommendation 6.3.5: use pet therapy*

Pet therapy was described in the survey as a method involving an animal, often a dog or cat, visiting the patient in the intensive care unit. The recommendation reached a consensus level of 86.1% (n=68/79, 95% CI: 0.77 – 0.92, Mdn 5, M 4.29, IQR 1). Participants from both countries, both clinicians and patients, described how pet therapy was useful. However, multiple barriers existed, including infection control issues and the risk of allergies among other patients and staff. One participant described how they offered pet therapy for long-term patients who were able to be brought outside the hospital to meet their pet.

Overall, 77.6% (n=66/85, Mdn 4, IQR 1) of all participants rated this recommendation as somewhat or very important, while only 42% (n=33/78, Mdn 3, IQR 2) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for pet therapy reached a high level of consensus in both countries. While the recommendation also received high ratings in terms of importance, pet therapy was not seen as being very feasible in the ICU. Qualitative comments suggested issues related to infection control and the risk of allergies amongst staff and patients.

#### *8.10.3.6 Recommendation 6.3.6: use therapeutic touch*

Therapeutic touch was described in the survey as a method using the hands to touch and calm a patient. This recommendation reached a consensus level of 82.4 % (n=84/102, 95% CI: 0.74 – 0.89, IQR 1). It is important to notice that the lower 95% confidence level (LCL) goes below 75% (LCL=74%), potentially affecting the validity of this recommendation.

While participants agreed to the recommendation, they emphasised the importance of considering the individual patient, as some patients would not appreciate that kind of touch from health professionals. Touch was also described by some as inappropriate for the very agitated patient. Finally, it was described how staff needed to feel comfortable using this method too. A Danish nurse explains:

> To have a positive effect, it [therapeutic touch] depends on nurses' personalities and if they feel calm within (Danish nurse, ID 2012).

Overall, 81.1% (n=77/95, Mdn 4, IQR 1) of all participants rated this recommendation as somewhat or very important, while 89% (n=73/82, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for using therapeutic touch reached a high level of consensus in both countries. The recommendation was also rated highly in terms of importance and feasibility.

### 8.10.4 Category 6.4: re-orientation

This category comprises five recommendations and describes how using different means to orientate the patient can help reduce and manage agitation. An Australian physician explained how sensory deficits in the critically ill patient added to patient distress and agitation:

> Sensory deficits may decrease the patient's awareness and understanding of their surroundings, increasing distress and potentially making them appear agitated or non-compliant (Australian physician, ID 1070).

An Australian family member explained how orientation could give the patient a sense of control and understanding, which could, in turn, reduce agitation:

> Schedules, clocks, and lighting adjusted to the time of day are all things which provide balance, rhythm and stability to a patient when everything else is out of their control, and sometimes also understanding. Being told the plan for the day (having it written somewhere for the patient (and family) to see provides reassurance and a sense of control/ understanding regarding their care, helping to reduce frustration and agitation (Australian family member, ID 1063).

#### *8.10.4.1 Recommendation 6.4.1: inform the patient about the plan for the day*

This recommendation reached a consensus level of 87.6 % (n=99/113, 95% CI: 0.80 – 0.92, Mdn 4, M 4.40, IQR 1).

A Danish nurse explained how knowing about the plan for the day could reduce patient frustrations:

> Predictability may give rise to cooperation and adherence to agreements, thus minimising the risk of escalating conflicts. It also minimises the risk of escalating conflict (Danish nurse, ID 2027).

Concerns were related to providing too much information (See the recommendation: explain their circumstances). Participants suggested using a white or blackboard when staff were unavailable

Overall, 95.1% (n=97/102, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. A total of 95% (n=84/88, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation to inform the patient about the day reached a very high level of consensus in both countries. The recommendation was also rated highly in terms of importance and very highly in terms of feasibility.

#### *8.10.4.2 Recommendation 6.4.2: use a personalised fixed daily schedule with familiar activities*

This recommendation reached a consensus level of 88.6 % (n=93/105, 95% CI: 0.81- 0.93, Mdn 5, M 4.38, IQR 1). The recommendation was seen as particularly useful for long-term patients who needed to be kept motivated and overcome fatigue. Some participants expressed how schedules needed to be flexible and adaptable to patient needs. Finally, it was described how having a fixed schedule was not very feasible in the ICU.

Overall, 87.1% (n=88/101, Mdn 4, IQR 0) of all participants rated this recommendation as somewhat or very important. A total of 82% (n=71/87, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation using personalised fixed daily schedules received a very high level of consensus in both countries. The recommendation was rated highly in terms of importance, and feasibility.

#### *8.10.4.3 Recommendation 6.4.3: irrespective of how much the patient appears to understand, explain to them their circumstances*

This recommendation reached 94.7% consensus (n=107/113, 95% CI: 0.89 – 0.98, Mdn 5, M 4.48, IQR 1). The importance of this recommendation was especially highlighted by previous patients and family members. A Danish patient explained:

> From my experience staff can't provide too much information or too many explanations. If staff had informed me better, I would have avoided all the frustrations/agitation I experienced (Danish patient, ID 2003).

An Australian family member also described the importance of providing patients with information:

> So for all that time, she had been lying there confused and waiting to be told why she was in the hospital and what was happening to her (Australian family, ID 1066).

Clinicians from both countries described concerns about providing too much information. It was described how too much talk and explanations could annoy, disturb and make a patient angry. A

An Australian nurse disagreed with the recommendation and described how she believed it was wrong to explain the circumstances:

> I don't explain the circumstances. I endlessly hear people being told, “you are in a hospital- just relax”. It never works. Explaining just sounds like a lecture (Australian nurse, ID 1022).

Overall, 94.2% (n=97/103, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. A total of 96% (n=85-89, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on explaining to patients their circumstances received a very high level of consensus in both countries. The recommendation was also rated highly in terms of importance and feasibility.

#### *8.10.4.4 Recommendation 6.4.4: use hearing aids in the hearing-impaired patient*

This recommendation reached a consensus level of 100% (n=106/106, 95% CI: 0.97- 1, Mdn 5, M 4.92, IQR 0). An Australian nurse (ID 1012) pointed out the importance of using hearing aids correctly, as a high-pitched squeal could be distressing for a patient.

Overall, 99% (n=101/102, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 98% (n=87/89, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on using hearing aids reached a very high level of consensus in both countries. The recommendation was also very highly rated in terms of importance and feasibility.

#### *8.10.4.5 Recommendation 6.4.5: use visual aids in the vision-impaired patient*

This recommendation reached a consensus level of 97,2% (n=103/106, 95% CI:92- 99, Mdn 5, M 4.83, IQR 0). There were no comments on this recommendation.

Overall, 98.1% (n=101/103, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important. All participant rating this recommendation (n=89/89, Mdn 5, IQR 1) rated the recommendation believed it was somewhat or very feasible. However, a significant difference was seen between the ratings of the two countries (U=1106.5, p=0.031), with only 59.4% (n=19/32) of the Danish participants rating very feasible compared with 80.7% (n=46/57) of the Australian participants.

In summary, the recommendation for using visual aims reached a very high level of consensus in both countries. The recommendation was also very highly rated in terms of importance and feasibility.

#### *8.10.4.6 Recommendation 6.4.6: use appropriate lighting adjusted according to the time of the day*

This recommendation reached a consensus level of 97.2 % (n=106/109, 95% CI: 0.92 – 0.99, Mdn 5, M 4.77, IQR 0). A Danish physician (ID, 1035) described how red light seemed to trigger agitation, and that while darkness was good for some during the night, others would feel afraid and hallucinate. Some Australian participants described how they were unable to adjust the lights in their ICUs.

Overall, 98% (n=99/101, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 93% (n=81/87, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, this recommendation reached a very high level of consensus in both countries and was rated very highly in terms of importance and feasibility.

#### *8.10.4.7 Recommendation 6.4.7: create familiar surroundings (e.g. with pictures or other recommendations from the patient's home)*

This recommendation reached 93.7 % (n=104/111, 95% CI: 0.88 – 0.97, Mdn 5, M 4.50, IQR 1) consensus. A Danish nurse (ID 2046) described how familiar smells from home could also be comforting; for example, a patient who usually smoked could be given his t-shirt as a pillow. Australian participants described concerns about the clutter in the room, making it challenging to maintain infection control and access safety equipment.

Overall, 93.1% (n=95/102, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 94% (n=88/89, Mdn 5, IQR 0) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for creating familiar surroundings reached a very high level of consensus in both countries. The recommendation was also very highly rated in terms of importance and feasibility.

#### *8.10.4.8 Recommendation 6.4.8: have a clock and calendar visible to the patient*

This recommendation reached a 92.8 % (n=103/111, 95% CI: 0.86 – 0.96, Mdn 5, M 4.62, IQR 1) consensus level. Concerns related to this recommendation included noise from a ticking clock disturbing patient sleep, patient distress if a clock was all they saw, and finally, patients not understanding calendars and clocks due to their decline in cognition.

Overall, 94% (n=87/89, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important, while 94% (n=84/89) rated the recommendation as somewhat or very feasible.

In summary, the recommendation of having a clock and a calendar visible to patients reached a very high level of consensus in both countries. It was also rated very highly concerning both importance and feasibility.

## 8.11 Theme 7: physical needs

This theme consisted of three categories and included eight recommendations related to mobilisation of patients, ensuring the right level of stimuli and promotion of sleep (see Table 51).

**Table 51 Theme 7: physical needs**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Mobilise patients | 7.1.1 | Support capable patients to be physically active (e.g. by supporting patients to sit on the edge of the bed or take small walks) | 99 | 92 | 99 (16) |
| Ensure the right level of stimuli | 7.2.1 | Minimise unnecessary stimuli[b]. | 97 | 80 | 98 (23) |
| | 7.2.2 | Group care and treatment activities, rather than disturbing the patient several times. | 96 | 92 | 97 (21) |
| | 7.2.3 | Clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients (stimuli can be auditory, e.g. sounds, visual, e.g. lights or moving objects, tactile, e.g. lines or equipment, social, e.g. interacting with people) | 87 | 92 | 90 (41) |
| | 7.2.4 | Offer quiet surroundings for the patient, for example a single bed room. | 95 | 83 | 95 (38) |
| | 7.2.5 | Use mental stimulation such as Lego, jigsaws, radio, TV, internet, magazines, pictures[c] | 88 | 80 | 85 (54) |
| Promote sleep | 7.3.1 | Preserve patients' usual sleep-wake cycle[b]. | 98 | 80 | 97 (24) |
| | 7.3.2 | Minimise interruptions at night from noise, light and activities. | 100 | 91 | 100 (4) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference (p<0.05) in ratings between countries AND one country rating below 75%

### 8.11.1 Category 7.1: mobilise patients

#### *8.11.1.1 Recommendation 7.1.1: support capable patients to be physically active (e.g. by supporting patients to sit on the edge of the bed or take short walks)*

This recommendation reached a consensus level of 99.1 % (n=112/113, 95% CI: 0.95 – 1, Mdn 5, M 4.78, IQR 0). Physical activity was described as an important way to prevent agitation by facilitating better sleep, calming and stimulating a patient. A Danish physiotherapist explained:

> Supporting, even very weak patients, to a sitting position on a firm surface, of cause with massive support and firm ground under their feet, can calm down a patient. They can feel their body in a different position than the lying (Danish physiotherapist, ID 2042).

A family member described how assisting patients to move was essential in increasing patient wellbeing:

> Movement wherever possible is "critical". It provides a small sense of self-control and patient contribution to a patient's experience in ICU. Being left to lie in bed without any attempts to assist movements can make patients feel frustrated and controlled, increasing agitation (Australian Family, ID 1063).

An Australian physician described how mobilisation could also be helpful in a subset of agitated patients.

> Helping to mobilise an agitated patient is very useful and can help with distraction but is very limited to a specific subset of patients (Australian physician, ID 1052).

Overall, 99% (n=95/98, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 92% (n=83/90, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for keeping patients physically active, reached a very high level of consensus in both countries, and was also rated very highly both in terms of importance and feasibility.

### 8.11.2 Category 7.2: ensure the right level of stimuli

This category included seven recommendations that overlap each other in several ways. Overall, the category describes how clinicians should ensure the correct level of stimulation, often involving protection from unnecessary stimuli and promoting sleep, rest and patient privacy.

#### *8.11.2.1 Recommendation 7.2.1: clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients (stimuli can be auditory, e.g. sounds, visual, e.g. lights or moving objects, tactile, e.g. lines or equipment, social, e.g. interacting with people)*

This recommendation reached a 97% (n=101/104, 95% CI: 0.92- 0.89, Mdn 5, M 4.68, IQR 0) consensus level. The recommendation was developed based on comments in round one describing the importance of reducing different types of stimuli. The recommendation was rated and validated in round two. A couple of participants mentioned that it would be difficult to achieve in the ICU. One Australian family member offered a different view:

> I think sensory deprivation is a big factor in agitation. I would prefer to be in an environment with plenty of activity, people and sound (Australian family member, ID 1003).

Overall, 98% (n=100/102, Mdn 5, IQR 0) rated this recommendation somewhat or very important. A total of 80% (n=70/88, Mdn 4, IQR 0.75) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on minimising stimuli reached a very high level of consensus in both countries. The recommendation was also rated very highly in terms of importance and rated highly in terms of feasibility.

#### *8.11.2.2 Recommendation 7.2.2: group care and treatment activities, rather than disturbing the patient several times*

This recommendation reached a consensus level of 95.6% (108/113, 95% CI: 0.90 – 0.98, Mdn 5, M 4.72, IQR 0). While clustering care was overall seen as useful, in particular at night-time, participants also emphasised the importance of considering the patient's capacity and energy levels. For instance, clustering too many activities could result in patients becoming exhausted and potentially more agitated. A Danish occupational therapist explained how this could be done:

> I experience it is essential to consider the patient's energy levels. Perhaps it is only possible to do the most important thing, for instance, to change a nappy. Then give the patient time to rest, before helping the patient again, perhaps with brushing their teeth (Danish occupational therapist, ID 2044).

Overall, 97.1% (n=100/103, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 92% (n=83/90, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation on grouping care activities reached a very high level of consensus in both countries. The recommendation was also rated very highly in terms of importance and feasibility.

#### *8.11.2.3 Recommendation 7.2.3: clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients (e.g., avoid unnecessary glucose monitoring, endotracheal suctioning, and neurological checks)*

This recommendation reached a consensus level of 87.3% (n=89/102, 95% CI: 0.79- 0.92, Mdn 5, M 4.46, IQR 1). An Australian nurse emphasised why this recommendation was important:

> Routine invasive devices or procedures (IDCs [indwelling urinary catheter], arterial lines, 12 lead monitoring, daily bloods, SpO2 [pulse oximetry] monitoring) should be carefully considered - are they actually necessary? Is the patient acutely unwell, or are they really a bed-blocked ward patient going through withdrawal who needs sleep, food and quiet? An accumulation of these interventions and interruptions to sleep can lead to the build-up of agitation (Australian nurse, ID 1082).

A Danish physician explained why he agreed:

> It is absolutely essential not to wake up a delirious patient who is finally sleeping (Danish physician, ID 2035).

An Australian family member explained:

> ICU generally is a very noisy place, and patients are rarely actually able to 'rest' or sleep… constant care and treatment activities are high frequency and exhausting in themselves, quite clearly contributing to increasing agitation (Australian family, ID 1063).

While there was an overall agreement with the recommendation, participants also described how it could be challenging to judge what kind of interventions were less important to patient outcomes. This was, in particular, true for novice practitioners. Participants explained how decisions should be based on professional judgement by experienced practitioners. A Danish nurse illustrated:

> I very much agree that we should, if possible, reduce routine interventions around the agitated patients, including the reduction of monitoring. However, it is important that the decision is based on professional judgement and not as a part of a fixed algorithm (Danish nurse, 1013).

Clinicians described the risk of not identifying patient deterioration. An Australian nurse gave an example where an agitated patient was left alone to calm down:

> There was a detrimental incident where the patient removed all invasive lines and left partial ECG monitoring attached. The patient was left alone to calm down but died because the patient went into PEA [Pulseless electrical activity] with unknown downtime (Australian nurse, ID 1072).

An Australian manager described how patient deterioration was missed due to staff letting the patient sleep:

> I once witnessed a SAH [Subarachnoid hemorrhage] patient that was extremely confused and aggressive sustain a vasospasm [narrowing of blood vessel] because nursing staff convinced the medical officer to let the patient sleep and not receive neurological observations hourly (Australian Nurse Manager ID 1040).

Finally, participants highlighted the importance of carefully handling the questions around monitoring on a case-to-case basis and documenting the final decisions in both nursing and medical journals.

All participants (n=103/103), Mdn 5, IQR 0) rated this recommendation as somewhat or very important, and 92% (n=83/90, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for minimising routine interventions reached a high level of agreement in both countries. It was also rated very highly in terms of both importance and feasibility. Although participants agreed that routine interventions less important to patient outcomes should be left out, several qualitative comments highlighted that leaving out interventions should be done carefully, and only qualified staff should make such decisions.

#### *8.11.2.4 Recommendation 7.2.4: offer quiet surroundings for the patient, for example a single bed room*

This recommendation reached a consensus level of 94.6% (n=106/112, 95% CI: 0.89 – 0.98, Mdn 5, M 4.71, IQR 0). Several participants described the importance of ensuring calm surroundings and reducing patient stimuli. However, some concerns existed. Clinicians explained how it could be dangerous to move an intubated agitated patient, how staff could feel isolated in a single bed room and struggle to get immediate support. Finally, a couple of patients described how they preferred having more people around.

Overall, 95.1% (n=98/103, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. A total of 83% (n=75/90, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. Some participants described how it was not always possible to find an appropriate quiet bed space.

In summary, this recommendation for offering quiet surroundings reached a very high level of consensus in both countries. The recommendation also reached very high ratings in terms of importance and feasibility.

#### *8.11.2.5 Recommendation 7.2.5: use mental stimulation*

Mental stimulation was defined in the survey as activities such as Lego, jigsaws, radio, TV, internet, magazines, and pictures. This recommendation reached 85.9% (n=61/71, IQR 1) consensus in Australia in the first round, but only 73.5% (n=25/34, IQR 1) consensus in Denmark. However, when re-rated in the second round, the recommendation reached 88% (n= 89/101, 95% CI 0.80 – 0.93, Mdn 4, M 4.21, IQR 1) consensus in both countries.

In the second round, a significant difference was seen in rating between stakeholder groups ($H(4) = 10.61$, $p=0.031$, $\eta^2 0.066$, $d=0.532$). When explored further, it was found that the ratings between

physicians and patients/families were significantly different (p=0.032). No physicians (0/9) rated this recommendation as very useful, while 60% (n=6/10) of patients/families did.

Participants explained how mental stimulation could activate patients in positive ways. However, there were also concerns related to the recommendation. Participants described how some patients could not participate due to their cognitive decline and how others would get irritated or hyper-stimulated, leading to agitated behaviours.

Overall, 85.3% (n=87/102, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important, while a total of 80% (n=69/86, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation for stimulating patients mentally reached a high level of consensus in both countries. The recommendation was also highly rated in terms of importance and feasibility.

### 8.11.3 Category 7.3: promote sleep

#### *8.11.3.1 Recommendation 7.3.1: preserve patients' usual sleep-wake cycle*

This recommendation reached a consensus level of 98% (n=101/103, 95% CI: 0.93 – 0.99, Mdn 5, M 4.68, IQR 1). This recommendation was developed based on several comments in the first Delphi round. A Danish researcher highlighted:

> There should be a major focus on maintaining a circadian rhythm with activities during the day and (preferably) sleep at night. It's hard to implement but is really good when it works (Danish researcher, ID 1033).

The recommendation was supported by participants in the second round. A Danish nurse explained:

> Interrupted or altered circadian rhythm may be a contributing factor to patients developing a state of confusion and/or agitation. Therefore, the normal circadian rhythm must be supported. For example, mobilisation or walking can be a contributing factor in promoting patients' natural fatigue (Danish Nurse, ID, 2025).

There were some concerns related to the recommendation. For instance, a Danish physiotherapist (ID 2043) described how patients were likely to require more sleep than usual. Several participants also described how the recommendation would be difficult to implement in the ICU.

Overall, 97.1% (n=100/103, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, and 80% (n=72/90, Mdn 4, IQR 0) rated the recommendation to be somewhat or very feasible. A significant difference was seen between the ratings of the two countries (U=1292.5, p<0.001), with only 66.7% (n=22/33) of the Danish participants rating the recommendation as somewhat or very feasible, compared with 87.7% (n= 50/57) of the Australian participants. In summary, the recommendation to preserve patients' usual sleep-wake cycle

reached a very high level of consensus. The recommendation was also rated very highly in terms of importance, but the recommendation was seen as less feasible by the Danish cohort. The qualitative comments suggested that while clinicians should aim to support patient sleep, reaching patients' normal sleep-wake cycle may not always be possible.

#### *8.11.3.2 Recommendation 7.3.2: minimise interruptions at night from noise, light and activities*

There was a consensus level of 100% (114/114, 95% CI: 0.97 – 1, Mdn 5, M 4.94, IQR 0) on this recommendation. There were no comments on this recommendation. All participants (n=103/103, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 91% (n=82/90, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. In summary, this recommendation on minimising interruptions at night reached a very high level of consensus in both countries. The recommendation was also rated very highly in terms of importance and feasibility.

## 8.12 Theme 8: provide individualised care

This theme consisted of one category with two recommendations (see Table 52).

**Table 52 Theme 8: provide Individualised care**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Importance of individualised care | 8.1.1 | Develop care plans based on patient preferences and values. | 91 | 88 | 93 (46) |
| | 8.1.2 | Non-drug interventions must be adjusted to the individual patient (e.g. patient needs, history and preferences, level of agitation, previous experiences with interventions)[b] | 100 | 94 | 97 (27) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference (p<0.05) in ratings between countries AND one country rating below 75%

### 8.12.1 Category 8.1: importance of individualised care

#### *8.12.1.1 Recommendation 8.1.1: develop care plans based on patient preferences and values.*

This recommendation reached 91.4% (n=96/105, 95% CI: 0.85-0.95, Mdn 5, M 4.61, IQR 0) consensus. The K-W test showed a significant difference between stakeholder groups (H (4) =

13.36, p=0.01. $\eta^2$ 0.094, d=0.643). The post hoc Bonferroni test, testing pairwise comparisons, showed significant differences between researchers and nurses (p=0.023) and researchers and patients/families (p=0.003). Of researchers, 67% (n=4/6) found this recommendation to be very or somewhat useful, compared with 93% (n=64/69) of nurses and 100% (n=10/10) of patients and family members.

Participants commented on the importance of care plans to ensure patient-centred and consistent care. Both patients and family members were considered important sources of information. Concerns related to this recommendation included care plans not being used or communicated consistently by the entire multidisciplinary team. Another concern was related to patient preferences. Some participants described how sometimes it was necessary to do things patients did not want or were resistant to based on the importance of patient outcomes and recovery. One example was mobilisation; another was family visiting hours. An Australian nurse worried that sometimes following patient and family preferences could lead to exploitation and unequal patient treatment:

> A patient's background should not be superior to the rules or legal laws. E.g. family that prefers to have everyone involved or visit patients despite the rules of 2 visitors per day for a certain amount of time. It needs to be justified or implemented with care so that other patients and their families are not being treated unfairly. The risk of this leniency or exemption may also cause further deterioration or manipulation from the patient/family to get what he/she wants (Australian nurse, ID 1072).

Overall, 93.1% (n=94/101, Mdn 5, IQR 1) of participants found this recommendation to be somewhat or very important, while 88% (n=74/84, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, there was a very high level of consensus on the recommendation for developing care plans to reduce and manage agitation, and the recommendation was considered very important and feasible. Researchers rated the recommendation lower than any other stakeholder group, but it is unclear why. While clinicians should be encouraged to build care plans based on patient preferences, they must always consider if such strategies support patient outcomes and recovery.

#### *8.12.1.2 Recommendation 8.1.2: non-drug interventions must be adjusted to the individual patient (e.g., patient needs, history and preferences, level of agitation, previous experiences with interventions)*

This recommendation reached a consensus level of 100% (n=106/106, 95% CI: 0.97 – 1, Mdn 5, M 4.89, IQR 0). This recommendation was developed based on 23 comments from all stakeholder groups in the first Delphi round describing how the usefulness of a NPS always depended on the individual patient, including the level of critical illness, level of agitation and mood on a specific day. An intervention could be useful one day but not the next, be useful for 10 minutes but not for 20 min etc. Overall, 97% (n=99/101, Mdn 5, IQR 0) of all participants rated the recommendation as somewhat or very important, while 94% (n=83/88, Mdn 4, IQR 1) rated the recommendation to be

somewhat or very feasible. In summary, this recommendation highlights the complexity of reducing or managing agitation in the ICU and the importance of being flexible and sensitive to individual patient responses. The recommendation reached a very high level of consensus, importance and feasibility in both countries.

## 8.13 Theme 9: interventions related to the context

This final theme included three categories and six recommendations describing important characteristics of the organisation and unit for preventing, minimising and managing agitation (see Table 53).

**Table 53 Theme 9: interventions related to the context**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Staff support | 9.1.1 | Additional staffing should be considered when there is an agitated patient in the ICU. | 95 | 64 | 96 (17) |
| | 9.1.2 | Staff caring for agitated patients should be offered debriefing. | 86 | 79 | 89 (51) |
| | 9.1.3 | Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift[b]. | 99 | 60 | 94 (19) |
| | 9.1.4 | Ongoing staff education about agitation and methods to reduce agitation should be provided. | 98 | 88 | 97 (37) |
| Leadership support | 9.2.1 | Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation. | 93 | 99 | 98 (47) |
| Multidisciplinary team collaboration | 9.3.1 | The multi-disciplinary team should collaborate to reduce and manage patient agitation. | 99 | 99 | 100 (18) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference ($p<0.05$) in ratings between countries AND one country rating below 75%

### 8.13.1 Category 9.1: support of staff

#### *8.13.1.1 Recommendation 9.1.1: additional staffing should be considered when there is an agitated patient in the ICU.*

This recommendation reached a consensus level of 95% (n=98/103, 95% CI:0.89 – 0.98, Mdn 5, M 4.75, IQR 0). A statistically significant difference was seen in rating between stakeholder groups (H (3) = 18.55, p<0.001, $\eta^2$ 0.148, d=0.835). When explored further, the significances were seen between nurses and physicians (p=0.044) and nurses and allied health (p=0.001). While 89% (66/74) of nurses strongly agreed with the statement, only 50% (n=5/10) of physicians and 46.2% (6/13) of the Allied health group strongly agreed.

Participants explained how a lack of staff resulted in inadequate care for the agitated patient and other patients who were in the unit at the same time as an agitated patient. Lack of staff also posed a risk to patient and staff safety and prevented staff from going on their normal breaks and having time away from the bedside. Finally, it was described how the lack of staff forced staff to use more sedatives. An Australian physician explained:

> Staffing ratios are perhaps the most important aspect of management, as without adequate staffing, there is no ability to deliver nonpharmacological interventions. (Australian physician, ID 1052).

There were some concerns related to additional staffing. Firstly, participants described how the recommendation was not feasible, as staffing levels were unlikely to improve. Secondly, there was the belief that rather than getting more staff, staff caring for this group of challenging patients should be better qualified, either through years of experience or training. An Australian nurse manager commented:

> My personal experience in regard to this recommendation is that bad, or junior nurses, are allocated the confused/agitated ICU patient when in reality, it should be the most senior nurse caring for these patients as they have a myriad of care planning capabilities (nurse manager, ID 1040).

There were also different suggestions as to what comprised *additional staffing*. Some mentioned how a 1:1 ratio was necessary during episodes of agitation, while others believed two staff members were required. An occupational therapist (ID 1083) argued that rather than increasing the number of nurses, which was already 1:1, the number of allied health staff should be increased when patient behaviours escalated.

Overall, 95.7% (n=88/92, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important. Many of the same comments existed as in the first round. An Australian nurse highlighted:

> There is little use for assessing for agitation and knowing about NPSs if we do not have the staffing to manage agitation (Australian nurse, ID 1031).

A total of 64% (n=56/88, Mdn 4, IQR 2) rated the recommendation to be somewhat or very feasible. Some Australian participants commented on how increased levels of staffing was an unrealistic request, as they were already short of staff.

In summary, the recommendation to consider additional staff reached very high levels of consensus and importance in both countries. However, the recommendation was not seen as very feasible in either country. The qualitative comments suggest that additional staff was essential for using NPSs, but the issue was unlikely to change due to the current climate with staff shortages in most places. The qualitative comments also suggested that staffing is complex and considerations must also be given to staff fatigue, qualifications and skills.

#### *8.13.1.2 Recommendation 9.1.2: staff caring for agitated patients should be offered debriefing*

This recommendation reached a consensus level of 86.4% (n=89/103, 95% CI:0.78, 0.92, Mdn 5, M 4.47, IQR 1). Ratings between stakeholder groups differed significantly (H (3) = 11.70, p=0.008, $\eta^2$ 0.088, d=0.621). More specifically, a significant difference (p = 0.004) was seen between physicians and nurses, where only 20% (n=2/10) of physicians strongly agreed to the recommendation, compared with 71.6% (51/74) of nurses. Comments on this recommendation only came from nurses. Nurses from both countries described debriefing as a social support method allowing staff to reflect and put things into perspective, deal with emotional reactions, and learn from an episode. Debriefing was seen as particularly useful after longer patient stays. Some concerns existed about this recommendation, including the method not being patient-centred, lack of time, and debriefing in its current form being ineffective. One participant stated, "all too often, debriefings are a mechanism of staff bullying" (Australian nurse, ID 1022).

Overall, 89% (n=81/91, Mdn 5, IQR 1) of all participants rated this recommendation as somewhat or very important. Participants described how debriefing was essential to providing high levels of care to a challenging group of patients.

A total of 79% (n=69/87, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. Australian nurses described how debriefing was non-existent in their unit. An Australian nurse suggested training staff to conduct debriefing sessions:

> Senior clinicians, including team leaders, should also be trained on how to conduct debriefing properly, not just the kind where you offer kind words and support, but real debriefing where you have to undergo training on how to conduct it, like the use of proper tools like PEARLS or Plus/Delta (Australian nurse, ID 1033).

In summary, this recommendation reached a very high level of consensus in both countries, although physicians rated the recommendation lower than other stakeholder groups. The recommendation was rated very highly in terms of importance, and highly in terms of feasibility. It was noted that all qualitative comments came from nurses, suggesting that the recommendation

may be more relevant to this group. The comments indicated that if conducted by trained professionals in safe environments, debriefing can provide social and psychological support to staff and potentially support staff to provide better care for a challenging group of patients.

#### *8.13.1.3 Recommendation 9.1.3: clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift*

This recommendation reached a consensus level of 99.1 % (n=105/106, 95% CI:0.95-1, Mdn 5, M 4.82, IQR 0). This recommendation was suggested in round one and agreed upon in round two. A Danish nurse explained:

> It is very physically and mentally draining to care for a hyperactive delirious patient, and one's energy and strength quickly get depleted. Breaks and perhaps a change of staff are important (Danish nurse, ID 2018).

The main concern expressed by Australian participants was related to the feasibility of the recommendation, as some staff already struggled to get their usual breaks. Some nurses described how resources were different in different urban and rural ICUs. Danish nurses described how it could be challenging for relief nurses to take over as they did not know the patient, and thus were less able to provide the same high level of care.

Overall, 94.2% (n=97/103, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important. Multiple comments described how caring for this group of patients was challenging both physically and emotionally. It was described how staff needed regular breaks to reduce levels of stress, reset and promote positive emotions. It was also suggested how frequent breaks helped maintain high work performance. Finally, it was described how staff change could be beneficial for the patient too. However, a break should not affect the quality of patient care. Australian family member was concerned:

> Depends on staffing levels at the hospital and whether or not frequent breaks would result in the patient being left alone - as was the case for my mother when she was in ICU (Australian Family, ID 1066).

Only 60% (n=53/88, Mdn 4, IQR 1.75) rated the recommendation to be somewhat or very feasible. Some Australian participants described how the recommendation was not realistic. An Australian nurse stated somewhat sarcastically:

> As it's already a cliché universally and often joked away, clinicians do not get the regular breaks programmed already articulated in the state awards. We wish we got our normal breaks. If we were to get 'more frequent' breaks, that would be beyond reality (Australian nurse, ID 1038).

In summary, the recommendation on ensuring frequent breaks for staff caring for agitated patients reached a very high level of consensus and importance in both countries. The qualitative comments suggested that if continuity of care was ensured while staff went on a break, frequent breaks were described as both necessary and beneficial for staff and patients. Despite the

importance of this recommendation, it was not seen as being very feasible in any of the two countries.

#### *8.13.1.4 Recommendation 9.1.4: ongoing staff education about agitation and methods to reduce agitation should be provided*

This recommendation reached 98% (n=100/102, 95% CI: 0.93- 0.99, Mdn 5, M 4.88, IQR 0) consensus. Multiple comments described how staff lacked knowledge on agitation, including causes of agitation and NPSs as alternatives to pharmacological agents and PR. An Australian nurse commented:

> Some staff don't know how important holding someone's hand or using therapeutic touch is (Australian nurse, ID 1050).

Other participants were concerned that education would simply become a tick-box exercise and that the real issue was staff not being interested in agitation and delirium. A nurse manager stated:

> Perhaps because the delirious and agitated patient is not interesting to ICU nurses.They want the ECMO [extracorporeal membrane oxygenation], the sick ventilated patient with a TOF [assessment of neuromuscular block] of 0 or the tamponade post CABG [coronary artery bypass graft] x4 that requires a chest reopening. From the perspective of the manager, this is ever prevalent as staff anecdotally mention they never get the "cool" allocations. (Australian nurse manager, ID 1040).

The same nurse manager suggested an alternative approach to education, reminding staff of the importance of psychosocial support:

> You need to make delirium cool like ECMO and incentivise... I don't know how you do that, though. Maybe try and bring it back to why people started to become nurses and make them remember how good it was for them to wash someone's hair, place a gentle compassionate hand on a vulnerable and scared body scared shoulder. Evoke that emotion and make them remember why they do this (Nurse Manager, ID 1040).

Overall, 96.7% (n=88/91, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while a total of 88% (n=78/89, Mdn 4, IQR 1) rated the recommendation to be somewhat or very feasible. Australian participants described how education had been reduced due to tight budgets and how the management of challenging behaviours was just not prioritised.

In summary, the recommendation for providing education on agitation reached a very high level of consensus, importance and feasibility in both countries. The qualitative comments suggested that staff may lack both knowledge and motivation to manage patient agitation.

### 8.13.2 Category 9.2: leadership support of NPSs

#### *8.13.2.1 Recommendation 9.2.1: nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation.*

This recommendation reached a consensus level of 93.2% (n=96/103, 95% CI: 0.87- 0.97, Mdn 5, M 4.64, IQR 0). An Australian researcher (ID 1006) suggested clinical leaders should implement policies that encourage the use of NPI to reduce and manage agitation. An Australian nurse

described how clinical leaders not only played an important role in reducing incidents of agitation but also in protecting staff and creating a supportive work culture:

> Clinical leaders should be involved. They should be developing and supporting strategies to reduce incidents of patient agitation. They also need to create a culture where it is understood that aggression towards nursing staff is not acceptable. It contributes to burnout and PTSD, and it shouldn't be seen 'as part of the job' in a workforce that is already under considerable strain, especially over the last two years (Australian nurse, ID 1082).

Overall, 97.8% (n=90/92, Mdn 5, IQR 0) of all participants rated this recommendation as somewhat or very important, while 99% (n=86/87, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

This recommendation on leadership support of NPSs reached a very high level of agreement in both countries and was rated highly in terms of both importance and feasibility. Clinical leaders can support their staff in different ways, both by introducing policies on NPSs and by developing a culture supportive of using NPSs.

### 8.13.3 Category 9.3: multidisciplinary team collaboration

#### *8.13.3.1 Recommendation 9.3.1: the multi-disciplinary team should collaborate to reduce and manage patient agitation*

This recommendation reached a consensus level of 99% (n=102/103, 95% CI: 0.95-1, Mdn 5, M 4.92, IQR 0). While the recommendation reached a high level of consensus, a significant difference in ratings was seen between stakeholders (H (3) = 9.5, p=0.02, $\eta^2$ 0.07, d=0.53). More specifically, nurses and physicians differed significantly in their ratings (p=0.016), with 70% of physicians (n=7/10) strongly agreeing with the recommendation, compared with 96% of nurses (n=71/ 74).

Multiple Australian nurses commented on this recommendation. Nurses described a lack of support from their medical colleagues and other multidisciplinary team members when dealing with patient agitation. Nurses explained how they did not feel listened to, and how dealing with patient agitation was not prioritised by their medical colleagues and was overall seen as nurses' responsibility. Some comments were rather negative:

> …the medical team does not comprehend the immense psychological and physical pressure it [caring for an agitated patient] places on the nursing staff, and sometimes the medical team just prescribe pharmacological agents and just walks away. The junior medical officers seem to underplay the severity of agitation in front of their seniors while appearing diplomatically and politically sympathetic towards nursing staff at the medical rounds in front of colleagues. Meanwhile, they actually do not provide adequate support (basically busy typing or charting medication on the computer), let alone working and supporting one another beyond their own discipline (Australian nurse, ID 1038).

This quote suggests that while nurses wanted a discussion around non-pharmacological options, the medical team offered little support other than prescribing drugs.

Participants described how poor collaboration could directly affect patient care. An Australian nurse explained:

> It would be useful for doctors and nurses to be on the same page for the plan instead of scrambling for a plan when patient becomes agitated and aggressive (Australian nurse, ID 1072).

Participants from both countries mentioned how different disciplines and their different perspectives could strengthen discussions around management. It was, for example, mentioned how including a pharmacist in the standard MDT to identify medication-induced agitation could be helpful. Participants also mentioned how a multidisciplinary approach required all members to have good collaboration skills and to follow agreed management plans. Almost all comments were from Australian participants, except a comment from a Danish researcher (ID 2031) who wondered what was meant by 'multi-disciplinary collaboration', and wished the recommendation was more directional.

All participants (n=100/100, Mdn 5, IQR 0) rated this recommendation as somewhat or very important, and 99% (n=88/89, Mdn 5, IQR 1) rated the recommendation to be somewhat or very feasible.

In summary, the recommendation of having a collaborating multidisciplinary team to manage agitation reached a high level of consensus and was highly rated in terms of both importance and feasibility. From the qualitative data, it appears that some Australian nurses found the existing multidisciplinary collaboration around patient agitation to be somewhat dysfunctional. From both qualitative and quantitative data, there is some evidence that the different disciplines, perhaps even the different countries, have different ideas on what the ideal collaborative work should look like and who is responsible for what when managing patient agitation.

## 8.14 Excluded recommendations

A total of 25 recommendations were excluded from the guidelines because they reached below 75% consensus in one or both countries. See Figure 26 for an overview of included and excluded recommendations.

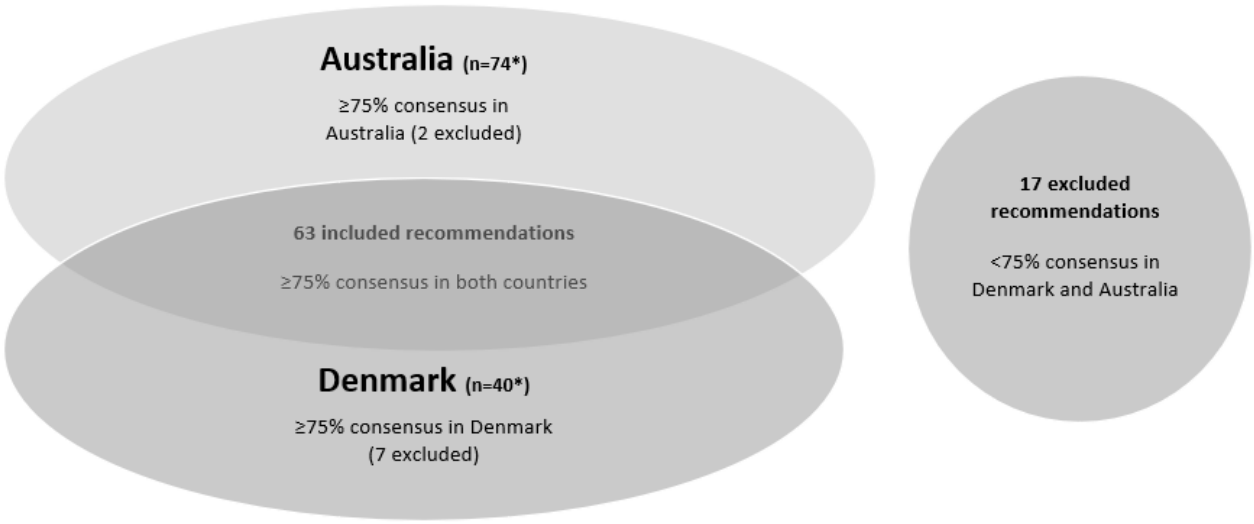
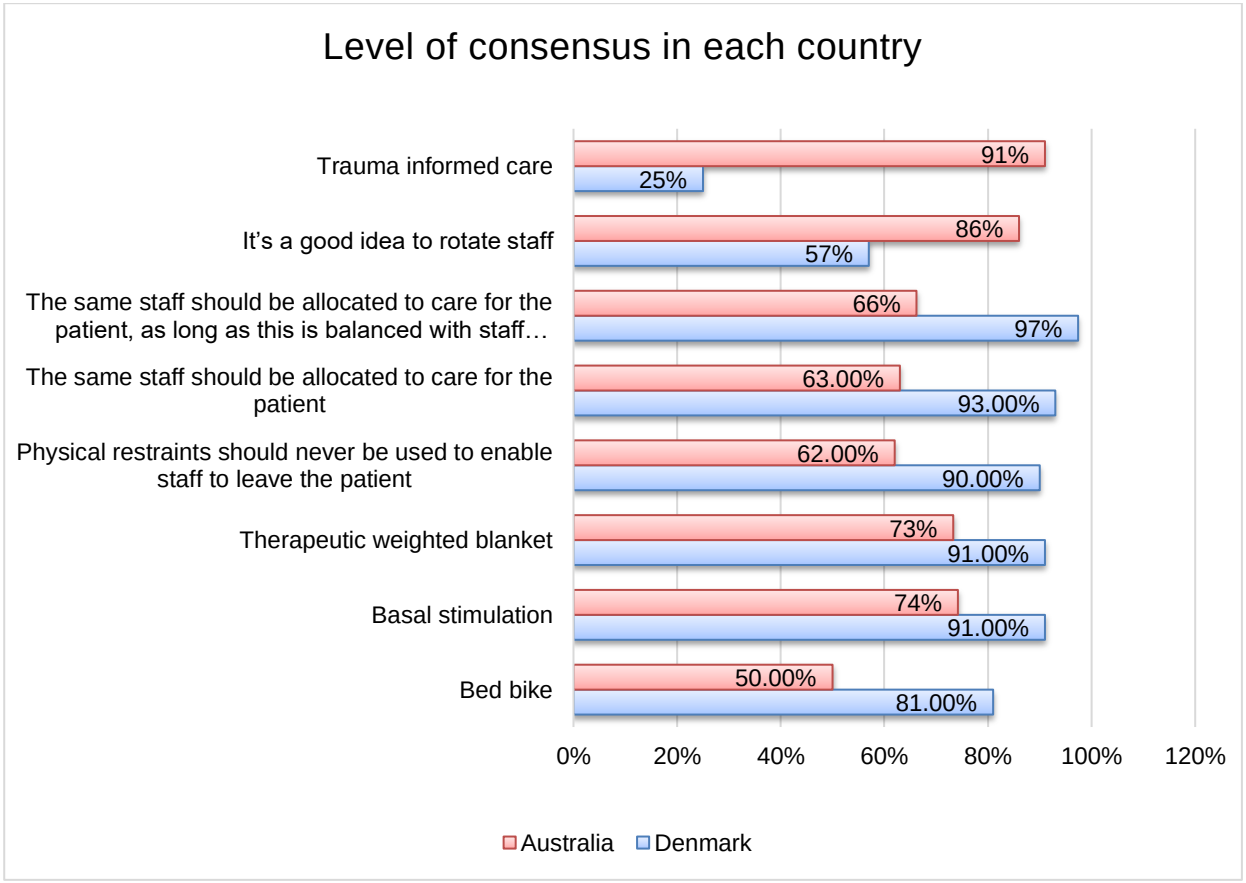



**Figure 26 Overview of included and excluded recommendations**

* Sample size first Delphi round

In some cases, there were significant differences in the ratings between the countries. See Figure 27 for an overview of the excluded recommendations that showed a significant difference ($p<0.05$) in ratings between the countries. Recommendations with significant differences between countries are also illustrated with figures in the text below.

**Figure 27 Recommendations with a significant difference in consensus**



### 8.14.1 Recommendations reaching 75% or more consensus in Denmark, but not in Australia.

Seven recommendations reached ≥ 75% consensus in Denmark but not in Australia.

#### *8.14.1.1 Bed bike*

This recommendation only reached consensus in Denmark in round one and therefore was rated again in round two. In both rounds, there was a statistically significant difference in ratings between the two countries. In the first round, the difference was 22% (z=2.4, p=0.017, 95%CI 0.04-0.41), with the recommendation reaching a consensus level of 91.7% (n=33/36, IQR 1) in Denmark compared with a non-consensus level of 69.4% (n=25/36, IQR 2) in Australia. In the second round the difference was 31.3% (z= 2.5, p=0.02, 95%CI 0.07-0.56), with the recommendation reaching a consensus level of 81.3% (n=26/32, IQR 1) in Denmark compared with s consensus level of 50% (n=9/18, IQR 1) in Australia While 84-90% of the Danish participants rated this recommendation, only 26-49% of the Australian participants did.

In the first round, Danish participants commented that the bed bike was useful when patients were more awake and able to collaborate. In the second round, Australian participants commented that a bed bike was not practical to use in ICU and that patients did not have the capacity to use it.

In summary, although this recommendation was not included in the final guidelines, the large number of Danish participants agreeing to this recommendation over the two rounds suggests that it is a topic that deserves more attention. A relatively low number of Australian participants responding to this recommendation, combined with their negative comments around feasibility, may suggest that the recommendation is less used and perhaps less supported in the Australian context.

#### *8.14.1.2 Basal stimulation*

Basal stimulation was defined in the survey as a holistic approach involving touch, positioning, body awareness and communication. This recommendation only reached consensus in Denmark in round one and therefore was rated again in round two. There was a statistically significant difference (z=2.1, p=0.03, difference 12.1%, 95% CI 0.03-0.5) in ratings between the two countries. The recommendation reached a consensus level of 88.9% (n=24/27, IQR 1) amongst the Danish participants compared with a non-consensus level of 61.9% (n=13/21, IQR 2) amongst the Australian participants. In the second round, the recommendation reached a consensus level of 90.6% (n=29/32, IQR 1) in Denmark compared with a non-consensus level of 74.2% (n=23/31, IQR 2) in Australia. More Danish participants (68-84%) than Australian participants (28-46%) rated the recommendation.

While Australian participants did not comment on the recommendation, the Danish participants described basal stimulation as a central strategy for reducing agitation. A Danish physician commented in the second round:

> I find that basal stimulation works for pretty much all patients. I guess it's about re-establishing some body awareness, a sense of where you are…But again, basic stimulation always works (Danish physician, ID 2033).

In summary, considering the high ratings on basal stimulation amongst the Danish participants and that the Australian participants almost reached 75% agreement in the second round, basal stimulation is likely to be an important strategy in reducing agitation and must be further explored.

#### *8.14.1.3 Therapeutic weighted blanket*

This recommendation only reached consensus in Denmark in round one and therefore was rated again in round two. There was a statistically significant difference in ratings between the two countries in both the first (z=2.6, p=0.001, 27.8%, 95% CI 0.07-0.49) and the second (z=1.9, p=0.05, difference 18.1%, 95% CI 0.002 – 0.41) round. In the first round, the recommendation reached a consensus level of 91.4% (n=32/35, IQR 1) in Denmark, compared with a non-consensus level of 63.6% (n=14/22, IQR 2) in Australia. In the second round, the recommendation reached a consensus level of 91.4% (n=32/35, IQR 1) in Denmark, compared with 73.3% (n=22/30, IQR 1) consensus level in Australia. Between 88-92% of the Danish participants rated the recommendation, while only 30-44% of the Australian participants rated the recommendation.

A Danish researcher (ID 2031) described how the method was particularly useful in patients who were agitated due to neurological damage. Danish participants described that while it could be useful for some patients, there was a risk that patients would feel restrained by the heaviness of the blanket and that patients, in particular those agitated, could become overheated. Australian participants described how a blanket would need to be approved by the hospital, and how cost and maintenance could be a problem.

In summary, the very high ratings from Danish participants combined with high levels of experience within this group suggest that the intervention may be important in reducing agitation. Although the recommendation could not be endorsed in the final set of recommendations, the use of a therapeutic blanket should not be discouraged. More research is needed to determine the effectiveness of the recommendation and the potential harms related to it.

#### *8.14.1.4 Physical restraints should never be used to enable staff to leave the patient.*

The recommendation *Physical restraints should never be used to enable staff to leave the patient* reached a strong consensus level of 90% (n=36/40, IQR 0) in Denmark, compared with a low non-consensus level of 61.6% (n=45/73, IQR 3) in Australia. There was a statistically significant difference (z=3.2, p=0.001, 95% CI 0.11-0.46) of 28.4% in ratings between the two countries.

Based on participant feedback, the recommendation was modified before being introduced again in round two. The new recommendation "physical restraints should not be used as a substitute for direct observation" is described in more detail under section 8.5.4.2

#### *8.14.1.5 The same staff should be allocated to care for the patient*

This recommendation *The same staff should be allocated to care for the patient* only reached a high level of consensus in Denmark in round one. There was a statistically significant difference of 29.5% in ratings between the two countries ($z=3.4$, $p=0.001$, 95% CI 0.12-0.46) with the recommendation reaching 92.5% (n=37/40, IQR 1) consensus in Denmark compared with a non-consensus level of 63% (n=46/73, IQR 2) in Australia. There was also a significant difference seen between stakeholder groups ($H(4) = 21.61$, $p<0.001$, $\eta^2$ 0.163, $d=0.883$). More specifically, the difference existed between nurses and patients/families ($p=0.042$) and nurses and physicians ($p=0.042$), with only 24.7% (n=20/73) of nurses rating the recommendation as very useful compared with 63.6% (7/11) of family members and 80% (8/10) of physicians.

Based on participant feedback the recommendation was modified to "The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care", this recommendation is described in detail in Section 8.14.1.6

Participants described how having the same staff to care for the patient had several advantages. Firstly, it helped staff develop trusting relationships and know their patients, including what reduced and triggered agitation. Secondly, seeing familiar faces helped patients to feel safe. An Australian nurse commented:

> It can benefit agitated patients to be cared for by a consistent care team of familiar faces who have developed a rapport and effective behavioural management techniques with the patient (Australian nurse, ID 1067)

An Australian family member also agreed to the recommendation, but highlighted, similar to other participants, that it depended on the qualities of the clinicians.

> Allocation of the same staff is very useful if the staff member shows personal empathy and connection. This provides a point of stability and continuity of care, giving reassurance to the patient (and the family), helping to reduce confusion, disorientation and agitation (Australian family, ID 1063).

There were multiple other concerns related to the recommendation, particularly related to staff burnout and staff not coping with the additional workload. Participants from both countries described how the level of vigilance required when caring for an agitated patient could be constant and exhausting. A Danish nurse explained:

> It can be frustrating and exhausting caring for patients who are delirious and agitated. As a nurse, you may feel that the care you provide in inadequate. It is a good idea to use rotation amongst nurses and have debriefing after longer patient stays (Danish nurse, ID 2025).

Participants also described how some clinicians did not have the desire, competence or energy to care for agitated patients. Finally, an Australian nurse argued that patients were unlikely to remember or recognise staff anyway.

> I think the same person caring for a patient would be very tiring mentally, and make for a difficult shift. Staff mental health is important. Any proof that patients remember carers and recognise them? We find confused patients may remember what they were doing, but not the staff involved Australian nurse, ID 1054).

In summary, although this recommendation did not reach a consensus within the Australian context, the recommendation may still be applicable to the Danish context. There are many qualitative comments demonstrating the importance of primary carers. Nevertheless, if the recommendation was to be implemented, it is necessary to consider how to avoid staff fatigue and burnout.

#### *8.14.1.6 The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care.*

This recommendation was developed based on the feedback on the recommendation "The same staff should be allocated to care for the patient" (See Section 8.14.1.5) and was presented in round two. The recommendation reached 97.4% (n=37/38, IQR 1) consensus in Denmark, compared with 66.2% (n=45/68, IQR 1) consensus in Australia. There was a statistically significant difference (z= 3.7, p=0.000, 95% CI 0.15-0.48) of 31.2% in the ratings of between the two countries.

The comments related to the concern that certain staff were less qualified, less able to develop positive relationships thus less able to reduce patient agitation. An Australian patient stated:

> The quality of staff varies greatly, so you wouldn't want to be stuck with incompetent staff as a patient's only option (Australian family, ID 1066).

The comment is supported by an Australian patient (ID 1005) who believed patients should have a say in which staff members should be caring for them.

Although the recommendation had been changed to take into account the risk of staff fatigue and burnout, several comments from Australian participants indicated that this was still a concern. An Australian nurse highlighted:

> In terms of same staff – this has to be balanced with staffs' mental fatigue and burnout. Chronic exposure due to allocations and the associated impacts on long-term mental health must be considered (Australian nurse, ID 1015).

An Australian nurse questioned if agitated patients even remembered staff caring for them (ID 1054).

From these findings, it is clear there must be a balance between ensuring continuity of care by using the same staff and prioritising staff needs and wishes. Some Danish participants described

how working in teams, and rotating staff within these teams worked well. This approach may be a good solution taking into account both patient and staff needs.

#### *8.14.1.7 Patient diary*

The recommendation *Use a patient diary* developed based on feedback in round one. The recommendation reached a non-consensus level of 86% (n=37/43, IQR 2) in Australia in round two, compared with a 64.5% (n=20/31, IQR 2) non-consensus level in Denmark. Most comments in the second round were related to diaries being useful for patients after their ICU stay, but not during their ICU admission. Concerns related to diaries included errors written in diaries, patients feeling distressed about the content, and finally, patients never reading their diaries. The recommendation was rated again in the last Delphi round. Interestingly, this time the recommendation reached 75.9% (n=22/29, IQR 0.5) consensus in Denmark, compared with a 74.4% (n=32/43, IQR 2) non-consensus level in Australia.

When the recommendation was rated in the second round there was a significant difference seen between stakeholder groups (H (4)=14.06, p=0.007, $\eta^2$ 0.146, d=0.826. More specifically, the difference was seen between patients/families and researchers (p=0.033) and patients/families and physicians (p=0.035), with 75% (n=6/8) of patients/families finding this intervention very useful compared with 0% (n=0/4) of researchers and 0% (n=0/8) physicians. Similar to the second round, there was a significant difference seen between stakeholder groups in the third round (H (4)=11.26, p=0.024, $\eta^2$ 0.108, d=0.697). This time the difference was only found between patients/families and researchers (p=0.038), with 54.5% (n=6/11) of patients/families rating the recommendation to be very useful compared with 0% (n=0/5) of researchers. This time 14.3% (n=1/7) of physicians rated the recommendation to be very useful.

Similar to the second round, participants mentioned how diaries were useful for patients long-term but less valuable for reducing agitation in ICU. An Australian family member (ID 1004) described how patient diaries could be helpful to families during patients' ICU stay and, therefore should be encouraged. Again, it was mentioned how diaries require time to write, how some patients may not benefit from the diary, and how the content could potentially be used against staff.

In summary, the recommendation to use a patient diary only reached a consensus above 75% in Denmark. Patients and families found this strategy significantly more useful than researchers. The relationship between ICU diaries and patient agitation is unclear. Is it possible that participants rating the recommendation as useful were thinking of the reduction of agitation long-term and perhaps not within the ICU? If diary writing has an effect on patients in ICU where patients do not see the diary, is the effect caused by the writing and reading process nurses and families go through? It is clear that the recommendation requires more research.

### 8.14.2 Recommendations reaching ≥ 75% consensus in Australia, but not in Denmark

Two recommendations reached ≥ 75% consensus in Australia, but not in Denmark.

#### *8.14.2.1 It is a good idea to rotate staff who care for and treat agitated patients (e.g., during a shift or between shifts).*

This recommendation reached more than 75% consensus in Australia. Based on participant feedback, the recommendation was modified to "The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care" (see Section 8.14.1.6).

Related to the original recommendation, there was a statistically significant difference of 29.6% in ratings between the two countries (z=3.4, p=0.001, 95% CI 0.12-0.47), with the recommendation reaching 86.4% (n=57/66, IQR 1) consensus in Australia compared with a non-consensus level of 56.8% (n=21/37, IQR) in Denmark. There was also a significant difference between stakeholder groups (H(3) = 21.16, p<0.001, $\eta^2$ 0.183, d=0.948). The significance was identified to between nurses and researchers (p=0.035) and nurses and physicians (p=0.003), with 66.2% of nurses (n=49/74) rating the recommendation to be very useful compared with only 16.7% (n=1/6) researchers and 20% (2/10) of physicians.

A total of 40 individual comments described how staff rotation was essential to avoid staff fatigue, stress and burnout. An Australian nurse commented:

> Staff fatigue for these patients is a real problem. Knowing you will only be with them for a shorter time will reduce staff burnout and frustration towards the patient (Australian nurse, ID 1010).

Some participants described how it was unfair that the same staff, often male, agency staff, junior nurses or those with 'special skills', were allocated to care for the agitated patients. An Australian nurse explained:

> I absolutely agree with the recommendation to rotate staff. A unit I worked in had a habit of always allocating certain staff members to the delirious patients as "you are always so good and patient with them". They are mentally extremely draining to look after, especially when you never seem to get a break. Let's just say I no longer work in that unit except very occasionally (Australian nurse, ID 1019).

Overall, participants from both countries described how the rotation could ensure staff had more capacity and energy to look after agitated patients. For example, clinicians explained how they had the energy to use NPSs. In contrast, during long shifts with agitated patients, they were more likely to resort to using chemical restraints.

Finally, both patients and clinicians described how the staff rotation could be beneficial if the staff-patient relationship was dysfunctional.

Clinicians described how the rotation could be helpful both within and between shifts:

> Dealing with an agitated patient can be very draining, and if you have that patient for a 12-hour shift, it's very exhausting mentally and emotionally, and the nurse is more likely to go for pharmacological options rather than nonpharmacological options. Nurses should rotate after six hours for best patient outcomes (Australian nurse, ID 1028).

A Danish participant suggested rotating as frequently as every two hours:

> Perhaps staff need to rotate every two hours. Staff must use other methods to ensure continuity (Danish nurse, ID 2017)

Participants who disagreed with the recommendation described several benefits of having the same staff caring for the patient, including continuity of care and patients' increased sense of safety (note this is described in more detail under Section 6.14.1.6. It was described how the rotation of staff could cause agitation and confusion and should only be done if considered a benefit for the patient, and not for the sake of staff needs. A Danish researcher emphasised:

> The recommendation for rotation of caregivers in the agitated patient is NOT patient-centred. It may be that it is practical to share the burden of caring for a patient who is agitated, but it is not benefitting the patient and the relatives. They never get to know the staff, and the staff do not get to know the patient and the relatives. It is better to ensure additional staffing for these patients, so that there are more who can support each other in the care of the agitated patient (Danish researcher, ID 2031).

Finally, clinicians suggested that it should be up to the individual staff member to decide if rotation was required. Meanwhile, patients and families described how they believed they should also be consulted.

In summary, this recommendation did not reach consensus in Denmark. However, managers who allocate staff must still take into consideration staff capacity to care for agitated patients. It may be beneficial to consult staff and perhaps even patients and their family members when possible.

#### *8.14.2.2 Trauma Informed Care*

Trauma informed care was described in the survey as an approach used to care for individuals with a history of trauma. The recommendation was developed based on participant feedback in round one. It reached ≥75% consensus amongst Australian participants in rounds two and three but did not reach consensus ≥75% in Denmark and was therefore excluded from the final guidelines.

There were significant differences in ratings between the two countries in both the second ($z=4.2$, $p<0.0001$, difference 66%, 95% CI 0.35-0.98) and in the last round ($z=3.2$, p 0.002, difference 44%, 95 CI 0.17-0.70). In the second round, the recommendation reached 91.4% (n=32/35, IQR 0.5) consensus in Australia compared with 25% (n=2/8, IQR 0.50) in Denmark. In the third round, the recommendation reached a 93.5% (n=29/31, IQR 1) consensus in Australia compared with a 50% (n=5/10, IQR 2.25) non-consensus level in Denmark. Between 46-51% of the Australian

participants rated the recommendation compared with 21-26% of the Danish participants indicating that fewer participants in Denmark had experience with the recommendation. Participants did not comment on this recommendation in any of the rounds.

In summary, this recommendation only reached above 75% consensus in Australia. From the results, it is clear that the Australian cohort had more experience with this recommendation, with only very few Danish participants rating the recommendation. Unfortunately, there are very few comments describing how this intervention worked to reduce and manage agitation. It is clearly an intervention that deserves more attention.

### 8.14.3 Recommendations reaching below 75% consensus

Seven recommendations reached a consensus below 75%.

#### *8.14.3.1 Eye mask*

The recommendation on using an eye mask reached an overall consensus level of 47.5% (n=28/59, 95% CI 35-60, IQR 1). When tabulating the results, the recommendation reached 52.2% (n=24/46, IQR 1) consensus in Australia, compared with 30.8% (n=4/13, IQR 1.5) non-consensus in Denmark. Participants described how the mask could create darkness for a patient who needed sleep or rest, but on the other hand, could cause frustrations for patients who were unable to remove them themselves. Some participants described how they should be offered as an option. Australian participants expressed concerns about infection control and not having eye masks available. In summary, this intervention is likely to be of less use when attempting to reduce or manage agitation.

#### *8.14.3.2 Earplugs*

The recommendation on using earplugs reached a consensus level of 65.1% (n=54/83, 95% CI 0.54-0.74, IQR 0). When tabulating the results, the recommendation reached 56.5% (n=13/23, IQR 1) consensus in Denmark, compared with 68.3% (n=41/60, IQR 2) non-consensus in Australia. It was described how earplugs could be useful to minimise sound but, similar to eye masks, cause frustrations in patients who were unable to remove them. Participants also described how a distorted sound could cause confusion and agitation. In summary, this intervention is likely to be less useful when attempting to reduce or manage agitation.

#### *8.14.3.3 Massage*

This recommendation was rejected as it only reached an overall consensus level of 63.3% (n=50/79, 95%CI 52-73, IQR 1). More specifically, the recommendation reached 70% (n=21/30, IQR1) consensus in Denmark, compared with 59.2% (n=29/49, IQR 1) in Australia. While some participants believed the intervention was very useful, it was also explained how massage could be too stimulating for an already sensitive patient. Some described how the massage should be carried out with caution in the critically ill patient, and how staff needed special skills or training to

do it. Some participants described how there was no time to give patients massage, or that giving the massage was not a job for a critical care nurse. In summary, this intervention is likely to be less useful when attempting to reduce or manage agitation.

#### *8.14.3.4 Nature-based sounds*

The recommendation nature-based sounds reached an overall consensus level of 58.2% (n=46/79, 95%CI 47-68, IQR 0). There was a statistically significant difference (z=2.5, p=0.012, 95% CI 0.07-0.52) of 29.3% seen between the ratings of the two countries. The recommendation reached a consensus level of 39.3% (n=11/28, IQR 1) in Denmark, compared with 68.6% (n=35/51, IQR 1) in Australia. While some described nature-based sound therapy as calming and useful, it was also described how it could confuse and negatively stimulate patients in an already noisy ICU environment. Similar to using music, participants described the importance of having time limitations on the use of nature-based sounds. In summary, this intervention is likely to be less useful when attempting to reduce or manage agitation.

#### *8.14.3.5 Guided Imagery*

Guided imagery reached an overall consensus level of 70.8% (n=34/48, 95%CI 57-82, IQR 1). When tabulating the results, the recommendation reached a non-consensus level of 55.6% (n=5/9, IQR 1.5) in Denmark, and a consensus level of 74.4% (n=29/39, IQR 1) in Australia.

There were only two comments on this intervention. A Danish physician was positive towards the approach, commenting:

> I believe that guided imagery will have great potential but is very demanding in terms of resources. I have heard of nurses who can "talk the delirious to sleep": Here, we are at a crossroads of hypnotherapy, which is very interesting. (Danish physician, ID 2035).

In contrast, an Australian physician was more sceptical

> Guided imagery is rarely practical or possible in ICU patients who are unwell and often delirious (Australian physician, ID 1070).

This recommendation reached below 75% consensus in both countries, but according to the qualitative comments, its effect on agitation in ICU in the intensive care unit may still be worth exploring.

#### *8.14.3.6 Sing or hum*

This recommendation was developed based on participant feedback in round one. The intervention reached an overall consensus level of 63% (n=47/75, 95%CI 51-73, IQR 1). When tabulating the results, the recommendation reached 66.7% (n=18/27, IQR 1) consensus in Denmark, compared with 60.4% (n=29/48, IQR 1) in Australia. Participants described that while this depended heavily on the individual patients, it could be very useful. An Australian nurse described:

> I had a son sing to his mother whilst she was dying (he was an Opera singer), her agitation visibly reduced dramatically and she died a peaceful death. Anyone witnessing that agreed it was the singing that was the main factor (Australian nurse, ID 1012).

An Australian nurse (ID 1027) described using humming regularly since it seemed to help both the patient and herself. Although this recommendation reached a consensus of less than 75%, the qualitative comments suggest that clinicians should not be discouraged from singing or humming for patients when it seems appropriate for the individual patient.

This recommendation reached below 75% consensus in both countries, but according to the qualitative comments, its effect on agitation in ICU in the intensive care unit may still be worth exploring. Related to the qualitative comment presented above, it is still unclear if it was the social contact, the sensory stimulation or a combination that calmed down the patient.

#### *8.14.3.7 Rocking Chair*

The Rocking Chair was described in the first survey as a specially designed electrically powered chair. The recommendation reached a non-consensus level of 58.8% (n=10/17, IQR 1.5) in Australia in round two, compared with an 85.7% (n=18/21, IQR 1) consensus level in Denmark. The qualitative comments suggested that some patients benefitted significantly from the interventions while others became more agitated, nauseous or were at risk of falling out. These comments all came from Danish clinicians. There were two comments from Australian participants, one suggesting that the intervention was not for critically ill patients, the other that they had never seen it used in an ICU. The recommendation was rated again in the second round. Here the ratings had reduced to a consensus level of 36.4% (n=4/11, IQR 1) in Australia, and a 65% (n=13/20, IQR1) consensus level in Denmark.

In summary, it is interesting that the intervention reached a very high level of agreement in the first round in Denmark, but not in the second. Overall, very few people rated the recommendation, and therefore it is difficult to make any firm conclusions about this intervention.

### 8.14.4 Recommendations reaching below 75% non-consensus

Ten recommendations did not reach consensus in either country. The first two recommendations reached a non-consensus level above 75% in Australia; the last seven reached a non-consensus level below 75% in both countries.

#### *8.14.4.1 Spiritual/pastoral care person*

The recommendation *Offer access to a spiritual/pastoral care person* was developed based on participant feedback in round one stating that spiritual/pastoral care was useful for calming an agitated patient. It only reached agreement amongst Australian participants in rounds two and three, and therefore was excluded from the final guidelines.

In the second round, the recommendation reached 83.9% (n=52/62, IQR 1) consensus in Australia, compared with 71.4% (n=20/28, IQR 1) in Denmark. However, in the third round, the recommendation did not reach consensus in either country, with a 75.9% (n=44/58, IQR 1.25) non-consensus level in Australia compared with a 64% (n=16/25, IQR 2) non-consensus level in Denmark.

A Danish physician (ID 2033) described how they used a priest when patients were dying, which many patients appreciated. While some Australian participants described how the spiritual/pastoral care person was useful not only for religious people, others described how they were less useful for atheists or agnostics.

Although this recommendation did not reach a consensus, it was still rated above 75% in Australia, suggesting that the recommendation may be worthwhile for reducing and managing agitation in the Australian context.

#### *8.14.4.2 Clearly displayed names and/or photographs of mask-wearing carers*

The recommendation *Clearly displayed names and/or photographs of mask-wearing carers* reached more than 75% consensus in Australia in round one. However, when re-rated in round two, the recommendation did not reach consensus in either country.

The recommendation reached a 78.4% (n=40/51, IQR 1) consensus level in Australian in the first round, compared with a 73.1% (n=19/26, IQR 2) non-consensus level in Denmark. In the second round, a statistically significant difference of 23% (z-2.3, p=0.023, 95% CI 0.03-0.44) was found between the two countries, this time with a non-consensus level of 82.7% (n=43/52, IQR 2) in Australia compared with a non-consensus level of 59.3% (n=16/27, IQR 2) in Denmark.

In the first round, an Australian family member (ID 1063) and an Australian clinician (ID 1058) described how clearly displaying names or photographs would be useful and reassuring to patients and family members. Some concerns were mentioned by other participants, including patients not having the ability to see and understand the tags.

In round two, an Australian clinician described how name tags had been particularly useful during the COVID-19 pandemic due to the need to wear full PPE. A Danish clinician explained how they used transparent masks in their unit and saw the tags as less useful. Finally, a Danish patient stated

> I found it very difficult not to be able to see the faces of staff. It made it very difficult to assess facial expressions and reactions. More importantly, I struggled to recognise staff, which actually made me feel unsafe (Danish patient, ID 2003).

In summary, although this recommendation did not reach consensus, it overall received high ratings (>75%) in Australia, suggesting that it may still be a helpful intervention for reducing and

managing agitation in Australia. It is important for all clinicians to consider how they can make patients feel safer when wearing masks.

#### *8.14.4.3 Relaxing breathing exercises*

This recommendation was developed based on participant feedback in round one. The recommendation reached a non-consensus level of 53.3% (n=16/30, IQR 2) in Denmark and a non-consensus level of 73% (n=23/31, IQR 2) in Australia.  of 31 Australian participants agreeing to the recommendation). There were no comments on the recommendation. Due to the ratings of this recommendation, it can be concluded that the intervention is likely to be less useful in reducing agitation in ICU.

#### *8.14.4.4 BBAUM approach*

The BBAUM approach was described in the first survey as a calm intervention for challenging behaviours. This recommendation was developed based on feedback from Danish participants in round one. The recommendation was rejected as it did not reach consensus with an IQR of 2, and only 60% (n=15/25, 95% CI 41-77) of participants rating somewhat or very useful. In addition, very few had experience with this recommendation (<25% of all participants). There were no comments on the recommendation.

Due to the high IQR indicating a level of disagreement amongst participants, and the low number of people who rated the recommendation, it is difficult to make any conclusions about the usefulness of this recommendation.

#### *8.14.4.5 Gentle violence prevention as described by Leah Tranhold*

This recommendation was developed based on feedback from Danish participants in round one. This recommendation did not reach consensus with an IQR of 2, and only 63% (n=12/19, 95%CI 41-80) of participants rating somewhat or very useful. It was noticed that 75% (n=6/8) of the Danish participants rated somewhat or very useful. However, the IQR was 1.75, and therefore there was no consensus about this recommendation amongst Danish participants. The number of people rating this intervention was also very low. Similar to the BBAUM approach, this recommendation requires more investigations before any conclusions can be made about its usefulness.

#### *8.14.4.6 Explain to the patient what are and what are not acceptable behaviours*

The recommendation *Explain to the patient what are and what are not acceptable behaviours* did not reach consensus, and only 60.7% (n=51/68, 95%CI 51-69, IQR 2) rated the recommendation to be somewhat or very useful. There was a significant difference (z=2.3, p=0.021, 95% CI 0.05-0.22) of 22.3% seen between the ratings of the two countries with 46.2% (n=18/39, IQR 2) non-consensus level in Denmark compared with 68.5% (n=50/73, IQR 1) consensus in Australia. There was also a significant difference seen between stakeholder groups (H (4) = 10.95, p=00.027.

$\eta^2$ 0.065, d=0.527). The post hoc Bonferroni test, testing pairwise comparisons, showed a significant difference between the ratings of patients/families and physicians (p=0.025), with no physicians (n=0/10) rating this recommendation as very useful, compared with 50% (n=5/11) of patients/families. Further investigations showed that 90% (n=9/10) of patients and family members rated the recommendation as somewhat or very useful.

While some participants agreed that patients should be advised about their behaviours, others disagreed, explaining that patients were not agitated "on purpose". It was explained how agitation often had medical causes (delirium, sepsis, hypoxia etc.); thus, behaviours could not easily be corrected. Others explained how patients simply struggled to understand corrections and explanations and thus were unable to change their behaviours. An Australian researcher explained:

> Agitation, in my experience, frequently stems from a medical condition, not from a personality trait. Communication may be impaired in these cases, so expecting a patient to be able to change their behaviour may not be possible, but of course, communicating with the patient [in a way they understand] is a fundamental way we care for patients (Australian researcher, ID 1062).

In contrast, an Australian occupational therapist (ID 1075) and an Australian family member (ID 1004) described that the usefulness of the intervention depended not only on the patients' cognitive state, but also on their personality. Some participants were concerned about the way the message could be passed on to patients:

> I have seen many nurses yell at and reprimand patients. This is different to respectfully setting boundaries (Australian nurse, ID 1026).

A Danish researcher explained how correcting patients could even result in feelings of guilt and shame. She stated:

> This recommendation risks adding guilt and shame to the patient over the agitated episode. Instead, health professionals should express acceptance and ability to accommodate agitated behaviours (Danish researcher, ID 2031).

In summary, the ratings of this recommendation were spread. However, the majority of the ratings pointed towards a less useful intervention. The qualitative ratings suggested that often the agitated patients were unable to change their behaviours and that correction could potentially do more harm than good.

#### *8.14.4.7 Felicia Affolter method*

The Felicia Affolter method was described in the survey as guided interaction therapy. This recommendation was rejected since it did not reach consensus with an IQR of 1.75, and only 50% (n=12/24, 95%CI 31-69) of the participants rated the recommendation somewhat or very useful. In addition, the recommendation was rated by less than 25% of all participants. Only a Danish physiotherapist commented on this recommendation. He stated:

> The Affolter approach can be a really good approach. In particular, the nonverbal, tactile approach I consider to be effective, as it reduces irrelevant stimuli for the patient and supports grounding (Danish physiotherapist, ID 2043).

This recommendation was rated as being less useful in terms of reducing and managing agitation. However, due to the spread of data and the low number of participants rating this recommendation, no firm conclusions can be made about the usefulness of this intervention.

#### *8.14.4.8 Aromatherapy*

Aromatherapy did not reach consensus with an IQR of 1.25 and only 50% (n=21/42, 95%CI 36-64). (37.5% (n=3) of 8 Danish participants and 52.9% (n=18) of 34 Australian participants agreed to the intervention.) While some participants described having seen great outcomes of aromatherapy, others expressed concerns such as unwarranted and potentially dangerous effects on patients, in particular those with asthma or other allergies. Some participants suggested that training was needed by staff before using the intervention. It is difficult to make firm conclusions about the usefulness of this intervention due to the spread of data. However, with the qualitative comments indicating a potential risk associated with the recommendation and a lower CI of 36 the recommendation requires robust investigations before being implemented into ICUs.

#### *8.14.4.9 Reflexology*

Reflexology did not reach consensus with an IQR 2. Only 40% (n=14/35, 95%CI 26-56) rated this intervention to be somewhat or very useful. (of was rejected as only 44.4% (n=4) of 9 Danish participants, and 38.5% (n=10) of 26 Australian participants agreed to the intervention.) Participants described how this intervention had to be carried out by trained professionals, how patients potentially needed to pay themselves for the intervention, and finally, how the intervention could cause unwanted effects. Due to the broad spread of data, no conclusions could be made. However, the low CI of 26 is a concern and may suggest that the intervention is less useful. Future practitioners need to consider both the effectiveness and feasibility of this intervention.

#### *8.14.4.10 Acupuncture*

Acupuncture did not reach consensus with an IQR of 1.5. This recommendation received the lowest mean rating. Overall, only 16% (n=4/25, 95%CI 6-35) rated this intervention to be somewhat or very useful. (was rejected as only 20% (n=2) of 10 Danish participants and 13.3% (n=2) of 15 Australian participants agreed to the intervention. Only 25 of 114 (22%) had experience with the intervention. Some participants expressed how the intervention could be useful if patients were able to relax and accept the intervention. Concerns included the risk of triggering patient agitation, the risk of infection and finally, a concern that patients might use sharp objects against staff. It is a concern that an extremely low percentage of experienced participants rated the recommendation to be useful. However, with the low number of participants having experience with this recommendation, and the spread of data, it is impossible to make any firm conclusions about the usefulness of the intervention.

## 8.15 Barriers and facilitators to guideline implementation

Guidelines are only valuable when they are implemented into practice. Therefore, one of the objectives of this study was to understand the factors that might hinder or facilitate the implementation of guidelines on nonpharmacological prevention, minimisation and management of agitation in ICU. Advice from stakeholders in the first study phase informed the development of two 5-point Likert scales for barriers and facilitators to guideline implementation. In the second Delphi round, clinicians and researchers were asked to rate the extent to which they believed a number of factors that they were familiar with could be barriers or facilitators to guideline implementation in the ICU. Participants were also encouraged via open-ended questions to explain their responses and identify any add additional barriers or facilitators.

### 8.15.1 Barriers to guideline implementation

Danish and Australian participants had similar perceptions of barriers to guideline implementation, and all recommendations received very high mean scores (>3). Table 54 presents the results from the two countries individually and ranked according to mean ratings.

**Table 54 Barriers to guideline implementation, mean scores by country.**

| | Rank order | | % Rating* | | Barrier mean score (SD) | |
|---|---|---|---|---|---|---|
| **Country** | **Au** | **DK** | **Au** | **DK** | **Au** | **DK** |
| Lack of time | 1 | 1 | 95% | 89% | 4.54 (0.81) | 4.31 (0.83) |
| Changing existing habits | 3 | 2 | 89% | 80% | 4.21 (0.99) | 4.23 (0.91) |
| Inadequate equipment and facilities | 2 | 3 | 87% | 71% | 4.36 (0.95) | 3.97 (1.03) |
| Lack of trust in the guideline | 6 | 4 | 50% | 74% | 3.22 (1.38) | 3.89 (1.37) |
| Lack of confidence in NDI | 5 | 4 | 72% | 74% | 3.75 (1.23) | 3.89 (1.25) |
| Belief that NDI are resource-intensive | 4 | 4 | 75% | 74% | 3.80 (1.13) | 3.89 (0.99) |

*Rating somewhat or definitely a barrier

**Scale: 1=not a barrier at all, 2=somewhat not a barrier, 3=neutral, 4=somewhat a barrier, 5=definitely a barrier.**

The top-rated barrier for both countries was lack of time. Lack of trust in the guideline was perceived to be a greater barrier in Denmark (74% rated *somewhat a barrier* or *definitely a barrier* compared with 50% in Australia).

In the open-ended questions, participants from both countries described how it could be challenging to provide NPSs to critically ill patients who needed multiple modes of treatment, had

various levels of consciousness in the stressful ICU environment, where ultimately, the priority was safety for staff, patients, and patient survival.

> It is difficult to use NPSs in very sick ICU patients. For example, I just looked after a very sick agitated COVID patient. I was unable to adjust the light in the room, constant beeping from monitors that did not have a quiet alarm system. The agitated patient resulted in NIV (noninvasive ventilation) mask going on and off, poor patient saturations meant we had to prone and then unprone the patient, and I had a haemodynamic filter that made noise every time the patient moved or coughed – no amount of nice explanations worked (Australian nurse, ID 1027).

It was also described how sedating patients as soon as they moved could become a habit, and a much easier approach. An Australian nurse described:

> In ICU we are so used to sedation and it appears to be our standard approach (Australian nurse, ID 1015).

Changing habits was described as necessary, although this could be very challenging. Often staff felt that using NPSs was *yet another thing to do*. A Danish physician explained:

> It is HARD to change culture and habits. They are very ingrained. A common narrative quickly emerges in a staff group around what "you can" or "can't do", or what you think adds value or is just "another thing you get pulled over your head". I think it is super important to try to shape this narrative from the start, to get off to a good start, and to create a positive narrative that is carried by some "managing"/culture-carrying employees who very much want to believe that this is the right way to go. Otherwise, it will be very difficult (Danish physician, ID 2033).

Participants also explained how a lack of facilities could be a lack of space for mobilisation, for being with and doing activities with family, and a lack of single rooms.

Concerning additional barriers, Australian nurses described how guidelines could be challenging to implement if they were perceived as unsafe or not feasible. For example, it may not be possible to reduce stimuli in a busy and noisy ICU, or it may not be possible to sit next to a patient avoiding endotracheal tube removal compared to using PR. Participants also mentioned a lack of staff motivation, poor education and understanding of the importance of NPSs

> Our ICU has no resources (activities etc.) and lack of staff initiation to provide interventions. Some of this is poor education/understanding but it can be hard to change habits (Australian occupational therapist, ID 1075).

### 8.15.2 Facilitators to guideline implementation

Participants from the two countries gave high (means scores > 4.3) and similar ratings to the facilitators of guideline implementation. As shown in Table 55, all Likert Scale items describing facilitators to guideline implementation were described as *somewhat helpful* or *very helpful*. The top-rated facilitator in both countries was *A dedicated group to lead implementation*.

**Table 55 Facilitators to guideline implementation, mean scores by country.**

| | Rank order | | % Rating* | | Facilitator mean score (SD) | |
|---|---|---|---|---|---|---|
| **Country** | **Au** | **DK** | **Au** | **DK** | **Au** | **DK** |
| Dedicated group to lead implementation | 1 | 1 | 96.7% | 100% | 4.94 (0.57) | 4.94 (0.32) |
| Multidisciplinary collaboration | 2 | 2 | 100.0% | 100% | 4.89 (0.32) | 4.89 (0.32) |
| Supportive leadership | 3 | 1 | 98.4% | 100% | 4.85 (0.40) | 4.94 (0.24) |
| Clear plan for implementation | 4 | 3 | 98.4% | 97.1% | 4.62 (0.52) | 4.80 (0.47) |
| Clear outline of the evidence | 5 | 5 | 93.4% | 88.6% | 4.57 (0.62) | 4.31 (0.99) |
| A user-friendly design | 6 | 4 | 98.4% | 97.1% | 4.52 (0.54) | 4.59 (0.56) |

*Rating somewhat or very helpful

**Scale: 1=not helpful at all, 2=somewhat unhelpful, 3=neutral, 4=somewhat helpful, 5=very helpful**

In the open-ended questions, participants described how it was important to develop a positive narrative about the guideline. Such description could include arguments for why strategies should be used and the associated positive outcomes for patients, families and clinicians. Several Danish and Australian participants described how change needed to be led by senior staff

> Nurse managers and clinical directors should be visible in the implementation of these measures (Australian nurse, ID 1033).

## 8.16 Summary of findings

This Delphi study aimed to reach consensus among a broad group of stakeholders on NPSs for agitation in the adult ICU. It also sought to understand the importance and feasibility of these and, finally, the perceived barriers and facilitators to the implementation of these guidelines.

### 8.16.1 Strategies useful for reducing agitation in the ICU

Sixty-three recommendations were endorsed by the Danish-Australian expert panel consisting of 114 participants, including patients, families, ICU clinicians and researchers. The full set of recommendations and their linked evidence can be found in Appendix 44. The care principles identified suggested that clinicians should prioritise safety, always consider NPSs, use multiple NPSs, and that PR should be a last resort. Care strategies involved assessing for agitation, treating the underlying cause, including unmet needs, considering the staff-patient relationship and staff behaviours, family involvement, physical and psychosocial needs and ensuring the provision of individualised care. Finally, the context, including staff support, leadership support of NPSs and multidisciplinary team collaboration, was highlighted.

### 8.16.2 Negative effects of NPSs

While most NPSs were perceived as safe, participants also described how some could be harmful or increase agitation if not considered carefully. The recommendations that could be harmful if not carefully considered will be mentioned first. These are all provided as a “conditional” recommendation in the final guidelines (See Appendix 44).

Participants described how it is not always possible to keep a safe physical distance from a violent patient. Sometimes close proximity is necessary to give drugs, avoid extubation and calm down a patient. NPSs should generally be considered first, but there may be cases where the patient is very agitated and dangerous and where pharmacology needs to be the first choice. The recommendation “Respect patients’ need for personal space” can be harmful when patients need life-saving treatment and are at risk of removing equipment. A fidget toy can be misused as an airborne projectile, placing those close to the patient at risk. Such objects can also become a harbinger of infection if not kept consistently clean. Taking a patient outdoors can be dangerous if the patient is haemodynamically unstable. In addition, having an agitated patient outside the ICU can also pose a safety risk for staff. Pet therapy can pose a risk of infection and allergies. Minimising routine interventions can have fatal consequences if not carried out carefully. Offering quiet surroundings, such as moving the patient to a single bedroom, can also be dangerous if it involves moving an intubated agitated patient.

The Delphi participants also mentioned how interventions could trigger or exacerbate agitation or have other negative effects if not used carefully. These are not mentioned in the final guidelines, as clinicians should always consider the needs and characters of individual patients and families when using NPSs. Involving the family can, in some cases, trigger patient agitation. Telephone and video conferences are useful when families are unable to visit the patients but can trigger agitation if not managed well. Holding a patient hand can provoke agitation. Music can be perceived as noise by some patients. Therapeutic touch can exacerbate agitation in an already agitated patient. Informing the patient about the day can pose the risk of providing too much information. Furthermore, too much talk can annoy, disturb and make patients angry. Establishing familiar surroundings can create a safety risk related to cluttering the room as well as cause infection control issues. Having a clock visible risks disturbing patient sleep, and clocks and calendars can distress a patient not understanding their purposes. Furthermore, grouping activities can result in patients becoming exhausted and agitated. Mental stimulation can result in overstimulation and trigger agitation. Preserving patients' usual sleep-wake cycle can have negative consequences if patients need more sleep than usual. Basing care on patient values and preferences is not good if this does not reflect what is considered best for the patient. For example, agreeing with patients not to brush their teeth or mobilise them if they prefer not to.

### 8.16.3 Importance

Related to the importance of interventions, it was slightly surprising that some of the recommendations reaching high levels of consensus in both countries were seen as less important. These included involving a psychologist or psychiatrist and offering a fidget toy. Related to psychologists and psychiatrists, participants stated that these disciplines sometimes struggled to understand agitation in ICU and only treated patients who could communicate verbally. Regarding fidget toys, as mentioned above, participants raised concerns about infection control, the need for staff supervision and the risk of patients throwing the toy.

### 8.16.4 Feasibility

Most recommendations were seen as feasible. The nine recommendations not feasible included additional staff, frequent breaks, the ICU layout, involvement of a psychologist or psychologist, neuropaedagogy, ensuring comfortable surroundings, offering a fidget toy, taking the patient outdoors and using pet therapy. Causes were related to available resources, the ICU physical environment, rules and regulations. When planning guideline implementation, the perceived levels of feasibility and importance must be considered and adjusted according to local needs. The Danish participants did not see keeping a safe distance from a violent patient, preserving patients' usual sleep-wake cycle and involving the family in care as very feasible. Participants' comments suggested that they believed patients needed carers' close proximity to reduce agitation and keep patients safe and that patients often needed more sleep in the ICU than usual. It is slightly unclear why family involvement was less feasible, but this could be related to the type of care families are involved with.

### 8.16.5 Significant discrepancies

#### *8.16.5.1 Discrepancies between countries*

Although participants from the two countries agreed on most recommendations, there were also areas with significant discrepancies. The Danish participants saw bed bikes, diaries, basal stimulation, and therapeutic weighted blankets as useful strategies, whereas the Australian participants found trauma-informed care to be useful. While the Danish participants agreed that PR should never be used to enable staff to leave the patient, the Australian participants did not agree with this recommendation. The Danish participants also agreed that the same staff should be allocated to care for the patient, while, in contrast, the Australian participants agreed staff should rotate.

The two countries agreed on the importance of all included recommendations except two. The Danish participants did not see the recommendation *Play classical or relaxing music, preferably adjusted to patient preferences,* as important, while the Australian participants did. Furthermore, the Danish participants saw *neuropaedagogy* as important, while the Australian participants did not. The two countries also agreed on recommendations in terms of feasibility, except in three

areas. Although these recommendations were rated highly in terms of consensus and importance, the Danish participants did not see *keeping a safe physical distance from a violent patient*, *involving family/next of kin in care* and *preserving patients' usual sleep-wake cycle* as feasible. Yet, the Australian participants rated all of these recommendations as feasible.

#### *8.16.5.2 Discrepancies between stakeholder groups*

There were also areas with significant discrepancies between stakeholder groups. For example, nurses rated some recommendations significantly higher than other stakeholders. These were related to additional staffing, staff rotation, debriefing, prioritising safety, and maintaining a safe physical distance. Considering that nurses are beside the bed 24 hours a day and the exhausting nature of caring for agitated patients (Adams et al., 2021), this is perhaps not a surprising finding. The qualitative comments from many nurses in both countries confirm that caring is complex and challenging and that optimised care requires additional support. The finding also suggests that patients, families and other clinicians in the ICU may not fully understand the demanding nature of caring for agitated patients. This lack of awareness amongst other ICU professionals may also explain why nurses reached a higher level of agreement with the recommendation: *The multi-disciplinary team should collaborate to reduce and manage patient agitation* than their medical colleagues.

The data revealed that physicians rated *Developing a relationship with the patient*, *Using alternative communication methods* and *Neuropaedagogy* significantly lower than other stakeholder groups. It is important to acknowledge that the amount of time ICU physicians can spend with patients is often limited due to other competing commitments. One explanation for why physicians rated these recommendations lower than any other stakeholder group may be that these recommendations simply require additional or prolonged time with the patient, which they often do not have.

This study found that researchers rated *Developing care plans built on patient preferences* significantly lower than nurses and patients/family members. It is unclear why some researchers rated care plans as less useful to minimise agitation in the ICU. Researchers also rated *Checking that aggressive and violent agitated patients do not have access to objects that can be used to injure others* lower than any other stakeholder groups. While a Danish researcher explained that Danish patients do not use weapons in the ICU, a Danish nurse described experiencing a patient using scissors as a weapon. This discrepancy suggests this may be an area worthy of further exploration. It was also noticed that physicians and patients/families rated the allocation of the same staff higher than other groups. Finally, it was noticed that patients/families rated comfortable surroundings, mental stimulation and patient diary higher than other groups. These last findings suggest that patients and family members may value some types of NPSs differently to researchers and clinicians.

### 8.16.6 Recommendations excluded from the guidelines

There were 16 recommendations that reached below 75% consensus in both countries. These included eye masks, earplugs, massage, nature-based sounds, guided imagery, sing or hum, spiritual/pastoral care person, clearly displayed names and/or photographs, relaxing breathing exercises, BBAUM approach, gentle voice prevention, Felicia Affolter, aromatherapy, reflexology and acupuncture. Interestingly, of the six different NPSs that researchers claimed showed a significant effect in the systematic review of effectiveness (see Chapter 7), only two were included in the final set of recommendations. These included multicomponent nonpharmacological care interventions[49] and healing touch[50]. All other recommendations from the systematic review of effectiveness, including nature-based sounds, music, foot reflexology and aromatherapy, did not reach consensus in the Delphi study.

It must be noted that some recommendations received few ratings, which significantly decreases the validity of the findings for those recommendations. It was also noticed that most excluded recommendations were not associated with any harm. These included guided imagery, singing or humming, involving a spiritual/pastoral care person, having clearly displayed names and/or photographs, relaxing breathing exercises, BBAUM approach, gentle voice prevention, nature-based sounds and Felicia Affolter. More research is clearly needed to further investigate the effects of these NPSs. Participants reported concerns related to aromatherapy, reflexology, eye mask, earplugs, massage and acupuncture, which must be considered for future practice and research.

This study also gained insights into the perceived barriers and facilitators to future guideline implementation. The greatest barrier to guideline implementation was lack of time, while the greatest facilitator to guideline implementation was having a dedicated group to lead implementation.

## 8.17 An emerging model

A model was developed from the included recommendations (Figure 28). This model clearly shows how the different themes relate to each other and can form the basis for clinical decision-making when aiming to minimise and manage agitation. The model outlines the care principles that should guide all care, the different steps caregivers need to take when aiming to minimise and manage agitation, and the context-related recommendations affecting the successful use of NPSs.

[49] During pilot tests of laid people, this was translated to using several non-drug strategies simultaneously.
[50] During pilot tests of ICU clinicians this changed to therapeutic touch.

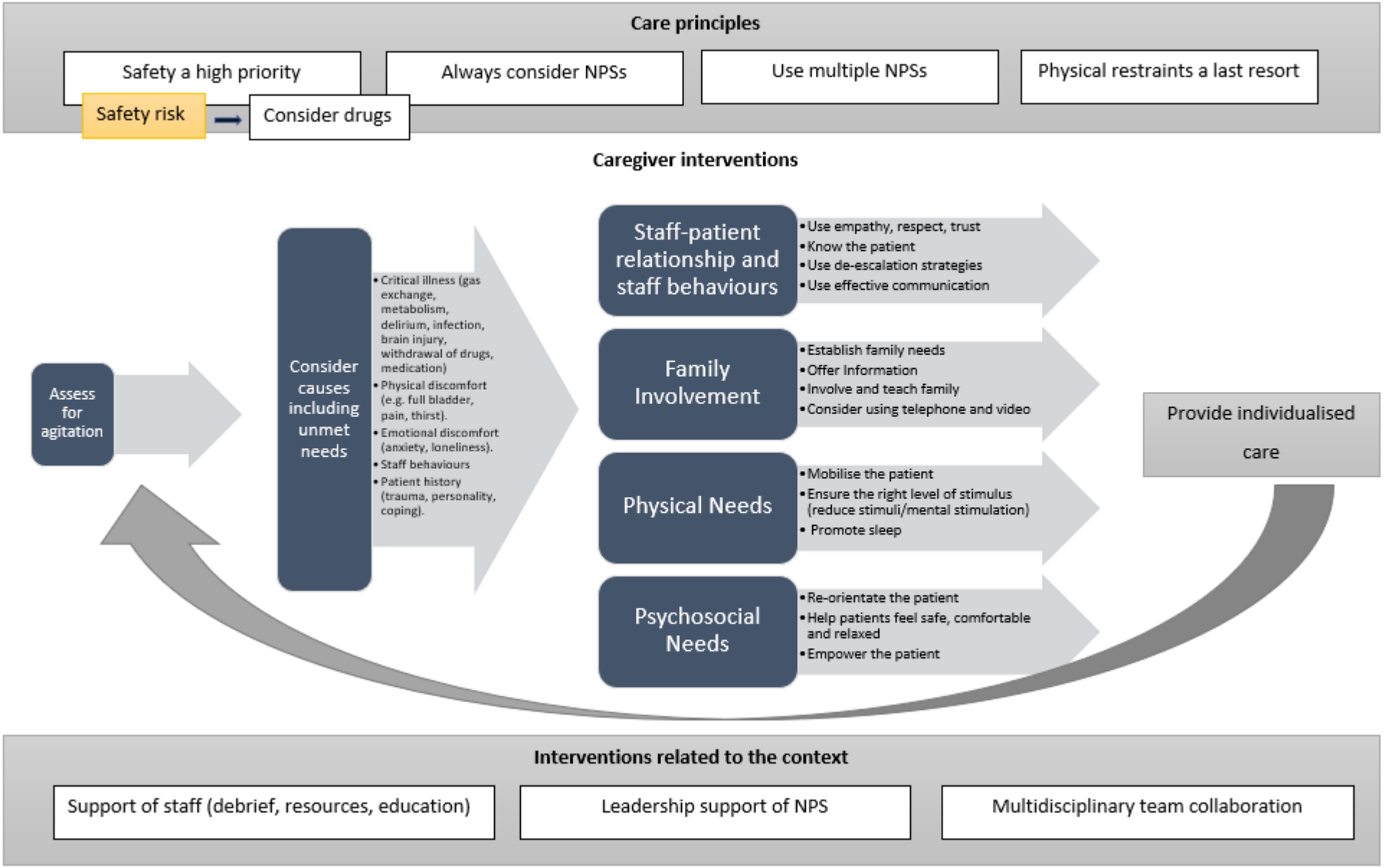



**Figure 28 Model for nonpharmacological prevention, minimisation and management of agitation**

## 8.18 Strengths and limitations of the Delphi study

There were many strengths of this Delphi study. A major strength was the size of the Delphi panel and the variety of Delphi panel members supporting disciplinary and globally representative guideline recommendations. Although the majority of the participants were nurses, all stakeholder voices were taken into consideration in this study. The excellent survey response rate (88-95%) from both countries across the Delphi rounds was also a significant strength, increasing the study's rigour (Keeney et al., 2011).

This was a robust Delphi study, meeting key quality criteria for Delphi research as described by Hasson and Keeney (2011), Diamond et al. (2014) and Junger et al. (2017). There was a clear justification for carrying out the study, and the study had a priori criteria for consensus, endorsement of recommendations, number of rounds, participant eligibility and criteria for removal or modification of recommendations. A high level of consensus was required in both countries for a recommendation to be endorsed. The validity of this study was enhanced through thoroughly tested surveys and an exhaustive translation process to ensure unambiguous survey questions. This Delphi study was also strengthened by including an extensive amount of qualitative data, which was synthesised and reported. In an area with a very limited knowledge base, the qualitative data was important and provided a better understanding of NPSs. Finally, this study reported not only on the recommendations reaching consensus but also on those that did not reach consensus. Although recommendations not reaching consensus are commonly not discussed in Delphi research, it is believed that the description of all NPSs is important and provides transparency.

This study also had a number of limitations. Delphi research does not offer indisputable facts and cannot replace higher levels of rigorous scientific knowledge. It must be acknowledged that the level of evidence this Delphi study produced is relatively low, and the findings may be subject to change. However, following JBI's pluralistic approach to evidence, the study is important because it presents the best available evidence. Expert evidence can be necessary to promote patient-centred care, and it would be unethical for patients, their families and the ICU staff to wait for better evidence to emerge. Carrying out research on NPSs for agitation in the ICU is challenging, and some answers may never be discovered through scientific evidence. An advantage of this Delphi, however, was that in addition to identifying what interventions reached a high level of consensus in both Denmark and Australia, it also explored if interventions were seen as patient-centred, safe, important and feasible. Such information can support clinicians when making decisions in their clinical practice.

The study also had an advanced starting point based on existing literature and advice from stakeholders. Having an advanced starting point has been criticised for directing responses in a certain direction. However, in this study, the advanced starting point was seen as a major advantage, as having a clear scope and framework in place in the first survey was likely to save

time for participants, decrease the perceived burden of participants and potentially increase the response rate. It is also likely that participants who provided advice on effective strategies in the early consultation phase appreciated the iterative nature of the study, meaning they did not have to repeat themselves. To allow some flexibility and creativity in the first survey round, open-ended questions were added.

Another limitation was the risk of response bias, meaning participants could have had a special interest in the area, and therefore, the findings may not reflect the opinions of other professionals or patient representatives. However, special interests and motivations were seen as essential as the success of a Delphi study depends on participant participation in all Delphi rounds. Furthermore, the significant interest in the area and the recruitment of 115 participants in only a few weeks suggests the results are still likely to represent the opinions of many clinicians, researchers, patients and their family members.

This online Delphi study is likely to have excluded some people, including those with no computer or internet and poor reading, communication and digital literacy skills. Reaching a broader group of people would have been beneficial. However, meeting face-to-face with all participants was impossible, given the distance between the researchers and the participants.

The idea of reaching "collective bias rather than wisdom" (Stewart, 1987, p. 99) is also a limitation of Delphi research. This idea relates to participants affecting each other's answers negatively[51] , causing bias rather than answers getting closer to *the truth*. Due to this concern, care was taken with the feedback provided to participants between rounds. Although stability over rounds was not measured and only minimal feedback was provided between rounds, it can be argued that the large number of participants, the anonymity promoting honesty and the thoroughly tested surveys increased the reliability of the study.

Most participants in this study were nurses, which can also be seen as a limitation. It is possible that different recommendations would have been endorsed if the other stakeholder groups were larger. However, bedside nurses are the ones who provide initial care for agitated patients, and they deal with these patients for prolonged periods of time. Therefore, when nurses showed the greatest interest in the topic, this was not a surprise, and it seemed both natural and fair to include nurses primarily.

The last survey was long and repetitive, asking participants about the importance and feasibility of recommendations. It is possible that some participants felt fatigued and provided less considered thought to the survey answers. However, only two participants did not complete this last survey, suggesting that participants were motivated and felt their answers to the questions were important.

[51] Participants changing their ratings to what the majority of people rate, or any reported harms or benefits.

It is likely that the wording of recommendations would have appeared in a more professional tone if we had not included patients and family members. However, the voices of patients and their family members are essential in developing meaningful guidelines (Armstrong et al., 2018; Involve, 2021). Furthermore, recommendations written in layperson language can also be used in a future patient and family version of the recommendations (Danish and English).

This Delphi study did not aim to get an in-depth understanding of the suggested recommendations, including how they could be carried out and what their active ingredients were. Therefore, the exact relationship between agitation and several recommendations remains unknown. Future research must investigate this, as such understanding is likely to support the implementation process and advance the development of future interventions.

Another limitation is that recommendations were not categorised according to their ability to prevent, minimise or manage agitation. This was not possible as the stakeholder groups and the previous literature did not clearly separate interventions according to abilities to prevent, minimise or manage agitation. Future research should consider if interventions have long-term effects, and thus the ability to prevent future episodes, or have immediate but short-term effects, and thus the ability to minimise and manage agitation.

The study findings and processes indicate that asking stakeholders for advice early in a project, ensuring inclusive and transparent communication, and meaningful Delphi questions and feedback can result in optimised engagement and low attrition rates.

## 8.19 Conclusion

This Delphi study is the first to obtain perspectives from a broad group of people on NPSs to reduce agitation in the ICU. It was a well-designed Delphi study with a large number of participants, a high response rate and a broad representation of stakeholders across Denmark and Australia.

The findings from this Delphi study provide robust evidence for preliminary guidelines on nonpharmacological minimisation and management of agitation in the adult ICU. Overall, the findings suggest that there are some overall care strategies that clinicians should follow, including always considering NPSs, using multiple NPSs, prioritising safety and using PR as a last resort. The care interventions include assessing for agitation, treating causes of agitation, establishing trusting relationships and optimising staff behaviours, involving families, considering patients' physical and psychosocial needs and providing individualised care. Finally, the context must be considered, including support of staff, leadership support and multidisciplinary team collaboration.

The data also revealed that participants from the two countries and the different stakeholder groups rated several recommendations differently. The qualitative comments explain some of

these differences as related to resources, culture and patient characteristics. For other recommendations, it remains unclear why participants rated differently.

Chapter 9 critically discusses the findings from all three study phases in the context of the existing literature and conceptual understandings of the nonpharmacological prevention, minimisation and management of agitation.

# CHAPTER 9: DISCUSSION

## 9.1 Introduction

Caring for agitated patients in the ICU is challenging, and while clinicians are encouraged to use NPSs when possible, no guidelines exist on the use of such strategies. To address this issue, this thesis aimed to develop preliminary patient-centred, evidence-based clinical practice guidelines for the nonpharmacological prevention, minimisation and management of patient agitation in Australian and Danish adult ICUs. A secondary aim was to identify the implications of developing clinical practice guidelines across two countries.

Guided by a uniquely developed conceptual framework and following a multi-phase mixed methods approach, the first phase of the study started with consulting various stakeholders to determine the scope of the guidelines. The second phase systematically explored the existing literature to develop tentative guideline recommendations. The final phase tested and explored nonpharmacological recommendations in a three-round modified Delphi study. From a guideline development perspective, this study has presented the scope and purpose of the guidelines, systematically reviewed the existing literature, and presented a list of unambiguous guideline recommendations that consider the patient-centredness, harms, importance and feasibility of the interventions (see Appendix 44) and presented the barriers and facilitators to guideline implementation. The resulting guidelines are complete but preliminary, as they must still be externally reviewed.

In this final chapter, the findings from each study phase will be integrated through joint displays and narrative weaving as per the chosen mixed methods design. The purpose of integration is to see how findings relate to each other and to make meta-inferences in order to address the overall aim (Fetters et al., 2013; Guetterman et al., 2015). The meanings, importance and relevance of the meta-inferences will then be discussed[52]. To address the secondary aim of this thesis, this chapter will also discuss the implications of developing guidelines across countries. The final section of this chapter discusses how the guidelines can be positioned amongst existing ICU guidelines and how they can be implemented.

[52] Personal note: of the two included countries, I had only worked clinically in Australian ICUs. I, therefore, travelled to Denmark to better understand and interrogate the differences between the countries discovered in the Delphi study. The journey involved presenting my preliminary results at a national ICU conference and visiting three ICUs and a research unit. I discussed my findings and concerns with multiple researchers and clinicians, and these discussions informed the explorations and discussions in this chapter.

## 9.2 Meta-inferences related to patient-centred NPS to prevent, minimise and manage patient agitation in the ICU

Four meta-inferences can be made from this study. The narrative weavings supporting the meta-inferences will be presented in Box 2-5 (see Joint Displays in Appendix 49).

### 9.2.1 Meta-inference one: The provision of NPS to reduce agitation depends on the establishment of a trusting relationship and staff behaviours related to patient relational needs

A key finding in this research is the importance of establishing a trusting staff-patient relationship and optimising staff behaviours to support patients' relational needs (see Box 4). Developing a trusting relationship in the ICU is about respecting the patient as a person, acknowledging the patient's suffering and getting to know the patient in order to provide individualised care. It is essential that patients do not feel threatened by staff but are met with care, acknowledgement, clear communication and empathy. When trusting relationships are established, staff are more likely to identify patient needs, patients are more likely to collaborate, and NPS are more likely to be effective. This study found that discontinuity of care and PR were two threats to the establishment of trusting staff-patient relationships.

**Box 4 Findings supporting meta-inference one**

In study phase one, stakeholders described the importance of developing a trusting relationship with the patient and knowing the patient. Allocating the same staff to look after the patient helped staff to know the patient and their needs and helped patients to feel safer. Stakeholders described a range of behaviours essential for minimising and managing agitation. These included active listening, showing respect, using non-threatening and calming behaviours, being present, showing empathy and seeing the patient as a person.

Study phase two showed that while the importance of establishing a trusting relationship and optimising staff behaviours was not mentioned in any ICU guidelines, three non-ICU guidelines on managing patient agitation emphasised the importance of the relationship and described it as a therapeutic alliance or collaborative relationship (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017). In these guidelines, the relationship was described as a way of acknowledging patient suffering. It helped to identify patient needs and collaborate with patients. The non-ICU guidelines also highlighted the importance of using non-threatening, non-judgemental, clear and empathetic communication skills. The three qualitative systematic reviews described how feelings of loss of control, confusion and an inability to communicate, dominated patients' ICU experiences. The reviews described how human connection and trusting relationships could help patients through a frightening time (Boehm et al., 2021; Freeman, Yorke, & Dark, 2021; Gaete Ortega, Papathanassoglou, & Norris, 2020).

**Box 4 Continued**

In the last study phase, participants in both countries agreed on the importance of establishing a relationship with the patient based on empathy, respect and trust. This relationship was described as essential for staff to know and understand patient needs, for staff to provide individualised care and for patients to trust staff and NPS. Participants also described how staff behaviours could affect patient agitation, and staff needed to consider how to approach patients in non-threatening and non-judgemental ways. The participants agreed that communication methods such as active listening, non-threatening behaviours to de-escalate behaviours, and the use of different communication methods, were helpful in reducing agitated behaviours. While physical restraints and rotation of staff were described as hindering the development of trusting relationships, such recommendations were rated significantly higher by Australian participants.

The importance of establishing a relationship of trust and optimising staff behaviours to reduce agitation is supported by the conceptual framework. The conceptual framework emphasises the importance of establishing trusting staff-patient relationships (Kitson et al., 2013a). A relationship of trust requires staff to acknowledge patient experiences, know and respect patients, and anticipate their needs (Kitson et al., 2013a). The FoC framework also describes how caregivers should engage with patients, listen actively, be present and compassionate and help patients to cope and stay calm to support patients' relational needs (Feo et al., 2018).

Similar to the findings of this study, a recent UK study by Freeman et al. (2022a) also found that the fostering of trusting staff-patient relationships and staff behaviours were essential factors in reducing agitation. The authors interviewed seven patients who had been agitated in the ICU and their family members. Patients and family members described how human contact was important and strategies such as reassurance and handholding were helpful. Conversely, staff's negative communication and behaviours could intensify feelings of vulnerability and trigger agitation (Freeman et al., 2022a). Several researchers have found that relationships of trust are essential for critically ill patients (Halvorsen et al., 2022; Wassenaar, van den Boogaard, van der Hooft, Pickkers, & Schoonhoven, 2015). In a meta-synthesis of patients' experiences of Nordic ICUs, Egerod et al. (2015) described how patients found strength in caring relationships. Clinicians were able to connect with patients and guide them toward recovery only when they acknowledged them as human beings with individual needs (Egerod et al., 2015). In another Scandinavian study, Karlsson and Bergbom (2015) interviewed ICU clinicians and found that patients would accept care interventions and find strength only when they felt safe and trusted staff. The importance of caring relationships was also highlighted in a study by Wåhlin et al. (2017). In a survey of 268 previous ICU patients, care activities relating to relationships and caring atmospheres were seen as more important than any other care activities, including activities related to pain and physical discomfort. The most important item was 'having trust in staff' (Wåhlin et al., 2017).

Scholars have also explored the importance of staff behaviours in the ICU. Basile et al. (2021) found that ICU patients felt dehumanised when staff talked over them, showed little interest in getting to know the person in front of them and only offered distressing comments (Basile et al., 2021). Conversely, patients felt humanised when clinicians were empathetic, empowering and acknowledged their unmet needs (Basile et al., 2021). The authors found that dehumanisation resulted in the loss of trust in staff and de-motivation to engage in recovery activities. These findings again emphasise the importance of staff members' caring behaviours and the development of trusting relationships to optimise the effect of NPS. The importance of the establishment of trusting relationships and positive staff behaviours for the effect of NPS provides significant insight that must be taken into account whenever attempts are made to implement or evaluate NPSs.

Beesley (2021) describes how dehumanising staff behaviours can stem from the ICU culture, staff burnout in busy ICUs, compassion fatigue and moral distress. Henriksen et al. (2021) found in a meta-analysis that providing humanised care in the ICU requires a specific skill set. Being able to fully focus both on technology and the person in the bed is challenging and often only fully accomplished by expert nurses. Several scholars have suggested how nurses need to master the technological side of care before they can transcend it and shift their attention towards patients and family members (Alasad, 2002; Crilly et al., 2019; Kvande et al., 2022; Tunlind et al., 2015). These findings suggest that using NPS effectively requires nurses to master multiple areas of critical care.

#### *9.2.1.1 Threats to the establishment of trusting relationships*

While data from this study emphasise the importance of trusting relationships to reduce patient agitation, discontinuity of care and physical restraints were identified as threats to the establishment of such relationships.

##### 9.2.1.1.1 Discontinuity of care

Close interpersonal relationships develop over time, and research suggests that continuity of care is necessary for establishing trusting relationships (Crocker & Scholes, 2009; Flinterud et al., 2019; Haggerty et al., 2003; Minton et al., 2018). Relational continuity of care means that the ICU staff, over time, get to know the patient, their motivation, preferences, coping mechanisms and stressors (Crocker & Scholes, 2009). Relational continuity of care is associated with multiple benefits for patients (Baird et al., 2016; Crocker & Scholes, 2009; Hofer & McDonald, 2019; Minton et al., 2018), notably the agitated patient (Freeman et al., 2022a, 2022c) and for nurse engagement and motivation (Flinterud et al., 2019; Segaric & Hall, 2015). Many participants, particularly Danish participants, agreed with these arguments and described how using the same staff to care for the patient was critical to reduce agitation, as it allowed staff to know the patient and develop trusting relationships. Nevertheless, the Delphi study also discovered that many, particularly Australian

participants, believed staff should rotate and not be allocated to the same agitated patient. This belief was primarily based on worries about staff fatigue and burnout.

While there seem to be many benefits of allocating the same staff to look after an ICU patient, other scholars have also found tensions between the desire to allocate the same staff and other competing interests. One study found that allocating the same staff in ICU was a barrier to improving staff's technical skills (Baird et al., 2016; Crocker & Scholes, 2009). Another study found that staff were concerned about becoming too emotionally involved (Baird et al., 2016). Agitated patients in the ICU may be at particular risk of discontinuity of care as they are often perceived as being challenging and, therefore, less desirable to care for (Williams, 2007). The current study found that caring for agitated patients can be physically and emotionally exhausting. Such feelings particularly pertained to fears of and guilt over not completing expected tasks and being blamed for causing adverse events (Adams et al., 2021). Both this current study and others have found that some nurses find it easier and, at times, prefer to care for sedated patients (Minton & Batten, 2021; Shapira, 2002).

Comments in the Delphi study about burnout and fatigue when caring for agitated patients are concerning. It is important to recognise that staff burnout in the ICU is a real problem (Chuang et al., 2016; Costa & Hammond, 2023), resulting in highly-qualified staff leaving the discipline (Chen & Nates, 2020). Supported by other studies (LeBlanc, 2016; Shapira, 2002; Zamoscik et al., 2017), this study also suggests that staff exhaustion may negatively affect care for agitated patients. Sacrificing staff without considering staff exhaustion and burnout for an apparently "best model" to ensure continuity of care does not provide a sustainable model. On the other hand, sacrificing continuity of care by ignoring the needs of patients and families seems equally short-sighted. The findings in this study suggest that there are larger issues related to interaction and connection with agitated patients and the type of support staff receive when caring for agitated patients. Nurses may lack the tools necessary to care for agitated patients and the organisational support to optimise their care. Lillis (2022) argues that relational continuity can be obstructed by the way organisations are managed. A neoliberal market focusing on individual responsibility, limiting expenditure, and privatisation has increased focus on production and effectiveness and made relationships more transactional (Lillis, 2022). Adding to this comes workforce shortage issues, excessive workloads and temporary workers, ultimately resulting in fragmented care and challenges for practitioners in maintaining continuity of relationships (Lillis, 2022). If relationships are not valued, this will change the nature of nursing and will likely have a negative effect on patient outcomes. The importance of organisations and leadership supporting the use of NPS is further discussed in Section 9.2.4. It was noted that Danish Delphi participants mentioned working and rotating in teams to ensure continuity of care. Such models are encouraging and warrant more research on how continuity of care can be strengthened in the ICU.

#### 9.2.1.1.2 Physical restraints

Several Danish and Australian participants, including patients and family members, believed that PR could exacerbate agitation and hinder the establishment of trusting staff-patient relationships. While Danish participants described how PR was not used in Danish ICUs, multiple Australian participants described how PR was sometimes necessary to keep patients safe while facilitating staff breaks and the provision of necessary clinical tasks. The findings are consistent with those of other studies describing how PR are not used in Danish ICUs (Holm & Dreyer, 2017; Kjeldsen et al., 2018; Svenningsen et al., 2015), while commonly (7-8%) used in Australian ICUs (Ankravs et al., 2020; Elliott et al., 2013; Maiden et al., 2020; Perez et al., 2021). The issues related to the use of PR *per se* and the significant differences in attitudes and prevalence of its use between the two countries warrant discussion.

Using PR in the ICU is not without risks, and it can be argued that the intervention is not a patient-centred approach. PR in the ICU has been described as ineffective, dangerous, traumatising and worsening agitation (Burk et al., 2014b; Chang et al., 2008; Franks et al., 2021; Perez et al., 2019; Smithard & Randhawa, 2022). Similar to the findings of the current study, nurses have described PR as increasing patient agitation, negatively influencing the nurse-patient relationship and negatively affecting nurse moral distress (Perez et al., 2021). Perez et al. (2022) interviewed five patients and six family members from Australian ICUs. They found that patients experienced agony, uncertainty, fear, helplessness and a lack of trusting relationships as a result of being physically restrained during their critical illness. With shackled hands, basic human instinctual entitlements were restricted, such as sharing a hug, wiping away a tear or using nonverbal communication. All patients suffered from post-traumatic stress disorder (PTSD) due to their experiences of being physically restrained. Family members also reported feeling traumatised after seeing their loved one being physically restrained (Perez et al., 2022). Researchers are starting to better understand how patients' poor psychological state in the ICU can lead to psychological difficulties and PTSD after ICU discharge (Bienvenu, 2021; Murray et al., 2020) and how such mental health issues can negatively affect patients' quality of life (Teixeira et al., 2021). In light of the conceptual framework of this study and the existing literature, it is argued that PR does not classify as a patient-centred NPS. The main reason for this is that PR does not support the establishment of trusting relationships, and in fact, is likely to hinder such relationships. PR is also likely to promote patient agitation and result in negative patient experiences.

The observation that PR is utilised in Australian ICUs but not in Danish ICUs merits some speculation. Similar to the current study, Martin et al. (2005) found that PR was frequently used in ICUs in the USA but never in Norway. The authors argued that this could relate to Norwegian patients being more heavily sedated and having a higher nurse-to-patient ratio. However, recent research suggests that patients in Nordic countries are kept more awake (Berntzen et al., 2019;

Egerod et al., 2013b; Holm & Dreyer, 2018; Kjeldsen et al., 2018; Laerkner et al., 2017; Lind et al., 2018; Olsen et al., 2020; Strøm et al., 2010; Tingsvik et al., 2018). There are also standards and research to suggest that the nurse-to-patient ratio for mechanically ventilated patients is 1:1 in both Denmark and Australia (Chamberlain et al., 2018; Laerkner et al., 2015; Maiden et al., 2020; Susanne Ilkjær et al., 2013). Thus levels of sedation and nurse-to-patient ratio may not fully explain the use of physical restraints in Australian ICUs.

Current laws and guidelines may affect the use of PR. It is a complex and lengthy process to use PR in Danish ICUs, and the decision-making processes involving ICU physicians and the chief psychiatrist must be thoroughly argued and documented (Clause 19) (Nielsen, 2022; Retsinformation, 2019). In Australia, ICUs follow the broad principles provided by the Australian Commission on Safety and Quality in Health Care (ACSQHC, 2022). However, major policy variations exist between territories, states, health districts and hospitals (Perez et al., 2022; RANZCP, 2017). Typically, a senior staff member with relevant training, often a nurse (Maiden et al., 2020), can instigate the use of restraints (NSWH, 2020; SAH, 2020). Thus on review of each country's national guidelines and laws, combined with a reflection of personal experiences and discussions with ICU professionals in both countries on how these guidelines and laws are applied, a compelling argument has emerged for concluding that Danish clinicians use PR less frequently because Danish laws on PR use are stricter.

The approach in Danish ICUs may also be influenced by the traditional Lutheran values of equality and the Danish philosopher Knud Ejler Løgstrup who had a strong focus on human interactions, ethics and trust (Uhrenfeldt et al., 2018). Influential Nordic nursing scholars, including Kari Martinsen, Katie Eriksson and Karin Dahlberg, build on Løgstrups philosophies and focuses on protecting those in need of help, developing caring relationships and understanding each unique human and their needs (Alligood, 2017). The strong focus on care, equality, trust and openness is also reflected in the Danish welfare system (Andreasson, 2017; Hofstede & Hofstede, 2001).

With expanding ICUs (Vincent & Singer, 2010), more awake ICU patients (Devlin et al., 2018a), worsening staff shortages (Chen & Nates, 2020; Xu et al., 2021) and the exhausting nature of caring for agitated patients (Adams et al., 2021), staff may be tempted to increase the use of PR. Rule-orientated, compliance-driven environments that focus on holding individuals accountable for mistakes may also encourage the use of PR (Khatri et al., 2009, p. 314). Unfortunately, such risk-averse ICU cultures are commonplace in many countries, and they tend to be associated with a lack of leadership support (Alostaz et al., 2022; Cui et al., 2021a; Everingham et al., 2014; Freeman et al., 2022b; Kydonaki et al., 2019; Perez et al., 2021; Unoki et al., 2020). It is important to raise awareness of how the use of PR can negatively affect the establishment of trusting relationships, thus hindering the effect of all NPS. Although PR is currently not used in Danish ICUs, organisations and clinicians must be aware of the values underpinning this to avoid future

temptation to employ PR as a method to manage increasing workloads and increase productivity. My Delphi study highlighted this vulnerability by describing a Danish physician contending that PR could be used more in Denmark to reduce sedation and subsequently shorten the ICU length of stay. The risk of this becoming a potential future trending sentiment may warrant further exploration.

Overall, existing literature supports the importance of developing trusting relationships and optimising staff behaviours to minimise agitation in the ICU. However, in busy ICUs, discontinuity of care and the use of physical restraints may pose significant threats to the development of trusting relationships. The Danish ICUs may be using models that better facilitate the development of trusting relationships. More research is required to better understand how staff can ensure relational continuity of care, and the factors affecting clinicians' decisions to use PR to reduce agitation.

### 9.2.2 Meta-inference two: The provision of NPS to reduce agitation depends on engagement with family

The data from this study indicate that it is crucial to always take into account the role of the family and their potential for involvement in care (see Box 5) when aiming to reduce agitation. As ICU patients often cannot adequately express their needs, family members who know the individual patient's preferences and reactive behaviours are vital for identifying these needs. Families can also be helpful in calming an agitated patient. However, the family needs appropriate education about agitation and ways in which they can support their agitated loved one. Clinicians must also be equipped to facilitate appropriate family member input to prevent a paradoxical increase in patient agitation and family member feelings of stress and guilt.

**Box 5 Findings supporting meta-inference two**

In the first phase of this study, stakeholders described the importance of involving family to minimise agitation. Family involvement included strategies such as being present, calming a patient, reading a newspaper, reorientating the patient or holding a hand. Stakeholders described how families needed factual information about agitation to better understand the condition and to allow them to constructively support the patient. Conversely, a lack of knowledge about agitation could induce family member frustration, withdrawal from patient engagement, and even induce traumatisation. Stakeholders further described how family members could hinder effective management through counterproductive patient engagement.

The second study phase found sparse information about family involvement in the existing guidelines. One ICU guideline described how it supported family visitation (Donato et al., 2021), while a non-ICU guideline described the importance of informing the family about agitation, so they could be supportive in reducing agitation (Luauté et al., 2016).

**Box 5 Continued**

All three qualitative reviews described the importance of involving the family as they could provide protection, comfort, and guidance and orientate the patient (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020). Family members could, for example, be involved in personal hygiene, such as brushing the patient's hair or performing oral care (Boehm et al., 2021).

In the final study phase, participants agreed on five recommendations concerning family involvement. These related to identifying families' capacities to be involved, providing information, teaching, involving in care, and finally making use of alternative ways of communicating with family if they were unable to see the patient face-to-face. While all interventions were seen as important, the Danish participants saw family involvement in care as less feasible. One explanation provided by Danish participants was the need to support patient dignity and integrity. Concerns related to the well-being of involved family members were also raised. Family members were at risk of feeling guilty, stressed and overly responsible for the patient.

The findings of this study are supported by the conceptual framework emphasising the importance of involving families to better understand patient needs and to support patients' relational needs (Cohen-Mansfield, 2000; ILC, 2022). It is widely recognised that families are important partners in ensuring patient-centred care in the ICU (Davidson et al., 2017; Egerod et al., 2015; Nygaard et al., 2022). For example, the ABCDE bundle (Balas et al., 2012), guiding ICU patient care internationally, changed in 2017 to include family engagement (Pun et al., 2020) and was renamed the ABCDEF[53] bundle (Marra et al., 2017). However, the role of families in reducing patient agitation is an area that has only recently started attracting attention.

The systematic review of nurses' experiences of caring for agitated patients also found that it could be helpful to partner with families when aiming to reduce patient agitation (Adams et al., 2021). Since this review, Freeman et al. (2022b, 2022c) interviewed patients, family members and clinicians to explore how they experienced agitation in the ICU. They found that family involvement could help patients through episodes of agitation. However, similar to the current study, staff described how some families sometimes struggled to see their loved one agitated, and how some family members felt overly responsible and guilty if something went wrong. Freeman et al. (2022b) also found that families could burden staff who were already overwhelmed with caring for an

[53] A: assess, prevent and manage pain, B: both spontaneous awakening and spontaneous breathing trials, C: Choice of analgesia and sedation, D: delirium assessment, prevention and management, E: early mobilisation and F: family engagement and empowerment (Marra et al., 2017).

agitated patient. It is clear that it can be challenging to engage families in care when aiming to reduce patient agitation, and there may be a risk of increasing patient agitation or even causing harm to family members. Unfortunately, communication with families in the ICU is often suboptimal, with families being left isolated (Adams et al., 2017; Nygaard et al., 2022). Authors claim that optimal family engagement requires understanding family needs, good communication skills and organisational support (Bloomer, 2023; Nygaard et al., 2022).

Interestingly, the Delphi study found that Danish participants saw family involvement in care activities as less feasible. This is a surprising finding since a recent survey of Nordic[54] ICU nurses from 196 adult ICUs showed that in Denmark, 85% of families sometimes, often or always participated in patient care activities - a percentage higher than for any other Nordic country (Frivold et al., 2022). However, the Nordic study did not define what was meant by care activities. Some comments from Danish participants in the Delphi study suggested they considered care activities as intimate care activities, such as bathing or toileting. They described how family members should not be regarded as carers and that health professionals needed to protect patient dignity and integrity in the long term. Supporting this view, a Swedish study showed that nurses asked close relatives to leave the room when providing personal care to protect the integrity and dignity of the patient (Åsa & Siv, 2007). In contrast, involving family members in care activities, including bathing, is not new in Australia and has shown positive effects on perceived family-centred care (Mitchell et al., 2009). These findings suggest that there may be some cultural differences between the two countries related to the involvement of families.

Considering both the risks of overburdening families and the cultural differences that may be found in ICUs worldwide, it is somewhat concerning when an exploratory descriptive study from the USA (McAdam et al., 2008) made the generalisable suggestion that families should be mandatory voluntary carers in the ICU by supporting staff with care activities such as washing and positioning. This thesis suggests that while family engagement is essential when aiming to reduce patient agitation, clinicians should think carefully about what defines safe and appropriate family involvement. This may be particularly important in ICUs with few resources.

### 9.2.3 Meta-inference three: The provision of NPS to reduce agitation must consider of causes of agitation and patient needs

The findings of this study suggest that care must consider patients' unique needs when attempting to prevent, minimise or manage agitation (see Box 6). This meta-inference is closely related to identifying causes of agitation, as these are often related to unmet psychosocial or physical (incl biomedical) needs.

[54] Nordic countries = Sweden, Denmark, Finland and Norway

**Box 6 Findings supporting meta-inference three**

In the first phase of this study, stakeholders described how it was essential to identify causes of agitation and support patients' physical and psychosocial needs to minimise and manage agitation. The physical needs were related to reducing stimuli, allowing sleep and rest, treating medical causes of agitation and optimising patient comfort and physical activity. The psychosocial needs related to feeling safe, respected and cared for and also the need to feel empowered and understood.

In the second phase, the existing evidence suggested various approaches for identifying causes of agitation and supporting patients' physical and psychosocial needs. The systematic reviews of effectiveness included several studies, including nature-based sounds (3 RCTs) (Aghaie et al., 2014; Rajora et al., 2019; Saadatmand et al., 2013), music therapy (Jong Yoen & Soohyun, 2019; To et al., 2013), reflexology (Allahbakhhsian et al., 2020), healing touch (Davis et al., 2020) and aromatherapy (Mashouf et al., 2017). All interventions showed a significant effect ($p<0.05$), but our confidence in the results was very low due to the studies' low methodological rigour. One guideline from outside the ICU suggested supporting patient sleep. This was supported by the qualitative systematic reviews suggesting patients entered a vicious cycle of sleep deprivation and agitation. Three guidelines from outside the ICU also emphasised the importance of comfortable surroundings (temperature, light, ventilation and colours) (Baldaçara et al., 2018; Garriga et al., 2016; Richmond et al., 2012). The systematic review of effectiveness did not identify any interventions that considered psychosocial needs. Guidelines from outside ICU suggested debriefing patients after episode of agitation (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017), orientating patients and providing explanations (Baldaçara et al., 2018; Richmond et al., 2012) and involving and empowering patients (Garriga et al., 2017; Patel et al., 2018; Richmond et al., 2012; Vieta et al., 2017). One qualitative systematic review also described the importance of talking to patients about their episodes of agitation (Ortega et al., 2020), orientating patients (Gaete Ortega et al., 2020), involving patients in care due to their overwhelming sense of powerlessness and dependence (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020), using therapeutic touch to connect with patients (Freeman et al., 2022a; Gaete Ortega et al., 2020) and finally to involve family as a way of calming and orientating patients (Boehm et al., 2021; Freeman et al., 2022a; Gaete Ortega et al., 2020).

In the last study phase, participants agreed about several interventions related to identifying causes of agitation and promoting psychosocial comfort, including helping the patient feel safe, empowered, comfortable, relaxed and re-orientated, and physical comfort related to mobilisation, ensuring the right level of stimulus and promotion of sleep. The participants also agreed that multiple NPS should be used simultaneously.

The conceptual framework for this study suggested a link between unmet needs, patients' inability to communicate needs, and agitated behaviours (Algase et al., 1996; Cohen-Mansfield, 2000). It also suggested that patient-centred care consisted of supporting physical, psychosocial and relational needs (Feo et al., 2018). Overall, the conceptual framework strongly supports the findings in this thesis, suggesting that holistic care that considers patients' unique needs is essential when aiming to prevent, minimise and manage agitation.

The existing literature also supports the importance of having a holistic approach to care when aiming to reduce patient agitation. In an ethnographic study, Sampson et al. (2019) explored staff approaches to agitation in people living with dementia. Through observations and staff interviews, they proposed two existing models of care. In the first, the *moral judgement* model, staff saw agitation as purposeful bad behaviours directed toward staff. In this model of care, staff focused almost exclusively on patients' physical needs and provided little authentic, compassionate care. Staff also withdrew and avoided contact with the agitated patients, which further exacerbated agitation (Sampson et al., 2019). In the second *needs-based* model, which reflected a holistic approach to care, staff saw agitation as behaviours that were distressing for the patient, caused by dementia, and likely to respond to interventions. This understanding meant that rather than approaching patients with avoidance and criticism, staff were compassionately interested in knowing the patient, identifying unmet needs and finding solutions (Sampson et al., 2019). The needs-based model, which was more likely to reduce agitation, emphasises the importance of understanding agitation and having a holistic investigative approach.

The current study indicated that clinicians had to consider many factors in order to provide individualised care, including levels of agitation, causes or triggers of agitation, patient history and preferences. Delphi participants made it clear that no one nonpharmacological approach would fit all patients. Because of the heterogeneity of patients’ needs and preferences, getting to know the patient was described as paramount. Knowing the patient supported staff to identify and support patient needs. The importance of knowing individual patients and their preferences in order to provide individualised care in the ICU is well known (Crocker & Scholes, 2009; Minton et al., 2018). It is likely that individualised care has become more important for contemporary ICU care, where patients are more awake. In a Danish ethnographic study exploring caring for awake patients in the ICU, Laerkner et al. (2017) found that treating patients as unique individuals with personal preferences was crucial. What was reassuring and comforting for one patient could be worrying and distressing to another (Laerkner et al., 2017).

One of the challenges of caring for more awake patients in contemporary ICUs is in supporting all of patient’s comfort needs (Berntzen et al., 2018, 2019). Not being able to relieve patient distress may partly explain why staff felt exhausted and morally distressed when caring for agitated patients (Adams et al., 2021). The conceptual framework of this thesis provides an encouraging view of this

issue. It states that when comfort in some areas cannot be fully ensured, the support of comfort in other areas can compensate for this (Berntzen et al., 2020; Kolcaba & Wilson, 2002). This theory is supported by the FoC framework, which encourages clinicians to amalgamate areas of care so that the whole relational, physical and psychosocial picture is addressed as one rather than focusing on areas of care in isolation. It is also supported by the current study's findings, encouraging clinicians to use multiple NPS.

For clinicians in the ICU, this approach of employing multiple NPS means that when they feel unable to remove physical discomfort that provokes agitation, such as an in-situ endotracheal tube, they can still optimise patient comfort in other areas without turning to psychoactive pharmacological agents. For example, they can help the patient to feel safe, involve the patient in care, increase relaxation by ensuring comfortable surroundings or reduce excessive stimuli. It is also important to remember that when discomfort cannot be easily removed, motivated and caring staff can implement strategies that channel their own behaviours towards helping patients to transcend and "rise above" their discomforts (Kolcaba & Wilson, 2002).

There has been an increased focus on tailored and individualised nursing care and medicine over the last decade (Suhonen et al., 2022). Guideline developers have faced challenges as most recommendations are developed to fit the average patient, an approach that often does not allow for individual judgements (Vincent et al., 2021). However, similar to Vincent et al. (2021), who developed individualised guideline recommendations for sepsis in the ICU, the guidelines presented in this study strongly encourage clinicians to consider individual care needs before applying any NPS.

### 9.2.4 Meta-inference four: The provision of NPS to reduce agitation depends on the ICU culture and staff support

The provision of nonpharmacological patient-centred care to prevent, minimise and manage patient agitation in the ICU requires additional effort from staff. Staff must deal with agitated patients who are often confused, distressed and interrupting treatment in a technical environment focused on saving lives. How staff care for agitated patients in ICU largely depends on the organisational culture and how staff are supported to take on the role (see Box 7).

**Box 7 Findings supporting meta-inference four**

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|---|
| Stakeholders in study phase one argued that to safely use NPS as opposed to using sedation or PR, staff needed support from leadership and the organisation. This support is related to adequate resources, time and education. Stakeholders also suggested that staff needed leadership that supported and valued the use of NPS and acknowledged the work required from staff. Finally, the importance of staff debriefing and having safety procedures in place was mentioned. |

**Box 7 Continued**

In study phase two, non-ICU guidelines suggested debriefing staff (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017), ensuring adequate staff (Richmond et al., 2012; Vieta et al., 2017), training staff (Baldaçara et al., 2018; Garriga et al., 2016; Luauté et al., 2016; Richmond et al., 2012) and promoting interdisciplinary collaboration (Baldaçara et al., 2018; Luauté et al., 2016; Patel et al., 2018; Richmond et al., 2012). The guidelines also highlighted that safety should be of high priority (Baldaçara et al., 2018; Garriga et al., 2016). One qualitative systematic review supported staff education (Freeman et al., 2022a).

In the last study phase, participants agreed on the importance of additional staffing, debriefing, frequent breaks, education, multidisciplinary collaboration, leadership support, and the prioritisation of safety. All interventions were seen as important. However, changing the ICU layout and ensuring adequate staffing and frequent breaks were not perceived as feasible interventions.

The conceptual framework supports the findings that the context of care can either hinder or facilitate care delivery and must, therefore, always be considered (Feo et al., 2018). The context includes policy and system-level factors such as quality and safety policies, resources, leadership and culture (ILC, 2022). The systematic review of nurses' experiences of caring for agitated patients in the ICU (Adams et al., 2021) highlighted how managing patient agitation in ICU can be exhausting and cause feelings of guilt, dissatisfaction and failure.

This section will highlight two important points to provide more insights into how staff can be better supported to deliver NPS. The first point relates to the emotional burden experienced by staff and how staff can be better supported to deal with agitated behaviours. It is widely known within dementia care that caring for patients who exhibit agitation can be stressful and lead to burnout and career frustrations (Costello et al., 2019; Hazelhof et al., 2016; Zwijsen et al., 2014). Such stress can negatively influence caring behaviours and patient outcomes (Cooper et al., 2018; Sarafis et al., 2016), increase turnover, poor staff behaviours towards patients and absenteeism (Hazelhof et al., 2016). Considering the current climate of high ICU staff burnout (Chuang et al., 2016) and worries related to inadequate staffing (Chen & Nates, 2020), it is imperative to advance our understanding of staff support in this care context.

According to a qualitative study within dementia care (Kadri et al., 2018), staff's needs, vulnerabilities and experiences of abuse were not acknowledged by their clinical leaders. Ultimately, this resulted in a paradox where healthcare workers were expected to deliver patient-centred care and maintain close relationships with agitated patients while operating in a task-orientated system that did not care for and acknowledge staff who had no control over their

unfavourable working conditions (Kadri et al., 2018). Research demonstrates that fundamental patient-centred care depends on leaders who support and acknowledge staff (Mudd et al., 2022). ICU nurse unit managers can play an important role in supporting the well-being of nurses (Adams et al., 2019a). They must strive to create a healthy and trustworthy work environment that acknowledges staff experiences when caring for agitated patients. The current study identifies how this can be done by offering education on de-escalation strategies, debriefing of staff and an increased focus on staff safety. Perhaps not surprisingly, research suggests that when staff are supported, have the required skill set and create a caring environment to reduce agitation, they are more likely to experience positive patient encounters (LeBlanc, 2016; Wedin et al., 2020).

The second point relates to the ICU culture and the belief that if organisations value patient-centred care above task-orientated care, NPS would no longer be invisible hard work. Instead, there would be an acknowledgement of the additional resources such care requires. Research within dementia care can provide insights into how organisations and cultures affect staff's ability to care for agitated patients. Sampson et al. (2019) observed that when organisations valued and prioritised the use of NPS, this resulted in more focus on education and ensuring adequate resources. Several Delphi participants described how inadequate resources compromised their ability to provide NPS. Insufficient staffing is a known risk factor for decreased patient safety, poor quality care and nurse emotional exhaustion (Aiken et al., 2017; Duffield et al., 2011; McHugh et al., 2020). Providing nonpharmacological care can be challenging in a highly technological environment. For instance, Minton et al. (2018) described the challenges of supporting patients' needs for human connection and reduced stimuli in the ICU caused by the dominance of safety procedures and a strong biomedical focus.

It is pivotal that leadership trusts staff and encourages them to reduce the use of NPS. A Just Safety Culture (Khatri et al., 2009), also known as a psychologically safe culture, offers an open, honest and trusting environment where clinicians can question current practices, express concerns and admit mistakes without being blamed. A just culture is the opposite of a blame culture. A culture of blame is unwilling to take risks, lacks trust in people and is fearful of criticism (Khatri et al., 2009). Blame cultures arise from hierarchical, control-based management styles valuing rules, compliance and accountability (Khatri et al., 2009) and can result in increased use of PR (Cui et al., 2021a; Perez et al., 2021; Unoki et al., 2020). It is not difficult to imagine how staff would feel more engaged, responsible and motivated to use NPS in a psychologically safe and just ICU culture. However, Khatriv et al. (2009) emphasise that organisations may need to revise their values, norms and staff expectations. Changing the culture of a workplace to value NPS requires a commitment to change and major changes in how ICU staff are valued and rewarded (Detert & Edmondson, 2007). Leadership support and effective communication are essential to sustain a just culture (O'Donovan et al., 2019; Vogelsmeier & Scott-Cawiezell, 2007).

### 9.2.5 Summary of meta-inferences

Overall, the results from this study suggest that successful implementation of NPS requires the establishment of optimised staff behaviours with trusting staff-patient relationships, consideration of family member engagement and capacity to be involved, a holistic investigative approach to patients' unique needs and causes of agitation, and finally leadership and organisational prioritisation of NPS and support of staff. Together, these different elements reflect the concepts which underpin the provision of patient-centred fundamental care (Kitson et al., 2013a), suggesting that fundamental care is essential to reduce ICU agitation. Caring for agitated patients requires highly skilled nurses. An emphasis on traditional technical and biomedical nursing skills will not adequately prepare ICU nurses for the challenges involved in reducing agitated behaviours. Discontinuity of care and physical restraints were identified as threats to the development of trusting and caring staff-patient relationships. It is imperative to be aware of these threats in resource-constrained, busy and expanding ICUs.

## 9.3 Developing practice guidelines across countries – lessons learned

A secondary question of this thesis was to discuss the implications of developing guidelines across countries. This section will explore and discuss the advantages and challenges of engaging stakeholders across countries and what it means for guideline development when there are disparities between countries.

### 9.3.1 Consulting stakeholders on the scope of the guidelines

This study shows that the implementation of clinical practice guidelines may be jeopardised if key stakeholders are neither adequately consulted on the guidelines' scope nor had their needs adequately addressed. The scope of the final guidelines was considerably impacted by the stakeholder consultation phase. As an illustration, stakeholders felt the end-users should be the multidisciplinary team rather than only nurses. The stakeholders claimed that creating recommendations for only nurses would significantly complicate multidisciplinary collaboration and, ultimately, implementation of the guidelines. This suggestion by stakeholders changed the final guideline scope, and I needed to consider how to involve multidisciplinary team members and not just nurses in the Delphi study. Overall, it is believed that the stakeholder consultation phase resulted in guidelines that are more implementable. It also resulted in increased attention drawn to the topic, networking with and between stakeholders, and increased recruitment for the Delphi study.

While consultation on the scope of the guidelines is essential, no guidance existed on how to do this. Since it was discovered that stakeholder engagement in guideline development was often not done or not done well (Armstrong & Bloom, 2017; Wyatt et al., 2014), it was decided that developing a framework for how to identify a well-founded guideline scope was required (Adams et

al., 2022b). Developing a new framework required reflections and multiple discussions on the methods used. Challenges arose. For example, there were different expectations for clinician reimbursement in the two countries. Interviewing patients and family members on the scope of the guidelines proved to be more challenging than expected. Developing a bi-lingual webpage, translating, and pilot testing all material was resource intensive. Offering stakeholders the option to provide written feedback resulted in some challenges related to managing the length and clarity of responses. There were also ethical challenges. While formal ethics approvals was not required in either country, ethical considerations were still crucial. The seven-step framework, that was developed for stakeholder consultation on the scope of the guidelines, discusses all of these challenges and provides advice on how to consult stakeholders in ethical and feasible ways. Although stakeholder consultation requires additional time and resources, it is strongly believed that the final scope of the guidelines more precisely reflects the needs of stakeholders, thus increasing the likelihood of meaningful and implementable guidelines.

### 9.3.2 Disparities between countries

While ICU care in Denmark and Australia is similar in many ways, this study found some important differences. Disparities relating to continuity of care and PR have already been discussed. In addition to these, there were other NPS that seemed to be country specific. The interventions of bed bikes, diary use, basal stimulation and therapeutic weighted blankets reached a high level of consensus in Denmark, while trauma-informed care reached a high level of consensus in Australia. These disparities can expand our limited knowledge of NPS for agitation, and it is likely that countries can learn from each other. For example, basal stimulation, originating from Germany (Fröhlich, 1980), has been widely implemented in Danish ICUs (Svenningsen, 2008). The intervention has shown promising results relating to post-traumatic stress disorders, depressive symptoms and families' satisfaction with care (Liang et al., 2022). In the Delphi study, a Danish physician (ID 2033) stated: “I find that basal stimulation works for pretty much all patients…”. Similarly, trauma-informed care is a concept that has evolved over the last 40 years (Sciolla, 2017; Wilson et al., 2013) and is a well-known model in Australia (Isobel et al., 2021; Wilson et al., 2017). Scholars argue that the model has tremendous potential within the critical care environment where patients and families are victims of trauma and/or their past traumatic experiences can easily be triggered (Ashana et al., 2020; Schroeder et al., 2021). Future guideline developers may need to consider the role of interventions that only reach agreement in one country and how such interventions can be shared with and implemented in other countries. This study recommends having a section of the guidelines highlighting recommendations only reaching consensus in one country. Local guideline implementers can then decide whether they want to include such recommendations.

This study also found disparities between countries regarding interventions seen as important and feasible. Such differences may be explained by countries having different standards of care,

values, norms, funding, and expectations of culturally appropriate care. Some differences can be explained by Australia being a distinctive (Anglo) liberal welfare state compared with Denmark being a (Nordic) social democratic welfare state (Marston, 2005). One difference this creates is that, in contrast to Australia, Denmark has a fully public education and healthcare system funded by higher than Australian levels of taxation (Marston, 2005). Another influence, as discussed earlier, is the strong focus on the nurse-patient relationships and trust amongst Scandinavian nursing theorists.

Together these differences between countries raise the question of whether it is advisable to develop guidelines across countries. This study suggests that there are indeed multiple advantages to doing so, but that guidelines need to be contextualisable in order to be implementable. Moreover, successful implementation at a local level depends on successful local planning. It is recommended that local practitioners, managers and policymakers tailor the guidelines to their local environments before implementing them. While this may add additional considerations early in the implementation phase, this kind of work is crucial for mitigating potential implementation barriers. Furthermore, the process of contextualising guidelines is not similar to adaption, which is a comprehensive and resources intensive process (NHMRC, 2020). Contextualising guidelines means that local practitioners need to consider if all recommendations are feasible and meaningful in their local context. For example, taking a patient outdoors would not be feasible if there is no outdoor area. In addition, local guideline implementers may want to consider if they only want to implement the interventions reaching a high level of consensus in both countries.

The advantages of developing guidelines across countries include the avoidance of duplicating work and the possibility of supporting global health by expanding on existing internationally relevant knowledge. Analysing the differences between countries can help countries learn about their own strengths, weaknesses, history and values. It must be acknowledged, however, that this study only demonstrates the potential for developing guidelines across countries with sufficiently similar healthcare systems, social contexts, political systems and national wealth.

## 9.4 Considerations for implementation of the guidelines

Implementation of the guidelines is essential to improve clinical practice. However, changing practice in the ICU can be challenging, time-consuming and expensive (Kajdacsy-Balla Amaral & Rubenfeld, 2012). As suggested by this study, there are several barriers to be considered, such as insufficient resources, difficulties in changing habits, and lack of awareness of NPS. In addition, there is a risk that clinicians could become discouraged by feeling overwhelmed by the number of

recommendations, by the low level of evidence and the conditional[55] nature of the recommendations. There may also be confusion regarding where the guidelines sit in relation to other ICU guideline recommendations, such as those related to delirium, pain, immobilisation and pharmacological treatment of agitation. Below I will describe how the guidelines can be positioned in relation to existing guidelines and frameworks.

The existing well-recognised international PADIS guidelines have been described as comprehensive guidelines for promoting patient outcomes in the ICU and are consequently used for guiding education and practice (Lee et al., 2022). Although 'A' stands for agitation, the guidelines only provide pharmacological recommendations for agitation. Therefore, the updated PADIS guidelines could include the model for NPS for agitation (see Table 26 ) and provide a link to the 63 recommendations identified in this study. It must be acknowledged that agitation is intertwined with pain, delirium and sleep and that several recommendations provided by the current PADIS guidelines are similar to the recommendations identified in this study. For example, the PADIS guidelines (Devlin et al., 2018a) suggest using multicomponent interventions for delirium, including re-orientation, cognitive stimulation, use of clocks, improving sleep by minimising light and noise, reducing immobility, reducing hearing or visual impairment (e.g. enable use of glasses and hearing aids). They also provide advice related to the mobilisation of patients and suggest noise and light reduction to facilitate sleep. However, the PADIS guidelines do not offer a holistic and humanised model of care such as the one offered in Figure 28. This framework considers assessing and identifying causes of agitation, establishing trusting relationships, promoting staff behaviours, involving families, identifying patients' unique needs and supporting staff. This knowledge is critical and deserves considerably more attention if care is to be optimised in the ICU.

ICU scholars call for humanised ICUs and a better understanding of patient-centred care in the ICU (Egerod et al., 2020; Pandharipande et al., 2017). COVID-19 resulted in increased patient agitation (Maamar et al., 2022), possibly due to pathophysiological changes in the CNS, COVID-19 drugs side effects, heavy use of sedatives, but also reduced focus on NPS due to heavy staff workloads, patient isolation and visitor restrictions (Kotfis et al., 2020). The lived experiences of de-humanised and poor care during the pandemic reinforced a growing need to implement patient-centred care models, in particular for novice staff (Fernández-Castillo et al., 2021). In addition to this need, the COVID-19 pandemic severely exacerbated the shortage of nurses worldwide (Bourgault, 2022) and reinforced the importance of comprehensive care models that support ICU clinicians' well-being (Guttormson et al., 2022; Toscano et al., 2022).

[55] Appendix 44 shows all recommendations together with their certainty of evidence and strength of recommendation. Recommendations are conditional for example if they are perceived to be less feasible or there are any risks of harm reported.

Research suggests that using an implementation science strategy in the ICU is important (McNett et al., 2020). Implementation strategies commonly used to implement guidelines in the ICU include educational meetings, ongoing training, provider-orientated interventions, distributing educational material, opinion leader input and bundles (McNett et al., 2020; Zerfas et al., 2022). While the evidence for most of these strategies is low (Zerfas et al., 2022), implementation through bundles, such as the ABCDEF bundle, has shown promising results (Barnes-Daly et al., 2017; Sosnowski et al., 2022). The well-known ABCDEF bundle focuses on A: assess, prevent and manage pain; B: both spontaneous awakening and spontaneous breathing trials; C: Choice of analgesia and sedation; D: delirium assessment, prevention and management; E: early mobilisation and; F: family engagement and empowerment. One of the identified barriers to the implementation of the current ABCDEF bundle is patient agitation (Sosnowski et al., 2022). A stronger focus on the ways clinicians can deal with agitated behaviours in nonpharmacological ways is likely to strengthen the current ABCDEF bundle. I suggest strengthening the current ABCDEF bundle to include the provision of **F**undamental care to prevent, minimise or manage patient agitation (ABCDEF**$F_2$**). This expanded bundle is likely to further improve outcomes such as length of stay and survival while also improving patient, family and staff experiences. The ABCDEF bundle was initially designed as a way of humanising care in the ICU (Marra et al., 2017). Insights from the current study bundle can move care in the ICU closer towards that goal.

Guideline implementers should consider the barriers and facilitators to guideline implementation identified in this study. For example, having a supportive leadership team, a dedicated group to lead implementation, and a user-friendly design with real-life examples were described as essential. This study also identified factors such as lack of resources and changes to existing habits as major barriers. Future research should evaluate these facilitators and barriers in more detail, for example, using complex design evaluation methods (Craig et al., 2008).

## 9.5 Conclusion

This chapter presented and discussed the meta-inferences developed from this study. It also discussed the implications of developing guidelines across countries and highlighted important considerations for the implementation of the guidelines.

A new understanding of caring for agitated patients in the ICU has evolved from the study findings. Unique to this is the strong focus on establishing trusting staff-patient relationships and optimising staff's caring behaviours, involving family, identifying causes of agitation and patients' unmet needs and supporting staff to provide NPS. By using NPSs, staff connect with patients, support their individual unmet needs, motivate and give them strength to engage in health recovery activities and rise above discomforts that cannot be easily relieved. This study also discovered potential

threats to patient-centred care, including PR and discontinuity of care. How ICU clinicians deal with agitation is likely to reflect the broader organisational culture and the value the organisation places on care for agitated patients and care for their staff. Using NPS requires unique skills and staff who feel safe and empowered to take on the role supported by their leaders with adequate resources, knowledge and training, and emotional support.

Furthermore, this chapter makes it clear that it is possible and advantageous to develop guidelines across countries. Developing international guidelines avoids duplication of work and ensures better patient outcomes globally. In addition, bringing knowledge and evidence together from different sources can arguably create more comprehensive guidelines. This study also created an awareness of different cultures and how these affect patient-centred care. It highlighted the importance of leadership valuing and supporting NPS. While developing guidelines across countries is important, it requires careful planning. Different countries have different cultures and resources and, therefore, different perspectives on the usefulness, importance and feasibility of interventions. Guideline developers need to consider these differences and how they can develop guidance that allows contextualisation of recommendations.

The NPS guidelines developed by this research, including the model (Figure 28) on NPSs for agitation, should be included in the next updated PADIS guidelines. The ABCDEF bundle should expand to become an ABCDEF$_2$ (F=fundamental care to prevent, minimise and manage patient agitation) bundle, which can be used as an excellent implementation strategy to ensure optimal care for all ICU patients.

Chapter 10 concludes this thesis by emphasising the significant original contributions of this research, its strengths and limitations, and the implications of the study relating to education, practice and future research.

# CHAPTER 10: CONCLUSIONS

## 10.1 Introduction

The overall aim of this study was to develop preliminary evidence-based, patient-centred clinical practice guidelines for the non-pharmacological prevention, minimisation and management of patient agitation in Australian and Danish adult ICUs. A secondary aim was to identify the implications of developing clinical practice guidelines across two countries.

A multiphase mixed methods design enabled this study to comprehensively address the research aims. In the first study phase, a novel method for stakeholder consultation was developed. Using this method, various stakeholders from two countries were involved to determine the appropriate scope of the guidelines. The lack of evidence identified through systematic reviews of the existing literature necessitated expert input to develop recommendations through a modified Delphi study.

Through the development of preliminary guidelines, this study provides a new and holistic understanding of how to reduce patient agitation in the ICU. Central to this is the establishment of trusting staff-patient relationships, the optimisation of staff behaviours, and the consideration of appropriate ways to involve family members. ICU clinicians must have a holistic and investigative approach to identifying and treating the causes of agitation. The successful implementation of patient-centred NPS largely depends on a supportive ICU leadership and culture that supports and addresses staff needs. Important threats to patient-centred care, including discontinuity of care and PR, have been identified and discussed. The advantages of developing guidelines across countries have been recognised while specific considerations and prerequisites to this process have been elucidated, such as the need for additional resources, careful planning and similarities in health care systems.

This chapter concludes the thesis by highlighting the original contributions of each study phase, discussing the strengths and limitations of the study and providing directions for future practice, education and research.

## 10.2 Significance and originality

This study has significantly added to the existing knowledge. Prior to this work, clinicians were left with minimal guidance on alternatives to using pharmacological agents in the ICU when seeking to reduce patient agitation. Furthermore, prior to this study, no guidance existed on how to develop an ethical, feasible and meaningful guideline scope across two countries. This study thus extends knowledge in these areas. The significant original contributions to knowledge found in different stages of this study are described below.

### 10.2.1 Conceptual framework

The conceptual framework provided a new conceptual understanding of agitation in the ICU. Moreover, using a conceptual framework to guide guideline development is a relatively novel approach. This study provides insights into how such frameworks can be utilised and why it is important to ensure rigorous guideline development. While a potential limiting factor was the use of theories from dementia care, patients in both the ICU and dementia care environments share three important characteristics of relevance: they often exhibit agitated behaviours; they have difficulties expressing their needs; and they often have unmet needs. There adopted theories from dementia care are therefore deemed particularly relevant.

### 10.2.2 Literature review

This review is the first to report on ICU nurses' experiences of caring for agitated patients. It demonstrates that caring is complex and can be physically and emotionally challenging. The review demonstrates nurses' lack of direction on how best to minimise agitation. These findings are significant because they shed light on why inconsistencies in treatment exist, why excessive use of sedation and PR occurs, and provide insights into ICU nurses' reduced role satisfaction and burnout. This review focussed exclusively on nurses' experiences and not those of patients, family members or other ICU clinicians.

### 10.2.3 Study phase one: stakeholder consultation

This study phase developed a novel seven-step framework for how to engage international stakeholders to determine the scope of clinical practice guidelines. This phase demonstrated that consultation on the guidelines' scope is feasible and critically important for the implementability of guidelines. Therefore, consultation should be incorporated into the development of all clinical practice guidelines. This study phase did not use verbatim transcription to capture the nuances of workshops and interviews. Although such a method would have allowed in-depth analysis, this was not the aim of stakeholder consultation and was unlikely to have significantly changed the results of the study.

### 10.2.4 Study phase two: identifying the existing evidence

The first systematic review, is the first to summarise what is currently known about the effect of non-pharmacological strategies for agitation in the ICU. Unfortunately, the findings showed that the effects of various strategies are unclear, primarily due to various methodological issues related to the existing studies. Aromatherapy, foot reflexology, music, healing touch, multi-component non-pharmacological interventions and nature-based sounds showed promising effects but required further investigations. This review calls for future research with rigorous research designs and encourages researchers to consider alternative methodological approaches. A potential limitation of this review was the subjectiveness involved when grading the evidence. To mitigate this, transparent explanations were made to support the final decisions.

The second systematic review summarised existing guideline recommendations on non-pharmacological strategies for agitation in all healthcare settings and combined this with reviews of patients' experiences of agitation in the ICU. This work has never been comprehensively synthesised before. The review showed a low certainty of existing evidence and low trust in guideline recommendations, with most of the existing guidelines being of poor quality. In addition, many guideline recommendations stemmed from outside the ICU context, meaning they would not necessarily apply to the ICU setting.

### 10.2.5 Study phase three: Delphi study

This study is significant as it is the first to comprehensively provide rigorously obtained consensus-based recommendations for non-pharmacological prevention, minimisation and management of agitation in the ICU. In addition to identifying guideline recommendations, it also considered the risks, importance and feasibility of these and presented the barriers and facilitators to guideline implementation. The patient-centred, evidence-based guideline recommendations identified in this study are likely to reduce the overuse of pharmacological agents in the ICU and prevent multiple negative outcomes associated with agitation, such as interruption of life-saving treatment and negative patient, family and staff experiences.

This robust Delphi study, with broad representation from two countries and excellent survey responses over three Delphi rounds, nonetheless needed to acknowledge potential limitations inherent to this study type. Delphi research has been criticised for reaching "collective bias rather than wisdom" (Stewart, 1987, p. 99). This critique was dealt with by carefully selecting the type of feedback provided to participants between rounds, having a large and diverse panel and ensuring anonymity, thus encouraging honest responses. Finally, researchers have argued that measuring stability over rounds is a more reliable way of measuring consensus (Heiko, 2012). However, in this study, ensuring stability over rounds was neither practical nor ethical, as it would have required longer surveys and more Delphi rounds. Such an approach was likely to result in participant fatigue and attrition, which in turn could negatively affect the trustworthiness of the results. This study used the IQR to measure consensus, as this method has been described as accurate and robust for Delphi research (Gracht, 2008; Heiko, 2012). To ensure high-quality recommendations, consensus was defined as ≥75%, a limit often set by guideline developers to ensure high-quality recommendations (Oladega et al., 2021; Strang et al., 2018; Wopker et al., 2021).

## 10.3 Strengths and limitations of this study

While the strengths and limitations of this research have been described throughout all chapters, a few deserve reiteration here. Specifically, two major strengths followed by five important overall limitations will be described here. The first major strength in this study is that it allowed various stakeholders to be involved regardless of their location, language and literacy skills. This study

gave equal consideration to all voices, and all perspectives were all prioritised. There were some challenges related to involving this broad base of people, including the time needed to develop easily understood material (such as recruitment materials and surveys) and to recruit people from different professional and non-professional areas. However, these challenges were justified by the high level of engagement, which significantly strengthened the quality of the findings by offering different perspectives and adding breadth and depth to our limited understanding of non-pharmacological strategies.

The second major strength is the robust guideline development process facilitated by a multiphase mixed methods design. In this design, one study informs the next to address a central aim (Greene et al., 1989). If the need for a guideline and the exact scope had not been explored in the first study phase, it is less likely that an implementable guideline would have been developed. Stakeholder consultations also increased the validity of and informed the systematic reviews by pointing out important interventions and outcomes. The stakeholder consultation and the systematic reviews resulted in the development of tentative recommendations. These were then 'tested' and further explored in the Delphi study. This study also considered the patient-centredness, harms, importance and feasibility of each recommendation and barriers to guideline implementation. Furthermore, recommendations are specific, unambiguous and described in ways also easily understood by laypeople in both Danish and English, and there is a clear link between recommendations and the evidence supporting these (see Appendix 44). These strengths align with NHMRC's standards for guideline development[56] and the AGREE II tool[57] , suggesting that the final guidelines are of high quality.

The AGREE II tool (Brouwers et al., 2010) does not downgrade guideline development involving consensus as long as rigorous methods are used and guideline developers are transparent about these. Yet, one could argue that in order to contribute to a low knowledge base, consensus methods must produce reliable and credible evidence. Therefore, it was ensured that the included Delphi study met key quality criteria for Delphi research (Diamond et al., 2014; Hasson & Keeney, 2011; Jünger et al., 2017), including a priori criteria for consensus, endorsement of recommendations, number of rounds, participant eligibility and for removal or modification of recommendations. Related to consensus, a high level of consensus was required in both countries for a recommendation to be endorsed. The validity of the Delphi study was enhanced through rigorously tested surveys and an exhaustive translation process to ensure unambiguous survey questions. Furthermore, a significant amount of qualitative data was analysed, which facilitated a better understanding of the recommendations. Finally, this study reported not only on the

[56] See Section 3.7.3 for an overview of how this study fulfilled the NHMRC standards.
[57] Internationally recognized quality appraisal tool for guidelines

recommendations reaching consensus but also on those that did not reach consensus, adding to the transparency of the study findings.

The first important limitation is that the final guideline recommendations are all built on low levels of evidence. However, it is important to recognise that it is the strongest evidence currently available. Researching NPSs for agitation in the ICU is challenging, and some answers may never be fully discovered through rigorous experimental designs. It is important to note that the various ss largely align with the causal mechanisms described in the conceptual framework, including biological causes, unmet needs and lowered stress threshold. Therefore, although the evidence base is low for all practices, there is a conceptual justification for the effectiveness of the interventions. Furthermore, it is worth noting that even the widely accepted international PADIS guidelines only have two of its 37 recommendations rated as strong and that most are conditional (Devlin et al., 2018b). This suggests that Critical Care societies may be open to implementing the guidelines despite their low levels of evidence.

The second limitation is that by having included a broad group of stakeholders and giving equal voice to all meant including suggestions that, for some, could be perceived as “common sense”. By including such recommendations, there is a risk of potentially diminishing more sophisticated and/or specific interventions. On the other hand, often, it is these “common sense” strategies that clinicians do not get right (Feo et al., 2019), and therefore, they are still worthy of acknowledgement in the guidelines.

The third limitation is that this study included a large number of nurses compared to other stakeholder groups, which would have affected the final included recommendations. The great interest from nurses in this study was expected as nurses are those who most commonly deal with agitation when it occurs in the ICU. Their experiences of caring for agitated patients were seen as critical to the outcomes of the study, and therefore the limitation was acceptable and expected.

The fourth limitation is that since the existing evidence did not clearly separate all interventions in terms of their ability to prevent, minimise and manage agitation, it was impossible to separate recommendations into such categories. Dividing recommendations into these categories may facilitate a better understanding of when recommendations should be used.

Finally, the guidelines are only generalisable to Danish and Australian ICUs. It seems, however, reasonable to suppose that these guidelines can be adapted to other countries' ICUs. Considering the poor quality of guidelines outside the ICU (see Section 7.3.6), it also seems possible that the guidelines can be adapted to contexts outside the ICU.

## 10.4 Implications of the study

This study has led to an enhanced understanding of agitation in the ICU and care strategies to reduce agitation-related behaviours. While the study occurred across Denmark and Australia, it is likely that the recommendations can be adapted or contextualised to other countries and contexts. The section below will discuss how the findings contribute to future education, clinical practice and research.

### 10.4.1 Education and practice implications

It is clear from this research that ICU clinicians need diverse skill sets to provide safe, effective and patient-centred care that minimises agitation. On one side, it is necessary that they master the technical and biomedical side of critical care; on the other, they must also see the critically ill person and their family members. Based on this, it is imperative that ICU clinicians have an investigative and holistic approach to care, are adequately prepared to develop trusting relationships, recognise the effects of their behaviours and attitudes on agitation, and have the skills to communicate effectively with families.

The findings from this thesis can provide an excellent foundation for teaching in ICU settings and critical care curriculums. An important first step may be to increase knowledge and awareness of what patient agitation is, how it presents and what it is caused by. The first part of the conceptual framework (see Chapter 3) can be helpful for this purpose. The FoC framework can be an important tool to illustrate the different dimensions of care and how they relate to each other. The model showing NPSs for agitation (see Figure 28), based on 63 guideline recommendations, is an important tool to support clinicians' clinical decision-making processes to ensure consistent, safe and effective practices that are likely to improve patient outcomes. The final guidelines can provide more detailed information about the different areas of this tool. Simulation workshops, preferably for multidisciplinary teams, either face-to-face (O'Brien et al., 2018) or online (Piot et al., 2022), may be important platforms for learning how to de-escalate agitated behaviours in safe and patient-centred ways. ICUs may even consider training practitioners in NPSs. They can then become specialists who can provide advice and guide practice in clinical fields. The guidelines can also allow clinicians, managers and policymakers to reassess current practices and standards of care while providing them with evidence to advocate for more resources and support for staff.

Fully implementing NPSs and making them part of life in the ICU requires a supportive ICU culture. A supportive culture is a "just" or a "no-blame" culture that acknowledges the hard work it requires to reduce the use of sedation and the use of PR. By acknowledging this work, a range of system changes should take place, such as staff training, policies for debriefing, and provision of material and resources necessary to use NPSs. For some, it may not seem feasible to reduce levels of sedation and use NPSs. However, it is crucial that managers, policymakers and clinicians consider the long-term savings associated with a decrease in pharmacological costs, adverse events, ICU

length of stay, patients and family PTSD and staff burnout and attrition. Future research may want to explore the real cost-effectiveness of using NPSs in the ICU. Considering the low quality of existing guidelines on the management of agitation within other areas of health care, health practitioners from other areas may want to consider adapting the guidelines to their settings.

### 10.4.2 Recommendations for future research

Throughout this thesis, the paucity of evidence on approaching ICU patient agitation with NPSs has been emphasised. It is clear that there is an urgent need to develop a larger evidence base on how we can optimise care for agitated patients in ICU. Such information can direct us toward what is effective and will provide decision-makers with more knowledge on the resources required to implement effective interventions. Developing guidelines across countries is not new, but exactly how this can be done in effective, rigorous and ethical ways must be incorporated into existing guideline development manuals. While recommendations for future research have been raised throughout this study, the most significant recommendations will be highlighted here and described in order of importance:

1. Review the developed guidelines before they can be implemented as explained in Section 3.7.3 (NHMRC, 2020). At least two independent reviewers, experts in the field or methodologists, should provide feedback using the AGREE II tool. The guidelines can also be sent out for public consultation, which gives various stakeholders an opportunity to comment on the final guidelines (NHMRC, 2020). After this process, they must be published through relevant journals or local guideline organisations.
2. Develop a family/next of kin version (in layperson language) of the current guidelines.
3. Implement and evaluate the effect of the developed guidelines. Implementation can, for example, be done using the integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework (Harvey & Kitson, 2015), a framework that is particularly suitable for complex interventions (Roberts et al., 2021).
4. Identify the role of continuity of care for agitated patients in the ICU and what it means to patients, families and staff. Explore how continuity of care can be ensured without threatening the well-being of staff?
5. Evaluate the short and long-term effects of NPSs using rigorous methods[58]. Table 34 highlights areas that require special attention when measuring the effects of NPSs. Attention must also be paid to those providing care[59] , their relationships with patients[60], patients' individual needs [61] and contextual factors influencing care.

[58] Alternative methods may be realist evaluation, complex intervention design, cohort studies, case-control etc.
[59] Is this a staff member who feels supported to carry out the intervention?
[60] Does the patient trust the person carrying out the intervention?
[61] As an example, imagine giving massage to someone who never liked being touched.

6. Explore how family members can best be supported and involved when their loved one exhibits agitation in the ICU.
7. Describe the relationship between the use of psychoactive pharmacological agents, such as sedation and analgesia, patient agitation, PR, staff resources, staff workload and ICU culture in Danish and Australian ICUs.
8. Examine the need for specific agitation assessment tools. Clinicians in this study used RASS, SAS and the Brøset scale to measure agitation. There were some indications throughout this study that these tools may not be sufficient for practice and research. It is possible that scales can be adopted from other contexts. Alternatively, and perhaps in relation to getting more explicit about what agitation is in the ICU (including early and late signs), a new tool can be developed for the ICU environment. A rigorous tool is necessary to routinely assess patients for agitation and to measure the effects of NPSs on agitation.
9. Systematically evaluate the risk factors for agitation to provide clinicians with more insights into how agitation can be prevented.
10. Investigate in more detail how to motivate clinicians to use NPSs rather than sedation and PRs.

## 10.5 Conclusion

This chapter concludes the thesis by describing its original contributions to knowledge, the strengths and limitations of these contributions and the implications the study has on future education, practice and research. Until now, clinicians' need for evidence-based guidance on NPSs for agitation in the ICU has been unrecognised. This thesis offers 63 evidence-based patient-centred practice recommendations to prevent, minimise and manage patient agitation. Together these form a new model of care that emphasises the importance of developing trusting relationships, optimising staff behaviours, engaging families, identifying causes of agitation and patient needs and supporting staff to use NPSs. Reducing the use of pharmacological agents by using NPSs can be challenging and requires special skills and an investigative and individualised approach. This study identified potential threats to patient-centred care, including discontinuity of care and physical restraints. Supportive leadership teams and psychologically safe cultures that encourage open and honest dialogue are essential to overcome such threats.

This thesis offers new guideline development methods, including the use of a conceptual framework and an ethical framework to consult international stakeholders on the scope of the guidelines. It suggests multiple advantages to developing guidelines across countries, such as avoiding duplication of work, improving care across borders, expanding knowledge and increasing insights on how existing cultures and values affect care. However, the process requires resources,

careful planning, and transparent information on guideline recommendations to allow local contextualisation before implementation.

This study presents the best evidence to date on how to reduce agitation with NPSs in the ICU. It is hoped that the guidelines will encourage clinicians to reflect on their current practices, identify gaps and, if needed, change or improve existing practices to enhance care for ICU patients. The findings of this thesis can form an essential basis for teaching critical care in both tertiary education and clinical areas. Considering the serious consequences of patient agitation in the ICU and the negative effects of excessive use of pharmacological agents and PR, patient-centred NPSs deserve considerably more attention.

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# APPENDICES

## Appendix 1 Caring for patients displaying agitated behaviours in the intensive care unit–A mixed-methods systematic

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Review paper

# Caring for patients displaying agitated behaviours in the intensive care unit – A mixed-methods systematic review

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ABSTRACT

*Background:* Patient agitation is common in the intensive care unit (ICU), with consequences for both patients and health professionals if not managed effectively. Research indicates that current practices may not be optimal. A comprehensive review of the evidence exploring nurses' experiences of caring for these patients is required to fully understand how nurses can be supported to take on this important role.

*Objectives:* The aim of this study was to identify and synthesise qualitative and quantitative evidence of nurses' experiences of caring for patients displaying agitated behaviours in the adult ICU.

*Methods:* A mixed-methods systematic review was conducted. MEDLINE, CINAHL, PsycINFO, Web of Science, Emcare, Scopus, ProQuest, and Cochrane Library were searched from database inception to July 2020 for qualitative, quantitative, and mixed-methods studies. Peer-reviewed, primary research articles and theses were considered for inclusion. A convergent integrated design, described by Joanna Briggs Institute, was utilised transforming all data into qualitative findings before categorising and synthesising to form the final integrated findings. The review protocol was registered with PROSPERO CRD42020191715.

*Results:* Eleven studies were included in the review. Integrated findings include (i) the strain of caring for patients displaying agitated behaviours; (ii) attitudes of nurses; (iii) uncertainty around assessment and management of agitated behaviour; and (iv) lack of effective collaboration and communication with medical colleagues.

*Conclusions:* This review describes the challenges and complexities nurses experience when caring for patients displaying agitated behaviours in the ICU. Findings indicate that nurses lack guidelines together with practical and emotional support to fulfil their role. Such initiatives are likely to improve both patient and nurse outcomes.



## 1. Introduction

Agitation in the intensive care unit (ICU) has been defined as "a psychomotor disturbance characterized by a marked increase in both motor and psychological activities, often accompanied by a loss of control of action and a disorganization of thought".[1] Studies report that agitated behaviours are common in the ICU, with the incidence ranging between 31.8 and 70.8 per cent.[2–8]

Agitation must be managed effectively as the behaviours are associated with several negative outcomes including increased length of stay,[5,9] increased ventilator days,[9] unplanned extubation,[5,9–14] unplanned line removal,[5] nosocomial infections,[5] increased use of restraints,[8] post-traumatic stress,[15] and decreased patient mobilisation.[16] Agitation and the way it is managed in the ICU may also affect family members.[17,18]

Key strategies to manage care for patients displaying agitated behaviours include a systematic assessment, identifying triggers, treating underlying causes, and providing relief from distress.[19] Although seemingly straightforward, management can be challenging. Identifying the exact causes of agitation can be difficult as

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patients in the ICU are often unable to describe their signs and symptoms adequately, and their complex presentations may involve multiple contributing factors. Common causes include hypoxaemia, infections, intoxication, uncomfortable body position, anxiety, full bladder, nicotine withdrawal, delirium, and drug side effects.[20] Such factors cause physical or psychological distress that eventually results in agitation.[20] Traditionally, sedation combined with physical restraints has been used to manage agitation.[21] However, less sedation has been associated with improved survival, shorter duration of mechanical ventilation, and shorter length of stay.[22 24] Studies also indicate that physical restraints can be physically and psychologically harmful to the patient and can potentially exacerbate agitated behaviours.[12,25 27] While it is unclear whether 'restraint-free' environments require more staff or an increased use of pharmacological agents, guidelines encourage clinicians to carefully consider risks and benefits before using physical restraints.[24]

Nurses spend more time at the bedside than any other clinician in the ICU. Through frequent observations and continuous care, they play a major role in minimising agitated behaviours. However, research indicates that nurses may be using chemical[28 32] and physical restraints[33 35] more than necessary and lack knowledge on alternative strategies.[36 38] In an integrative review, Teece et al. [39] found the use of both physical and chemical restraints, and the decision-making processes behind their use were influenced by personal experiences and views rather than being evidence based. An integrated review revealed a lack of knowledge of 'standard care' for patients with agitated behaviours in the ICU and a dearth of research in this area.[40] Furthermore, care for agitated patients in the ICU may not be optimal. Freeman et al. [41] found that 76.3 per cent of 163 UK health professionals believed that management could be improved and many felt unsure about how to manage agitation in the ICU.[41] A comprehensive search failed to identify any previous systematic reviews exploring how nurses experience caring for patients with agitation in the ICU. Such information is crucial for informing future practice and research to ensure high-quality care for patients displaying agitated behaviours in the ICU.

## 2. Objectives

The aim was to identify and synthesise the best available qualitative and quantitative evidence of nurses' experiences of caring for patients displaying agitated behaviours in the adult ICU. More specifically, this review was interested in identifying strategies nurses use when caring for patients displaying agitated behaviours and the factors affecting this care.

## 3. Methodology

A mixed-methods review was chosen as it provides a more comprehensive foundation for decision-making than single-method reviews.[42] A convergent integrated approach, as described by Joanna Briggs Institute (JBI), was deemed appropriate due to the nature of the research question.[43] This approach allows reviewers to transform and combine qualitative and quantitative findings. A process of meta-aggregation was followed,[44] integrating qualitative and quantitative research findings across studies to create generalisable statements. Such statements can then be used to guide practice, policies, and future research. Meta-aggregation does not attempt to re-interpret data, to find new meaning in data or generate theory.[45] The systematic review protocol was registered with PROSPERO International Prospective Register of Systematic Reviews registration number CRD42020191715.

### 3.1. Data sources and search strategy

This study used the SPIDER framework to identify key parameters as it has been suggested to be more effective for mixed-methods studies than the traditional PICO, population, intervention, comparison and outcomes, tool.[46] Two modifications were made to the framework (Table 1). The last component (research type) was removed to avoid missing papers that did not explicitly specify the research type, and 'context' was added because of the importance of the ICU environment. Overall, the search strategy was broad and sensitive to avoid missing relevant articles. An initial focused search in the Medical Literature Analysis and Retrieval System Online (MEDLINE) was undertaken to identify keywords and subject headings. With support from all team members and a librarian, the first author created a search template (Supplementary file). The search of MEDLINE, Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsycINFO, Web of Science, Emcare, Scopus, ProQuest, and Cochrane Library was completed in July 2020. All identified articles were imported from the databases into Endnote X9 where duplicates were removed. The initial retrieval of papers for appraisal depended on their relevance to the research question. The first author reviewed the title and abstracts of retrieved articles. A full-text screening was then conducted to ensure that the retrieved articles met the inclusion criteria. Citations and reference lists were also screened for relevant articles. The first author discussed whether the identified papers met the inclusion criteria with a second reviewer.

### 3.2. Eligibility criteria

#### 3.2.1. Inclusion criteria

Studies were eligible for inclusion if they contained descriptions and illustrations of nurses' experiences of caring for patients displaying agitated behaviours in the adult (18 y or older) ICU. This review sought to include qualitative, quantitative, and mixed-methods studies. Quantitative studies included all types of descriptive studies. Qualitative studies included methodologies such as phenomenology, grounded theory, ethnography, and action research. Mixed-methods studies were only considered if the data from the quantitative or qualitative components could be extracted. We only included primary, peer-reviewed, and published studies. We decided to include theses and dissertations because these have been subjected to a rigorous review process. To carry out a broad exploratory search, no limitation was placed on the age of the data. Studies had to be published in English.

#### 3.2.2. Exclusion criteria

Grey literature was excluded as it was unlikely to have undergone a rigorous peer-reviewed process.

### 3.3. Quality appraisal process

The results of systematic mixed-methods reviews are intended to have immediate applicability to practice; thus, it was important to only include studies of sufficient quality and to provide a transparent report of this quality. All studies that met the inclusion criteria were appraised by two investigators independently (A.A., T.C., and D.C. were involved in this process) using JBI's 'Checklist for Qualitative Research' for qualitative studies[44] (and the qualitative component of mixed-methods studies) and 'Checklist for Analytical Cross-Sectional Studies' for quantitative studies (and the quantitative component of mixed-methods studies).[47] The JBI organisation confirmed that the 'Checklist for Analytical Cross-Sectional Studies' was the correct tool to use for surveys/questionnaires Supplementary materials. For every item fulfilled in the checklists,

**Table 1**
SPIDEC (a modified SPIDER framework).

| S | PI | D | E | R[a] |
|---|---|---|---|---|
| S | PI | D | E | C |
| **Sample** | **Phenomenon of interest** | **Design** | **Evaluation** | **Context** |
| Population. | Interest related to event, activity, process. | Research methods. | Attitudes, views, experiences. | Setting. |
| Critical care nurses. | Caring for an agitated patient. | Interviews and surveys, observations. | Experiences. | Intensive care units. |

[a] Research type.

the qualitative studies were allocated 10% and the quantitative studies 20%. From this scoring system, all studies were ranked as providing weak, adequate, moderate, or strong evidence (see Tables 2 and 3 for more details). A study was assessed as weak if up to 49% of the critical appraisal items had not been fulfilled, adequate if 50–69% had been fulfilled, moderate if 70–85% had been fulfilled, and strong if 86–100% had been fulfilled. It was decided to exclude studies of weak evidence. Where two reviewers were unable to reach a consensus on the inclusion of a paper, a third reviewer was invited to contribute to a final decision.

### 3.4. Data extraction

Qualitative and quantitative data were extracted by one reviewer using JBI's standardised data extraction tool SUMARI, System for the Unified Management, Assessment and Review of Information.[48] A second reviewer assessed the accuracy of extraction. Data extracted included (i) characteristics of primary research reports including populations, study methods, phenomena of interest, context, and outcomes of relevance to the review question (Table 4) and (ii) findings relevant to the research question. Quantitative data comprised descriptive statistical data whether statistically significant or not. Qualitative data extraction was conducted to remain as close to the originally reported themes as possible to prevent re-interpretation.[59] As the original themes were often broad and not always exclusively focussed on nurses' experiences of agitated behaviours, it was decided to screen each theme for emerging concepts or descriptions of experiences of agitation. Verbatim extracts of the authors' analytical interpretations were then labelled as 'findings', similar to the way Hannes and Pearson[59] searched for 'obstacles' in their original themes. Data were extracted only when it was clear that the reported experiences were related to patient agitation. For instance, papers on experiences of delirium were only included if it was clear that the experiences involved agitated behaviours. All qualitative findings were assigned a level of credibility determined by their associated illustrations from participants' voices or researcher observations. Findings were unequivocal (U) when their illustration was beyond a reasonable doubt, credible (C) if there was not a clear and logical link between a finding and the associated illustration, and nonsupported (NS) if they were not supported by an illustration.[48] All extracted data and attributions of credibility were checked for accuracy and agreed upon by a second reviewer.

### 3.5. Data transformation and synthesis

Following extraction, quantitative data were converted into textual descriptions.[43] All findings were aggregated into categories based on the similarity of meaning using the JBI-SUMARI tool. Each category was accompanied by a category description, an explanatory statement conveying the meaning of a group of findings. These categories were then subjected to synthesis to produce a single comprehensive set of overarching integrated findings. An example of this process together with levels of credibility is illustrated in Table 5. Findings were discussed within the authorship team to ensure rigour in the interpretation of findings.

## 4. Findings

A PRISMA flow diagram[60] of the results of the search process and appraisal is illustrated in Fig. 1. One quantitative and 10 qualitative studies were included in the review. The included studies were published between 2002 and 2019 and came from Scotland,[49,51] Denmark,[50] Canada,[52,54] Norway,[53] United Kingdom,[41,55,58] USA,[56] and Sweden.[57] Of the qualitative studies, one study provided a strong level of evidence,[49] seven provided a moderate level of evidence,[50 54,56,58] and two provided adequate levels of evidence[55,57] (Table 2). The quantitative study provided a moderate level of evidence (Table 3). From the studies, a total of 51 qualitative findings and one quantitative finding were organised into nine categories and then grouped into four integrated findings. Each integrated finding is described in more detail below.

### 4.1. The strain of caring for patients displaying agitated behaviours

Caring for a patient displaying agitated behaviours was seen as dangerous, stressful, and demanding and prevented nurses from doing other duties that were expected from them. This meant that there was a strain applied to nurses when caring for this group of patients. Such strain had emotional consequences affecting nurses'

**Table 2**
Critical appraisal using the JBI Checklist for Qualitative Research.

| Citation | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | Q10 | Level of evidence |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Shapira (2002) | U | Y | Y | U | Y | Y | Y | U | Y | Y | Moderate |
| Price (2004) | U | Y | Y | Y | Y | N | N | U | Y | N | Adequate |
| Zamoscik et al. (2017) | U | Y | Y | Y | Y | N | N | Y | Y | Y | Moderate |
| Collet et al. (2019) | Y | Y | Y | Y | Y | N | N | Y | Y | Y | Moderate |
| Everingham (2012) | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | Strong |
| LeBlanc (2016) | Y | Y | Y | Y | Y | N | N | Y | Y | Y | Moderate |
| Tsang et al. (2019) | Y | Y | Y | Y | Y | N | N | Y | Y | Y | Moderate |
| Lind et al. (2018) | U | Y | Y | Y | Y | N | N | Y | Y | Y | Moderate |
| Tingsvik et al. (2013) | U | Y | Y | Y | Y | N | N | U | Y | Y | Adequate |
| Kydonaki et al. (2019) | U | Y | Y | Y | Y | N | N | Y | Y | Y | Moderate |
| % | 30.0 | 100.0 | 100.0 | 80.0 | 100.0 | 10.0 | 20.0 | 70.0 | 100.0 | 90.0 | |

**Table 3**
Critical appraisal using the Checklist for Analytical Cross-Sectional Studies.

| Citation | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Level of evidence |
|---|---|---|---|---|---|---|---|---|---|
| Freeman et al. (2019) | Y | Y | N/A | N/A | Y | U | N/A | Y | Moderate evidence |
| % | 100.0 | 100.0 | 0.0 | 0.0 | 100.0 | 0.0 | 0.0 | 100.0 | |

Y = yes; N = no; U = unclear; N/A = not applicable.
0–49%: Low evidence; 50–69%: adequate evidence; 70–85: moderate evidence; 86–100: strong evidence.

wellbeing and their caring behaviours. This integrated finding comprises two categories generated from 13 findings.

#### 4.1.1. Category 1: an exhausting role

Five credible findings supported this category. Keeping both patients and health professionals safe was viewed as "a really big job" and nurses had to constantly "be on guard" and close to the bed. The risks involved were significant.[49,52 54]

> "everything could happen in a minute .... always like a time bomb"[52]

> "Most of the patients have small margins, and if they remove their endotracheal tube they might not survive. So you have to be much more alert ..."[53]

Nurses felt responsible, even during their breaks.[49] Caring for patients displaying agitated behaviours required extra resources and support from colleagues.[49]

#### 4.1.2. Category 2: emotional consequences of caring for patients displaying agitated behaviours

Eight credible findings supported this category. Caring for patients with agitated behaviours was described as emotionally challenging. As described above, nurses' perceptions of why patients became agitated adversely affected nurses emotionally. Compounding this emotional adversity was the additional patience required when caring for patients with agitated behaviours. Nurses described how they would be 'soft and sweet' towards patients at the beginning of a shift but feel angry and frustrated by the end.[52,56,58] It was observed that nurses would become visibly angry and engage in power struggles with patients displaying agitated behaviours.

> One nurse, generally unruffled and empathetic, put her hands on her hips, glared at the patient and said, "Fine, go ahead and get pneumonia. I don't care.".[56]

Feelings of guilt, dissatisfaction, and failure occurred when nurses felt the need to prioritise patient safety and therefore felt unable to support other patient needs or carry out other duties.[49,52,54,56]

> "Then [the patient is] all over the place it seems like you have not done your job (...) you did not meet the needs."[52]

Such feelings also occurred when an adverse event happened due to patient agitation.[49]

> "... I would feel a failure personally but that's because I am used to the days when you were there all the time, you didn't turn your back on the patient, you didn't leave the patient and so that really was a failure on your part ... deep down you think well if I had only done this if I had only done that ... it is dangerous for the patient because they potentially then have to be anaesthetised ... have their tube put back down maybe, or have a central line put in".[49]

Finally, nurses described feeling vulnerable and scared when caring for patients displaying agitation and aggression. Nurses described how they received minimal emotional support,[58] and they questioned if violent situations could have been dealt with better or if aggression towards nurses had simply become an acceptable part of nursing.[49]

### 4.2. Attitudes of nurses

Nurses described a variety of attitudes towards patients displaying agitated behaviours. This integrated finding comprises one category generated from six findings.

#### 4.2.1. Category 3: attitudes towards patients displaying agitated behaviours

One unequivocal and five credible findings supported this category. While some nurses empathised with patients displaying agitated behaviours and felt 'professional' and satisfied when able to calm them down,[52] others had a different perspective. Patients who rejected or impeded care[56] and patients with substance use disorders[49,56] were held accountable for their agitated behaviour. In these patients, such behaviours were seen as conscious and intentional.[56]

> "I think it's more like his personality to be that way (i.e., agitated). You know, as I get to know the family and talk with them, that's how he is in their home. I think a lot of it is his baseline personality".[56]

Some nurses described how they were adversely affected by their colleagues' negative attitudes and stigma towards patients with agitation.

> "I find that people are quick to stigmatize them. (...) I would get report that this person is 'crazy'. 'Excuse me!?' You cannot say that. It's almost an ethical thing. I personally have a hard time with that because I think it's not right"[52]

Nurses in one study openly admitted that they preferred to care for sedated patients who were cooperative and compliant.[56] A nurse explains,

> "To me, the easiest patient is the one on the balloon pump, on the ventilator with 10 different drips. You can control everything about him ... Those are the easiest patients. If a behavior is uncontrollable, you know what? It doesn't have to be agitation ... they take a lot of time ... the majority of your more skilled nurses, prefer the sicker pt, where you don't have to deal with the psychological, or I should say behaviors".[56]

**Table 4**
Characteristics of included studies.

| Study and year | Methodology, methods for data collection and analysis | Country | Phenomena of interest | Setting | Participant characteristics and sample size | Description of the main results | Strengths and limitations |
|---|---|---|---|---|---|---|---|
| Qualitative studies | | | | | | | |
| Everingham et al.[49] 2012 | Heideggerian, hermeneutic phenomenological approach. Purposive sampling. In-depth interviews, phenomenological analysis. | Scotland | Experience of caring in a technological environment with a focus on sedation and factors influencing decision-making in the ICU. | One 18-bed mixed ICU in Edinburgh | 16 Nurses | Reduced sedation caused patient agitation and distress affecting patient comfort and safety. Nurses experienced difficulties in providing evidence-based, holistic, and safe care simultaneously. Teamwork between doctors and nurses was less than ideal. Consequently, the implementation of changes in sedation practice is failing. | ***Strengths***: reflexivity, pilot interview, and investigator triangulation. ***Limitations***: Interviews took place in the ICU at the patient's bedside. Relationship between the researcher and participants was not adequately considered |
| Collet et al.[50] 2019 | Qualitative design, eight focus group interviews, semi-structured interview guide, framework analysis. | Denmark | Experiences and approaches to delirium management. | Five mixed ICUs in regional and university hospitals | 24 Nurses and 15 physicians | Delirium management lacks clear aims and guidelines. When nurses and physicians in the ICU do not have clear guidelines, they rely on personal experiences and the best evidence they can find. | ***Strengths***: interview guide based on previous literature and investigator triangulation. ***Limitations***: methodology was not described and little information about the settings |
| Kydonaki et al.[51] 2019 | Qualitative exploratory, purposive sampling, focus groups, combined analytical strategies from thematic analysis and grounded theory | Scotland | Challenges experienced when managing sedation and analgesia | Eight ICUs | 25 Nurses, eight physiotherapists, 11 doctors, and one pharmacist. | Challenges around new sedation practices included difficulties in managing agitated behaviours and 'difficult to sedate' patients. | ***Strengths***: member checking and investigator triangulation. ***Limitation***: minimal information about the sample |
| LeBlanc[52] 2016 | Interpretive phenomenology, purposive sampling, semi-structured interviews, data analysis with an interpretive phenomenological approach | Canada | Experiences of caring for patients with delirium | Two university hospital mixed ICUs in Ontario | Eight nurses. | Nurses described how they saw their role as helping both families and patients through the experiences of delirium. They saw caring as exhausting, the patients' mental state as important, and ensuring patient safety as a big job. | ***Strengths***: pilot interview, reflexivity, and investigator triangulation. ***Limitations***: relationship between the researcher and the participants not adequately considered. |
| Lind et al.[53] 2018 | A qualitative approach, purposive sampling, focus group interviews, thematic analysis. | Norway | Experiences of caring for nonsedated mechanically ventilated patients | 10-Bed mixed ICU, university hospital | 12 Nurses | Nurses described both positive and challenging aspect of caring. Themes included excitement and uncertainty; inspiring but demanding nurse–patient relationship; teamwork and working against the tide. More strategic implementation and improved interprofessional collaboration may improve experiences. | ***Strengths***: interview guide builds on previous literature. ***Limitations***: methodology not described and relationship between the researcher and the participants not adequately considered. |
| Tsang et al.[54] 2019 | Qualitative descriptive study, purposeful sampling, focus group interviews, thematic analysis. | Canada | Experiences, beliefs, and perceptions on the management of pain, agitation and delirium (PAD) | A community hospital, 14 bed, mixed ICU | 43 Nurses | Many factors including nurse opinion, environmental factors, healthcare team, patients, and families affected PAD management. A multifaceted and multidisciplinary quality improvement program is needed to optimise PAD management. | ***Strengths***: investigator triangulation, reflexivity, audit trail, and member checking. ***Limitations***: two of the focus group facilitators also worked in the ICU |
| Price[55] 2004 | A qualitative approach, convenience sampling, critical incidence technique, semi-structured interviews, Norman's qualitative data analysis performed. | United Kingdom | Experiences and reflections of recognising, assessing, and supporting patients' psychological needs. | Two ICUs in a London teaching hospital. | 12 Nurses | Six categories included effects on patients; environmental factors; nurses education and attitudes; factors affecting psychological assessment and communication; and family effects. Nurses must pay attention to families, improve communication, and be aware of current issues. | ***Strengths***: pilot interview. ***Limitations***: age of data, only one investigator, data analysis unclear, minimal information about setting and participants, relationship between researcher and participants not adequately considered, no information on the trustworthiness of the study, and no conclusion of the study. |

**Table 4** (*continued*)

| Study and year | Methodology, methods for data collection and analysis | Country | Phenomena of interest | Setting | Participant characteristics and sample size | Description of the main results | Strengths and limitations |
|---|---|---|---|---|---|---|---|
| Shapira[56] 2002 | Ethnographic fieldwork, qualitative and quantitative methods, analogue scales, observations and interviews. | USA | Process of emotion management by surgical ICU nurses | Surgical ICU, California | 34 Nurses working in the surgical ICU, nine nurses participated in interviews, and 47 patients included. | Nurses preferred patients who were technologically and behaviourally controlled – this allowed for emotional detachment necessary for their work. The emotional detachment was more difficult to achieve with family members. | ***Strengths***: use of theoretical framework, prolonged engagement (17 months of fieldwork). ***Limitations***: age of data, data analysis not described, only one investigator, and trustworthiness and limitations of study not discussed |
| Tingsvik et al.[57] 2013 | A qualitative approach, convenience sampling, semi-structured interviews, content analysis | Sweden | Experiences of caring for lightly sedated mechanically ventilated patients | Three mixed ICUs, one central, and two district hospitals. | Nine nurses | Caring for lightly sedated patients is a challenge that requires experience and knowledge. Communication, individualised care, integrity, and patient participation are important factors. Nurse satisfaction increases when this is done successfully. | ***Strengths***: investigator triangulation, reflexivity, and pilot interviews. ***Limitations***: unclear if all voices have been represented as unclear who said what |
| Zamoscik et al.[58] 2017 | A qualitative approach, purposive sampling, focus group interviews, thematic analysis. | United Kingdom | Experiences of delirium and delirium assessment and management. | 20-Bed mixed ICU in a large teaching hospital | 12 Nurses | Delirium was not a priority. Nurses lack confidence in assessing delirium. There was a lack of effective therapies. Nonpharmacological strategies must be acknowledged. Psychological support for nurses dealing with delirious patients should be considered. | ***Strengths***: pilot interview, member checking, investigator triangulation, and audit trail. ***Limitations***: time pressure precluded further data collection and no male nurses |
| Quantitative studies | | | | | | | |
| Freeman et al.[41] 2019 | Web-based questionnaire survey | United Kingdom | Views and opinions on strategies to manage patient agitation | Eight adult critical care units | 114 Nurses, 25 doctors, 13 physiotherapists, six healthcare support workers, and five pharmacists. | 98.5% Acknowledged the increased risk of harm for patients who are agitated in the ICU; 76.3% felt that the management of agitation could be improved. Many felt equipped to recognise delirium and agitation but lacked the knowledge to manage agitated behaviours. | ***Strengths***: questionnaire likely to be valid and reliable, and triangulation of data. ***Limitations***: only unpublished material (email exchange with author) was included since it was not possible to extract nurses' experiences from the published material; low response rate (18.1%) |

### *4.3. Uncertainty around assessment and management of agitated behaviours*

Nurses described a lack of consensus and guidance for how to assess and manage patients displaying agitated behaviours. This synthesised finding comprises four categories generated from 25 findings.

#### *4.3.1. Category 4: assessment of agitation*

Three unequivocal findings and one credible finding supported this category. While some nurses found it easy to identify agitated behaviours,[56] others wished they had proper assessment tools to identify agitated behaviours and causes of agitation.[51,56,61] Not being able to identify the causes of agitation leads to uncertainty around management.[51]

#### *4.3.2. Category 5: the role of sedation when caring for patients displaying agitated behaviours*

Six unequivocal and three credible findings supported this category. In terms of pharmacological management of agitated behaviours, the included studies only discussed the role of sedation. A complex issue arose around balancing the risks and benefits of sedation. Some nurses seemed to understand the benefits of keeping patients more awake[49,53,58] and that chemical sedation should be a 'last resort'.[52] However, nurses also felt frustrated when not being able to comfort the more awake patients displaying agitated behaviours.[57] They questioned whether it was ethical and safe not to sedate these patients.[49,53,58] Some nurses were concerned about the long-term consequences of experiencing agitation.[49,54]

> "To be totally honest 'I' haven't seen the benefits of it as in …. does it help the patient being woken up every day? I don't know if that's coming back yet. Are we getting to that stage that the patients are remembering the wakening periods? I don't know if that is helping them or not …".[49]

Others described how they themselves would have preferred to be deeply sedated to experience complete amnesia to the agitation event.[54] Nurses also described how they saw sedation as the only solution when patients became agitated[49,50,58] while wishing that other treatment options existed.[58]

#### *4.3.3. Category 6: nonpharmacological care strategies*

One unequivocal and nine credible findings supported this category. Surprisingly few nonpharmacological caring strategies were mentioned in the included studies. Nurses used effective communication,[58] supported patient sleep,[55] and partnered with families.[52 54] Although ethical and medical concerns existed around the use of physical restraints, nurses still believed that they

played an important role in controlling patient agitation.[52] One study described the importance of knowing when and how to respond to patients with agitated behaviours.[52] By drawing on previous experience and knowledge, nurses were able to determine if nonpharmacological strategies were appropriate. A nurse reflected,

> "You sort of know what to expect and you know their physiology that they are relatively safe. You know that they can be hypertensive for a while without causing immediate danger. I mean it has to be obviously on your radar. It has to be in the back of your mind that you don't want to get him to be hypertensive for a long time but he's safe. He's still safe to do this"[52]

**Table 5**
Synthesised finding 3: uncertainty in how to manage agitated behaviours.

| Synthesised finding | Category | Findings |
|---|---|---|
| **Uncertainty in how to manage agitated behaviours**. Nurses described a lack of consensus and guidance on how to manage patients displaying agitated behaviours. The role of pharmacological and nonpharmacological strategies and the factors affecting nurses' decision-making processes around these strategies are poorly understood. | Category 4: assessment of agitation | How to identify agitated behaviours (U)<br>Scepticism about assessment (C)<br>Identifying causes of agitation (U)<br>Lack of appropriate assessment tools (U) |
| | Category 5: the role of sedation when caring for patients displaying agitated behaviours | Uncertainty around when to sedate (U)<br>Sometimes a need for immediate sedation (C)<br>The moral component (U)<br>Questioning optimal sedation (C)<br>Distressing to observe and manage (U)<br>Sedation should be a last resort (C)<br>Chemical and/or physical restraints at times necessary (U)<br>When sedation is necessary (U)<br>Difficult to achieve individual sedation (U)<br>Easier to increase sedation (NS)<br>Lack of time and tolerance (NS) |
| | Category 6: nonpharmacological care strategies | Challenging and rewarding (C)<br>Difficult to use nonpharmacological strategies (C)<br>Partnering with family members (C)<br>Knowing when and how to respond (C)<br>A familiar voice or face (C)<br>Family causing patient agitation (C)<br>Difficult families (C)<br>Value of communication (C)<br>Improving sleep patterns (U)<br>The challenging ICU environment (C)<br>Inability to make the patient comfortable (NS) |
| | Category 7: lack of training and consensus on how to manage patients displaying agitated behaviours | Lack of guidance and consensus (C)<br>Lack of training (quantitative finding)<br>Unsure about how to manage (NS)<br>Individual preferences (NS) |

Credibility of findings: U = unequivocal, C = credible, NS = not supported by citations.

Barriers related to nonpharmacological strategies were mentioned. Interestingly, families were also seen as obstacles to managing patients' agitation by fuelling anxieties and stressors[54,56] or by requiring nurses' support for themselves in an already stressful and time-critical environment.[56] Another obstacle to patient care was when nurses had to physically distance themselves from a potentially dangerous patient.[52]

> "It's really difficult because we're trying to give care to help the patient but with delirium, it's really hard because they fight with us or be a danger for themselves and to us at the same time. It's time consuming, emotional, and we're always on guard every time that we need to do something. Sometimes the care is not being done and it could be harmful to the patient"[52]

The ICU environment was also considered a barrier in caring for patients displaying agitated behaviours, either when patients were too close and disturbing to each other or when the ICU layout hindered appropriate proximity for observing agitated behaviours.[51] Caring for patients displaying agitated behaviours was seen as both challenging and rewarding when nurses succeeded in calming down a patient.[52]

#### *4.3.4. Category 7: lack of training and consensus on how to manage patients displaying agitated behaviours*

One credible finding and one quantitative finding supported this category. Nurses experienced disagreements and inconsistencies around the management of agitated behaviours, particularly with regards to the use of physical and chemical restraints.[52]

> 'Can we please all try and do that same?' So, we have the consistency there?' You have to sell it to your colleagues. Hopefully, you get someone there with experience as well, and who has a good set of nerves and who (laughing) has a willingness.[52]

Participants also described how they felt unsure about how to deal with agitation.

> "I have no idea how to address it (agitation)."[52]

Freeman[41] found that 24 of 39 nurses had not received adequate training in managing patient agitation.

### *4.4. Lack of effective collaboration and communication with medical colleagues*

Not feeling understood, recognised, or involved in decision-making by the medical team when caring for a patient displaying agitated behaviours caused frustrations and feelings of powerlessness. This synthesised finding comprises two categories generated from seven findings.

#### *4.4.1. Category 8: medical colleagues lack understanding of the demanding nature of caring for patients displaying agitated behaviours*

Three credible findings supported this category. There was a feeling that the medical team did not prioritise and take

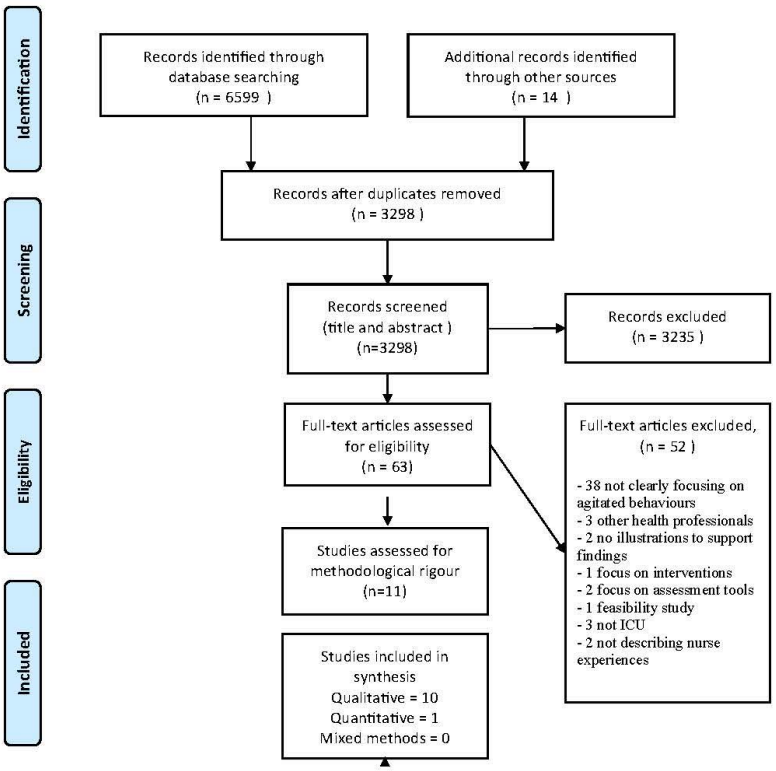


**Figure 1.** PRISMA flowchart of literature search (July 2020)[60].

responsibility for the management of agitated behaviours[58] and that they simply expected nurses to deal with this part of patient care.[49] Nurses described how the medical team did not understand the demanding nature of caring for this group of patients

> "… they're quite good at saying switch off sedation or no we don't want this, we don't want that, but then they walk off and they're not the ones at the end of the bed for 12.5 hours …".[49]

*4.4.2. Category 9: nurses not feeling recognised and involved in decision-making processes around sedation*

One unequivocal and three credible findings supported this category. It was described how the medical team did not recognise or trust nurses' assessment of agitation.[52] Nurses mentioned different approaches on how to "get through" to the medical staff. One nurse would call the physician to the bedside to 'capture the moment', whereas another used the CAM-ICU (Confusion Assessment Method for the ICU) findings to help him describe the agitated behaviours more effectively.[52]

Nurses also experienced a lack of involvement and autonomy in decision-making processes around sedation strategies.[49,51] The rigidity of implementing care bundles became a tick box exercise, reducing nurses' autonomy. For example, nurses preferred to reduce sedation when they had more time rather than before their break or early morning.[51] Lack of autonomy also left nurses feeling powerless when witnessing the distress and discomfort patients with agitation seemed to experience.[49]

> "It's a very frustrating thing to have an agitated, uncomfortable patient, just because the doctors decided let's wake them up. That can be really frustrating … bearing in mind that I can't prescribe [sedatives or rescue therapies] … You know a prescription might allow me to have some autonomy in when and where sedation is used …".[49]

Nurses felt dependent on their medical colleagues, and some wished that they had the authority to at least administer rescue medication.[49]

## 5. Discussion

By systematically integrating qualitative and quantitative data, this systematic review has contributed to new knowledge on how nurses experience caring for patients displaying agitated behaviours in the ICU.

This review shows how managing agitated behaviours in the ICU can be exhausting and cause feelings of guilt, dissatisfaction, and failure for nurses. The burden associated with caring for patients displaying agitated behaviours is well known and includes caregiver frustrations and intervention difficulties,[62] nurse distress,[63 65] and increased costs and use of resources,[62,66] which is increased when patients are aggressive and violent.[65,67] Wong et al.[65] provide one explanation for why caring for agitated patients can be challenging. They call the phenomenon the 'patient care paradox' meaning spending an extra effort on caring for someone

vulnerable who at the same time is threatening staff. This creates ethical and clinical challenges for nurses. The emotional exhaustion and moral distress nurses experience while caring for patients displaying agitated behaviours must be addressed as such experiences can lead to staff burnout.[68,69] Indeed, agitated patient behaviours have been linked to caregiver burnout and stress within many areas of nursing[64,70] and have led to less than optimal care, increased absenteeism, increased turnover, and negative reactions towards patients.[64] In the current climate of high levels of ICU health professional burnout[71] and concerns around adequate staffing,[72] ways to support nurses caring for patients with agitated behaviours must be explored further. Responsibilities lie not only with the individual caregiver but also within the team, the care culture, and the organisation. Nurse managers in the ICU play a major role in supporting the wellbeing of nurses.[73] Nurse managers must strive to create a healthy and trustworthy work environment that acknowledges nurses' experiences when caring for patients with agitated behaviours. Unfortunately, "blaming cultures" - characterised by a lack of trust in staff - are common in the ICU.[51,74] Such cultures must be prevented as they create fear in nurses, and nurses may use restraints excessively to avoid being blamed.

The demanding nature of caring for patients displaying agitated behaviours may explain why some nurses possessed negative attitudes towards these patients. Such attitudes were particularly seen towards patients who were suffering from alcohol or drug abuse. A recent Swedish study by Wedin et al.[75] revealed similar findings. ICU nurses described how they were concerned for their safety, dreaded caring, and lacked empathy towards the intoxicated agitated patient often experienced as unreliable, manipulative, aggressive, and violent. Aggression and violence are not unusual in the ICU,[76,77] and research indicates that nurses lack strategies for dealing with such behaviours.[78] In a meta-ethnography of the lived experience of delirium in the ICU, Ortega et al.[79] describe how patients felt they had to engage in violence to defend themselves and felt helpless, anxious, and a strong need for human connection. Agitation in the ICU is often related to delirium,[80] and therefore, this finding suggests that the agitated patient can be vulnerable and in need of empathy and personal engagement. Teece[81] explains how patients displaying agitated behaviours in the ICU require a different type of care than patients who are deeply sedated and thus more compliant. She argues that a culture change is necessary because although agitated patients are often 'unpopular' and not seen as 'proper' ICU patients, they require high levels of care.[81] Wedin et al.[75] found that when nurses were able to create caring environments characterised by empathy and respect, they were more likely to experience positive patient encounters. In this review, nurses felt 'professional' and 'satisfied' when they were able to minimise agitation.[52] Lind et al.[53] described a similar finding. Caring for nonsedated patients who were sometimes unpredictable and agitated required a different skill set. Nurses had to consider how to provide person-centred care and communicate in respectful ways. While this was seen as challenging, nurses also saw the opportunity to communicate with critically ill patients, establish relationships, and identify the needs of patients as a great advantage, exciting, and inspiring.[53] More research is needed to explore the role of the nurse–patient relationship during patient agitation and the factors that can positively support nurses' motivation to care for this group of patients.

The most extensive integrated finding from this review, involving most credible findings, suggests that nurses need support and guidelines on how to manage agitated behaviours. Wedin et al.[75] confirm this finding in a recent Swedish study describing how ICU nurses felt well equipped to provide lifesaving interventions in the ICU but lacked effective strategies to support agitated behaviours. There is also evidence suggesting that other ICU clinicians, including physiotherapists and physicians, experience similar challenges.[41,51] While Shapira[56] found in her early work that nurses easily identified agitated behaviours, more recent scholarship indicates that nurses may struggle with this task.[51] It seems natural to question if caring for more awake patients in the ICU requires a more nuanced picture of agitated behaviours. This hypothesis is supported by a more recent ethnographic study[82] showing how clinicians struggled to differentiate between agitation, anxiety, and patient irritability. Research shows that even experts disagree about what constitutes agitated behaviours and how concepts like aggressive behaviours, restlessness, disturbing behaviours, rejection of care, and anxiety[62,83,84] relate to agitation. It is important to recognise agitated behaviours as early as possible as this will increase treatment options and the success of these.[85] However, current agitation assessment tools may not be sufficient. Many assessment tools for agitation in the ICU exist. The Richmond Agitation Scale[86] and the Sedation Agitation Scale[87] are recommended in current guidelines[24] as they are said to be the most reliable and valid tools.[88] These tools were originally designed to determine levels of sedation and may not be sufficient in describing nuances of agitation which is essential for effective management. Identifying agitation and causes of agitated behaviours are critical elements of caring for patients displaying agitated behaviours.[1,19,89,90] More research is needed to explore if nurses possess sufficient knowledge to identify agitation and causes of such behaviours and if they find current assessment tools to be sufficient.

Nurses in this review also lacked clarity on the roles of sedation and nonpharmacological strategies. Some nurses believed sedation was the only solution when patients became agitated.[49,50,58] This finding is similar to findings in a national multicentre ICU study from China. Wang et al. [91] found that 51.34 per cent of clinicians did not employ nonpharmacological strategies for the management of pain, agitation, and delirium.[91] Mo et al.[92] found that the majority (97%) of health professionals reported using pharmacological agents, such as antipsychotics and sedatives, for the treatment of hyperactive delirium. The 2018 Clinical Practice Guidelines on pain, agitation, sedation, and delirium were unable to recommend nonpharmacological nurse-led strategies to reduce agitation.[24] This review found minimal information about effective nonpharmacological strategies nurses employ when caring for patients who display agitated behaviours. With a lack of guidance on nonpharmacological strategies and a lack of evidence on such approaches, it is perhaps not surprising that health professionals working under time pressure often choose physical or chemical restraint options. Although physical and chemical restraints have been the traditional ways of treating agitated behaviours, growing evidence shows that other approaches in the ICU may be beneficial, including nature-based sound therapy,[93] music,[94] touch[95], and foot reflexology.[96] Outside the ICU, person-centred approaches and communication skills training have also proven beneficial.[97,98] Further research is needed to explore the effectiveness of nurse-led nonpharmacological approaches to prevent or minimise agitated behaviours and if evidence-based approaches used in other areas of nursing can be applied to the intensive care unit.

Finally, this review highlights how unmet support needs from their medical colleagues caused nurses to feel frustrated and powerless. This is consistent with findings from a study exploring delirium care.[99] Nurses described how physicians did not trust their observations and they did not see situations as 'urgent'. Interestingly, doctors described how they struggled to find appropriate pharmacological solutions, acknowledging that this issue delayed their communication with nurses.[99] Nurse–physician conflicts in ICUs are common and causes include poor communication, mistrust, unclear decision-making processes, and inadequate

sharing of knowledge.[100] There are two major concerns when communication about the care and management of patients with agitated behaviours is dysfunctional. Firstly, nurses may experience that their clinical reasoning is not valued or important, which may negatively affect patient care and lead to feelings of moral distress.[101] Secondly, Wong et al.[65] identified poor communication and hierarchical challenges between doctors and nurses in the emergency department as threatening the safety of both patients with agitated behaviours and health professionals. This review suggests that nurse–doctor communication about the management of patients with agitated behaviours must be strengthened. Several interventions have been developed to improve ICU nurse–physician communication including implementation of communication tools and checklists and team training[102] and multidisciplinary ICU rounds.[103] Studies also suggest that standardised delirium assessment tools can support nurses when communicating their observations to doctors.[104]

In summary, this review highlights that caring for patients displaying agitated behaviours can be challenging and reveals that nurses are seeking guidelines and support to provide high-quality person-centred care to this cohort.

## 6. Limitations of the review

Although the authors conducted broad systematic searches, there is always a risk that relevant papers may not have been revealed during the searches. Due to the paucity of evidence on the topic, no date limitation was applied. Therefore, some findings may no longer apply to contemporary ICUs. However, it is believed that while agitation may have become more prevalent, it is unlikely that the experience of caring for patients displaying agitated behaviours has changed.

None of the studies exclusively aimed to describe how nurses experienced caring for patients displaying agitated behaviours, revealing the need for more qualitative research on this topic. Furthermore, this review only identified one study with quantitative data.[41] Minimal information was extracted from this paper due to the difficulties of separating nurses' experiences from the experiences of other health professionals. Therefore, larger-scale quantitative studies providing a current picture of nurses' experiences of caring for patients displaying agitated behaviours is needed.

## 7. Conclusion

Caring for patients displaying agitated behaviours in the ICU can be both challenging and demanding. While some nurses thrive with the challenges, others struggle – showing negative attitudes and seeking practical and emotional support and guidance on what 'best practices' look like. The findings from this systematic review are significant as they may support a better understanding of why suboptimal care, including inconsistencies and excessive use of physical restraints and sedation, occurs. Increased guidance and knowledge for nurses could reduce the perceived burden of care and improve patient care. Best practice for person-centred nurse-led approaches to prevent, minimise, and manage agitated behaviours must therefore be identified and inform clinical practice guidelines. Researchers could consider if evidence-based approaches used in other clinical areas of nursing can be transferred to the ICU setting. Multidisciplinary educational programs on 'best practices' to reduce patient agitation should be developed to ensure optimal care and effective collaboration.

Considering how prevalent agitation is in the ICU and the serious consequences it has on patient outcomes and nurse well-being, it is concerning that our knowledge about the best care for this group of patients is so limited. Future research must aim to increase our understanding of the care of patients with agitated behaviours and explore the key elements affecting this care.

## CRediT authorship contribution statement

**Anne Mette Adams**: Conceptualisation, Methodology, Validation, Investigation, Formal analysis, Writing – original draft, Writing – review & editing; **Diane Chamberlain**: Conceptualisation, Methodology, Validation, Writing – review & editing; **Mette Grønkjær**: Conceptualisation, Writing – review & editing; **Charlotte Brun Thorup**: Conceptualisation, Writing – review & editing; **Tiffany Conroy**: Conceptualisation, Methodology, Validation, Writing – review & editing, Supervision. All authors have given final approval of the final version of the manuscript to be published, agree to be accountable for all aspects of the work and acknowledge that those who are entitled to authorship are listed as authors.

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## Conflict of interest

No conflict of interest has been declared by the authors.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.aucc.2021.05.011.

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# Appendix 2 Ethical and feasible stakeholder engagement in guideline development.

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Methodology paper

# Ethical and feasible stakeholder engagement in guideline development

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ABSTRACT

*Background:* Stakeholder engagement impacts on the relevance and usability of guidelines. Consequently, guideline developers are advised to engage with a diverse group of stakeholders. One of the most critical and challenging phases of guideline development is determining the guideline scope, and there is currently scant guidance for how stakeholders can be engaged in feasible and ethical ways.
*Aim:* This article aims to provide practical guidance for how diverse stakeholders can be engaged to determine the scope of a guideline.
*Methods:* Supported by previous frameworks and by drawing on experiences from a research project aiming to develop a clinical practice guideline on non-pharmacological approaches for agitation in the intensive care unit, this paper describes a 7-step process for stakeholder engagement. Guideline developers need to consider the aim of their project, identify relevant stakeholders, decide on the level of engagement, plan how to engage in feasible and ethical ways, consider how to increase the trustworthiness of a project, and finally consider how to evaluate the project.
*Conclusion:* Consultation of diverse stakeholder groups is feasible, but it is essential to plan the activities and be aware of the steps to take to ensure an effective and ethical process.


**Summary of relevance**

**Problem**
- Failure to engage relevant stakeholder groups when determining the scope of clinical practice guidelines may result in inadequately addressing existing needs, thus compromising the implementation of the guideline.
- No guidance exists on how guideline developers can involve diverse international stakeholders in feasible and ethical ways.

**What is already known**
Evidence shows that often stakeholder engagement is not done, or not done well.

**What this paper adds**
This paper describes the steps guidelines developers can take to increase the likelihood of ensuring ethical and feasible stakeholder engagement.

## 1. Introduction and background

The implementation of evidence-based practice is challenging (Braithwaite, Glasziou, & Westbrook, 2020). Although guidelines are tools developed to support this process (Steinberg, Greenfield, Wolman, Mancher, & Graham, 2011), the lack of guideline uptake is a major concern internationally (Girlanda, Fiedler, Becker, Barbui, & Koesters, 2017; Heneghan, Perera, Mant, & Glasziou, 2007; Reinecke et al., 2015). Lack of guideline uptake can occur when end-users do not agree with recommendations (Spitaels et al., 2017), when a guideline format is not user friendly (Cahill, Suurdt, Ouellette-Kuntz, & Heyland, 2010), or when the recommendations are not feasible (Perez, Wisnivesky, Lurslurchachai, Kleinman, & Kronish, 2012). Research has explored ways to improve knowledge uptake and to develop guidelines with a form and content that more easily can be implemented (National Health and Medical Research Council, 2020). Evidence shows stakeholder engagement can have an impact on the relevance and usability of the final guideline (Armstrong, Mullins, Gronseth, & Gagliardi, 2018), thus increasing the likelihood of successful implementation (Health & Excellence, 2015; World Health Organization, 2014). Within guideline development, stakeholders include those who have a legitimate interest in a guideline and/or who may affect, or be affected by it.

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Stakeholders may include health professionals, patients and their representatives, those financing, managing or monitoring care, employers, and manufacturers (Cluzeau et al., 2012).

Despite emerging evidence for engaging diverse stakeholder groups when developing practice guidelines, often this is not done or not done well (Armstrong & Bloom, 2017; Wyatt et al., 2014). Facilitating ethical and feasible stakeholder engagement can be challenging, and many attempts of engagement have been criticised for being ineffective or tokenistic in nature (Ocloo & Matthews, 2016). Tokenistic engagement means that projects present a false appearance of inclusiveness. Tokenistic engagement occurs when stakeholders are not holding real influence, when their input is underestimated and not taken seriously, and when stakeholders are not allowed to contribute in ways that are meaningful and respectful to them (Romsland, Milosavljevic, & Andreassen, 2019).

Determining a meaningful and feasible guideline scope[1] is considered one of the most essential and challenging phases of guideline development (World Health Organization, 2014). This paper aims to provide guidance on how diverse stakeholder groups can be engaged to determine the scope of clinical practice guidelines. The guidance will be supported by existing frameworks and a clinical example.

## 2. Philosophical foundation and theoretical lens

Pragmatism formed the philosophical foundation for this paper. Pragmatism was chosen as it is outcome orientated and focuses on solving practical problems in the real world (Creswell & Clark, 2017; Kaushik & Walsh, 2019). According to pragmatism, researchers can and should use multiple methods and sources of knowledge to solve a problem (Creswell, 2014; Kaushik & Walsh, 2019).

The integrated knowledge translation (IKT) framework was chosen to guide the guideline development process. IKT is "a model of collaborative research, where researchers work with knowledge users who identify a problem and have the authority to implement the research recommendations" (Kothari, McCutcheon, & Graham, 2017, p. 299). IKT aligns well with pragmatism (Nowell, 2015), and is a promising framework to increase knowledge uptake (Straus, Tetroe, & Graham, 2013). Traditionally those who produced knowledge and those who used the knowledge were seen as two separate groups, where knowledge got transferred from production in the first group to implementation in the last (Landry, Amara, Pablos-Mendes, Shademani, & Gold, 2006). IKT aims to bridge these two groups early in the research process with the purpose of making research relevant and useful to its end-users (Kothari & Wathen, 2013). In IKT, researchers and knowledge users work together in all stages of a research project to solve complex real word problems (Kothari & Wathen, 2013). IKT share many similarities with models such as Engaged Scholarship[2], Participatory Research[3] and Co-production[4] (Kothari & Wathen, 2013). But in contrast to these models with backgrounds in social science, social justice and education, IKT originates from health research and focuses on increasing knowledge use to improve patient care (Kothari & Wathen, 2017; Nguyen et al., 2020). IKT brings together researchers and stakeholders such as health care providers and policymakers (Kothari & Wathen, 2013). However, IKT scholars have started exploring the opportunities to engage patients and the public in their research (D. Banner et al., 2019; D. J. Banner et al., 2020).

To our knowledge, no papers have described the step-by-step process for how all relevant stakeholders, including patients and their families, can be engaged in IKT research. To ensure feasible and ethical engagement with a broad group of stakeholders, this study was guided by patient and public engagement experts, including the International Association for Public Participation (IAP2) and the UK's National Institute for Health Research community engagement program INVOLVE (INVOLVE, 2015).

## 3. Steps for stakeholder engagement

Successful stakeholder engagement largely depends on thoughtful planning. To help future guideline developers, we propose seven critical steps for stakeholder engagement. These steps include clarifying the aim, identifying stakeholders and where to find them, considering if Human Research Ethics Committee (HREC) review is required, planning how to engage, ensuring the project's trustworthiness and integrity, and evaluating the project.

## 4. A clinical example

The seven steps are illustrated by examples of how we engaged Danish and Australian stakeholders to identify a guideline's scope. The guideline aimed to describe the non-pharmacological management of agitation in the intensive care unit (ICU). Non-pharmacological management is critical to avoid the harmful effects seen from an overuse of sedatives and antipsychotic drugs (Devlin et al., 2018).

## 5. Step 1: Clarify the aim of engagement

Guideline developers must articulate a well-defined aim for stakeholder engagement and justify why it is needed (Andrews et al., 2012). By clarifying the aim, clear boundaries and limitations can be set and appropriate methods chosen. The aim will depend on the stage of guideline development. For example, will stakeholders help select a topic, scope the guideline, identify and synthesise the evidence, develop recommendations and/or disseminate and implement the recommendations? Our project aimed to engage stakeholders to advise on the appropriate scope of a clinical practice guideline. A mixed-methods systematic review indicated the need for a guideline (Adams, Chamberlain, Grønkjær, Thorup, & Conroy, 2021), and systematic searches suggested that no guidelines existed on the topic. The aim of our stakeholder consultation was not to address a research gap.

## 6. Step 2: Identify all relevant stakeholders

When identifying relevant stakeholders, it is beneficial to ask the following questions. Who will be directly and indirectly affected by the guideline? Who would want to be involved? Are there any organisations representing the condition that is the focus of the guideline? For example, the UK's National Institute for Health Care Excellence (NICE) invites organisations, representatives of service users and registered stakeholders with specific knowledge of or experience with a condition to comment on the scope of their guidelines. In our project, relevant organisations or representatives of service users did not exist, and therefore we invited previous patients and their families with personal experiences of agitation in the ICU. We also invited ICU clinicians and researchers.

It is also necessary to consider how many stakeholders to engage. Most commonly, the aim of a scoping project is not to make generalisations, and therefore a large number of stakeholders is not necessary. However, guideline developers should have an inclusive

[1] A guideline's scope sets out what it will and will not cover (NICE, 2015).
[2] Engaged scholarship: Participative research process expanding the capabilities of scholars to gather perspectives of key stakeholders.
[3] Participatory research: Address community issues in collaborative consultation with people with lived experiences.
[4] Co-production/co-creation: Active involvement of consumers in the knowledge production process.

approach and ideally seek a range of perspectives from individuals with diverse backgrounds (National Health and Medical Research Council, 2020). We knew that non-pharmacological practices to reduce and manage agitation in ICU varied between countries and within countries. Therefore, we mapped out a variety of stakeholders groups from the different geographical locations. We eventually included around 50 stakeholders, which was manageable while also providing comprehensive information from various people.

## 7. Step 3: Consider how to find stakeholders

It is essential to consider how to find stakeholders. The Guidelines International Network (GIN) Public working group, a broad group of researchers, health professionals and consumers, suggests using either open or targeted invitations or a combination of these (Cowl, Armstrong, Schaefer, & Fielding, 2021). Open invitation means publicly publishing a draft guideline scope and asking anyone to provide feedback. The advantage of this method is that anyone can be involved, and since stakeholders are unknown to the guideline development group, they are unlikely to feel pressured to agree with the group, thus reducing bias. The risk is that nobody provides feedback because nobody feels responsible, or too many provide feedback leaving guideline developers overwhelmed with responses (Cowl et al., 2021). Targeted invitations mean sending out invitations directly to relevant stakeholders. This method can be more effective as it takes less time to find stakeholders, and if they are trained, they will know exactly what is required from them. The disadvantage is that important voices may be lost (Cowl et al., 2021). We used both open and targeted invitations. We contacted researchers directly while also reaching out broadly through professional and patient organisations. These organisations then reached out to their members via emails and newsletters.

We struggled to find previous patients and their family members. The engagement of lay people in projects involving diverse international stakeholder groups has shown to be challenging (Ingoe, Eardley, Rangan, Hewitt, & McDaid, 2020). Ocloo and Matthews (2016) warn that stakeholders can struggle with a lack of confidence and feel they do not have much to contribute. In our project, this was illustrated by one stakeholder who contacted us writing, "I am just an ordinary person with some experiences in this area," and then, unfortunately, withdrew from the project. We believe that meeting individuals and describing the study personally increases stakeholders' trust in the study and their self-confidence, thus encouraging participation. Unfortunately, due to COVID restrictions, we did not have access to post ICU patient support groups which hindered this level of personal contact.

## 8. Step 4: Consider if your project requires a Human Research Ethics Committee (HREC) review

Stakeholder consultation should be an integral part of all health research. The Australian National Health and Medical Research Council (2016) states consultation activities are more likely to result in ethically conducted patient-centred research. However, the concept of engagement is relatively new, and confusion exists around ethics and the risks involved for stakeholders. Scholars argue that ethics approval is not needed when patients and the public are consulted or involved in developing the processes and scope of projects as opposed to being subjects or participants of research (Involve, 2009). Consultation in guideline development poses a very low risk of harm to stakeholders. This is because being consulted differs from participating in research where data, such as personal information and experiences, are collected, transcribed, analysed, published and stored. Therefore consultation of stakeholders rarely causes ethical concerns (Australian Clinical Trials Alliance, 2021). However, regardless of the nature of their engagement in a project, ethical dilemmas can arise (Pandya-Wood, Barron, & Elliott, 2017; Salerno, Coleman, Jones, & Peters, 2021). Examples of this can be when stakeholders feel pressured to participate; when they provide certain answers due to their relationship with a guideline developer; when stakeholders do not fully understand their role or the aim of a project; or when guideline developers breach confidentiality. Due to these concerns, we recommend following ethical principles for stakeholder engagement (Pandya-Wood et al., 2017; Salerno et al., 2021), while also contacting a relevant ethics committee for advice on local requirements.

## 9. Step 5: Plan how to engage

Once the *why* stakeholder engagement is needed and the *who* stakeholders are is clear, it is time to identify *how* to engage stakeholders. It is crucial to make a tailored plan that will suit the project's purpose and the characteristics of the involved stakeholders. Guideline developers should work ethically and recognise the limitations of resources available. Below we describe the importance of considering the level of engagement, what questions to ask the stakeholders, the different forms of engagement, how to ensure clear and effective communication, how to maximise benefits and minimise harm, and finally, how to allocate sufficient time and resources.

### *9.1. Decide on the level of engagement*

IKT projects require varying levels of engagement at various times (Andrews et al., 2012). Guideline developers must be clear about the level of engagement required for their project. The IAP2 Public Participation Spectrum can help to define the exact role of the stakeholders (see levels of engagement Fig. 1)

The level of engagement ranges along a continuum from informing through to collaborating and empowering. At the lower level of engagement, stakeholders are informed but not able to influence decision-making processes. In contrast, at the higher end, the decisions are fully led by the stakeholders. Levels of engagement may depend on many factors, such as the aim of the project, the financial resources, and the timeframe. In guideline development, *inform* can be used to inform and raise awareness about guidelines and their updates. *Consultation* can be used in different phases but is commonly used to get advice on the guideline's relevance, scope or review tentative recommendations. *Involvement* and *collaboration* often refer to stakeholders who are members of the guideline development group where they can be review evidence or carry out research. Finally, *empower* refer to stakeholders who help implement and disseminate research.

We decided to consult stakeholders about the guideline scope. While consultation has been criticised for being tokenistic (Arnstein, 2019) and a 'tick box' exercise compared with approaches that collaborate and empower stakeholders, it can be a vital step in international guideline development, allowing a larger group of people to be heard. Consultation suited our aim, and while stakeholders were not able to make final decisions, their advice directly influenced the determination of the final scope, and they were continuously kept informed about the progress of the guideline development.

### *9.2. Decide to engage diverse stakeholder groups separately or simultaneously*

Professionals and laypeople can be engaged separately or simultaneously, and there are advantages and disadvantages to both options. Separately engaged groups may facilitate the development of unique and more directly relevant questions for each group. For instance, Serrano-Aguilar et al. (Serrano-Aguilar et al., 2015) carried

INCREASING IMPACT ON THE DECISION

| | INFORM | CONSULT | INVOLVE | COLLABORATE | EMPOWER |
|---|---|---|---|---|---|
| PUBLIC PARTICIPATION GOAL | To provide the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solutions. | To obtain public feedback on analysis, alternatives and/or decisions. | To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered. | To partner with the public in each aspect of the decision including the development of alternatives and the identification of the preferred solution. | To place final decision making in the hands of the public. |
| PROMISE TO THE PUBLIC | We will keep you informed. | We will keep you informed, listen to and acknowledge concerns and aspirations, and provide feedback on how public input influenced the decision. | We will work with you to ensure that your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision. | We will look to you for advice and innovation in formulating solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible. | We will implement what you decide. |

**Fig. 1.** IAP2 Spectrum of Public Participation ("IAP2 Spectrum of Public Participation," 2018), published with approval from the IAP2 working group.

out a Delphi study to reach agreement amongst consumers on priorities for a practice guideline and Tong et al. (Tong et al., 2012) invited 30 consumers to participate in two 3-hour workshops to select the topic and outcomes on early-stage chronic kidney disease. While such methods may be effective, they are also resource-intensive. We engaged diverse groups simultaneously to integrate several views into a project with strict time and resource restrictions.

### 9.3. Consider what questions to ask the stakeholders

A proposed guideline scope, built on the existing literature, should be developed before consultation commences. Guideline developers can then seek input on the proposed questions for the guideline to address, the population, including potential subgroups, end-users, setting, interventions, and meaningful outcomes (Cowl et al., 2021). We also found it helpful to also ask stakeholders about the predicted barriers to guideline implementation.

Regrettably, we did not ask stakeholders to rank outcomes and interventions. Such information is essential for conducting relevant systematic reviews that will inform the guideline recommendations, and therefore, we recommend future guideline developers do this during the scoping phase.

### 9.4. Offer different forms of consultation

Consultation can take different forms and can occur online or face-to-face, through workshops, meetings, open online discussions, or submission of written feedback. Traditional research methods such as surveys, interviews and focus groups may also be appropriate if the aim of a project is not to get input on a proposed scoping document but to answer a specific research question (Del Campo, Gracia, Blasco, & Andradas, 2011; Tong et al., 2012). For example, research questions could be 'what are the lived experiences of patient agitation in ICU?' or 'what are the views of agitation management in ICU?'.

To maximise opportunities for stakeholder input, we offered three different modes of online engagement, including workshops, one-on-one meetings and the opportunity to provide written feedback. There are several advantages of online patient engagement (Grant et al., 2018). Overall, the modes allowed us to hear the voices of multiple people at their convenience, regardless of time, geographical location, educational levels, income and ethnic backgrounds. Providing a diversity of methods for input and feedback also offered environments where stakeholders could feel safe and comfortable speaking up. We believe that by providing these modes, our strategy was as inclusive and flexible as possible. We have summarised the perceived advantages and disadvantages of each method in Table 2.

Although there are several advantages of online consultation, there are also disadvantages. These include not being able to ensure stakeholders fully understand the tasks required from them (Grant et al., 2018) and not being able to reach homeless people, people with mental or chronic illnesses, people from lower socioeconomic backgrounds without a computer and internet connection, and those with poor reading or communication skills. These people

may have a greater need for health care than the wider population (Ocloo & Matthews, 2016). Reaching these groups would have been valuable and potentially uncovered equity issues. However, this would have required meeting people face-to-face rather than online, which was not possible in our project due to the geographical distance between stakeholders. We suggest guideline developers are aware of the limitations of online engagement and consider if and how barriers can be mitigated.

### 9.5. Ensure clear and effective communication

While collaboration across borders has become increasingly popular, it can be challenging to ensure clear and effective communication with people speaking different languages (Dusdal & Powell, 2021). Translation of documents and other material can be a lengthy process and researchers, therefore, often restrict themselves to their native language (Alkhaffaf et al., 2021; Berk, Jorm, Kelly, Dodd, & Berk, 2011). We believe this can become a significant limitation of a project and can lead to important voices being lost. We advise guideline developers working with multinational groups to accurately translate all recruitment material and conduct meetings in stakeholders' native language.

It is essential that stakeholders are fully informed before agreeing to be involved (Andrews et al., 2012; IAP2, 2017; Wright, Foster, Amir, Elliott, & Wilson, 2010). When stakeholders do not feel clear about what is expected from them, this can hinder engagement (Ocloo & Matthews, 2016). We developed a bilingual online platform for people with different literacy competencies to ensure all stakeholders were fully informed. The platform offered several videos and text describing the purpose of the guideline development and how stakeholders could be involved. We developed participant information sheets describing the project's purpose and expectations to stakeholders. We advised stakeholders that participation was voluntary and that they could withdraw at any time without consequences. We pilot tested all material on individuals from Denmark and Australia, including health professionals, a participatory disability researcher, "lay" people and members of minority groups. We highly recommend testing all material, as this process encouraged us to make several changes. For instance, we realised that two different information sheets were necessary to accommodate different audiences. We developed an *easy read* and a *standard* version, and participants could choose which version they preferred. In the *easy read* version, we were conscious about using plain inclusive language without medical terminology and jargon and infographics when possible. The *standard version* contained more detailed background information without infographics.

### 9.6. Maximise benefits and minimise harm

Guideline developers should ensure maximum benefits for stakeholders and minimal harm (Salerno et al., 2021). It may be appropriate to reimburse stakeholders for their participation, as limited resources, for example, caring responsibilities, time, money for transport, limited internet access etc can hinder participation (Ocloo & Matthews, 2016). We required participants to have access to a computer with an internet connection and spend a significant amount of time (more than one hour) reading and answering several questions. Since reimbursing consumers in consultation projects aligns with the principles of patient and public involvement (Hayes, Buckland, & Tarpey, 2012 [updated 2021]), we decided to provide a small reimbursement (AU$30 voucher) for all participants. However, we advise offering incentives carefully, in particular when there is a risk that a large group of stakeholders will register their interest. Guideline developers can state that only a limited number of stakeholders will receive a voucher on a 'first come, first served' basis to avoid exceeding budget limits. Guideline developers can also decide only to reimburse certain stakeholder groups such as patients and family members. We experienced that health professionals participated during their working hours, were able to claim hours spent on the project as professional development hours and found a few health professionals described feeling uncomfortable receiving reimbursements. Considering the differences in resource access and reciprocity, we believe guideline developers should prioritise reimbursement of patients and family members over healthcare professionals.

Stakeholders must be able to provide advice without feeling any undue burden (Salerno et al., 2021), and guideline developers must work sensitively to avoid or minimise potentially emotionally upsetting situations (Pandya-Wood et al., 2017). In our project, we knew that thinking back to their time in the ICU could be uncomfortable for some stakeholders. To moderate this, we carefully developed questions that focused on the purpose of the project (see Table 1). We did not ask in-depth questions such as '*what do you feel about it?*' or '*how was your emotional reaction to that?*' We anticipated that focusing on the specific questions would minimise the risk of participants finding the involvement emotionally burdening. Although stakeholders are unlikely to become distressed during a meeting, we had a backup plan in case it would happen. Participants were always able to contact the principal investigator for a debrief, and we had a list of free online counsellors available, as suggested by the literature (Pandya-Wood et al., 2017; Wright et al., 2010).

To align with principles of respect in public involvement, stakeholders must also feel appreciated and respected (INVOLVE, 2015; Pandya-Wood et al., 2017). Researchers and guideline developers are encouraged to promise stakeholders feedback on how their participation influenced decision-making ("IAP2 Spectrum of Public Participation," 2018). Therefore, all stakeholders in our project received a summary of our findings, a description of how their feedback contributed to the final scoping document, and rationales for why some feedback was not incorporated. We also asked stakeholders if they would like to be publically acknowledged for their participation in future publications.

Guideline developers must be conscious of how they handle personal and sensitive information (Pandya-Wood et al., 2017). For instance, recording meetings and conversations may be preferable since notetaking can interrupt the flow of discussions. However, the reasons for recording must be clear and permissions obtained. Unless the aim is to carry out research, it is not necessary to transcribe recordings word by word, and personal information, such as names and institutions, should not be written down. All recordings must be destroyed promptly after notetaking, as storing such data involves risks for the stakeholders and may require ethics approval. Due to the nature of workshops, it is not possible to guarantee confidentiality. However, participants can be advised to leave their video off and leave out their real names if they prefer. They must also be reminded to respect the privacy of fellow stakeholders and not repeat sensitive information outside the workshop.

### 9.7. Allocate sufficient time and resources

It is important to allocate sufficient time and resources for an IKT project (Andrews et al., 2012). Guideline developers need to allocate money for reimbursements. They also need to allocate time to develop materials and for stakeholders to read through the material and think about it before giving feedback. Insufficient time may result in inadequate feedback and stress for stakeholders (Pandya-Wood et al., 2017). We gave stakeholders between two to three weeks to review the scoping documents, with additional time available to any participant who requested it.

**Table 1**
Examples of questions for stakeholders.

| Examples of questions |
|---|
| Is the guideline needed? Please explain your answer. |
| Do you think there are other aspects the guideline should cover? Please explain your answer. |
| Who will find the guideline useful? |
| What strategies do you think work for (insert group impacted by the guideline)? |
| What kind of results are you hoping for? |
| Do you predict any difficulties when trying to use the guideline? |

**Table 2**
The perceived advantages and disadvantages of different engagement methods.

| Method | Advantages | Disadvantages | Advice |
|---|---|---|---|
| **Written feedback** | Enable busy shift workers to participate Convenient for both stakeholders and guideline developers. Allows a larger number of people to be engaged. | While some responses were lengthy and detailed with references and explanations, others were brief. Answers from stakeholders may be unclear. | We recommend receiving written feedback before running the workshops and one-on-one meetings. This sequential approach can provide an opportunity to seek clarification on some written feedback. |
| **One-on-one meetings** | Can be carried out at a negotiated time that suits stakeholders. Offers more speaking time, thus an opportunity to provide more detailed feedback. | Can be time-consuming for guideline developers. Require guideline developers to be available outside regular working hours when including stakeholders from other time zones. | Provide questions in advance and encourage stakeholders to come prepared. On average, meetings took between 20 and 40 minutes. This method can be valuable for groups that are challenging to reach. For instance, we experienced that patients and family members preferred this option. |
| **Workshops** Workshops are different from focus groups. Focus groups are helpful research methods to reach an in-depth understanding of a phenomenon (Gawlik, 2018). In contrast, the aim of workshops is not to develop new knowledge. A workshop is: "a meeting of people to discuss and perform practical work in a subject or activity" ("Cambridge Dictionary," 1995-2021). Workshops are often used when consulting stakeholders in research projects (Gutman et al., 2020; Honey-Rosés et al., 2020; Northway et al., 2014; Rapport et al., 2014). | Allows for discussion of the proposed guideline scope with other stakeholders We experienced passionate and enthusiastic stakeholders who asked both us and each other questions. | Power imbalances can occur. Time-consuming for stakeholders. | To promote comfortable group dynamics and avoid power imbalances, group stakeholders with similar backgrounds. A total of 6–8 individuals in each group allow all stakeholders to answer all questions. 2.5–3-hour workshops provide enough time to hear everybody's advice and opinions on all questions. We recommend having two facilitators in each workshop, one being an experienced facilitator.Provide questions in advance and encourage stakeholders to come prepared. Have a clear agenda for the workshop and set ground rules, including showing respect and maintaining confidentiality. |

## 10. Step 6: Consider how you will increase the trustworthiness and integrity of your project

Using rigorous research methods may not be necessary for engagement activities (Doria et al., 2018), but can increase the quality and integrity of a study. We experienced that dealing with data from multiple stakeholders from different countries required a systematic approach. We used the software program Nvivo (QSR International, 2021) to organise the notes from the meetings. These notes were then analysed using content analysis. Content analysis is a research method that is suitable when combining different types of data. It is a method that is particularly suited when dealing with descriptive, focused and narrow questions that do not require deep and complex interpretation (Liamputtong, 2009). To ensure transparency, guideline developers are also encouraged to feed back the results to stakeholders with a description of how the final decisions were made. To support the integrity of our project, all stakeholders were encouraged to declare any conflicts of interest, such as financial or other interests that could potentially influence considerations on the topic. If significant conflicts of interests were found, stakeholders would be asked to withdraw from the project. This was important since potential conflicts of interest of guideline developers can damage people's trust and confidence in the guidelines (National Health and Medical Research Council, 2020).

## 11. Step 7: Evaluating the project and assessing the impact of engagement

While stakeholder input is essential to the development of quality guidelines, few studies demonstrate the impact of engagement. Such evaluation is essential to support future engagement projects and secure funding (Andrews et al., 2012). Evaluating the impact of engagement is also important to stakeholders who want to know if their contribution made a difference (Hardavella, Bjerg, Saad, Jacinto, & Powell, 2015). Several tools exist to evaluate the impact of engagement (Boivin & Abelson), yet, much evidence in this area has been criticised as being weak and anecdotal (Russell, Fudge, & Greenhalgh, 2020). Due to resource issues, we did not assess the impact of our project. However, we recommend that future guideline developers use robust methods to evaluate their project and recognise that robust assessment must be planned early on as it is time-consuming and may require ethical approval.

## 12. Discussion

By critically reflecting on stakeholder engagement, this paper offers a seven-step framework for how to plan and operationalise feasible and ethical stakeholder engagement (see Table 3) when determining a guideline scope. Since we engaged our stakehold-

**Table 3**
Steps for stakeholder engagement.

| Steps | Tasks |
|---|---|
| 1 | Clarify the purpose of engagement. |
| 2 | Identify all relevant stakeholders. |
| 3 | Consider how to find stakeholders. |
| 4 | Consider if your project requires a Human Research Ethics Committee (HREC) review. |
| 5 | Plan how to engage: |
| • Decide on the level of engagement. | |
| • Decide to engage stakeholder groups separately or simultaneously. | |
| • Consider what questions to ask the stakeholders. | |
| • Offer different forms of engagement. | |
| • Ensure clear and effective communication. | |
| • Maximise benefits and minimise harm. | |
| • Allocate sufficient time and resources. | |
| 6 | Consider how you will increase trustworthiness and integrity. |
| 7 | Evaluating the project and assessing the impact of engagement. |

ers in 2021, some principles for IKT engagement in spinal cord injury research have been developed. (Hoekstra et al., 2022; The University of British Columbia). When mapping the IKT principles to our 7-step process, we notice that our project reflects seven of the eight principles. Principle two states, "partners share in decision making." We consulted stakeholders, and therefore they did not hold the power to make final decisions on what should be included in our guidelines. However, we believe that each level of engagement in the IAP2 spectrum of public participation is equally beneficial at different stages of a research project. With more than 50 international stakeholders involved in the early stage of guideline development, shared decision making was not feasible. To allow stakeholders more influence on the final scope, consensus methods may be useful (French et al., 2019; McMillan, King, & Tully, 2016), although they require considerably more time and resources (Trevelyan & Robinson, 2015).

While we did not have the resources required to accurately measure the impact of the engagement process, it was clear that the engagement significantly impacted the development of the guideline. To provide one example, stakeholders believed that the guidelines should be for the multidisciplinary team, not just for nurses, as was initially proposed. They stated that developing recommendations only for nurses would hinder implementation and complicate multidisciplinary collaboration. This finding changed the draft scope, the design of further guideline development and most likely the implementability of the guidelines. We also experienced that stakeholder consultation resulted in outcomes that we had not expected. These included important networking with stakeholders and between stakeholders, which could positively influence later stages of guideline development and implementation.

## 13. Conclusion

There is no consensus on best practices for consulting diverse stakeholder groups simultaneously in a knowledge translation project. This paper describes a starting point for guideline developers through a practical example and existing frameworks. While getting advice from stakeholders may seem straightforward, developing well-founded guideline scopes in ethical ways requires several considerations.

In our study, we experienced that the consultation of international stakeholders greatly impacted the final guideline scope and highlighted areas that the research team had not considered. Overall, we believe the process made a significant contribution to the development of an effective and implementable guideline. Consultation requires additional resources in terms of time and finances. Still, it is feasible even for novice guideline developers, and unlike other types of engagement projects, we believe this can be done without additional training of researchers and stakeholders. Ethical engagement is feasible, valuable and should be incorporated into the development of all clinical practice guideline projects.

## Author agreement

This submitted article is the authors' original work. The article is not under consideration for publication elsewhere. All authors have seen and approved the manuscript being submitted.

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## Author contribution

Anne Mette Adams: Conceptualisation, Methodology, Investigation, Writing – original draft, Writing – review & editing, Diane Chamberlain: Conceptualisation, Writing – review & editing, Mette Grønkjær: Writing – review & editing, Charlotte Brun Thorup: Investigation, Writing – review & editing, Tiffany Conroy: Conceptualisation, Methodology, Investigation, Writing – review & editing, Supervision.

All authors have given final approval of the final version of the manuscript to be published, agree to be accountable for all aspects of the work and acknowledge that those who are entitled to authorship are listed as authors.

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There are no financial or other conflicts of interest to declare in association with this paper, and this manuscript has not been published previously in any other journal, nor is it under consideration in any other journal.

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## Ethical statement

The project that formed the basis of this manuscript was exempted from ethics review. This decision was based on advice from the Flinders University Ethics committee, as the stakeholders were acting as specialist advisors in the planning and designing of a guideline scope, thus not directly participating in research.

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# Appendix 3 Nonpharmacological interventions for agitation in the adult intensive care unit: A systematic review

(Use  to navigate back to your previous location in the thesis. This function can be used for all appendix, table and figure hyperlinks)

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Supplementary files for this publication are referred to in Appendices 33-39

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Review paper

# Nonpharmacological interventions for agitation in the adult intensive care unit: A systematic review

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ABSTRACT

*Background:* Person-centred nonpharmacological strategies should be used whenever possible to reduce agitation in the intensive care unit due to issues related to an overreliance on physical restraints and psychoactive drugs. However, the effect of nonpharmacological interventions to reduce agitation is unclear.

*Objectives:* The objectives of this study were to systematically review studies that evaluate the effectiveness of nonpharmacological interventions designed to prevent and minimise or manage patient agitation in the adult intensive care unit.

*Methods:* This systematic review was conducted following the Joanna Briggs Institute's Systematic Review of Effectiveness method and a priori PROSPERO protocol. Quantitative studies were identified from seven databases, including MEDLINE, EmCare, CINAHL, Web of Science, PsycINFO, Scopus, and Cochrane Library. In addition, grey literature from several repositories and trial registers was searched. The primary outcome of interest was the effect on prevention, minimisation, and management of agitation. The quality of the evidence was assessed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE).

*Results:* Eleven studies were included (n = 882). Meta-analyses of two studies demonstrated significantly lower levels of agitation (measured with the Richmond Agitation Sedation Scale) in the group receiving a multicomponent nonpharmacological intervention than in those receiving usual care. Individual studies showed a significant effect of nature-based sounds, music, foot reflexology, healing touch, and aromatherapy. The type of the endotracheal suction system did not affect levels of agitation. Overall, the certainty of the findings was rated very low. Harms and adverse effects were not reported in any studies.

*Conclusions:* Nonpharmacological interventions have the potential to reduce levels of agitation in the intensive care unit. However, inconsistencies in reporting, low quality of methodological designs, and small sample sizes impact the certainty of the results. Future trials must include larger sample sizes, use rigorous methods to improve knowledge in this field, and consider a range of other outcomes.



## 1. Introduction

Patients in the intensive care unit (ICU) can exhibit many distressing neuropsychiatric symptoms such as anxiety, depression, psychosis, agitation, and apathy. Agitation is particularly challenging[1] and is a major concern for clinicians internationally.[2] The behaviours are common,[3–5] often disrupting life-saving treatment, and are associated with a long list of adverse outcomes such as unplanned extubation,[6,7] line removal,[8] and increased length of stay.[9] Agitation can be disturbing for people experiencing it[10–12] as well as healthcare professionals[2,13] and family members.[12,14,15] Chevrolet et al. define agitation in ICU as "*a psychomotor disturbance characterised by a marked increase in both motor and psychological activities, often accompanied by a loss of control of action*

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*and a disorganisation of thought*".[16] Agitation has a behavioural component that can manifest on a continuum ranging from restlessness, tension, and irritability to hostility and aggressiveness. Clinicians tend to equate agitation with delirium,[17] but it is important to differentiate the two conditions. Patients can be agitated without being delirious,[18] as many other factors can contribute to agitation, including unmet needs or discomfort,[19] drug withdrawal,[20] poor gas exchange, metabolic disturbances,[19] and head trauma.[21] However, agitation is often seen in delirious ICU patients. Delirium has been described as a state of sudden severe confusion or altered level of consciousness[22] and manifests as hypoactive (43.5%), hyperactive (1.6%), or, most commonly, a mix of the two (54.9%).[23] Agitation is a symptom of delirious patients who are hyperactive, indicating major behavioural differences between hypoactive and hyperactive delirious states. Focusing on interventions for agitation may provide a more nuanced picture of how hyperactive delirious states can be managed, thus adding to the limited evidence of nonpharmacological interventions in this field[24,25] while also providing support for agitated patients who fall outside the delirium spectrum.

Traditionally, agitation in ICUs has been mitigated with pharmacological agents such as sedatives, antipsychotic drugs, and opioids. While these drugs still play an essential role in the ICU, particularly to facilitate weaning and extubation,[26 28] they should be used with caution due to significant adverse effects such as respiratory depression, haemodynamic instability, longer ICU stays, more days with mechanical ventilation, and, in some cases, worsening of agitation and delirium.[26,29 31] The 2013 International Guidelines for the Management of Pain, Agitation, and Delirium (PAD) advise clinicians to use nonpharmacological interventions when possible and before administering sedatives.[22] However, this guideline and the updated version from 2018[26] do not provide evidence-based recommendations on nonpharmacological interventions for agitation. Concerningly, research shows an overuse of sedation[29 32] and interventions that may not be patient-centred, such as physical restraints.[32 34] Patient-centred care is care based on each patient's unique needs, preferences, and values[35,36] and is essential to provide high-quality care and improve patient outcomes.[37] Clinicians feel uncertain about how to provide patient-centred care to agitated patients,[2,38] and decision-making is often based on personal views and experiences rather than on an evidence base.[2,39] Therefore, there is an urgent need to identify effective person-centred nonpharmacological approaches to reduce agitation.

A Danish/Australian advisory group consisting of patients, family members, clinicians, and topic experts provided advice on critical areas of a proposed guideline. The guideline scope was determined from this advice, and an *a priori* protocol[40] for this systematic review was formed. Advisory group members believed recommendations for nonpharmacological interventions for agitation in the ICU were needed due to existing inconsistent practices, a need to protect the most vulnerable ICU patients, overuse of sedation and restraints, and poor staff well-being due to injuries and feelings of powerlessness. Synthesising the evidence for nonpharmacological interventions to reduce agitation is a critically important topic. Therefore, this systematic review aimed to evaluate the effectiveness of nonpharmacological interventions designed to prevent, minimise, or manage patient agitation in the adult ICU.

## 2. Methods

This systematic review followed a priori PROSPERO protocol (CRD42021254918),[40] the Joanna Briggs Institute's (JBIs) method for Systematic reviews of effectiveness,[41] and was reported as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[42] Published and unpublished studies in English describing nonpharmacological interventions for agitation in the adult ICU were considered for inclusion. Studies that mixed nonpharmacological and pharmacological components were excluded to enable a more precise indication of the effect of nonpharmacological interventions. Based on advice from the advisory group, the primary outcome measure was the effect on prevention, minimisation, and management of agitation, which had to be measured using a validated tool. Parameters such as heart rate, stress hormones, and antipsychotic or sedative drugs were not considered exclusively related to agitation as these could be related to other factors in the ICU. Intermediate outcomes considered were the use of pharmacology and physical restraints to reduce agitation and staff and family confidence in managing agitated behaviours. Secondary outcomes included adverse events such as unplanned extubations, nosocomial infections and device removal, length of ICU stay, quality of life, risk of patient post-traumatic stress, patient satisfaction, family satisfaction, and workforce injuries. This review considered studies that used comparative designs such as randomised controlled trials (RCTs), quasi-experimental studies, and before-and-after studies with comparators such as usual care (i.e., usual nursing care). Systematic reviews on nonpharmacological interventions for agitation have been criticised for only including RCTs as this experimental design is often inappropriate or unfeasible for nonpharmacological interventions.[43] Cohen-Mansfield et al.[44] argue that due to the lack of effective nonpharmacological interventions, any evidence of effect is a step in the right direction. When reviews include only RCTs, there is a risk that meaningful studies are excluded and clinicians are left with insufficient or untimely treatment options.[44] Due to these arguments, this review also considered analytical and descriptive observational studies if there were no higher levels of evidence. No date limitations were applied as the effect of interventions was unlikely to have changed over time.

### 2.1. Search strategy

This review aimed to identify both published and unpublished studies. An initial limited search in MEDLINE was undertaken to identify relevant topic keywords and Medical Subject Headings. A search strategy was developed from the keywords and Medical Subject Headings and checked by an experienced librarian before being adapted for each database. An overview of all search strategies can be found in Supplementary material 1. Databases included MEDLINE (OVID, 1946–June 2021), EmCare (OVID 1995–June 2021), Cumulative Index to Nursing and Allied Health Literature (CINAHL, 1982–June 2021), Web of Science (1956–June 2021), PsycINFO (1806–June 2021), and Scopus (1788–June 2021). In addition, the following repositories and registers were searched: Cochrane Central Register of Controlled Trials, Australian New Zealand Clinical Trials Register (ANZCTR), EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/ctr-search/search), the World Health Organization International Clinical Trial Registry Platform (www.who.int/ictrp/search/en), US National Library of Medicine Trials Register (www.clinicaltrials.gov), ProQuest Dissertations & Thesis Global, and OpenGrey. Reference lists of all relevant studies were also screened.

### 2.2. Study selection

Records identified in the searches were exported into Covidence software,[45] where all duplicates were removed. AA and TC independently screened a random selection of record titles and

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abstracts to determine if they appeared to meet the inclusion criteria. After reaching an agreement on these articles, AA screened the remaining articles. Relevant articles were retrieved in full text and assessed in detail against the inclusion criteria by two independent reviewers (AA/DC/TC). A third reviewer was invited to provide their view when disagreements occurred between the two independent reviewers. Reasons for excluding full-text articles are provided in Supplementary material 2.

### 2.3. Assessment of methodological quality

All studies meeting the inclusion criteria were assessed for external and internal validity by two independent reviewers using the JBI's standardised appraisal tools for RCTs and quasi-experimental studies (Supplementary material 3).[41] Disagreements were resolved by discussion, and where consensus could not be reached, a third reviewer was involved. When the studies lacked essential information, primary authors were contacted. The questions in the appraisal tool were rated 'Yes', 'No', 'Unclear', or 'Not applicable'. 'Not applicable' was, for example, used when the reviewers believed blinding methods were not possible. The overall methodological quality of each study was then calculated by adding all 'Yes' ratings and dividing them with the number of applicable questions to get a percentage. Studies were rated 'low methodological quality' if rated less than 50%, adequate if rated between 50 and 69%, moderate if rated between 70 and 85%, and strong if rated between 86 and 100%. Since studies of low quality may compromise the quality of systematic review practice recommendations,[46,47] it was decided to exclude all studies with 'low methodological quality'.

### 2.4. Data extraction

Two independent reviewers extracted data using a purposefully designed data extraction template (Supplementary material 4). Data included details about the populations, study methods, interventions, and outcomes of significance to the review objective.

### 2.5. Data synthesis

Due to the variability of study characteristics (design, intervention, population) and lack of reported data, meta-analysis was not possible for all included studies. A narrative summary is presented for studies not included in a meta-analysis. Two RCTs describing multicomponent nonpharmacological interventions were pooled using the JBI System for the Unified Management, Assessment, and Review of Information (SUMARI) tool.[48] The effect sizes were expressed as standardised mean difference for continuous data. Their 95% confidence intervals (CIs) were calculated for analysis. Statistical heterogeneity was assessed using the standard chi-squared and I-squared tests. Statistical analyses were performed using the fixed-effects model based on guidance by Tufanaru et al.[49] Publication bias could not be assessed due to the low number of included studies.

### 2.6. Assessing certainty in the findings

Clinicians need to know how trustworthy a body of evidence is before making clinical decisions.[50] The certainty of the evidence was rated using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.[51] Two researchers did the ratings and developed a Summary of Findings table (Table 3) using GRADEpro GDT.[52]

## 3. Results

The results from the search process are presented in Fig. 1 (See Supplementary material 5 for a full list of results). A total of 6000 potentially relevant articles were identified; 2571 duplicates were removed. Titles and abstracts were screened of the remaining 3429 articles, excluding 3394 records. Overall, 35 studies went through a full-text analysis, leaving 15 articles for quality appraisal. Four studies were of low methodological quality and were excluded, leaving eight RCTs and three quasi-experimental studies for inclusion.

### 3.1. The methodological quality of included studies

An overview of the critical appraisal is provided in Tables 1 and 2. Four studies were excluded due to low methodological qualities[53–56] (See Supplementary material 6 for detailed explanations). Of the included studies, four were of adequate quality,[57–60] six of moderate quality,[61–66] and one of strong quality.[67] Some studies reported using random allocation techniques but did not describe how true randomisation was achieved;[61,64] others did not describe appropriate concealment methods.[60,65] In some studies, participants were not similar at baseline; this was related to levels of agitation[60,61,64] and the proportion of males and females.[57,61,66] Due to the nature of the interventions, blinding participants and assessors was sometimes impossible or would have little effect on the outcome. For example, knowing if a suction system was open or closed was unlikely to affect levels of agitation.[60] Creative methods or placebos were used for blinding in some studies. For example, Aghaie et al.[62] did not inform participants about the group they were assigned to, the purpose of wearing headphones, and the outcome measures until after the experiment. In terms of measurements of outcomes, one study was unclear about when measurements were done,[58] and many studies did not describe how inter-rater reliability was ensured.[57–61,66] In two studies, the exact differences between the interventions and usual care were unclear.[58,65] The statistical methods used were often unclear, insufficient, or results inadequately reported.[57,63,64,66,67]

### 3.2. Characteristics of the studies

The characteristics of the 11 included studies are provided in Table 4. Data of publication ranged from 2012 to 2021. Six studies were undertaken in Iran,[57,58,60,62,64,66] one in Korea,[67] one in China,[65] one in India,[63] one in the USA,[59] and one in Canada.[61] The sample sizes varied from 6 to 160. A total of 882 participants were involved, with the youngest mean age of a group being 41.23 ± 15.31 years[66] and the oldest 73.7 ± 5.2 years.[65] Although this review included all types of quantitative studies, only RCTs[58,60–66] and quasi-experimental studies[57,59,67] were identified. The inclusion criteria varied. Most studies excluded patients with a mental illness,[60,62–67] with drug or alcohol addiction[57,62–66] and neurological disorder.[60,63–67] Some studies only included conscious participants[60,62] or had a Glasgow Coma Scale score of at least 7[57] or 9.[63,66] Some only included patients who were able to communicate.[66,67] Most studies did not define criteria for levels of consciousness.[58,59,61,64,65] One study[57] included patients who were agitated, while another[59] excluded patients who were very agitated or combative. Three studies excluded patients receiving sedatives during the intervention,[57,61,67] one if they received high doses of sedatives,[60] and one if participants needed an emergency stat dose of sedatives.[63] Most studies did not describe or control for the use of sedation, antipsychotic drugs or analgesia before, during, and after the interventions.[58,59,62–66] All studies used the Richmond Agitation Sedation Scale (RASS) to measure levels of agitation,

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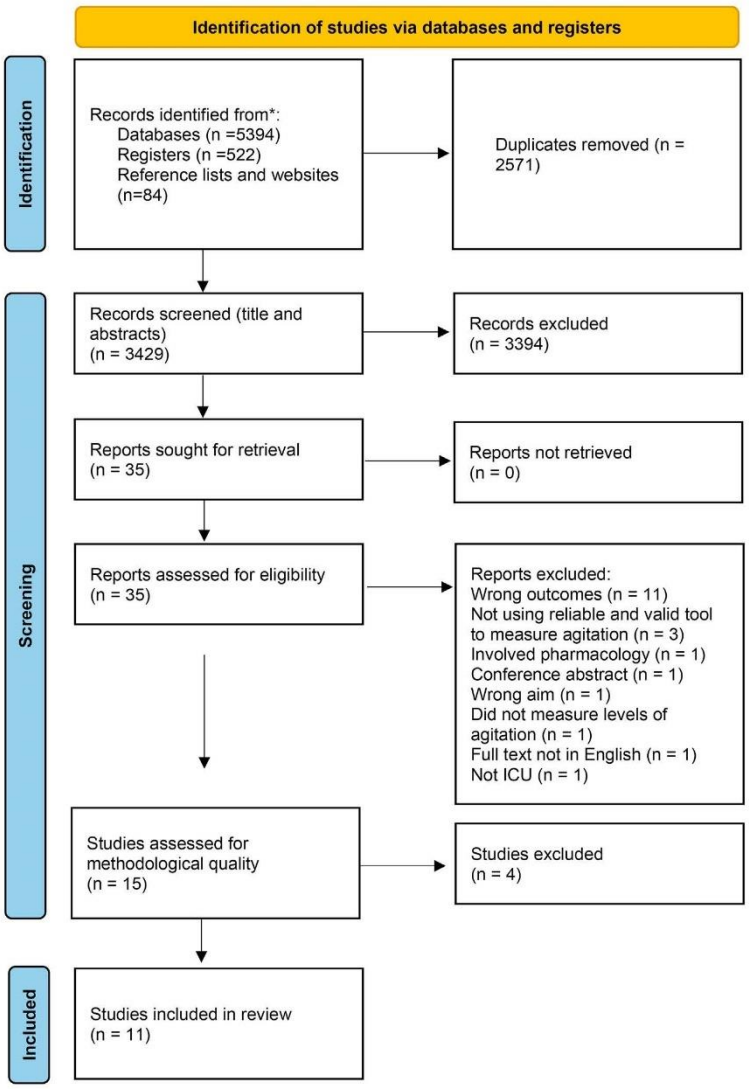


**Fig. 1.** PRISMA Flowchart. Under this can be the explanation of ICU: intensive care unit, *Report of records identified from each database or register searched. See Supplementary material 5.
From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021; 372:n71. doi: 10.1136/bmj.n71.

except one study[61] using the Ramsay Sedation Scale. Apart from two studies measuring the ICU length stay,[58,63] none of the included studies measured any of the secondary or intermediate outcomes considered for this review.

### 3.3. *Effect of interventions*

The interventions in this review fell under five categories: multicomponent interventions, nature-based sounds, music therapy, sensory interventions, and suction methods. Due to the heterogeneity of the included studies and lack of data, pooling for meta-analysis was only possible for two studies. The overall strength of the evidence is summarised in Table 3. The GRADE ratings show our confidence that the observed effect of the interventions reflects a true effect of the intervention. Although seven individual interventions[57,59,62–64,66,67] and a meta-analysis of two studies[58,65] demonstrated a statistically significant effect on agitation and one study showed some effect,[61] the overall certainty of this evidence was very low. Two studies examined the effect on length of ICU stay: one found a significant effect,[58] and another did not find any differences between the intervention and control groups.[63] The certainty of the evidence for this outcome was also

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**Table 1**
Quality assessment of methodological quality using JBIs' checklist of randomised controlled trials.

| Study | Q1 | Q2 | Q3 | Q 4 | Q 5 | Q 6 | Q 7 | Q 8 | Q 9 | Q 10 | Q 11 | Q 12 | Q 13 | Total (%) | Methodological quality |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Abbasinia et al.[58] | Y | Y | Y | Y | NA | N | U | Y | Y | U | U | Y | Y | 67 | Adequate |
| Aghaie et al.[64] | U | Y | N | Y | NA | Y | Y | Y | Y | Y | Y | N | Y | 75 | Moderate |
| Allahbakhhsian et al.[62] | Y | Y | Y | NA | NA | N | Y | Y | Y | Y | Y | U | Y | 82 | Moderate |
| Dastdadeh et al.[60] | Y | U | H | NA | NA | NA | Y | Y | Y | Y | U | U | Y | 60 | Adequate |
| Guo et al.[65] | Y | U | Y | N | NA | Y | U | Y | Y | Y | Y | Y | Y | 75 | Moderate |
| Rajora et al.[63] | Y | Y | Y | NA | NA | U | Y | Y | Y | Y | U | N | Y | 73 | Moderate |
| Saadatmand et al.[66] | Y | Y | N | Y | NA | Y | Y | Y | Y | Y | U | U | Y | 75 | Moderate |
| To et al.[61] | U | Y | N | Y | Y | Y | Y | Y | Y | Y | U | Y | Y | 77 | Moderate |

Y = yes; N = no; U = unclear; N/A = not applicable.
0–49%: low methodological quality; 50–69%: adequate methodological quality; 70–85: moderate methodological quality; 86–100: strong methodological quality.
Q1. Was true randomization used for assignment of participants to treatment groups?
Q2. Was allocation to treatment groups concealed?
Q3. Were treatment groups similar at baseline?
Q4. Were participants blind to treatment assignment?
Q5. Were those delivering treatment blind to treatment assignment?
Q6. Were outcomes assessors blind to treatment assignment?
Q7. Were treatment groups treated identically other than the intervention of interest?
Q8. Was follow-up complete and, if not, were differences between groups in terms of their follow-up adequately described and analysed?
Q9. Were participants analysed in the groups to which they were randomized?
Q10. Were outcomes measured in the same way for treatment groups?
Q11. Were outcomes measured in a reliable way?
Q12. Was appropriate statistical analysis used?
Q13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?

very low. The studies were grouped into five categories, as described in the following section.

### 3.3.1. Multicomponent nonpharmacological interventions

Two RCTs[58,65] investigated the effectiveness of multicomponent nonpharmacological interventions to reduce agitation. The studies included patients undergoing oral tumour resection[65] and coronary artery bypass graft[58] and provided a preoperative video[58] or a visit to the ICU.[65] Both studies were built on the Hospital Elder Life Program (HELP) for the prevention of delirium. They involved reorientation, therapeutic activities, promotion of sleep, adequate hydration and nutrition, provision of vision and hearing aids, and staff training. Abbasinia et al.[58] also included reduction of psychoactive drugs and early mobilisation, while the study by Guo et al.[65] added music therapy. Both interventions lasted for approximately 3 days. Abbasinia et al.[58] only measured the RASS once a day, and it is unclear when this was done. Levels of agitation may vary depending on the time of the day and procedures carried out around the patient; therefore, not stating when agitation was measured and whether it was measured consistently poses a threat to internal validity. Both studies lacked information on how the interventions differed from usual care and if patients received psychoactive drugs before or after the interventions.

The study by Abbasinia et al.[58] saw lower levels of agitation in the intervention group (0.06 ± 0.25) than in the control group (0.36 ± 0.80) on the last day; however, these differences were not statistically significant (P = 0.057). Guo et al.[65] saw a significantly lower level of agitation in the intervention group (0.2 ± 0.3) than in the control group (0.5 ± 0.4) on the last day (P= < 0.001). The two studies were pooled in a meta-analysis, including 220 participants. The pooled analysis showed that multicomponent nonpharmacological interventions significantly reduce levels of agitation (see Fig. 2).

### 3.3.2. Nature-based sounds

Three RCTs[63,64,66] investigated the effect of nature-based sounds versus placebo. In all three studies, the nature-based sounds consisted of birds' songs, soothing rain sounds, river streams, and waterfall sounds. The sounds were played once in the intervention groups using a media player and headphones for between 60 min[63] and 90 min.[66] In the study by Aghaie et al.,[64] the duration of the

**Table 2**
Quality assessment of methodological quality using JBIs' checklist of quasi-experimental studies.

| Study | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | Total (%) | Methodological quality |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Davies[59] | Y | Y | NA | N | Y | U | Y | U | U | 50 | Adequate |
| Jong Yoen Park[67] | Y | Y | Y | Y | Y | Y | Y | Y | U | 89 | Strong |
| Mashouf[97] | Y | N | NA | N | Y | Y | Y | U | N | 50 | Adequate |

Y = yes; N = no; U = unclear; N/A = not applicable.
0–49%: low methodological quality; 50–69%: adequate methodological quality; 70–85: moderate methodological quality; 86–100: strong methodological quality.
Q1 = Is it clear in the study what is the 'cause' and what is the 'effect' (i.e., there is no confusion about which variable comes first)?
Q2 = Were the participants included in any comparisons similar?
Q3 = Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?
Q4 = Was there a control group?
Q5 = Were there multiple measurements of the outcome both pre and post the intervention/exposure?
Q6 = Was follow-up complete and if not, were differences between groups in terms of their follow-up adequately described and analysed?
Q7 = Were the outcomes of participants included in any comparisons measured in the same way?
Q8 = Were outcomes measured in a reliable way?
Q9 = Was appropriate statistical analysis used?

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**Table 3**
Summary of findings.

| Nonpharmacological interventions for reducing agitation in the adult ICU | | | |
|---|---|---|---|
| Outcomes | Effect | No of participants (studies) | Certainty of the evidence |
| **Multicomponent nonpharmacological care interventions compared to usual care** | | | |
| **Agitation**<br>Follow-up: day 3 of the intervention. | Meta-analysis showed SMD difference 0.75 lower (95% CI: −1.02 to 0.47), indicating a large effect size. | 220 (2 RCTs) | ⊕◯◯◯<br>Very low[a,b,c] |
| **Length of ICU stay** | Meta-analysis was not possible. Significantly lower in I (3.53 ± 0.57 days) compared with C (4.06 ± 1.28 days), P = 0.042 | 60 (1 RCT) | ⊕◯◯◯<br>Very low[a,b,c] |
| **Nature-based sounds compared to placebo** | | | |
| **Agitation**<br>Follow-up: immediately after the intervention. | Meta-analysis was not possible. Studies found a significant reduction of agitation in the intervention group. | 300 (3 RCTs) | ⊕◯◯◯<br>Very low[b,c,d,e] |
| **Length of ICU stay** | No significant differences of length of stay between the groups | 120 (RCT) | ⊕⊕◯◯<br>Low[b,c] |
| **Music therapy** | | | |
| **Agitation**<br>Follow-up: immediately after the intervention. | Meta-analysis was not possible. One RCT with 25 patients showed a trend toward lower levels of agitation. A pilot study with 6 participants showed a significant decrease of agitation. | 56 (one RCT and one quasi-experimental study) | ⊕◯◯◯<br>Very low[c,f,g,h] |
| **Sensory interventions** | | | |
| **Agitation**<br>Follow-up: immediately after the intervention. | Meta-analysis was not possible. One RCT and three quasi-experimental studies showed a significant effect. | 327 (one RCT and three quasi-experimental studies) | ⊕◯◯◯<br>Very low[b,c,f,i] |
| **Suction methods – closed compared to open suction systems** | | | |
| **Agitation**<br>Follow-up: immediately after the intervention. | Meta-analysis was not possible. The type of suction system used had no effect on the level of patient agitation. | 60 (one RCT) | ⊕◯◯◯<br>Very low[b,c,j] |

CI = confidence interval; MD = mean difference; RCT = randomised controlled trial; SMD = standardised mean difference.
**GRADE Working Group grades of evidence:**
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.
[a] Serious risk of bias (differences between intervention and usual care unclear).
[b] Serious indirectness (psychoactive drugs received before/during the intervention is unclear).
[c] Serious imprecision (related to small sample size/short intervention/short-term follow-up).
[d] Serious risk of bias (lack of inter-rater reliability).
[e] Serious risk of bias: data analysis and reporting unclear.
[f] Serious indirectness (different intervention components between studies).
[g] Serious risk of bias (unclear if true randomisation was used).
[h] Serious risk of bias (control and intervention groups not similar at baseline).
[i] Serious indirectness (mostly men included).
[j] Serious risk of bias (three patients were deeply sedated throughout the study).

intervention was unclear. The placebo groups wore headphones without sound. Meta-analysis was not possible due to inadequate data reporting. The study by Saadatmand et al.[66] found that the intervention group had significantly lower levels of agitation ($P \leq 0.01$). Aghaie et al.[64] replicated the study by Saadatmand et al. except that their intervention was carried out during weaning from mechanical ventilation. Nevertheless, the authors found similar results to Aghaie et al. A more recent study by Rajora et al.[63] on 120 patients from the respiratory ICU found a significant reduction of agitation from baseline among the intervention group. This study also found no significant differences in ICU length of stay between the groups.

### 3.3.3. *Music therapy*

Two pilot studies, one RCT[61] and one crossover quasi-experimental study,[67] investigated the effect of music therapy. The designs, content, and frequency of interventions varied across the two studies, and therefore, pooled effect sizes could not be calculated. The RCT by To et al.[61] took place in the general ICU during a 4-h sedation vacation (interrupting sedation infusions). Twenty-five patients (intervention group) listened to Mozart piano sonatas via headphones, and 25 patients (placebo group) used headphones without music. If patients became restless and agitated at any time, sedation infusion was commenced, and the 'sedation vacation' was seen as unsuccessful. While patients in the

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**Table 4**
Characteristics of included studies.

| Study details | Design | Sample (I/C/P) and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| **Multicomponent nonpharmacological care interventions** | | | | | | | | | |
| Abbasinia 2021[58]<br>Iran | RCT | I: n = 30, mean age 56.46 ± 9.89<br>C: n = 30, mean age 58.93 ± 10.57<br>Mechanical ventilation unclear.<br>Patients recovering from CABG | Cardiac ICU | Multicomponent nonpharmacological intervention (preoperative video and HELP including reorientation, therapeutic activities, reduced use of psychoactive drugs, promotion of sleep, early mobilisation, adequate hydration/ nutrition and provision of vision and hearing adaptions). | Usual care | Until ICU discharge ≈ day 4. | RASS<br>Once daily on day 2 and 3 | **Agitation:** no significant differences in levels of agitation between I (0.06 ± 0.25) and C (0.36 ± 0.80), P = 0.057.<br>**Length of ICU stay:** significantly lower in I (3.53 ± 0.57 days) than in C (4.06 ± 1.28 days), P = 0.042. | Staff training required.<br>Part of intervention outside ICU<br>Short-term follow-up.<br>Assessments only done once daily - unclear when.<br>Unclear if/how inter-rater reliability was ensured.<br>Participants and assessors not blinded<br>Differences between intervention and usual care unclear.<br>Unclear if patients received psychoactive drugs during the intervention and if they were mechanically ventilated. |
| Guo, 2016[65]<br>China | RCT | I: n = 81, mean age 73.3 ± 6.1<br>C: n = 79, mean age 73.7 ± 5.2<br>Mechanical ventilation unclear.<br>Patients recovering from oral cancer resection surgery. | Surgical ICU | Multicomponent nonpharmacological intervention (preoperative visit to ICU, modified HELP including reorientation, therapeutic activities, promotion of sleep, adequate hydration/ nutrition, music, etc.). | Usual care | Until ICU discharge ≈ day 4. | RASS<br>Twice a day, between 7 and 8 morning and between 19 and 20 evening for 3 days post-surgery. | **Agitation:** levels of agitation were lower in I than in C all 3 days after surgery.<br>P < 0.05. Levels of agitation in the last day were 0.5 ± 0.04 in C compared 0.2 ± 0.3, in I,<br>P = <0.001. | Staff training required.<br>Part of interventions outside ICU<br>Allocation concealment unclear<br>Participants not blinded.<br>No arguments for sample size.<br>Long-term effect not investigated.<br>Differences between intervention and usual care unclear.<br>Unclear if patients received psychoactive drugs during the intervention |
| **Nature-based sounds** | | | | | | | | | |
| Rajora, 2019[63]<br>India | RCT | I: n = 60, mean age 47.07 ± 10.66<br>C: n = 60, mean age 46.90 ± 10.95<br>All mechanically ventilated. | Respiratory ICU | Nature-based sounds via headphones. | Placebo: headphones without nature-based sounds | 60 min × 1 | RASS<br>Before, then 15, 30, 45, and 60 min after commencing the intervention, and 30 min after the intervention. | **Agitation:** significant reduction of agitation in I compared to C at all time points. (P = 0.003 at 15 min, P = 0.001 at 30 min, P = 0.001 at 45 min, P = 0.001 at 60 min and P = 0.001 after 30 min)<br>**Length of stay**<br>No significant | Brief intervention period with short-term follow-up.<br>Unclear if assessor was blinded.<br>Unclear how inter-rater reliability was ensured.<br>Lack of appropriate statistical analysis.<br>Unclear if patients received psychoactive |

(continued on next page)

**Table 4** (*continued*)

| Study details | Design | Sample (I/C/P) and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | differences between the groups. | drugs during the intervention |
| Aghaie et al. 2014[64] Iran | RCT | I: n = 60, mean age 58.10 ± 6.05 C: n = 60, mean age 56.66 ± 5.84 All mechanically ventilated. Patients recovering from CABG surgery. | Cardiac ICU | Nature-based sounds via headphone. | Placebo: headphones without nature-based sounds | During weaning from mechanical ventilation, unclear for how long. | RASS Agitation recorded at baseline, and after the first trigger (unclear what this means) and at 20 min intervals throughout the procedure, immediately after the procedure, and 20 and 30 min after extubation. | **Agitation:** authors report that I had significant lower levels of agitation than C. | Unclear if true randomisation was used. Data analysis and reporting very unclear. Only included patients between 45 and 65 years of age (different levels of agitation at baseline) Brief intervention period with short-term follow-up. Unclear if patients received psychoactive drugs during the intervention |
| Saadatmand[66] Iran | RCT | I: n = 30, mean age 41.23 ± 15.31 C: n = 30, mean age 46.60 ± 16.76 All mechanically ventilated. | General ICU | Nature-based sounds via headphones. | Placebo: headphones without nature-based sounds. | 90 min | RASS Before and at the 30th, 60th, 90th minutes and 30 min after intervention. | **Agitation:** a significant difference was found between the agitation scores in the two groups ($P < 0.001$). The odds of having higher scores of agitation in C was ≈ 11.24 times of the same odds in the I. | Control group included 20 males and 10 females. Unclear how inter-rater reliability was ensured. Brief intervention period with short-term follow-up. Unclear if patients received psychoactive drugs during the intervention |
| **Music therapy** | | | | | | | | | |
| Jong Yoen Park, 2019[67] Korea | QE crossover | I: n = 3, C: n = 3, overall mean age 45.33 ± 16.49 All mechanically ventilated. | Surgical ICU | Music therapy (preferred music first, classical relaxation music last). | Music therapy (Classical relaxation music first, preferred music last). | 30 min with classical or preferred music, 60 min washout period, 30 min with classical or preferred music. | RASS Before and after each music session. | **Agitation:** significantly lower levels after both the preferred music intervention ($Z = -2.24$, $P = 0.025$) and classical relaxation music intervention ($Z = -2$, $P = 0.046$) than before. There was no significant difference in the decrease in the median RASS score between the two music interventions ($U = 15$, $P = 0.523$) | Pilot study (inadequately powered). Participants their own controls Short "wash out" period Assessors not blinded. Brief intervention period with short-term follow-up. |
| To[61] Canada | RCT | I: n = 25, mean age 50.25 + 19.25 C: n = 25, mean age 50.52 + 17.45 All mechanically ventilated. | General ICU | Mozart Piano Sonatas via headphones. | Placebo: headphones without music. | 4 h | RAMSEY sedation scale Measurements were obtained at baseline, at every 30 min during the | **Agitation:** there was a trend for more successful sedation vacations (meaning no agitation) in the | Pilot study (inadequately powered). Unclear if true randomisation was used. |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Patients undergoing 4-h sedation vacation | | | | | intervention and ended at 4 h. | music group (64%) compared to the control group (52%). | Higher levels of agitation in music group at baseline<br>10 females in control group compared to 3 in intervention group.<br>Brief intervention period with short-term follow-up. |
| **Sensory interventions** | | | | | | | | | |
| Allahbakhhsian 2020[62]<br>Iran | RCT | I: n = 40, mean age 55.90 ± 8.31<br>C: n = 40, mean age 56.30 ± 7.11p<br>: n = 40, mean age 57.32 ± 8.62<br>Not mechanically ventilated.<br>Recovering from CABG | Cardiac ICU | Foot reflexology | Control: usual care<br>Placebo: superficial heel touch. | 15 min × 1 | RASS<br>Before (T1), after (T2), and 10 min after (T3) the intervention. | **Agitation:** agitation was reduced in all groups from T1 to T3 (P ˚ 0.05). I showed a significantly higher reduction at T2 (P < 0.001) and T3 (P < 0.001). In I, agitation levels reduced by 1.844 scores (95% CI: -2,768, 0.921), while the reduction was only 0.822 scores (95% CI: −1.792, 0.147) for the placebo group. | Researcher trained by a professional reflexologist for 1 year<br>Assessor not blinded.<br>Serious indirectness as only men included<br>Brief intervention period with short-term follow-up.<br>Unclear if patients received psychoactive drugs during the intervention |
| Davies 2020[59]<br>USA | QE | n = 87, mean age = 63.38 ± 16.09<br>Mechanical ventilation unclear. | 5 general ICUs | Healing touch (HT) | No comparison | 7–15 min once daily in 1–2 days. | RASS<br>Before, after, and 5 min after. | **Agitation:** significant decreases in agitation scores following HT Pre (−0.59 ± 1.25) to post (−0.86 ± 1.16) first session, P < 0.01. Pre (−1.03 ± 1.61) to post (−1.52 ± 1.48) second session, P < 0.002. | Staff training required.<br>Feasibility study (inadequately powered).<br>Mean RASS scores were all below 0.<br>No comparisons.<br>Unclear how inter-rater reliability was ensured.<br>Brief intervention period with short-term follow-up.<br>Unclear if patients received psychoactive drugs during the intervention |
| Mashouf, 2017.[57]<br>Iran | QE | n = 40, mean age 49.36<br>Gender (m/f): 26/14<br>All mechanically ventilated. | General ICUs | Aromatherapy by lavender oil | No control | 60 min × 1 | RASS<br>Before, every 15 min during the intervention, then every 30 min until 2 h after the intervention. | **Agitation:** levels before and after aromatherapy was significant (P < 0.001). The greatest reduction of agitation was seen 180 min after the intervention. | No comparison group<br>No arguments for sample size.<br>65% males.<br>Unclear how inter-rater reliability was ensured.<br>Brief intervention period with short-term follow-up. |

(continued on next page)

**Table 4** (*continued*)

| Study details | Design | Sample (I/C/P) and characteristics | Setting | Intervention | Comparison | Duration and frequency | Scale and measurement points | Study results | Limitations |
|---|---|---|---|---|---|---|---|---|---|
| **Suction methods** | | | | | | | | | |
| Dastdadeh,[60] Iran | RCT | I: n = 30, mean age 65 ± 18<br>C: n = 30, mean age 66 (±20)<br>All mechanically ventilated. | General ICU | Open endotracheal suction | Closed endotracheal suction | One suctioning | Before, during, and immediately after, 5 min after and 15 min after the suctioning | **Agitation:** the type of suctioning system used had no effect on the level agitation ($P < 0.126$). | Allocation concealment unclear.<br>Three participants in the "open suction" group were deeply sedated throughout the intervention.<br>Brief intervention period with short-term follow-up.<br>Unclear if patients received psychoactive drugs during the intervention |

C = control group; CABG = coronary artery bypass graft; HELP = Hospital Elder Life Program; I = intervention group; ICU = intensive care unit; p = placebo; QE = quasi-experimental; RASS = Richmond Agitation Sedation Scale; RCT = randomised controlled trial.

music group were more likely to remain off sedation infusions than the control group (64% vs 52% success), a major limitation is that the control group had higher levels of agitation at baseline (Ramsay 4 vs 3 in the music group). Statistical significance is not reported. In the crossover quasi-experimental study by Jong Yoen et al.,[67] six mechanically ventilated patients listened to either preferred music or classical relaxation music for 30 min, and after a 60-min break, they would swap to the other music option (either preferred or classical relaxation music). This study found no significant difference in agitation between the two music interventions, but a significant decrease in agitation after both preferred music ($P = 0.025$) and classical music ($P = 0.046$), suggesting that both classical music and preferred music were effective in reducing levels of agitation. A significant limitation of this study was the inclusion of only six participants.

### 3.3.4. Sensory interventions

One RCT[62] and two quasi-experimental studies[57,59] evaluated the effect of sensory interventions. The RCT focused on foot reflexology,[62] and the others on healing touch[59] and aromatherapy.[62] Due to these studies' different designs and interventions, the results could not be statistically pooled.

A three-armed RCT examined the effect of foot reflexology on male patients in the cardiac ICU.[62] This study included an intervention group (n = 40) receiving 15 min of foot reflexology, a control group (n = 40) receiving usual care, and a placebo group (n = 40) group receiving 15 min of superficial heel touch. The intervention was carried out by the researcher, who had received training for 1 year by a professional reflexologist. The study found that agitation reduced significantly in all three groups. However, the intervention group showed a significantly higher reduction immediately after ($P < 0.01$) and 10 min after the intervention ($P < 0.001$).

In a quasi-experimental feasibility study, Davies et al.[59] aimed to identify the effect of healing touch on 87 patients from five general ICUs. A caring relationship between the nurse and the critically ill patient provided a foundation of this healing touch intervention. All nurses involved had received at least one of four healing touch courses. The study found a significant reduction of agitation after both the first healing touch session (before $-0.59 \pm 1.25$, after $-0.86 \pm 1.16$, $P < 0.01$) and the second healing touch session (before $-1.03 \pm 1.61$, after $-1.52 \pm 1.48$, $P < 0.02$). A major limitation of this study was the low RASS scores, making it challenging to interpret the findings.

A quasi-experimental study with 40 participants examined the effect of lavender oil aromatherapy.[57] According to the authors, aromatherapy with lavender oil has proven effective on a range of conditions such as inflammation, pain, stress, depression, and muscle spasm. This study found a significant reduction of agitation after aromatherapy with lavender ($P < 0.001$) and that the greatest reduction of agitation was seen 180 min after the intervention commenced.

### 3.3.5. Suction methods

In an RCT, Dastdadeh et al.[60] compared the effectiveness of open and closed endotracheal suction tube systems on 60 mechanically ventilated patients. Patients were randomly allocated to closed suction or open suction systems. The intervention was done once per patient. They found that the type of the suction system used did not affect the level of patient agitation ($P < 0.126$).

## 4. Discussion

This systematic review aimed to synthesise the best available evidence to identify effective nonpharmacological interventions for agitation in the ICU. An exhaustive search found 11 studies of

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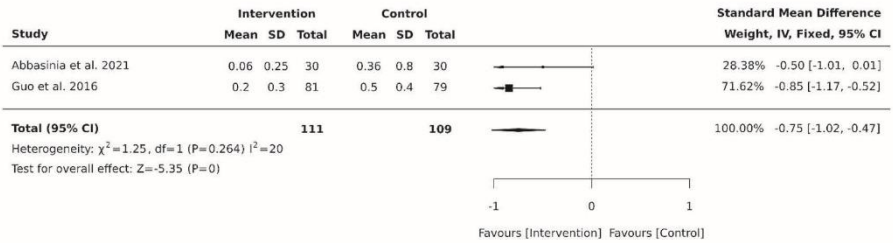


**Fig. 2.** Synthesis of multicomponent care interventions. CI, confidence interval; SD, standard deviation.

sufficient quality to be included in this review, five published within the last 3 years.[58,59,62,63,67] Meta-analyses of two studies demonstrated a significant effect of multicomponent nonpharmacological interventions. Several individual studies showed a significant effect, including nature-based sounds, music, foot reflexology, healing touch, and aromatherapy.

The included studies had several limitations to their designs and were often inadequately described. Issues included allocation concealment, blinding of assessors, groups not being similar at baseline, not clearly outlining the differences between usual care and intervention, and finally not ensuring that outcomes were measured in similar ways. Harms, feasibility, and acceptability by patients and staff were also poorly reported. Overall, sample sizes were small and interventions were short in length, carried out once only, and measured immediately after the intervention. Other systematic reviews on agitation have faced similar issues. Brasure et al.[68] reviewed 125 RCTs on agitation within dementia care and were unable to make conclusions due to the variety of comparisons and low quality of methodological designs. Similarly, a 2019 meta-synthesis[69] of 15 systematic reviews on nonpharmacological interventions for aggressive patients in the emergency department concluded that little and poor-quality evidence existed on effective strategies. The complex nature of agitation combined with the characteristics of nonpharmacological interventions challenges rigorous studies in this area.

Despite missing data and low methodological quality, the included studies may still provide important insight into what may be working. This argument is supported by Cohen-Mansfield et al,[44] scholars with extensive knowledge on agitation within dementia care. They highlight that while methodological quality is important, researchers must also consider what is meaningful and practically possible. They argue that nonpharmacological interventions are often low-cost, low-risk interventions that even when they are small or prove little effect may be extremely valuable for clinicians and patients for whom the alternative, for example, physical restraints and medication, is associated with much higher risks. It is clear that research on nonpharmacological interventions for agitation in the ICU is in its early stages. While RCTs are ideal, they may not be feasible and ethical and are designs with a higher potential for bias. Researchers may consider observational studies, including prospective and retrospective cohort studies, case–control series, and realist evaluation. Since multiple factors often cause agitation, a multicomponent approach may be most effective, preferably with a complex intervention approach[70] involving iterative cycles with continuous stakeholder engagement.[71] Other outcomes related to agitation must also be considered, such as the use of physical restraints, use of medication, adverse events, length of mechanical ventilation, patient and staff experiences, workforce injuries. We have developed a list for future researchers to consider when developing studies in this field; please see Table 5.

Based on the findings in this review, a diverse range of interventions, including multicomponent interventions, music, nature-based sounds, and sensory interventions, seem promising. The perhaps most promising intervention is the multicomponent nonpharmacological intervention. Systematic reviews on delirium in the ICU have also demonstrated the impact of multicomponent nonpharmacological interventions.[72,73] One explanation is that delirium, as with agitation, has multiple causes and, therefore, multicomponent interventions are more likely to target several risk factors.[74] In this review, the multicomponent interventions were built on the HELP, a complex intervention focusing on mobilisation, fluids, nutrition, sensory aids, orientation, and therapeutic activities. Originating from the US with a goal to preserve physical and cognitive functioning,[75] this program has successfully reduced the incidences of delirium amongst elderly patients worldwide.[76] However, translation of research can be challenging, and implementation of the HELP in the UK National Health Service was not achievable due to lack of resources.[77] More research is needed to explore the effects of multicomponent interventions on agitation in the ICU and the feasibility of carrying out such interventions. Furthermore, while such interventions may be effective for agitation, it is still unclear what elements of the nonpharmacological interventions contribute to improvements in clinical outcomes.

Nature-based sounds also showed some effects on agitation. The sounds of nature have shown to have a positive effect on the health and well-being of people in general.[78] The theories of why nature-based sounds create such a powerful reaction in individuals stem back to the theory of evolution. Like mindfulness, one explanation is that nature sounds do not require direct attention and therefore increase our awareness through unconscious and cognitive processes.[78] Another explanation describes how nature is perceived as less threatening and less arousing, thus reducing stress.[78] While Buxton et al[78] describe how nature sounds can be helpful to reduce stress in noisy urban areas, Minton and Batten[79] explored how such interventions could minimise patient stress and delirium in a hectic ICU environment. They concluded that many nature-based interventions could be implemented, including sounds, views, light, pictures, and posters. Changing patients' physical position changes their views of the environment, and watching nature reminds patients that they are alive and that there is a life beyond the ICU.[79]

Music may be beneficial for agitation, both classical[61,67] and patients' preferred music.[67] Robust literature supports this statement. Music has been used for decades within health. A recent meta-analysis of 12 RCTs showed strong evidence that music can reduce agitation in persons who have dementia.[80] Another systematic review states that music effectively reduces stress.[81] Scholars have described how music decreases physiological arousal and affects stress-related emotional states, including anxiety, worry, and restlessness, by modulating activities in our brain structures.[82] Music, in particular classical music, has been described as effective in reducing pain and levels of stress in the

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**Table 5**
Suggestions for future researchers.

| Limitations of included studies | Suggestions for future researchers |
|---|---|
| Lack of reporting. | Report how several steps are taken to ensure a rigorous study: randomisation, allocation concealment, characteristics of the groups including GCS, levels of sedation, mechanical ventilation, etc. Information on follow-up and detailed information on statistical analysis. |
| Only RCTs and quasi-experimental studies were identified. | It is challenging to develop rigorous RCTs or quasi-experimental studies on nonpharmacological interventions for agitation in the ICU. Therefore, researchers may want to consider other research designs informed by complex interventions frameworks. |
| Lack of clear definitions of agitation. | Authors must report how they define agitation. Consensus on what constitute agitated behaviours in the intensive care unit is needed. Such an agreement will ensure consistent observations, measurements, interpretation, and understanding of what may work. |
| The role of theory in intervention design and evaluation is unclear. | Researchers must be clear about the theoretical framework used to design and evaluate a study. |
| Limitations to the tools measuring agitation. | Provide solid arguments for the tools used to measure agitation. Identification and verification of tools to measure agitation in the ICU are needed. |
| Only a few outcomes were considered. | Other outcomes worth exploring:<br>- Drug use.<br>- Use of physical restraints.<br>- Adverse events such as unplanned extubations, nosocomial infections, and device removal.<br>- Post-traumatic stress.<br>- Patient experiences and satisfaction.<br>- Family experiences and satisfaction.<br>- Workforce well-being and injuries.<br>- Length of mechanical ventilation. |
| Short duration of studies. | Studies that carry out interventions over long periods and follow-up patients over more extended periods would provide more insight into the short- and long-term effects of interventions. |
| Blinding issues. | Creative blinding methods may be used. For instance, participants may not need to know the precise aim of interventions and when and what outcomes are measured. Researchers can use sham interventions without the active ingredient. |
| Inter-rater reliability is not ensured. | Ensure that all outcome assessors measure agitation in accurate and consistent ways. |
| No information about psychoactive medication. | Interventions must describe the type of psychoactive drugs patients receive hours before, during, and after an intervention. |
| Lack of information about the circumstances and expected active ingredient (who was involved, what was done, when, how often, and in what circumstances were the interventions applied).<br>*This information helps the reader understand when and why an intervention may be effective and assist future researchers in developing similar interventions.* | Describe the circumstances of an intervention. What could potentially cause agitation in this patient group? Were patients weaning from mechanical ventilation? From drugs? Was the intervention carried out in the morning or evening? After mobilisation? In a quiet room? etc. Ensure that other causes of agitated behaviours are dealt with before an intervention starts, for instance, discomfort due to pain, thirst, or a full bladder. |
| No studies explored if different sub-groups required different types of treatment. | ICU patient sup-groups may require different nonpharmacological approaches. More research is needed to explore this. |
| Harms, feasibility, and acceptability by patients, family members, and staff were not reported, making it difficult for clinicians and guideline developers to know if interventions should be recommended. | Interviews and observations may provide valuable insight into the feasibility and acceptability of interventions. |

GCS = Glasgow Coma Scale; ICU = intensive care unit; RCT = randomised controlled trial.

ICU.[83] However, clinicians must be aware that since music evokes feelings, playing heavy metal or techno may be ineffective or even harmful.[83]

Lavender aromatherapy may also reduce agitation, although the evidence in this area is sparse. Lavender is said to have antipain, antianxiety, antidepressant effects similar functions of increased benzodiazepines and gamma-aminobutyric acid in the amygdala.[84] A meta-analysis including 15 studies showed some evidence that aromatherapy, including smearing and inhalation, can reduce agitation and aggression in patients suffering from cognitive impairment. A nonrandomised study showed that aromatherapy alleviated stress and improved sleep in the ICU,[85] and an RCT showed a reduction of anxiety, heart rate, and blood pressure after exposure to lavender aromatherapy. These studies support that lavender possibly can be used as a low cost and inexpensive method to prevent or reduce low levels of agitation.

Foot reflexology may reduce agitation in the ICU.[62] The researcher providing this intervention was trained by a professional reflexologist for 1 year prior to the study, which poses a major limitation to the feasibility of this intervention. However, some studies have described how the intervention is easy to learn and apply.[86] A systematic review and meta-analysis reviewing 10 studies of reflexology for anxiety found that reflexology had some positive effect on anxiety amongst patients undergoing cardiac procedures.[87]

Healing touch also showed some effects in this review. Healing touch is believed to reduce stress and promote relaxation work through body–mind communication between the autonomic, endocrine, and immune systems.[59] Limited research has been carried out on the ICU population, but similar to the study by Davis et al.,[59] a pilot study within dementia care also found an effect of healing touch on agitation.[88] An RCT found an effect of healing

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touch on anxiety and length of stay in patients undergoing coronary artery bypass.[89] A qualitative Swedish study from the emergency department[90] explored patients' experiences of "caring touch" (a combination of healing touch and tactile massage) and found that the intervention provided trust and consolidation for most acutely ill patients. However, some patients expressed ambivalence towards the "caring touch".[90] When researchers interviewed US nurses about "healing touch", they expressed a desire to provide the intervention. Still, barriers such as lack of time, patient acceptability, and lack of training were common concerns.[91]

Forty-five percent of the included studies were published within the last 3 years, suggesting an increased awareness and need for effective nonpharmacological interventions. While waiting for rigorous evidence, it may be worthwhile to explore how interventions and recommendations from other areas of health may apply to the ICU. For instance, a large body of work has been done on agitation and aggression within psychiatry, and different working groups have developed guideline recommendations.[92–94] It may also be that interventions proven to be effective in other areas of health can be helpful in the ICU context. For instance, a recent network meta-analysis within dementia care, including 65 RCTs, found that massage therapy, animal-assisted intervention, personally tailored activities, and pet robot interventions were the most effective nonpharmacological interventions for agitation.[95] A recent scoping review on the management of the agitated psychiatric patient found that de-escalation techniques, risk assessment and programs involving staff training, patient involvement, and leadership were the most effective interventions and alternatives to physical restraints.[96] We suggest that future research involve relevant stakeholders when developing interventions or guidelines to fully understand what is feasible and acceptable in the ICU context.

### *4.1. Limitations to the RASS scale when measuring levels of agitation*

All studies, except one, used the RASS scale, a scale that has been said to be valid and reliable[97] and that has been used in several studies measuring the effectiveness of pharmacology on agitation.[98] However, there are several limitations to this scale that was originally developed to measure levels of sedation. First, on the scale, −4 to −1 describe levels of sedation, not levels of agitation. If RASS scores increase in sedated patients, it is an indication of a more awake patient rather than increased levels of agitation. This makes it challenging to ensure accurate analysis and interpretation of research results. For example, in the study by Davis et al.,[59] the authors claim that levels of agitation decreased from a mean of −0.59 ± 1.25 to a mean of −0.86 ± 1.16. One could argue that patients were simply more awake after the HT sessions. Second, issues arise with the RASS scale when patients are sedated/unconscious and agitated. Other scholars have pointed out the difficulties of rating two constructs, sedation and agitation, in one scale.[99] We recommend that authors pay special attention to interrater reliability and scales that more precisely measure agitation and are able to capture the breadth of these behaviours. Multiple and more nuanced scales, such as the Overt Agitation Severity Scale[100] and the Cohen-Mansfield Agitation Inventory,[101] exist outside the ICU setting that can potentially be modified and tested to suit the ICU environment. Related to levels of agitation, the included studies did not provide information about the frequency and duration of agitation, and no authors discussed what constitutes clinically meaningful changes in levels of agitation, making it difficult to fully understand the reported statistically significant differences.

### *4.2. Strengths and limitations of the review*

We conducted an exhaustive search and rigorously evaluated studies to ensure reliability in study inclusion and quality ratings. We reduced bias by excluding studies of low quality and by only including studies that used validated tools to measure agitation. However, there are limitations to this review. Only studies in English were included, which may have excluded some relevant studies. Although we followed the GRADE approach for grading the certainty of the evidence, this assessment is a subjective process, and even though the reviewers in this article agreed about the ratings, others may not. However, we have attempted to provide transparent and explicit explanations for our judgements throughout this review.

## 5. Conclusion

Despite an urgent need to identify effective nonpharmacological interventions, this review found insufficient evidence to draw firm conclusions on ways to reduce agitation in the ICU. Multicomponent nonpharmacological interventions, nature-based sounds, music, foot reflexology, healing touch, and aromatherapy may offer some benefits but need to be further studied. While this study calls out for rigorous research designs, it also encourages researchers to consider alternative methodological research approaches. RCTs are at the top of the evidence hierarchy but may not be meaningful, feasible, and ethical when researching agitation in a complex and ever-changing critical care environment. In addition to the effect on agitation, future research should also consider other important patient-centred, family-centred, and clinician outcomes.

It is a concern that no consensus exists on what nonpharmacological strategies should be recommended for agitation in the ICU. As a result, agitation is more likely to be managed pharmacologically or with methods that may not be effective or person-centred. While waiting for rigorous evidence, clinicians and researchers need to continuously discuss the role of nonpharmacological approaches while also considering how high-quality care for this vulnerable population can be ensured internationally.

## Conflict of interest

The authors have no conflict of interest to declare.

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## CRediT authorship contribution statement

**Anne Mette Adams:** Conceptualisation, Methodology, Validation, Investigation, Analysis, Writing – original draft, Writing – review & editing. **Diane Chamberlain:** Methodology, Validation, Writing – review & editing. **Mette Grønkjær:** Writing – review & editing. **Charlotte Brun Thorup:** Writing – review & editing. **Tiffany Conroy:** Conceptualisation, Methodology, Validation, Writing – review & editing, Supervision.

All authors have given final approval of the final version of the manuscript to be published, agree to be accountable for all aspects of the work, and acknowledge that those who are entitled to authorship are listed as authors.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.aucc.2022.02.005.

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# Appendix 4 Search template July 2020

Based on Medline

| | | |
|---|---|---|
| **Sample** | 1 | nurses/ or exp nurse practitioners/ or nurse specialists/ or nurse clinicians/ or nurses, male/ or nursing staff/ or nursing staff, hospital/ or “health personnel”/ |
| | 2 | (nurse or nursing or "health care professional*" or "health care staff" or "health professional*" or clinician*).tw,kf. |
| | 3 | 1 or 2 |
| **Phenomenon of Interest** | 4 | aggression/ or agonistic behavior/ or delusions/ or paranoid behavior/ or problem behavior/ or wandering behavior/ or confusion/ or delirium/ or emergence delirium/ or psychomotor agitation/ or anger/ or rage/ or anxiety/ or psychological distress/ or fear/ or panic/ or irritable mood/ or dangerous behavior/ |
| | 5 | ((difficult or inappropriate or agonistic or problem* or aggressive or abusive or challenging or disturbed or disruptive or agonistic or inappropriate or repetitive or purposeless or non-specific or dangerous) adj1 (behavi?or*)).tw,kf. |
| | 6 | ("hyperactive delirium" or agitat* or aggressi* or confus* or restless* or delirium or delirious or delusions or paranoid or anger or rage or anxiety or "psychological distress" or fear or panic or restless or "resist* care" or panic or irrit* or hyperactiv* or "excessive motor activity" or "psychomotor activity" or pacing or pushing or biting or grabbing or scratching or pulling or kicking).tw,kf. |
| | 7 | 4 or 5 or 6 |
| **Evaluation** | 8 | (view* or experienc* or opinion* or attitude* or perce* or belie* or feel* or know* or understand* or perspective* or think* or consider or assum* or appreciat* or recogni?e* or acknowledge* or accept* or see* or deem* or interpret*).tw,kf. |
| | 9 | attitude/ or "attitude of health personnel"/ or Perception/ |
| | 10 | 8 or 9 |
| **Design** | 11 | interviews as topic/ or focus groups/ or narration/ or qualitative research/ or "Surveys and Questionnaires"/ or Interview/ or Personal Narrative/ or Cross-Sectional Studies/ or Cohort Studies/ or Research Design/ |
| | 12 | ((("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide) adj3 (interview* or discussion* or questionnaire*)) or ("focus group*" or qualitative or ethnograph* or fieldwork or "field work" or "key informant" or "grounded theory" or questionnaire* or survey* or interview* or "case stud*" or observ* or "personal narrativ*" or phenomenolog* or "action research" or "feminist research" or cohort or cross-sectional or descriptive or correlational or comparative or quantitative or “mixed-methods” or prospective or retrospective)).tw,kf. |
| | 13 | 11 or 12 |
| **Context** | 14 | Critical Illness/ or Critical Care/ or exp Intensive Care Units/ |
| | 15 | ((ICU or (intensive or critical)) adj3 (care or unit*)).tw,kf. |
| | 16 | (critical* adj3 (ill* or care)).tw,kf. |
| | 17 | Respiration, Artificial/ |
| | 18 | ((mechanical* or artificial) adj3 (respiration or ventilat*)).tw,kf. |
| | 19 | 14 or 15 or 16 or17 or 18 |
| | 20 | 3 and 7 and 10 and 13 and 19 |
| **Excluding** | 21 | Intensive Care, Neonatal/ or Intensive Care Units, Pediatric/ |
| | 22 | ("neonatal" or "p?ediatric").tw,kf. |
| | 23 | 21 or 22 |
| **Final result** | 24 | 20 not 23 |

/: MeSH, .tw.kf: Title or abstract, word in author provided keyword

# Appendix 5 JBI critical appraisal for qualitative research

## INTRODUCTION

JBI is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide, South Australia. JBI develops and delivers unique evidence-based information, software, education and training designed to improve healthcare practice and health outcomes. With over 70 Collaborating Entities, servicing over 90 countries, JBI is a recognised global leader in evidence-based healthcare.

### JBI Systematic Reviews

The core of evidence synthesis is the systematic review of literature of a particular intervention, condition or issue. The systematic review is essentially an analysis of the available literature (that is, evidence) and a judgment of the effectiveness or otherwise of a practice, involving a series of complex steps. JBI takes a particular view on what counts as evidence and the methods utilised to synthesise those different types of evidence. In line with this broader view of evidence, JBI has developed theories, methodologies and rigorous processes for the critical appraisal and synthesis of these diverse forms of evidence in order to aid in clinical decision-making in healthcare. There now exists JBI guidance for conducting reviews of effectiveness research, qualitative research, prevalence/incidence, etiology/risk, economic evaluations, text/opinion, diagnostic test accuracy, mixed-methods, umbrella reviews and scoping reviews. Further information regarding JBI systematic reviews can be found in the JBI Evidence Synthesis Manual.

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# JBI CRITICAL APPRAISAL CHECKLIST FOR QUALITATIVE RESEARCH

Reviewer_____Date_____

Author_____Year_____ Record Number_____

| | | Yes | No | Unclear | Not applicable |
|---|---|---|---|---|---|
| 1. | Is there congruity between the stated philosophical perspective and the research methodology? | ☐ | ☐ | ☐ | ☐ |
| 2. | Is there congruity between the research methodology and the research question or objectives? | ☐ | ☐ | ☐ | ☐ |
| 3. | Is there congruity between the research methodology and the methods used to collect data? | ☐ | ☐ | ☐ | ☐ |
| 4. | Is there congruity between the research methodology and the representation and analysis of data? | ☐ | ☐ | ☐ | ☐ |
| 5. | Is there congruity between the research methodology and the interpretation of results? | ☐ | ☐ | ☐ | ☐ |
| 6. | Is there a statement locating the researcher culturally or theoretically? | ☐ | ☐ | ☐ | ☐ |
| 7. | Is the influence of the researcher on the research, and vice- versa, addressed? | ☐ | ☐ | ☐ | ☐ |
| 8. | Are participants, and their voices, adequately represented? | ☐ | ☐ | ☐ | ☐ |
| 9. | Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body? | ☐ | ☐ | ☐ | ☐ |
| 10. | Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data? | ☐ | ☐ | ☐ | ☐ |

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

# DISCUSSION OF CRITICAL APPRAISAL CRITERIA

*How to cite: Lockwood C, Munn Z, Porritt K. Qualitative research synthesis: methodological guidance for systematic reviewers utilizing meta-aggregation. Int J Evid Based Healthc. 2015;13(3):179–187.*

1. **Congruity between the stated philosophical perspective and the research methodology**

   Does the report clearly state the philosophical or theoretical premises on which the study is based? Does the report clearly state the methodological approach adopted on which the study is based? Is there congruence between the two? For example:

   A report may state that the study adopted a critical perspective and participatory action research methodology was followed. Here there is congruence between a critical view (focusing on knowledge arising out of critique, action and reflection) and action research (an approach that focuses on firstly working with groups to reflect on issues or practices, then considering how they could be different; then acting to create a change; and finally identifying new knowledge arising out of the action taken). However, a report may state that the study adopted an interpretive perspective and used survey methodology. Here there is incongruence between an interpretive view (focusing on knowledge arising out of studying what phenomena mean to individuals or groups) and surveys (an approach that focuses on asking standard questions to a defined study population); a report may state that the study was qualitative or used qualitative methodology (such statements do not demonstrate rigour in design) or make no statement on philosophical orientation or methodology.

2. **Congruity between the research methodology and the research question or objectives**

   Is the study methodology appropriate for addressing the research question? For example:
   A report may state that the research question was to seek understandings of the meaning of pain in a group of people with rheumatoid arthritis and that a phenomenological approach was taken. Here, there is congruity between this question and the methodology. A report may state that the research question was to establish the effects of counselling on the severity of pain experience and that an ethnographic approach was pursued. A question that tries to establish cause-and effect cannot be addressed by using an ethnographic approach (as ethnography sets out to develop understandings of cultural practices) and thus, this would be incongruent.

3. **Congruity between the research methodology and the methods used to collect data**

   Are the data collection methods appropriate to the methodology? For example:

   A report may state that the study pursued a phenomenological approach and data was collected through phenomenological interviews. There is congruence between the methodology and data collection; a report may state that the study pursued a phenomenological approach and data was collected through a postal questionnaire. There is incongruence between the methodology and data collection here as phenomenology seeks to elicit rich descriptions of the experience of a phenomena that cannot be achieved through seeking written responses to standardized questions.

4. **Congruity between the research methodology and the representation and analysis of data**

   Are the data analyzed and represented in ways that are congruent with the stated methodological position? For example:

   A report may state that the study pursued a phenomenological approach to explore people's experience of grief by asking participants to describe their experiences of grief. If the text generated from asking these questions is searched to establish the meaning of grief to participants, and the meanings of all participants are included in the report findings, then this represents congruity; the same report may, however, focus only on those meanings that were common to all participants and discard single reported meanings. This would not be appropriate in phenomenological work.

5. **There is congruence between the research methodology and the interpretation of results**

   Are the results interpreted in ways that are appropriate to the methodology? For example:

   A report may state that the study pursued a phenomenological approach to explore people's experience of facial disfigurement and the results are used to inform practitioners about accommodating individual differences in care. There is congruence between the methodology and this approach to interpretation; a report may state that the study pursued a phenomenological approach to explore people's experience of facial disfigurement and the results are used to generate practice checklists for assessment. There is incongruence between the methodology and this approach to interpretation as phenomenology seeks to understand the meaning of a phenomenon for the study participants and cannot be interpreted to suggest that this can be generalized to total populations to a degree where standardized assessments will have relevance across a population.

6. **Locating the researcher culturally or theoretically**

   Are the beliefs and values, and their potential influence on the study declared? For example:

   The researcher plays a substantial role in the qualitative research process and it is important, in appraising evidence that is generated in this way, to know the researcher's cultural and theoretical orientation. A high quality report will include a statement that clarifies this.

7. **Influence of the researcher on the research, and vice-versa, is addressed**

   Is the potential for the researcher to influence the study and for the potential of the research process itself to influence the researcher and her/his interpretations acknowledged and addressed? For example:

   Is the relationship between the researcher and the study participants addressed? Does the researcher critically examine her/his own role and potential influence during data collection? Is it reported how the researcher responded to events that arose during the study?

8. **Representation of participants and their voices**

   Generally, reports should provide illustrations from the data to show the basis of their conclusions and to ensure that participants are represented in the report.

9. **Ethical approval by an appropriate body**

   A statement on the ethical approval process followed should be in the report.

10. **Relationship of conclusions to analysis, or interpretation of the data**

    This criterion concerns the relationship between the findings reported and the views or words of study participants. In appraising a paper, appraisers seek to satisfy themselves that the conclusions drawn by the research are based on the data collected; data being the text generated through observation, interviews or other processes.

# Appendix 6 checklist for analytical cross-sectional studies

## INTRODUCTION

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### JBI Critical Appraisal Tools

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# JBI CRITICAL APPRAISAL CHECKLIST FOR ANALYTICAL CROSS SECTIONAL STUDIES

Reviewer_____Date_____

Author_____Year_____ Record Number_____

| | Yes | No | Unclear | Not applicable |
|---|---|---|---|---|
| 1. Were the criteria for inclusion in the sample clearly defined? | ☐ | ☐ | ☐ | ☐ |
| 2. Were the study subjects and the setting described in detail? | ☐ | ☐ | ☐ | ☐ |
| 3. Was the exposure measured in a valid and reliable way? | ☐ | ☐ | ☐ | ☐ |
| 4. Were objective, standard criteria used for measurement of the condition? | ☐ | ☐ | ☐ | ☐ |
| 5. Were confounding factors identified? | ☐ | ☐ | ☐ | ☐ |
| 6. Were strategies to deal with confounding factors stated? | ☐ | ☐ | ☐ | ☐ |
| 7. Were the outcomes measured in a valid and reliable way? | ☐ | ☐ | ☐ | ☐ |
| 8. Was appropriate statistical analysis used? | ☐ | ☐ | ☐ | ☐ |

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

# EXPLANATION OF ANALYTICAL CROSS SECTIONAL STUDIES CRITICAL APPRAISAL

*How to cite:* Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Qureshi R, Mattis P, Lisy K, Mu P-F. Chapter 7: Systematic reviews of etiology and risk . In: Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global

**Analytical cross sectional studies Critical Appraisal Tool**

Answers: Yes, No, Unclear or Not/Applicable

### 1. Were the criteria for inclusion in the sample clearly defined?

The authors should provide clear inclusion and exclusion criteria that they developed prior to recruitment of the study participants. The inclusion/exclusion criteria should be specified (e.g., risk, stage of disease progression) with sufficient detail and all the necessary information critical to the study.

### 2. Were the study subjects and the setting described in detail?

The study sample should be described in sufficient detail so that other researchers can determine if it is comparable to the population of interest to them. The authors should provide a clear description of the population from which the study participants were selected or recruited, including demographics, location, and time period.

### 3. Was the exposure measured in a valid and reliable way?

The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed.

Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.

### 4. Were objective, standard criteria used for measurement of the condition?

It is useful to determine if patients were included in the study based on either a specified diagnosis or definition. This is more likely to decrease the risk of bias. Characteristics are another useful approach to matching groups, and studies that did not use specified diagnostic methods or definitions should provide evidence on matching by key characteristics

### 5. Were confounding factors identified?

Confounding has occurred where the estimated intervention exposure effect is biased by the presence of some difference between the comparison groups (apart from the exposure investigated/of interest). Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of cohort design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.

### 6. Were strategies to deal with confounding factors stated?

Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured.

## 7. Were the outcomes measured in a valid and reliable way?

Read the methods section of the paper. If for e.g. lung cancer is assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If lung cancer is assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

Having established the objectivity of the outcome measurement (e.g. lung cancer) instrument, it's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

## 8. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured.

For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

# Appendix 7 Search strategy August 2022

**Medline**

| # | Medline |
|---|---|
| 1 | Critical Illness/ or Critical Care/ or Intensive Care Units/ or Intensive Care/ or Respiration, Artificial/ |
| 2 | (ICU* or ((intensive or critical) adj3 (care or unit*))).tw,kw. |
| 3 | ((critical* adj3 ill*) or ((mechanical* or artificial) adj3 (respiration or ventilat*))).tw,kw. |
| 4 | Or/1-3 |
| 5 | Psychomotor Agitation/ |
| 6 | ("Hyperactive delirium" or agitat* or psychomotor).tw,kw. |
| 7 | Or/5-6 |
| 8 | 4 and 7 |
| 9 | Intensive Care, Neonatal/ or Intensive Care Units, Pediatric/ |
| 10 | (neonatal or p?ediatric).ti,kw. |
| 11 | 9 or 10 |
| 12 | 8 not 11 |
| 13 | limit 15 to English language |

/: MeSH
.tw.kf: Title or abstract, word in author provided keyword

**CINAHL**

| # | CINAHL for EBSCO |
|---|---|
| S1 | (MH "Critical Illness") OR (MH "Critical Care") OR (MH "Intensive Care Units+") OR (MH "Respiration, Artificial+") |
| S2 | TI ( (ICU* OR ((intensive OR critical) N2 (care OR unit*))) ) OR AB ( (ICU* OR ((intensive OR critical) N2 (care OR unit*))) ) |
| S3 | TI ( ((critical* N2 ill*) OR ((mechanical* OR artificial) N2 (respiration OR ventilat*))) ) OR AB ( ((critical* N2 ill*) OR ((mechanical* OR artificial) N2 (respiration OR ventilat*))) ) |
| S4 | S1 OR S2 OR S3 |
| S5 | (MH "Psychomotor Agitation") OR (MH "Agitation") |
| S6 | TI ( ("Hyperactive delirium" OR agitat* OR psychomotor) ) OR AB ( ("Hyperactive delirium" OR agitat* OR psychomotor) ) |
| S7 | S5 OR S6 |
| S8 | S4 AND S7 |
| S9 | (MH "Intensive Care Units, Pediatric") OR (MH "Intensive Care Units, Neonatal") |
| S10 | TI ( (neonatal OR p#ediatric) ) OR SU ( (neonatal OR p#ediatric) ) |
| S11 | S9 OR s10 |
| S12 | S8 NOT S11 |
| S13 | S11 NOT S14 (narrow by language: English) |

TS: title, abstract, author keywords, and keywords Plus

**PsycINFO**

| # | PsycINFO |
|---|---|
| 1 | intensive care/ or artificial respiration/ |
| 2 | (ICU* or ((intensive or critical) adj3 (care or unit*))).tw,id. |
| 3 | ((critical* adj3 ill*) or ((mechanical* or artificial) adj3 (respiration or ventilat*))).tw,id. |
| 4 | Or/1-3 |
| 5 | agitation/ |
| 6 | ("Hyperactive delirium" or agitat* or psychomotor).tw,id. |
| 7 | Or/5-6 |
| 8 | 4 and 7 |
| 9 | Intensive Care, Neonatal/ or Intensive Care Units, Pediatric/ |
| 10 | (neonatal or p?ediatric).ti,id. |
| 11 | Or/9-10 |
| 12 | 8 not 11 |
| 13 | limit 15 to English language |

## Appendix 8 Clinician recruitment flyer

**Have you experienced managing agitated patients who were confused, restless, irritable, or aggressive in the adult ICU? Then we need your advice!**

# INVITATION

## to join the advisory group

Patient agitation is prevalent in the ICU and associated with poo outcomes. Challenges with managing agitation include overuse restraints and sedation, violence towards staff, patient post-trau stress, and staff exhaustion. Research indicate that nurses lack g effective non-pharmacological strategies. To address this gap, a Australian study aims to develop evidence-based practice guide non-pharmacological strategies to prevent and manage agitatior adult ICU.

Researchers are seeking advice from ICU clinicians to determir of the guidelines. Understanding the needs of clinicians is esser ensure meaningful and relevant guidelines.

If this sounds like something for you, or for someone you know register your interest on our website: www.agitationicu.com or mette.adams@flinders.edu.au

### What is expected of you?

You are asked to read a 2 pages document describing the scope of the guidelines and provide feedback on this document through one of these options:

- Through an online workshop
- Through a one-on-one meeting
- Through writing

### Requirements

- 18 years or older
- You have experience with managing patient agitation in an Australian adult ICU.

### What will you get?

- A $30 voucher
- Updates on the progress of the study

## Appendix 9 Patient/family recruitment flyer

**Have you as a patient experienced being confused, restless, irritable, or aggressive in the intensive care unit? Or did you visit a loved one who had these symptoms? Then we need your advice!**

# INVITATION

## to join an advisory group

Patient agitation is common in ICU, and is a conc
confusion, restlessness, irritability, or aggression.
challenging to manage and unfortunately often as
patient outcomes.

We are seeking advice from previous ICU patient
members, friends or relatives to develop meaning
guidelines on nurse strategies to prevent and min

If this sounds like something for you, or for some
register your interest on our website: www.agitati
mette.adams@flinders.edu.au

### What is expected of you?

You are asked to read a 2 pages document describing the guidelines and provide feedback on this document through one of these options:

- Through an online workshop
- Through a one-on-one meeting
- Through writing

### Requirements

- 18 years or older
- You have experience with patient agitation in an Australian adult ICU.

### What will you get?

- A $30 voucher

**Har du som patient oplevet at være forvirret, rastløs, irritabel eller aggressiv, mens du var indlagt på intensivafdelingen? Eller har du som pårørende besøgt en patient, der havde disse symptomer? Så har vi brug for din hjælp!**

**INVITATION**

**Til deltagelse i en rådgiv**

Agitation er en tilstand, d … rret, rastløs, irritabel el… hos patienter indlagt på en … tilstand, der desværre kan v… for patienten.

Vi søge… ældre intensive patienter og deres pårørend… elf-centrerede retningslinjer for sygepleje tiltag, der … ge og minimere agitation.

Hvis dette lyder som noget for dig eller for nogen, du kender, bedes du registrere din interesse på vores hjemmeside: www.agitationicu.com eller via e-mail mette.adams@flinders.edu.au

AALBORG UNIVERSITET

Flinders UNIVERSITY

**Hvad forventes der af dig?**

Du bedes læse en kort beskrivelse af retningslinjen og bagefter kommentere på denne. Hvad er vigtigt og nyttigt for patienter og for sundhedspersonalet? Feedback kan gives gennem en af følgende muligheder:

- En online workshop
- Et individuelt online møde
- Ved at give skriftlig feedback.

**Krav**

- … 18 år eller ældre.
- … som patient … rende oplevet … forbindelse … gelse på en … eling … sne).

**Som tak for din hjælp, vil vi tilbyde:**

- 150 DKK
- Opdateringer om projektets fremskridt.

**PROJEKT ANSVARLIG**
Anne Mette Adams, Flinders University, South Australia.

**EMAIL**
mette.adams@flinders.edu.au

**WEBPAGE**
www.agitationicu.com

**DANISH VERSION**

# Appendix 10 Clinician recruitment newsletter

## Invitation to participate in an advisory group

Patient agitation in ICU is prevalent and associated with several poor patient outcomes. Management of patients who are restless, confused, irritable and even aggressive is challenging and linked to overuse of physical restraints and sedation, violence towards staff, patient post-traumatic stress and staff exhaustion. Research indicates that nurses lack guidance on effective non-pharmacological strategies. To address this gap, a Danish-Australian study aims to develop evidence-based practice guidelines for non-pharmacological strategies to prevent, minimise and manage agitation in the adult ICU.

In the early phase of the guideline development, we plan to consult p to determine the scope of the guidelines. We want to understand current issues and concerns and consider such aspects to ensure that the guidelines are meaningful and relevant.

You are eligible to join the advisory group if you have experience with caring for patients displaying agitated behaviours in the adult intensive care unit.

If you choose to take part in this study, you will be invited to review and provide feedback on a 2-3 pages guideline scoping document. Feedback can be provided in three ways: by participating in an online workshop; by participating in an online one-on-one meeting; or by submitting written comments.

You will receive a $30 voucher in recognition of your contribution, and we will keep you updated on the progress of the study.

If you are interested in learning more about the project or if you wish to register your interest, please go to the webpage www.agitationicu.com

Kind regards

Anne Mette Adams
Associate Lecturer and PhD Candidate
College of Nursing and Health Sciences
Flinders University
mette.adams@flinders.edu.au

**Invitation til deltagelse i en rådgivende gruppe**

Agitation er en tilstand, der gør, at man som patient kan blive forvirret, rastløs, irritabel og aggressiv. Tilstanden forekommer ofte hos patienter indlagt på en intensivafdeling. Det er en udfordrende tilstand, der desværre kan være forbundet med alvorlige kon for patienten.

Vi søger hjælp og gode råd fra tidligere intensiv rende til at udvikle patient-centrerede retningslinjer for sygepleje til mere agitation. Du kan deltage, hvis du som patient eller p i forbindelse med indlæggelse på en intensiv afdeling.

DANISH VERSION

Hvis du vælger at de ort beskrivelse af retningslinjen og kommentere på denne. Du kan give d es enten gennem en online workshop, i et individuelt online møde eller ved at give a tilbagemelding.

Som tak for din hjælp tilbyder vi 150 DKK samt opdateringer om projektets fremskridt.

Hvis dette lyder som noget for dig, bedes du registrere din interesse på vores hjemmeside: https://da.agitationicu.com/advisory-group

Med venlig hilsen,

Anne Mette Adams
Underviser og ph.d. kandidat
College of Nursing and Health Sciences
Flinders University
mette.adams@flindes.edu.au

# Appendix 11 Guideline scope draft

## Guideline scope – draft

This document aims to allow members of the advisory group to review the draft scope and comment on the appropriateness of the guidelines. All comments from the advisory group members are important and will be noted. A summary of the comments and key themes will be provided to all participants.

### 1 Title of Guidelines

Nurse-led nonpharmacological prevention, minimisation, and management of agitated behaviours in the adult intensive care unit

### 2 Background

a) Agitation in ICU has been defined as "a psychomotor disturbance characterised by a marked increase in both motor and psychological activities, often accompanied by a loss of control of action and a disorganisation of thought" (1).

b) Characteristics of agitated behaviours in ICU include confusion, restlessness, irritability, aggression expressed through repetitive movements, pulling catheters and dressings, kicking legs, attempting to sit up, banging on side rails and grimacing. Often patients are disorientated and have irrational thoughts. In ICU, patient agitation is often accompanied by abnormal vital signs such as increased respiratory rate, heart rate, blood pressure and metabolic rate (2-4). All these factors may directly or indirectly negatively affect patient outcomes.

c) The occurrence of agitated behaviours in ICU patients ranges from 13 to 70 per cent (5-19).

d) Agitation in ICU is linked to unplanned extubation[1], increased length of stay, unplanned line removal, nosocomial infections[2], arrhythmia[3], more mechanical ventilator[4] days, reduced mobilisation, and patient post-traumatic stress[5] (6, 11, 15, 20-26).

e) Causes of agitation can be physical such as brain injury, infection, lack of oxygen to the brain; psychological, such as anxiety and fear; environmental such as constant noise, touch and light; or unmet needs, such as the need to go to the toilet or change position in bed (4, 11, 27-29).

f) Current practice often involves the use of physical restraints (30-32) and [illegible]7). Existing guidelines on the management of agitated behaviours fa[illegible] pharmacological[6] strategies (38, 39).

g) There is a need for guidance on appropriate non[illegible]revention, minimisation, and management of agitated behaviours. Imp[illegible]ment may speed patient



[1] Removal of the artificial breathing tube that helps the patient to breathe.
[2] Infections acquired during the process of receiving healthcare.
[3] Irregular heart rhythm.
[4] A mechanical ventilator is a machine that takes over the work of breathing when a person is not able to breathe enough on their own
[5] Post-traumatic stress disorder is a mental disorder that can develop after a person is exposed to a traumatic event.
[6] Nonpharmacological strategies are strategies that do not involve medication

recovery and prevent physical and psychological complications and therefore has the potential to generate cost savings.

# 3 The scope of the guidelines

This section contains suggestions for what the guidelines could include and what kind of nonpharmacological approaches the research team will consider when reviewing the literature.

## 3.1 The main questions the guidelines are addressing:

a) What nonpharmacological interventions prevent the incidence of agitated behaviours in ICU. This will include the identification and modification of precipitating factors.

b) What nonpharmacological strategies can be applied to minimise or manage agitated behaviours in ICU?

c) Do different conditions or patient groups require different approaches (for instance patients who are pregnant, obese, have physical disabilities or are physically frail, heavy drinkers, intoxicated, speaking a different language, from a different cultural background, are dying, are violent)

### 3.1.2 Clinical management that will not be covered:

Pharmacological management of agitated behaviours.

## 3.2 Intended end users

The guidelines are intended for nurses caring for critically ill patients.

## 3.3 Target population

The population to which the guideline recommendations will apply are critically ill adults (18 years and older) admitted to the intensive care unit.

## 3.4 Setting

The guidelines are to be relevant in all critical care settings that carry out invasive haemodynamic monitoring [7] and mechanical ventilation [8], except for recovery wards/ post-surgical wards, high acuity areas, the emergency department.

## 3.5 Outcomes

What kind of outcomes are important to indicate the effect of interventions?

a) Frequency, severity, and duration of agitated behaviours, both long and short term, as measured with reliable and valid tools such as the Sedation Agitation Scale (SAS) and the Richmond Agitation-Sedation Scale (RASS). Other scales will be considered.

[7] Invasive haemodynamic monitoring means continuous monitoring of the movement of blood and pressures in veins, arteries, or the heart. This method requires insertion of a small tube, a catheter, into an artery, vein, or the heart.

[8] A mechanical ventilator is a machine that takes over the work of breathing when a person is not able to breathe enough on their own.

b) Associated complications such as unplanned extubations[9], nosocomial infections[10], device removal.

c) Patient or family-reported outcomes

d) Length of ICU stay

e) Injuries to patients and staff

Other secondary outcomes that will be considered include family satisfaction, staff satisfaction and/or confidence in managing agitated behaviours, decreased use of physical restraints, decreased use of sedatives or antipsychotic drugs.

## 3.6 Status

This is the consultation draft of the guideline scope. The consultation period is 1st March to 24th March 2021.

**References are available on request; please contact mette.adams@flinders.edu.au**

[9] Removal of the tube that helps patients breathe.
[10] Infections acquired during the process of receiving health care.

# Appendix 12 Welcome letter

Anne Mette N. Adams

Flinders University, College of
Nursing and Health Sciences
GPO Box 2100
Adelaide SA 5001

email:
mette.adams@flinders.edu.au

Date: 26th of February 2021

Re: **Nurse-led non-pharmacological prevention, minimisation and management of agitated behaviours in the adult intensive care unit.**

Dear xxx,

Thank you for your interest in the advisory group. The aim is to source your opinion and advice on the draft of the scope of the guideline: **Nurse-led non-pharmacological prevention, minimisation and management of agitated behaviours in the adult intensive care unit.**

Please read the **Participant Information Sheet**, attached to this email for convenience.

The **Guideline Scope** is also attached. Consider the questions below after reading the Guideline Scope document. I have attached a **Form for Providing Written Feedback**. Please fill out this form before the 18th of March and forward it to Anne Mette Adams (mette.adams@flinders.edu.au).

If you have any conflicts of interests to declare, we ask you to also fill out the **Conflicts of Interest Form** and forward this to Anne Mette. There is more information about this below.

In appreciation of your time and input, you will receive a voucher when we have received your feedback.

We are looking forward to hearing from you and we are happy to answer any questions you may have about participating in the advisory group.

Kind regards,

Anne Mette Adams
Associate Lecturer and PhD Candidate
Email mette.adams@flinders.edu.au

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## Questions

Please read through the **Guideline scope** document and consider the following questions:

### 3.1 The main questions the guidelines are addressing.

Are the guidelines needed? Please explain your answer.

Do you think there are other aspects the guidelines should cover? Please explain your answer.

What strategies do you think works for agitated behaviours in ICU?

Do you think interventions from other patient care areas may apply to the intensive care unit? If yes, what areas should we consider?

### 3.2 Intended end-users

Who do you think will find the guidelines useful?

### 3.3 Target population

Is the target population an appropriate focus? Please explain your answer.

### 3.4 Setting

What setting(s) do you think is appropriate for the guidelines?

### 3.5 Outcomes

What kind of patient outcomes or results are you hoping for?

How will we know if approaches are effective – what will we see short- and long-term?

### Other questions

Are there barriers to the implementation of the guidelines?

## Conflicts of interest

Managing conflicts of interest is an important part of developing guidelines. This process identifies if those who are involved in developing guidelines have any financial or other interests that can potentially influence, or appear to influence, proper consideration on a specific topic. For example, you may have significant shares in a company that has developed a particular type of therapy that might be recommended in the guidelines. Conflicts of interest can damage peoples' confidence and trust in our work. As an advisory group member, we ask you to declare any conflicts of interests. If we find significant personal interests, we might ask you to withdraw from the group. Please complete the attached declaration form if you have anything to declare.

# Appendix 13 Participant information sheet - easy read

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**PARTICIPANT INFORMATION SHEET - EASY READ**

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**Title:** Determining the scope of clinical practice guidelines through stakeholder consultation.

You are invited to participate in an advisory group because you have experience with agitation in the intensive care unit either as a patient or a family member. You may also be invited because you are an intensive care unit clinician or a researcher with experience and knowledge of the management of agitated behaviours.
This information sheet tells you about our research project and what it means to participate in the advisory group.

This research project is being conducted by:

**Chief Investigator**
Anne Mette Adams, College of Nursing and Health Sciences, Flinders University, South Australia.
Email: mette.adams@flinders.edu.au

**Co-Investigators**
Tiffany Conroy, Flinders University, South Australia.
Diane Chamberlain, Flinders University, South Australia.
Mette Grønkjær, Aalborg University, Denmark.
Charlotte Brun Thorup, Aalborg University, Denmark.

**Why is this study important?**
This study aims to gather a broad group of people, also called stakeholders, to participate in an advisory group. The advisory group will help the research team to determine the appropriate scope (breadth) of a set of practice guidelines for nurses on strategies that do not involve medication to prevent and minimise agitated behaviours in the intensive care unit. Agitation, showing as restlessness, irritability, confusion and aggression, often occurs in the intensive care unit and is linked to many negative patient outcomes. The advisory group members will provide their opinions and advise on what they believe the guidelines should and should not cover, whom the guidelines should be for and which actions the research team should focus on. We are interested in knowing what you believe is important for future intensive care unit patients, their families and clinicians providing care. This study is being completed as part of a doctorial study.

ENGLISH VERSION

**Join us if you fulfil these requirements:**

- Adult = 18 years and up
- You have experience with agitated behaviours in the adult intensive care unit. For example, you have experienced being agitated yourself, you visited a family member or a friend who was agitated, you have managed agitation as a clinician, or you have expertise in agitated behaviours through research.
- You can read and understand either plain English or Danish.
- You have a computer available and an internet connection.

We hope to recruit members from a wide range of backgrounds and encourage people with disabilities, people from ethnic minority groups and indigenous populations to participate.

**What is expected of you?**

- You are asked to set aside time (30-60 min) to read a 2-3 pages guideline *scope document*. Reviewing means reading the document carefully while considering your own experiences and knowledge. For more information see below: **What kind of advice do the guideline developers need?**
- You are prepared to share your opinions about the guidelines.
- You choose one (or more) of the following options to provide your feedback:
    1. Attend a 3-hour online workshop (this will run in your language and with people who have similar experiences as you. For instance, previous patient and family members will meet with other previous patients and family members).
    2. Attend a one-on-one online meeting with Anne Mette, the project lead.
    3. Provide written feedback.

**What kind of advice do the guideline developers need?**

When you read through the *scoping document*, we want you to consider the following questions:

- Do you think the guidelines are needed? Please explain your answer.
- If these guidelines were to be used in your local area, is there anything that we would need to consider?
- Do you think specific groups of patients would need special considerations? Please explain your answer.
- What do you think nurses should consider when caring for patients displaying agitated behaviours?
- What do you believe nurses can do to prevent agitated behaviours from occurring in the first place?
- What do you think nurses can do to minimise or manage agitated behaviours?

- What do you think we would find in an intensive care unit where nurses are using effective strategies? Or with other words, how would we know if the strategies nurses are using to prevent or manage agitation are effective?

**What will happen to the information you provide?**

Your advice is important, and all of the advice will be summarised and reviewed. All information will be deidentified and you will not be linked with any specific comments. The information you provide is for advice only and will not be used in research products.

**What do you get from participating?**

- You will receive a $30 voucher.
- This is your opportunity to contribute to improving the care provided to patients in ICU.
- We will keep you updated on the progress of the study.

Note that we are looking for a limited number of people for the advisory group. On our website, you can see if you are still able to participate. See https://www.agitationicu.com/advisory-group.

**Can you withdraw from the project?**

Yes, you can withdraw from the project at any time without any consequences. Participation is voluntary. You should be aware that the advice you provide up until you withdraw will form part of the project.

You will be able to read more about this study and watch our informative videos on our homepage https://www.agitationicu.com/.

Should you have any further questions, please do not hesitate to contact Anne Mette Adams on mette.adams@flinders.edu.au

Yours sincerely,

Anne Mette Adams

# Appendix 14 Participant Information Sheet Standard


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**PARTICIPANT INFORMATION SHEET - STANDARD**

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**Title:** Determining the scope of clinical practice guidelines through stakeholder consultation.

You are invited to participate in an advisory group because you have experience with agitation in the intensive care unit (ICU) either as a patient or a family member. You may also be invited because you are an ICU clinician or a researcher with experience and knowledge of the management of agitated behaviours. This information sheet tells you about our research project and what it means to participate in the advisory group.

This research project is being conducted by:

**Chief Investigator**
Anne Mette Adams, College of Nursing and Health Sciences, Flinders University, South Australia
Email: mette.adams@flinders.edu.au

**Co-Investigators**
Dr Tiffany Conroy, College of Nursing and Health Sciences, Flinders University, South Australia.
Associate Professor Diane Chamberlain, Flinders University, South Australia
Professor Mette Grønkjær, Aalborg University and Aalborg University Hospital, Denmark
Postdoc. Charlotte Brun Thorup, Aalborg University Hospital, Denmark

**What is the overall purpose of our research project?**
The overall purpose of our research project is to develop practice guidelines for nurses on non-pharmacologicalstrategies to prevent, minimise and manage agitated behaviours in the adult ICU. Such guidelines can support nurses to make clinical decisions based on evidence and thus optimise patient care.
Agitation in ICU is common and manifests as confusion, aggression, restlessness, and irritability. Agitation must be prevented when possible and managed well since the behaviours are associated with several negative patient outcomes. Caring for this group of patients in ICU is both complex and challenging.
Medication is often necessary when treating underlying causes of agitated behaviours and is sometimes essential to keep patients safe. However, medication often has negative side effects. Therefore, nurses are encouraged to also consider strategies that do not involve medication, the so-called non-pharmacological strategies. The problem is that no guidelines describe non-pharmacological strategies and the effects of these. This research is being completed as part of a PhD.

**What is the purpose of the advisory group?**

An advisory group, consisting of a broad group of stakeholders, will support the research team to determine the appropriate scope of the practice guidelines. The scope describes what the guidelines will and will not cover, whom the guidelines are meant for and which actions or interventions will be the focus of the guidelines.

Advisory group members are invited to share their views on what is needed to prevent and manage agitation in the ICU, and what should be included in and excluded from the guidelines. We are interested in knowing what you believe is important for future ICU patients, their families and for clinicians providing care.

**Join us if you fulfil these requirements:**

- Adult = 18 years and up
- You have experience with agitated behaviours in the adult ICU. For example, you have experienced being agitated during an ICU admission, you visited a family member or a friend who was agitated, you have managed agitation as a clinician or you have expertise in agitated behaviours through research.
- You can read and understand either plain English or Danish.
- You have a computer available and internet connection.

We hope to recruit members from a wide range of backgrounds and encourage people with disabilities, people from ethnic minority groups and indigenous populations to participate.

**What does participation in the advisory group involve?**

- You are asked to set aside time (30-60 min) to review a 2-3 pages draft of the *guideline scope*. Reviewing means reading the scoping document carefully while considering your own experiences and knowledge. For more information see below: **What kind of advice do the guideline developers need?**
- You are prepared to share your opinions about the guidelines.
- You choose one (or more) of the following options to provide your feedback:
    - Attend a 3-hour online workshop (this will run in your language and with people who have similar experiences as you. For instance, previous patient and family members will meet with other previous patients and family members).
    - Attend a one-on-one online meeting with Anne Mette, the project lead.
    - Provide written feedback.

**All feedback must be provided before the 8th of April**

**What kind of advice do the guideline developers need?**

When you read through the *scoping document*, we want you to consider the following questions:

1. Are the main questions the guidelines are addressing appropriate and addressing key issues:
    a. What non-pharmacological prevention strategies reduce the incidence of agitation in ICU patients?
    b. What non-pharmacological strategies can be applied to minimise or manage agitated behaviours in the ICU?

2. If these guidelines were to be implemented in your local area, is there anything that we would need to consider?
3. Is the patient population, all agitated adult patients in ICU, an appropriate focus? Is it possible that different patient groups require different approaches?
4. Is the setting, the adult intensive care unit, appropriate? Or do you believe other settings such as the high acuity unit or the emergency department should be included as well? Explain your answer.
5. How will we know if non-pharmacological approaches have a positive effect on the patient – what will we see short- and long term?
6. What kind of strategies do you think nurses need to consider to prevent, minimise or manage agitated behaviours?

**What will happen to the information I provide?**
Your advice is important, and all of the advice will be summarised and reviewed. All information will be deidentified and you will not be linked with any specific comments. The information you provide is for advice only and will not be used in research products.

**What do I get from participating?**

- You will receive a $30 voucher
- This is your opportunity to contribute to improving the care provided to patients in ICU.
- We will keep you updated on the progress of the study.

Note that we are looking for a limited number of people for the advisory group. On our website you can see if you are still able able to participate. See https://www.agitationicu.com/advisory-group.

**Can I withdraw from the project?**
Yes, you can withdraw from the project at any time without any consequences. Participation is voluntary.You should be aware that the advice you provide up until you withdraw will form part of the project.

If you have any questions about the research project, please do not hesitate to contact Anne Mette Adamsat mette.adams@flinders.edu.au. You can also learn more about the project on our webpage: https://www.agitationicu.com/

Yours sincerely,

Anne Mette Adams

## Appendix 15 Acknowledgement of stakeholders

I want to express my deepest appreciation to the stakeholders who offered advice on the scope of the guidelines during study phase one of this thesis. Your support has been invaluable to the outcome of the final guidelines.

| Denmark | Australia |
|---|---|
| Hanne Aaris Mouritsen | Naomi Morick |
| Birte Nymark Hansen | Jessica Best |
| Lone Høilund Kristiansen | Kylie Jacobs |
| Eva Holmsø Christensen | Renjith Hari |
| Birgitte Høj | Jacob Moir |
| Trine Haberlandt | Kyrylova Olena |
| Mette Ursula Nielsen | Alissa Robb |
| Lone Sørensen | Angely Bolzon |
| Inge Schultz Jørgensen | Cherie Waite |
| Susanne Fischer | Libin Jose |
| Anne Marie Gellert Bunzel | Jade Martin |
| Signe Villadsen | Wendy Ross |
| Signe Kragelund | Kylie O'Neill |
| Ditte Marie Willerslev | Alison Brannelly |
| Mette From | David Sellers |
| Anniezette Bøgelund Schou Nielsen | Rose Kennedy |
| Camilla Bekker Mortensen | Jamie Sutcliffe |
| Marie Oxenbøll Collet | Stuart Cook |
| Lone Musaeus Poulsen | Sharon Ng. |
| Inge Madsen De Haas | Resmi Skariah |
| Birgit Krogh | Sally Bamblett |
| Jan Andersen | Rosalind Elliott |
| | Kay Bruce |
| | Simone Dafoe |
| | Shane Patman |
| | Jaimie Henry |
| | Benjamin Cheung |
| | Matthew Maiden |

Each individual stakeholder has agreed to have their name published in an acknowledgement of their contribution.

## Appendix 16 Conflict of Interest Declaration Form

The purpose of this form is to identify any potential conflicts of interest.

Declarations will be reviewed by the primary guideline investigator and her supervisors to ensure that there are no grounds to expect a conflict of interest.

Conflicts of interest may include relationships with pharmaceutical companies or other companies whose services are related to the current guideline. Financial interests that require declaration may include stock ownership, employment, consultancies or honoraria. Organisational interest that requires declaration may include relationships with organisations with financial links or affiliations with industry groups that stand to benefit from or be affected by potential guideline recommendations.

To read more about the management and identification of conflict of interest (COI), see: https://www.nhmrc.gov.au/guidelinesforguidelines/plan/identifying-and-managing-conflicts-interest

Your declaration will be kept on a Flinders University password-protected computer and only used for real or perceived conflict of interest as related to the work of the guideline advisory group member or Delphi panel member.

I declare the following interests, and I will update this form if new interests arise.

| Name: | Guideline: *evidence-based practice guidelines for nurse-led non-pharmacological prevention, minimisation and management of agitated behaviours in the adult intensive care unit* |
|---|---|
| **Interests to be declared**<br><br>Type of conflict (e.g. financial, membership, close relationship, employment): | |

| | |
|---|---|
| Who is the conflict with (name of person or organisation):<br><br>Details of conflict (enter details about the conflict of interest, including the nature and circumstances of the conflict and how it relates to the guideline development) | |
| Name | |
| Signature | Date |

# Appendix 17 Recruitment Methods Delphi study

## Recruitment Methods Phase three Delphi study

| Participants | Recruitment methods |
|---|---|
| Patients and patient representatives | • Advisory group members who have indicated an interest in being contacted again will be invited to express their interest on our webpage.<br>• Snowballing through advisory group members who know of other patients/family members with similar experiences<br>• In Denmark, recruitment happens when patients come into the hospital three months after discharge. Nurses will share a flyer.<br>• In Australia, a post-ICU group will post an advertisement in their newsletter. The principal investigator will also come to one of their meetings to discuss the study and share an advertisement with members.<br>• Recruitment will also occur via relevant Facebook pages, including "Koma Piloterne" and PIPS<br>• The following organisations will be contacted and asked to post an advertisement in their newsletter or in an email to their participants:<br>○ Australian Patients Association https://www.patients.org.au/<br>○ Health Consumer NSW<br>○ Health consumers ACT<br>○ Health Consumers Queensland (HCQ)<br>○ Consumer Health Forum of Australia<br>○ Health Rights and Community Action Inc<br>○ Health Issues Centre Inc (HIC)<br>○ SHOUT (Self-Help Organisations United Together)<br>○ National Stroke Foundation<br>○ Hjerneskadeforeningen Danmark<br>○ Rigshospitalet follow-up clinic<br>○ Århus Universitets Hospital Intensiv Cafe<br>○ Aalborg After Care Clinic<br>○ UlykkesPatientForeningen |
| ICU nurses | • Advisory group members who have indicated an interest in being contacted again will be invited to express their interest on our webpage.<br>• Snowballing through advisory group members who know of other clinicians, managers or researchers with experience in managing agitation.<br>• Advertisement through "Anæstesi-, Intensiv- og Opvågningssygeplejersker". An organisation with 2000 members (FSAIO, 2021),<br>• Nordic Association for Intensive Care Nursing Research (NOFI).<br>• Australian College of Critical Care Nurses, 2500 members (CONNMO, 2021) |
| Researchers | • Advisory group members who have indicated an interest in being contacted will be invited to express their interest on our webpage. |

| Participants | Recruitment methods |
|---|---|
| | • Advisory group members were also advised to suggest other researchers in the area.<br>• Authors of relevant peer-reviewed papers or guidelines were contacted. |
| ICU physicians | • Advisory group members who have indicated an interest in being contacted will be invited to express their interest on our webpage.<br>• Snowballing through advisory group members who know of other clinicians, managers or researchers with experience in managing agitation.<br>• College of intensive care medicine of Australia and New Zealand<br>• Australia New Zealand Intensive Care Society, 1000 fellows (ANZICS, 2021)<br>• Dansk Selskab for Anæstesiologi og Intensiv Medicin, 1200 members (DASAIM) |
| ICU manager or director | • Recruitment through professional organisations.<br>• Snowballing through advisory group members. |
| Physiotherapists | • Advisory group members who have indicated an interest in being contacted will be invited to express their interest on our webpage.<br>• Australian College of Physiotherapists<br>• Danske Fysioterapeuter og www.fysio.dk |
| Occupational therapists | • Advisory group members who have indicated an interest in being contacted will be invited to express their interest on our webpage.<br>• Occupational Therapy Australia (OTAUS)<br>• Danske ergoterapeuter |
| Psychologists, social workers and others from the multidisciplinary ICU team | • Through snowballing methods. |

# Appendix 18 Recruitment newsletter professionals

## Invitation to participate in a Delphi study

Do you have experience with managing patient agitation in an intensive care unit? If so, we need your support.

Clinicians seek guidance on effective non-pharmacological strategies to prevent and minimise patient agitation in the intensive care unit. This Danish-Australian study aims to develop a practice guideline for nonpharmacological management of agitation.

Based on advisory group input and systematic reviews, several tentative recommendations have been developed. Our study now needs support from a broad group of people with expertise in this area to determine the appropriateness of these recommendations.

**Essential criteria for participation.**

***ICU clinician participants*** (e.g., nurses, physicians, managers, physiotherapists, occupational therapists, social workers, and psychologists) require the following:

- recent experience managing patient agitation in the adult ICU; and either
- a minimum of three years experience working in an adult ICU; or
- a postgraduate qualification in intensive care; or
- holding a managerial position in an ICU.

Source:https://www.rawpixel.com/image/600233/free-image-rawpixel

***Researcher participants*** require the following:

- published on agitation or related topics, including sedation, delirium, physical restraints, or comfort, within the last six years.

If you choose to participate in this study, you will be asked to complete three surveys over five months. Each survey will take between 20-50 minutes to complete.

After completion, you will be offered a professional development certificate and, you will have the chance of winning one of six $50 vouchers.

If you want to learn more about the study or if you wish to participate, please register your interest on our webpage https://www.agitationicu.com/delphi-expert-panel.

Thank you for taking the time to consider this study!

Kind regards,

Anne Mette Adams
Associate Lecturer and PhD Candidate
College of Nursing and Health Sciences
Flinders University
mette.adams@flinders.edu.au


Version 4, 3rd December 2020

## Appendix 19 Recruitment flyer patients and family members

**Have you as a patient experienced being restless, irritable, confused and perhaps aggressive in the intensive care unit? Or did you visit a loved one who had these symptoms? Then we need your help!**

# INVITATION

## to participate in a research study

Patient agitation is common in the intensive care unit and is characterised by a noticeable rise of behaviours such as restlessness, irritability, confusion, and aggression. Management of agitation can be challenging and, unfortunately, is often linked with overuse of drugs, physical restraints, and poor patient experiences.

This study aims to identify essential non-drug strategies to reduce agitation. We are seeking advice from you, as a previous patient or family member/next of kin, on what you believe works and is impor

If this sounds like something for you, or for someone you know, pl register your interest on our website: https://agitationicu.com/del expert-panel

Thank you for taking the time to consider this study!

AALBORG UNIVERSITET

Flinders UNIVERSITY

### What is expected of you?

You will be asked to:

- Complete 3 online surveys over a period of 5 months.
- Every survey will take between 20-50 minutes to complete.

### Requirements

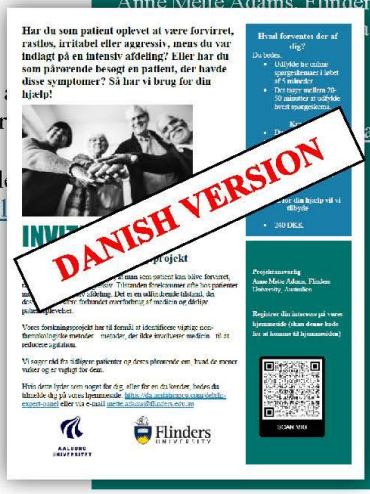
- 18 years or older
- You are a previous intensive care unit patient or family member/next of kin.
- You have experience with patient agitation from an adult intensive care unit.

### What will you get?

- A $50 online voucher

**Chief Investigator**

Anne Mette Adams, Flinders




Version 4, 3rd December 2021

# Appendix 20 Recruitment newsletter patients and family members

## Invitation to participate in a research study

Do you have experience with patient agitation in an intensive care unit, either as a previous patient or a family member/next of kin? If so, your advice is needed!

Patient agitation in the intensive care unit is very common. Agitation is characterised by a noticeable rise of behaviours such as restlessness, irritability, distress and aggression. Agitated patients are often confused and may try to get out of bed, pull on lines and tubes, and sometimes try to push or hit people around them.

Management of agitation can be challenging and, unfortunately, is often linked with an overuse of drugs, physical restraints and poor patient experiences. Therefore, we aim to develop a guideline on important non-drug strategies to manage agitation.

You are eligible to participate in this study if you are 18 years or older and have personal experience with agitation in the adult intensive care unit, either as a previous patient or a family member to a patient who was agitated.

If you agree to take part in this study, you will be asked to fill out three online surveys over five months. Each survey will take between 20-50 minutes to complete. In the surveys, you will be asked to rate the effectiveness and appropriateness of a range of strategies.

You will receive a $50 online voucher after the last surve

If you are interested in learning more about the project to our webpage by following this link: https://da.agitati the QR code.

Thank you for taking the time to consider this study.

Kind regards

Anne Mette Adams
Associate Lecturer and PhD Candidate
College of Nursing and Health Sciences
Flinders University
mette.adams@flindes.edu.au


Version 2, 3rd December 2021

# Appendix 21 Letter of Invitation Delphi Study

Anne Mette Adams
Flinders University

GPO Box 2100
Adelaide SA 5001

Telephone: +61 487772602
E-mail: mette.adams@flinders.edu.au

Delphi Panel Letter of Invitation

Date xxx

Dear xxx,

I am inviting you to participate in the research study titled "Non-pharmacological management of agitation in the adult intensive care unit – development of a clinical practice guideline".

The purpose of this Danish-Australian study is to develop an evidence-informed guideline on non-drug approaches to minimise agitated behaviours in the adult intensive care unit.

This study will take place between mid-January to mid-June 2022. As a participant, you will be required to complete three surveys. Each survey will take between 20 to 50 min to complete. Information required to complete each survey will be provided at its outset. You will be given a maximum of two weeks to complete the survey. The success of the Delphi study depends on timely responses provided by all panel members.

Privacy and confidentiality will be assured at all times. Your identification number is XXX, you will be asked to provide this number at the beginning of each survey.

It is important that you read and understand the attached Participant Information Sheet. You will be asked to provide your consent at the beginning of each survey. If you would like to participate in this study, please follow this link, which will take you to the survey (link inserted).

If you have any conflicts of interest to declare, we ask you to forward these in a separate e-mail to Anne Mette Adams. There is more information about this below.

If you would like more information, you can check our webpage www.agitationicu.com or contact Anne Mette N. Adams by e-mail at mette.adams@flinders.edu.au

We warmly invite you to be a part of the panel.

Yours sincerely,

Anne Mette Adams, Associate lecturer and PhD Candidate
College of Nursing and Health Sciences
Flinders University

ENGLISH VERSION

INSPIRING ACHIEVEMENT

Version 2, 30th November 2021

Flinders UNIVERSITY

## Conflicts of interest

Managing conflicts of interest is an important part of developing guidelines. This process identifies if those who are involved in developing guidelines have any financial or other interests that can potentially influence, or appear to influence, proper consideration on a specific topic. For example, you may have significant shares in a company that has developed a particular type of therapy that might be recommended in the guidelines. Conflicts of interest can damage peoples' confidence and trust in our work. As a Delphi panellist, we ask you to declare any conflicts of interest. If we find significant personal interests, we might ask you to withdraw from the group. Please write an e-mail to Anne Mette Adams (mette.adams@flinders.edu.au) if you have any conflicts of interest to declare.

# Appendix 22 Participant Information Sheet Patient and Family

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Government of South Australia | Health Central Adelaide Local Health Network

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**PARTICIPANT INFORMATION SHEET FOR PATIENTS AND FAMILY MEMBERS/NEXT OF KIN**

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**Title:** Non-pharmacological management of agitation in the adult intensive care unit – A Delphi study

**HREC Reference** 15710
**Project sponsor** Flinders University
**Location** Online, with both Danish and Australian participants

**Principal Investigator**
Anne Mette Adams, PhD Candidate, Flinders University.
College of Nursing and Health Sciences
Sturt Road, Bedford Park, South Australia, 5052
Telephone: +61 487772602
Email: mette.adams@flinders.edu.au

**Principal Supervisor**
Dr Tiffany Conroy, Flinders University,
College of Nursing and Health Sciences
Telephone: +61 8201 3246

**Associate supervisors**
Associate Professor Diane Chamberlain, Flinders University, South Australia
Professor Mette Grønkjær, Aalborg University, Denmark
Dr Charlotte Brun Thorup, Aalborg University Hospital, Denmark

ENGLISH VERSION

**1. Introduction**
You are invited to participate in this study because you have had personal experience with patient agitation in the intensive care unit, either as a previous patient or a family member/next of kin. Before you decide, it is important that you understand why this research is being done, and what it will involve. Please take your time to read through this document and ask questions if there is anything you would like more information about.

**2. Why is this study important?**
This study aims to develop a practice guideline on non-drug approaches to minimise patient agitation in the intensive care unit. Agitation is characterised by a noticeable rise of behaviours such as restlessness, irritability, distress, confusion, and aggression, and is very common in the intensive care unit. Agitation can be dangerous for the patient and distressing for both patients, family members and clinicians and ,therefore, must be managed well.

Medication is important when treating underlying causes of agitation and is sometimes essential to keep patients safe. However, medication often has side effects. Therefore, clinicians are encouraged to also consider strategies that do not involve medication, the so-called non-pharmacological strategies.
With advice from a Danish – Australian advisory group and by referring to the existing literature, several recommendations have been identified. We now need input from clinicians, managers, researchers and previous patients and family members to better understand how effective and acceptable these recommendations are.

**3. Who is undertaking the project?**
Anne Mette Adams is the recipient of an Australian Government Research Training Program Scholarship and is undertaking this study to obtain a Doctor of Philosophy (PhD) at Flinders University. Support is provided by a team of experienced researchers from both Flinders University, South Australia and Aalborg University, Denmark. This project is also supported by a research grant from the Australian College of Critical Care Nurses. Flinders University will own the results of this study.

**4. Do I have to take part in this study?**
This is a research project, and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced. You should be aware that data collected up to the time you withdraw will form part of the research project results. Your participation in this study shall not affect any other right to compensation you may have under common law.

**5. What is expected from you?**
The researchers do not expect the questions to cause any harm or discomfort to you.
If you agree to participate in the research study, you will be asked to:

- Complete three online surveys (known as rounds) over a period of 5 months. You will receive a link to the surveys in an email. Instructions will be provided for each survey. You will be asked to rate and comment on a list of recommendations to be included in the guideline. After each survey, the researcher will collate the information, remove recommendations that reach consensus from the survey and provide material for the next survey. Recommendations that have reached consensus after the third round will be included in the final guideline.
- Spend between 20-50 minutes on each survey round. The time needed to read through and comment on recommendations will vary. It is expected that the first round may require more time.
- Complete each survey within two weeks of receiving the request.

**6. Benefits of the study**
The sharing of your opinion of the recommendations may not benefit you directly. However, it is predicted that findings from this study will benefit adult patients in the intensive care unit, clinicians, educators, policymakers, and possibly family members of the patients.

**7. Expenses and payments**
After completing the third questionnaire you will receive a small reimbursement ($50 online voucher) for your time commitment and internet usage.

**8. Confidentiality and Privacy**
Only researchers listed on this form have access to the individual information provided by you. You will remain anonymous to the other participants throughout this Delphi study. Privacy and confidentiality will

be assured at all times. The research outcomes may be presented at conferences, written up for publication or used for other research purposes as described in this information form. You will not be named, and your individual information will not be identifiable in any research products without your explicit consent. No data, including identifiable, non-identifiable and de-identified datasets, will be shared or used in future research projects without your explicit consent.

**9. Data Storage**
The information collected will be stored securely on a password-protected computer and/or Flinders University server throughout the study. No data will be transferred overseas. All identifiable data will be de-identified for data storage purposes and securely stored at Flinders University for at least five years after publication of the results. Following the required data storage period, all data will be securely destroyed according to university protocols.

**10. Will I be able to find out the results of the project?**
A summary of the results will be provided to all participants via email. The study findings will also be presented at conferences and published in peer-reviewed journals.

**11. Queries and Concerns**
This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chair, on 7117 2229 or 8222 6841. The study has also received cross-institutional approval from Flinders University's Ethics committee.

**12. If I want to participate, what do I do?**
If you accept this invitation, you need to follow the link provided in your Letter of Invitation. This will take you to the first online survey. At the beginning of every survey, you will be asked to provide your consent to participate.

For further questions or information, you are welcome to contact me or my primary supervisor, Dr Tiffany Conroy. Our contact details are listed above.

Thank you for taking the time to consider this study.
Kind regards,

Anne Mette Adams

PhD Candidate
College of Nursing and Health Sciences
Flinders University

# Appendix 23 Participant Information Sheet Professionals

## PARTICIPANT INFORMATION SHEET FOR CLINICIANS, MANAGERS AND RESEARCHERS

**Title:** Non-pharmacological management of agitation in the adult intensive care unit – A Delphi study

**HREC Reference** 15710
**Project sponsor** Flinders University
**Location** Online with Danish and Australian participants

**Principal Investigator**
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**Associate supervisors**
Associate Professor Diane Chamberlain, Flinders University, South Australia
Professor Mette Grønkjær, Aalborg University, Denmark
Dr Charlotte Brun Thorup, Aalborg University Hospital, Denmark

ENGLISH VERSION

### 1. Introduction

You are invited to participate in this study because you have knowledge or experience with the management of patient agitation in the intensive care unit. Before you decide, it is important that you understand why this research is being done, and what it will involve. Please take your time to read through this document, and ask questions if there is anything you would like more information about.

### 2. Why is this study important?

The aim of this study is to develop a practice guideline on non-pharmacological approaches to prevent and minimise patient agitation in the adult intensive care unit. Agitation is characterised by a noticeable rise of behaviours such as restlessness, irritability, distress, confusion, and aggression, and is very common in the intensive care unit. Agitation can be dangerous for the patient and distressing for both patients, family members and clinicians and therefore must be managed well.

Medication is important when treating underlying causes of agitation and is sometimes essential to keep patients safe. However, medication often has side effects. Therefore, clinicians are encouraged to also consider strategies that do not involve medication, the so-called non-pharmacological strategies.
With advice from a Danish – Australian advisory group and by referring to the existing literature, several tentative recommendations have been identified. We now need input from clinicians, managers, researchers and previous patients and family members to better understand how effective and acceptable these recommendations are.

**3. Who is undertaking the project?**
Anne Mette Adams is the recipient of an Australian Government Research Training Program Scholarship and is undertaking this study to obtain a Doctor of Philosophy (PhD) at Flinders University. Support is provided by a team of experienced researchers from both Flinders University, South Australia and Aalborg University, Denmark. This project is also supported by a research grant from the Australian College of Critical Care Nurses. Flinders University will own the results of this study.

**4. Do I have to take part in this study?**
This is a research project and you do not have to be involved. If you do not wish to participate, your employment will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced. You should be aware that data collected up to the time you withdraw will form part of the research project results. Your participation in this study shall not affect any other right to compensation you may have under common law.

**5. What is expected from you?**
The researchers do not expect the questions to cause any harm or discomfort to you.
If you agree to participate in the research study, you will be asked to:

- Complete three online surveys (known as rounds) over a period of 5 months. You will receive a link to the surveys in an e-mail. Instructions will be provided for each survey. You will be asked to rate and comment on a list of recommendations to be included in the guideline. After each survey, the researcher will collate the information, remove recommendations that reach consensus from the survey and provide material for the next survey. Recommendations that have reached consensus after the third round will be included in the final guideline.
- Spend between 20-40 minutes on each survey round. The time needed to read through and comment on recommendations will vary. It is expected that the first round may require more time.
- Complete each survey within two weeks of receiving the request.

**6. Benefits of the study**
The sharing of your opinion of the recommendations may not benefit you directly. However, it is predicted that findings from this study will benefit adult patients in the intensive care unit, clinicians, educators, policymakers, and possibly family members of the patients.

**7. Expenses and payments**
Upon completion of this study, you will be offered a certificate of continuing professional development. There will also be a draw of six random participants who will receive a $50 gift voucher. Note that during this process participant confidentiality will be maintained.

**8. Confidentiality and Privacy**

Only researchers listed on this form have access to the individual information provided by you. You will remain anonymous to the other participants throughout this Delphi study. Privacy and confidentiality will be assured at all times. The research outcomes may be presented at conferences, written up for publication or used for other research purposes as described in this information form. You will not be named, and your individual information will not be identifiable in any research products without your explicit consent. No data, including identifiable, non-identifiable or de-identified datasets, will be shared or used in future research projects without your explicit consent.

**9. Data Storage**
The information collected will be stored securely on a password-protected computer and/or Flinders University server throughout the study. No data will be transferred overseas. All identifiable data will be de-identified for data storage purposes and securely stored at Flinders University for at least five years after publication of the results. Following the required data storage period, all data will be securely destroyed according to university protocols.

**10. Will I be able to find out the results of the project?**
A summary of the results will be provided to all participants via email. The study findings will also be presented at conferences and published in peer-reviewed journals.

**11. Queries and Concerns**
This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chairperson, on 7117 2229 or 8222 6841. The study has also received cross-institutional approval from Flinders University's Ethics committee.

**12. If I want to participate, what do I do?**
If you accept this invitation, you need to follow the link provided in your Letter of Invitation. This will take you to the first online Survey. At the beginning of every survey, you will be asked to provide your consent to participate.

For further questions or information, you are welcome to contact me or my primary supervisor, Dr Tiffany Conroy. Our contact details are listed above.

Thank you for taking the time to consider this study.

Kind regards,

Anne Mette Adams
PhD Candidate
College of Nursing and Health Sciences
Flinders University

# Appendix 24 First Delphi Survey



**Dear Delphi panel member**

The purpose of this study is to reach an agreement on patient-centred non-drug strategies to reduce or manage patient agitation in the intensive care unit.

The results of this study will inform practice guidelines for nurses, physicians, and other carers in the intensive care unit.

Over a period of five months, you will be asked to complete three surveys. Each survey will take 20 - 50 minutes to complete. This first survey is the most time-consuming. The questions have been developed through the advice received from an advisory group and systematic reviews of the existing literature.

In this survey, we ask you to focus on how useful recommendations or strategies are to reduce or manage agitation. In later rounds, we will ask you if you think it is possible and practical to apply the recommendations to the intensive care unit setting you are familiar with.

It is important that you have read and understood the Participant Information Sheet, which was in your Letter of Invitation. You can find a copy of the Participant Information Sheet below. You will soon be asked if you consent to participate in this study. If you click "YES" it is understood that you are giving your informed consent to participate.

**Before you start:** Note that your answers will be saved automatically. You can always return to the survey by following the link in your Letter of Invitation.
When you press "submit" by the end of the survey, you will not be able to go back and make changes.

**Thank you for taking the time to complete this survey!**

Participant Information Sheet Patients, Family, Next of Kin
Participant Information Sheet Clinicians, Managers and Researchers

To continue, click on the yellow arrow in the bottom right corner.

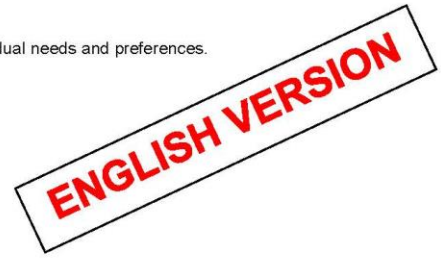
**Explanation of words**

**Agitation**: agitation is characterised by escalation of behavioural changes such as restlessness, repetitive movements and emotional distress. Agitated patients are often confused, resist care or interrupt care, can be aggressive and may have limited control of their actions.

**Non-drug strategies**: strategies that do not involve medication.

**Patient-centred strategies**: strategies based on a patient's individual needs and preferences.

Let's begin the survey.



Please enter your study ID located in your Letter of Invitation.

Do you consent to participate in this study?

- No I do not consent
- Yes I consent

Firstly, we would like to gather some information about you.

What country do you live in?

- Denmark
- Australia

What region of Denmark do you live in?

- Region Nordjylland
- Region Midtjylland
- Region Syddanmark
- Region Hovedstaden
- Region Sjælland

What state/territory do you live in?

- Australian Capital Territory
- New South Wales
- Northern Territory
- Queensland
- South Australia
- Tasmania
- Victoria
- Western Australia

What is your age?

What is your gender?

- Male
- Female
- Prefer not to answer
- Other (please specify) _____

How would you describe your status in relation to this study?

- Patient who has experienced being agitated in an intensive care unit.
- Family member/next of kin of a patient who was agitated in an intensive care unit.
- Physician
- Nurse
- Researcher
- Physiotherapist
- Occupational therapist
- Manager (for instance, nurse unit manager)
- Psychologist
- Psychiatrist
- Social worker
- Other – please specify _____

How many years have you worked with intensive care unit patients? (Include years regardless of full-time or part-time status. Include years in management, education or research positions related to intensive care).

- Less than 2 years
- 2-4 years
- 5-7 years
- 8-10 years
- 10-15 years
- 20+ years

What is your highest level of education?

- Bachelor
- Graduate Certificate
- Graduate Diploma
- Danish special uddannelse i intensivsygepleje
- Master
- Danish Kandidat
- PhD
- Fellowship
- Other, please specify _____

As a patient or a family member/next of kin when did your experience of agitation in the intensive care unit occur?

- Within the last three months
- 3-6 months ago
- 6-12 months ago
- 1-2 years ago
- 2-3 years ago.
- More than three years ago.

**NOTE** The questions below were asked in blocks of 3-4 questions. Each block had a heading and started with the following: Please rate the extent to which you agree or disagree with each of the following recommendations (choose the answer that suits you best). If you don't have experience with an intervention, please rate "I don't know".
Each block finished with the following: Feel free to explain your responses, add or reword recommendations. Please also describe if you believe any of the above-mentioned recommendations should not be included in a guideline, either because they are not patient-centred, effective, or perhaps harmful to the patient.

| | Strongly disagree | Somewhat disagree | Neutral | Somewhat agree | Strongly agree | Don't know |
|---|---|---|---|---|---|---|
| ICU patients should be regularly and systematically assessed for agitation. | | | | | | |
| Clinicians should identify and, when possible, treat causes of agitation. | | | | | | |
| Clinicians should support patients' fundamental care needs to reduce and manage agitation. *Fundamental care needs include physical, psychosocial and relational needs.* | | | | | | |
| The multi-disciplinary team should collaborate to reduce and manage patient agitation. | | | | | | |

| | Strongly disagree | Somewhat disagree | Neutral | Somewhat agree | Strongly agree | Don't know |
|---|---|---|---|---|---|---|
| Additional staffing should be considered when there is an agitated patient in the ICU | | | | | | |
| Ongoing staff education about agitation and methods to reduce agitation should be provided. | | | | | | |
| Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation. | | | | | | |
| It is a good idea to rotate staff who care for and treat agitated patients *(e.g., during a shift or between shifts).* | | | | | | |
| Staff caring for agitated patients should be offered debriefing. | | | | | | |
| The intensive care unit should be laid out in a way that makes observing agitated patients easier. | | | | | | |
| Clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients *(e.g., avoid unnecessary glucose monitoring, endotracheal suctioning, neurological checks).* | | | | | | |
| Intensive care units should have clear guidelines for the use of physical restraints. *Physical restraints mean any manually applied method that reduces a patient's ability to move freely.* | | | | | | |
| Non-drug approaches should be considered first when managing agitation | | | | | | |
| The safety of patients, staff and family/next of kin should be given high priority when managing agitation. | | | | | | |
| Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation. | | | | | | |
| Clinicians should offer family members information about agitation. | | | | | | |
| Clinicians should consider using several non-drug strategies for agitated patients simultaneously. | | | | | | |
| Clinicians should use physical restraints only as a last resort to ensure patient and staff safety. *Physical restraints mean any manually applied method that reduces a patient's ability to move freely.* | | | | | | |
| Physical restraints should never be used to enable staff to leave the patient. | | | | | | |

**Usefulness of strategies**
In the next section, we will ask how useful you believe strategies are. By usefulness, we mean the extent to which you believe strategies work and are helpful in reducing or managing agitation in patients admitted to an intensive care unit

Note that "useful" does not refer to how easy it is to use strategies or if it is possible to use the strategies considering the available resources. A later questionnaire will ask such questions

You can choose between six ratings
Not at all useful (does not work for any patients).
Not very useful (does not work for most patients).
Neutral (I have no opinion about this strategy).
Somewhat useful (works for some patients).
Very useful (works for most patients).
Don't know (I don't have experience with this strategy

**NOTE** The questions below were asked in blocks of 3-5 questions. Each block had a heading and started with the following: Please rate how useful you believe the following strategies are for either reducing or managing agitation in the intensive care unit. If you don't have experience with an intervention, please rate "I don't know". Each block finished with the following: Please also describe if you believe any of the above strategies should not be included in a guideline, either because they are not patient-centered or because they are harmful to the patient.

| | Not useful at all | Not very useful | Neutral | Somewhat useful | Very useful | I don't know |
|---|---|---|---|---|---|---|
| How useful is minimising interruptions at night? | | | | | | |
| How useful is taking the patient outdoors? | | | | | | |
| How useful is using an eye mask at night-time? | | | | | | |
| How useful is using earplugs at night-time? | | | | | | |
| How useful is offering quiet surroundings for the patient, for example a single-bed room? | | | | | | |
| How useful is it to group several care and treatment activities, rather than disturbing the patient several times? | | | | | | |
| How useful is respecting patients' need for personal space? | | | | | | |
| How useful is supporting capable patients to be physically active *(e.g. by supporting patients to sit on the edge of the bed or take small walks)*? | | | | | | |
| How useful is using a bed-bike? | | | | | | |
| How useful is a Rocking Chair? *A Rocking Chair is a specially designed electrically powered chair.* | | | | | | |
| How useful is informing the patient about the plan for the day? | | | | | | |
| How useful is using a personalised fixed daily schedule with familiar activities? | | | | | | |
| Irrespective of how much the patient appears to understand, how useful is explaining to them their circumstances? | | | | | | |
| How useful is appropriate lighting adjusted according to the time of the day? | | | | | | |
| How useful is it to have a clock and calendar visible to the patient? | | | | | | |

| | Not useful at all | Not very useful | Neutral | Somewhat useful | Very useful | I don't know |
|---|---|---|---|---|---|---|
| How useful is developing a relationship with the patient based on empathy, respect and trust? | | | | | | |
| How useful is knowing about the patient's background *(e.g. likes, dislikes, culture, history, values, fears and routines)*? | | | | | | |
| How useful is ensuring patient dignity? | | | | | | |
| How useful is allocation of the same staff to care for the patient? | | | | | | |
| How useful is using therapeutic touch? *Therapeutic touch means using hands to touch and calm a patient.* | | | | | | |
| How useful is holding a patient's hand? | | | | | | |
| How useful is reassuring the patient that they are safe? | | | | | | |
| How useful is creating familiar surroundings *(e.g. with pictures or other items from the patient's home)*? | | | | | | |
| How useful are clearly displayed names and/or photographs of mask-wearing carers? | | | | | | |
| How useful is involving patients in personal care activities? | | | | | | |
| How useful are care plans based on patient preferences and values? | | | | | | |
| How useful is debriefing the capable patient after an episode of agitation? | | | | | | |
| How useful is explaining to the patient what are and what are not acceptable behaviours? | | | | | | |
| How useful is using clear and concise language? | | | | | | |
| How useful is using "active listening"? *Active listening means listening carefully and demonstrating an interest in what a person has to say.* | | | | | | |
| How useful are hearing aids in the hearing impaired patient? | | | | | | |
| How useful are visual aids in the vision impaired patient? | | | | | | |
| How useful are alternative communication methods? *Alternative communication methods may include pen and paper, boards with icons and pictures, alphabet boards, computer communication systems.* | | | | | | |
| How useful is massage? *Massage is an intervention that includes tactile stimulation such as pressing, rubbing and manipulating soft tissue.* | | | | | | |
| How useful are comfortable surroundings *(i.e. by optimising room temperature, ventilation and/or design)*? | | | | | | |
| How useful is mental stimulation *(i.e. patient engagement with Lego, jigsaw, radio, TV, internet, magazines, pictures)*? | | | | | | |
| How useful is using a fiddle toy? *A fiddle toy is an object designed to be touched, squeezed or pulled to keep restless hands occupied.* | | | | | | |
| How useful is using a therapeutic weighted blanket? | | | | | | |

| | Not useful at all | Not very useful | Neutral | Somewhat useful | Very useful | I don't know |
|---|---|---|---|---|---|---|
| How useful are nature-based sounds? | | | | | | |
| How useful are Felicia Affolter methods? *Felicia Affolter methods involve guided interaction therapy.* | | | | | | |
| How useful is classical or relaxing music, preferably adjusted to patient preferences? | | | | | | |
| How useful is Guided Imagery? *Guided Imagery involves focusing on pleasant mental images to replace stressful feelings.* | | | | | | |
| How useful is aromatherapy? *Aromatherapy involves the use of essential oils extracted from plants. These oils are usually absorbed through the skin or heated and vaporised into the air.* | | | | | | |
| How useful is reflexology? *Reflexology involves the application of pressure to the reflex zones on the feet or hands, intended to promote wellness in the corresponding body structures.* | | | | | | |
| How useful is acupuncture? *Acupuncture involves inserting thin needles into the skin.* | | | | | | |
| How useful is involving a psychologist or psychiatrist in the treatment plan? | | | | | | |
| How useful is pet therapy? *Pet therapy involves an animal, often a dog or cat, visiting the patient in the intensive care unit.* | | | | | | |
| How useful is involving family members/next of kin in care? | | | | | | |
| How useful is teaching family members/next of kin to use non-drug strategies? | | | | | | |
| How useful is using telephone and/or video conferencing when family members/next of kin are unable to visit the patient in person? | | | | | | |

**The last two questions**

- From your experience, are there other strategies that are useful for reducing or managing agitation in the intensive care unit? If yes, please describe these below.

- From your experience, are there strategies that should be avoided because they are not useful, not patient-centered or harmful? If yes, please describe these below.

**Thank you for participating in this first Delphi survey. Your input is greatly appreciated, and we hope you will support us again in the second Delphi round.**

We expect the second round to commence in March 2022.

With kind regards from the research team Anne Mette Adams, Tiffany Conroy, Diane Chamberlain, Charlotte Brun Thorup and Mette Grønkjær

# Appendix 25 Second Delphi Survey



**Dear Delphi panel member**

Thank you so much for continuing to participate in this Delphi study. Your contribution will help shape a practice guideline on patient-centered non-pharmacological prevention, minimisation and management of patient agitation in the adult intensive care unit.

This second Delphi survey will take between 15-30 minutes to complete. The first part of the survey consists of items where an agreement was not reached between participants from the two countries, Denmark and Australia. In addition, there will be new items based on the suggestions from participants. In the second part of this survey, we ask clinicians and researchers about the potential barriers and facilitators to guideline implementation.

**Before you start:** Note that your answers will be saved automatically. You can always return to the survey by following the link in your email for the second Delphi survey. However, once you press SUBMIT at the end of the survey, you will NOT be able to go back and make changes.

**Thank you for taking the time to complete this survey!**

**Explanation of words**

**Agitation**: agitation is characterised by escalation of behavioural changes such as restlessness, repetitive movements and emotional distress. Agitated patients are often confused, resist care or interrupt care, can be aggressive and may have limited control of their actions.

**Non-drug strategies**: strategies that do not involve medication.

**Patient-centered strategies**: strategies based on a patient's individual needs and preferences.

**Reducing agitation**: a preventative strategy to reduce the occurrence, frequency, and severity of future episodes of agitation.

**Managing agitation**: a reactive strategy to stop or neutralise agitation when it occurs.

Let's begin the survey.

Please enter your study ID located in your "second Delphi Round Survey" email.

_____

Do you consent to participate in this study?

- No, I do not consent
- Yes, I consent

What country do you live in?

- Denmark
- Australia

How would you describe your status in relation to this study?

- Patient who has experienced being agitated in an intensive care unit. (1)
- Family member/next of kin of a patient who was agitated in an intensive care unit. (2)
- Physician
- Nurse
- Researcher
- Physiotherapist
- Occupational therapist
- Manager (for instance, nurse unit manager)
- ICU chaplain

**NOTE** The questions below were asked in blocks of 2-3 questions. Each block had a heading and started with the following: Please rate the extent to which you agree or disagree with each of the following recommendations (choose the answer that suits you best). If you don't have experience with an intervention, please rate "I don't know".
Each block finished with the following: Feel free to explain your responses

| | Strongly Disagree | Somewhat Disagree | Neutral | Somewhat Agree | Strongly Agree | Don't Know |
|---|---|---|---|---|---|---|
| The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care. | | | | | | |
| Physical restraints should not be used as a substitute for direct observation. *A physical restraint is any manually applied method that reduces a patient's ability to move freely*. | | | | | | |
| Clinical staff should check that aggressive and violent agitated patients do not have access to objects that can be used to injure others (e.g. sharp objects, weapons, hard objects that can be thrown) | | | | | | |
| Non-drug strategies for the prevention of agitation should be an integrated part of standard care. | | | | | | |
| Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift. | | | | | | |
| Clinicians should be trained to use de-escalation techniques. *De-escalation involves verbal and non-verbal techniques to calm down a patient*. | | | | | | |
| Non-drug interventions must be adjusted to the individual patient (e.g. patient needs, history and preferences, level of agitation, previous experiences with interventions). | | | | | | |
| Clinicians caring for and treating agitated patients should always have access to immediate practical support. | | | | | | |

**Usefulness of strategies**

The following section will ask how useful you believe strategies to be. By usefulness, we mean the extent to which you think the strategies work and are helpful in reducing or managing agitation in patients admitted to an intensive care unit.

Note that "useful" does not refer to how easy it is to use strategies or if it is possible to use the strategies within the context of your currently available resources. In the last part of this survey, clinicians and researchers will get an opportunity to describe the factors that may hinder or promote guideline implementation.

In the questions below, you can choose between six answers:
Not useful at all (does not work for any patients).
Not very useful (does not work for most patients).
Neutral (I have no opinion about this strategy).
Somewhat useful (works for some patients).
Very useful (works for most patients).
I don't know (I don't have experience with this strategy).

**NOTE** The questions below were asked in blocks of 2-3 questions. Each block had a heading and started with the following: Please rate how useful you believe the following strategies are for either reducing or managing agitation in the intensive care unit. If you don't have experience with an intervention, please rate "I don't know". Each block finished with the following: Feel free to explain your responses

| | Not useful at all | Not very useful | Neutral | Somewhat useful | Very useful | I don't know |
|---|---|---|---|---|---|---|
| How useful is it to preserve patients' usual sleep-wake cycle? | | | | | | |
| How useful is it to minimise unnecessary stimuli? *Stimuli can be auditory (e.g. sounds), visual (e.g. lights, moving objects), tactile (e.g. lines, equipment), social (e.g. interacting people) etc.* | | | | | | |
| How useful is a rocking chair? *A rocking chair is a specially designed electrically driven chair.* | | | | | | |
| How useful is using a bed-bike? | | | | | | |
| How useful is the BBAUM approach? *BBAUM involves calming interventions for challenging behaviours.* | | | | | | |
| How useful are the principles of "Gentle Violence Prevention" described by Leah Tranhold? | | | | | | |
| How useful is it for clinicians to use name tags and/or photographs of themselves when wearing facemasks? | | | | | | |
| How useful is neuropaedagogy? *Neuropaedagogy builds on knowledge of how the brain works and focuses on patient strengths rather than weaknesses.* | | | | | | |
| How useful is it to offer patients access to a Spiritual Support/Pastoral Care person? | | | | | | |
| How useful is providing Trauma-Informed Care (TIC)? *TIC is an approach to caring for individuals with a history of trauma.* | | | | | | |
| How useful are relaxing breathing exercises? | | | | | | |

| |
|---|
| How useful is Basal Stimulation? *Basal Stimulation is a holistic approach involving touch, positioning, body awareness and communication.* |
| How useful is mental stimulation? *Mental stimulation can involve activating the patient with Lego, jigsaws, radio, TV, internet, magazines, pictures etc.* |
| How useful is using a therapeutic weighted blanket? |
| How useful is it to use a patient diary? *A diary is written for patients during their ICU stay by nurses, families and others.* |
| How useful is it to sing or hum for or with a patient? |

If you are a previous patient or a family member/next of kin, this is the end of the survey. When you press 'next' your survey will be submitted, and you will not be able to make any changes. If you are a clinician or a researcher, you will be taken to the second part, focusing on barriers and facilitators to guideline implementation.

**Factors that can hinder or facilitate guideline implementation**

Guidelines are only valuable when they are implemented into practice. Therefore, we want to understand the factors you believe may hinder or facilitate the implementation of this clinical practice guideline on non-drug approaches to reduce and manage agitation in the ICU.

**Barriers to guideline implementation.**

Below are factors our advisory group members believe may hinder guideline implementation. Please rate the extent to which you believe these factors could be barriers to guideline implementation in the ICU (s) you know.

| | Definitely a barrier | Somewhat a barrier | Neutral | Somewhat not a barrier | Not a barrier at all | Don't know |
|---|---|---|---|---|---|---|
| Lack of trust in the clinical practice guidelines | | | | | | |
| Lack of confidence in non-drug interventions. | | | | | | |
| The belief that non-drug interventions are resource intensive. | | | | | | |
| The challenges of changing existing habits and behaviours among staff | | | | | | |
| Lack of time to use non-pharmacological interventions (high workload, insufficient staffing). | | | | | | |
| Inadequate equipment and facilities | | | | | | |

Feel free to explain your responses and add any additional facilitators you can think of.

**Facilitators to guideline implementation**

Below are factors our advisory group members believe may help guideline implementation. Please rate the extent to which you believe these factors can facilitate guideline implementation in the ICU (s) you know.

| | Not helpful at all | Somewhat unhelpful | Neutral | Somewhat helpful | Very helpful | Don't know |
|---|---|---|---|---|---|---|
| A user-friendly design of the clinical practice guideline | | | | | | |
| A clear plan for implementation and follow-up. | | | | | | |
| A clear outline of the strength of the evidence for each recommendation. | | | | | | |
| An involved and supportive leadership team. | | | | | | |
| Collaboration between members of the multi-disciplinary ICU team | | | | | | |
| A dedicated group of motivated clinicians to support implementation of and adherence to the guideline | | | | | | |

Feel free to explain your responses and add any additional barriers you can think of.

**Thank you for participating in this second Delphi survey!**

Your input is greatly appreciated, and we hope you will support us again in the third and last Delphi round.

We expect the next round to commence in May 2022.

With kind regards from the research team Anne Mette Adams, Tiffany Conroy, Diane Chamberlain, Charlotte Brun Thorup and Mette Grønkjær

# Appendix 26 Last Delphi Survey



**Dear Delphi panel member**

Thank you for your ongoing participation in our Delphi study. Your contribution will help shape a practice guideline on patient-centered non-pharmacological interventions to prevent, minimise and manage patient agitation in the adult intensive care unit.

This Delphi survey is long, but you have seen the recommendations before, and it is the same recommendations that we ask you to rate for importance, usefulness and feasibility. The survey should not take more than 20-30 minutes to complete.

The first part of the survey asks you to rate recommendations for their importance. The second part asks you to re-rate three strategies for their usefulness. We ask you to rate these again, since the Danish and Australian participants did not agree about these in the second Delphi round. Finally, we ask clinicians and researchers if they believe recommendations are feasible.

**Before you start**: Note that your answers will be saved automatically. You can always return to the survey by following the link in your email for the second Delphi survey. However, once you press SUBMIT at the end of the survey, you will NOT be able to go back and make changes.

Thank you for taking the time to complete this survey!

**Explanation of words**

**Agitation**: agitation is characterised by escalation of behavioural changes such as restlessness, irritability, distress and aggression. Agitated patients are often confused and may have limited control of their actions.

**Non-drug strategies**: strategies that do not involve medication.

**Patient-centered strategies**: strategies based on a patient's individual needs and preferences.

**Reducing agitation**: a preventative strategy to reduce the occurrence, frequency, and severity of future episodes of agitation.

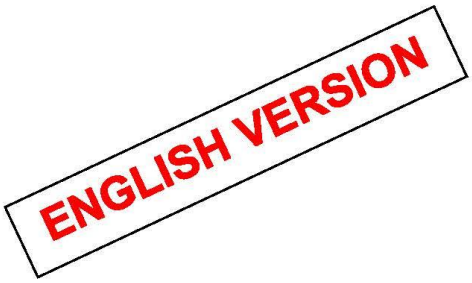
**Managing agitation**: a reactive strategy to stop or neutralise agitation when it occurs.

**Importance:** refers to the extent to which you think a recommendation is of value to reduce or manage agitation in patients admitted to an intensive care unit.

**Usefulness:** refers to the extent to which you think the strategies work and are helpful in reducing or managing agitation in patients admitted to an intensive care unit.

**Feasibility:** refers to the extent to which you think a recommendation is practical or possible, including cost effective, in the ICU (s) you are familiar with

Let's begin the survey.



Please enter your study ID

Do you consent to participate in this study?

- No, I do not consent
- Yes, I consent

What country do you live in?

- Denmark
- Australia

How would you describe your status in relation to this study?

- Patient who has experienced being agitated in an intensive care unit.
- Family member/next of kin of a patient who was agitated in an intensive care unit.
- Physician
- Nurse
- Researcher
- Physiotherapist
- Occupational therapist
- Manager (for instance, nurse unit manager)
- ICU chaplain

## Importance of recommendations

To provide an example, this section shows the first question block related to importance.

The following section will ask how **important** you believe recommendations are
Importance refers to the extent to which you think a recommendation is of value to reduce or manage agitation in patients admitted to an intensive care unit. If you don't have experience with a recommendation, please rate "I don't know.

| | Not important at all | Not very important | Neutral | Somewhat important | Very important | Don't know |
|---|---|---|---|---|---|---|
| ICU patients should be regularly and systematically assessed for agitation | | | | | | |
| Clinicians should identify and, when possible, treat causes of agitation. | | | | | | |
| Clinicians should support patients' fundamental care needs to reduce and manage agitation. | | | | | | |
| The multi-disciplinary team should collaborate to reduce and manage patient agitation. | | | | | | |
| Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation. | | | | | | |
| Additional staffing should be considered when there is an agitated patient in the ICU | | | | | | |
| Staff caring for agitated patients should be offered debriefing. | | | | | | |
| Ongoing staff education about agitation and methods to reduce agitation should be provided | | | | | | |

Feel free to explain your responses - especially if something was "not important at all" or "very important".

## Usefulness of strategies

The following section will ask how **useful** you believe strategies are.
Please rate how useful you believe the following strategies are. With usefulness, we mean the extent to which you think the strategies work and are helpful in reducing or managing agitation in patients admitted to an ICU. If you don't have experience with an intervention, please rate "I don't know".

| | Not useful at all | Not very useful | Neutral | Somewhat useful | Very useful | I don't know |
|---|---|---|---|---|---|---|
| How useful is to offer patients access to a Spiritual Support/Pastoral Care person? | | | | | | |
| How useful is providing Trauma-Informed Care (TIC)? TIC is an approach to caring for individuals with a history of trauma. | | | | | | |
| How useful is it to use a patient diary? A diary is written for patients during their ICU stay by nurses, families and others. | | | | | | |

Feel free to explain your responses - especially if something was "not useful at all" or "very useful".

## Feasibility of recommendations

To provide an example, this section shows the first question block related to feasibility.

We have now asked you how useful and important you believe recommendations are. Please continue answering the following questions, so that we can also understand if these recommendations are feasible in the ICU.
Feasibility refers to the extent to which you think a recommendation is practical or possible, including cost effective, in the ICU (s) you are familiar with.
Please rate how **feasible** you believe the following recommendations are. If you don't have experience with a recommendation, please rate "Don't know".

| | Not feasible at all | Not very feasible | Neutral | Somewhat feasible | Very feasible | Don't know |
|---|---|---|---|---|---|---|
| ICU patients should be regularly and systematically assessed for agitation. | | | | | | |
| Clinicians should identify and, when possible, treat causes of agitation. | | | | | | |
| Non-drug approaches should be considered first when managing agitation | | | | | | |
| Non-drug approaches for the prevention of agitation should be an integrated part of standard care. | | | | | | |
| Clinicians should support patients' fundamental care needs to reduce and manage agitation. | | | | | | |
| The multi-disciplinary team should collaborate to reduce and manage patient agitation. | | | | | | |
| Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation | | | | | | |

| |
|---|
| Additional staffing should be considered when there is an agitated patient in the ICU |
| Staff caring for agitated patients should be offered debriefing. |
| Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift. |

Feel free to explain your responses - especially if something was "not feasible at all" or "very feasible".

You have now come to the end of the survey. Don't forget to click the "submit" button below.

**Thank you for helping us!**

A summary of the results will be provided to all participants via email.

Patients and family members who have completed all three surveys will soon receive an online voucher. Clinicians and researchers will be offered a certificate of continuing professional development. There will also be a draw of six random participants who will receive a $50 voucher. Note that during this process, participant confidentiality will be maintained.

Thanks again for your support.

With kind regards from the research team Anne Mette Adams, Tiffany Conroy, Diane Chamberlain, Charlotte Brun Thorup and Mette Grønkjær

# Appendix 27 Feedback brief version after first Delphi round

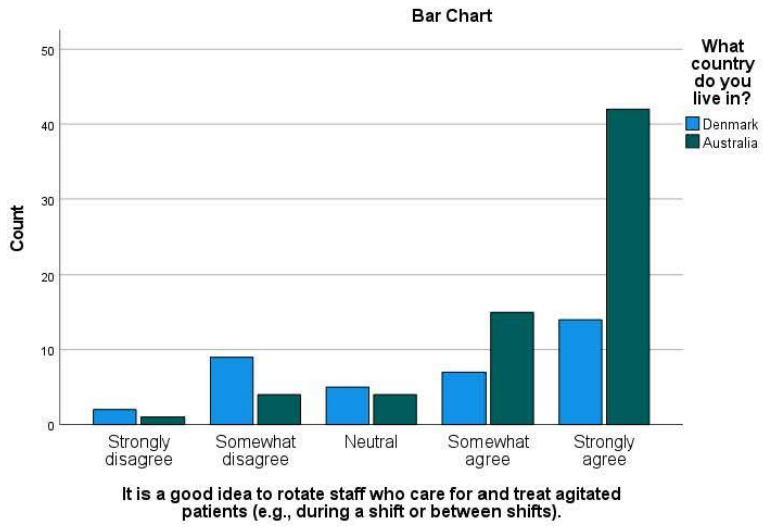
**Delphi feedback, short version, 22/2/22. Unpublished material, not to be shared.**

## Items to be re-rated in the second Delphi survey

Nine items reached agreements in only one country – these will be re-rated in the second Delphi survey (three of the items have been modified based on participant feedback).

**Recommendations**

| Item | | Denmark | | Australia | | Modified to |
|---|---|---|---|---|---|---|
| | | Sample size total | Agree or Strongly agree | Sample size total | Agree or Strongly agree | |
| **7.02** | It is a good idea to rotate staff who care for and treat agitated patients (e.g., during a shift or between shifts). | 37 | 56.8% | 66 | 86.4 | **Item 15.10** The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care |

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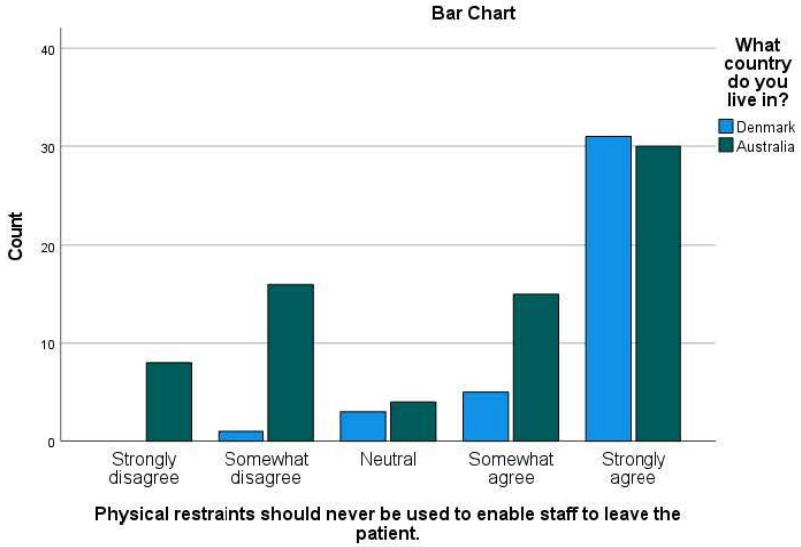
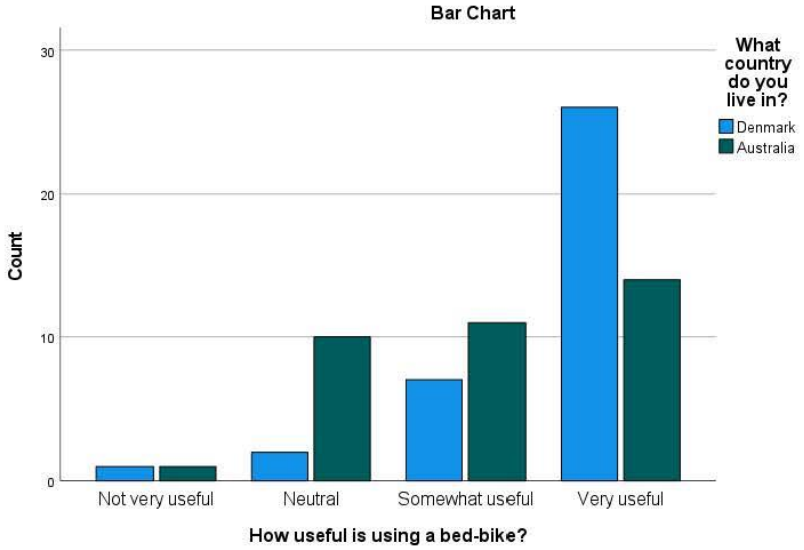
| Item | | Denmark | | Australia | | Modified to |
|---|---|---|---|---|---|---|
| | | Sample size total | Agree or Strongly agree | Sample size total | Agree or Strongly agree | |
| **10.03** | Physical restraints should never be used to enable staff to leave the patient. | 40 | 90% | 73 | 61.6 | **Item 10.04** Physical restraints should not be used as a substitute for direct observation |

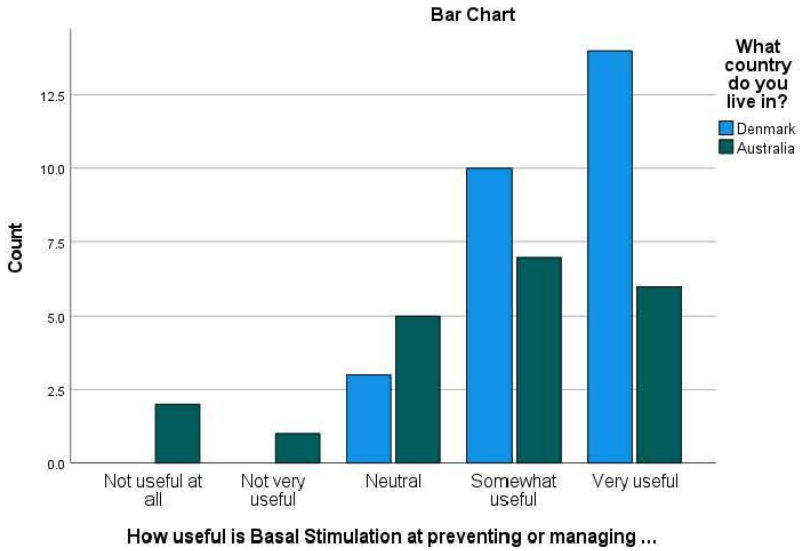


## Usefulness of interventions

| Item | | Denmark | | Australia | |
|---|---|---|---|---|---|
| | | Sample size total | Somewhat useful or very useful | Sample size total | Somewhat useful or very useful |
| **13.02** | How useful is using a bed-bike? | 36 | 91.7% | 36 | 69.4% |



| Item | | Denmark | | Australia | |
|---|---|---|---|---|---|
| | | Sample size total | Somewhat useful or Very useful | Sample size total | Somewhat or Very useful |
| **18.16** | How useful is Basal Stimulation at preventing or managing agitation? | 27 | 88.9 | 21 | 61.9 |

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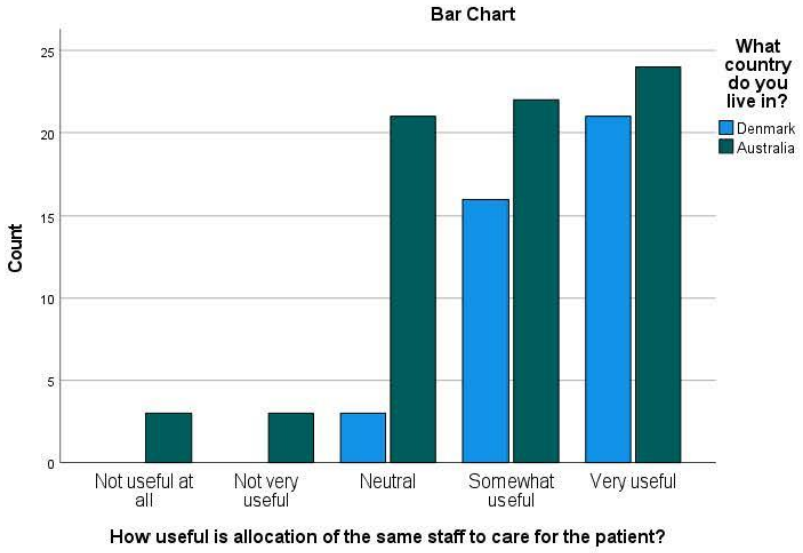
| Item | | Denmark | | Australia | | Modified to |
|---|---|---|---|---|---|---|
| | | Sample size total | Somewhat or Very useful | T Sample size total | Somewhat or Very useful | |
| **15.04** | How useful is allocation of the same staff to care for the patient? | 40 | 92.5% | 73 | 63% | **Item 15.10** The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care |

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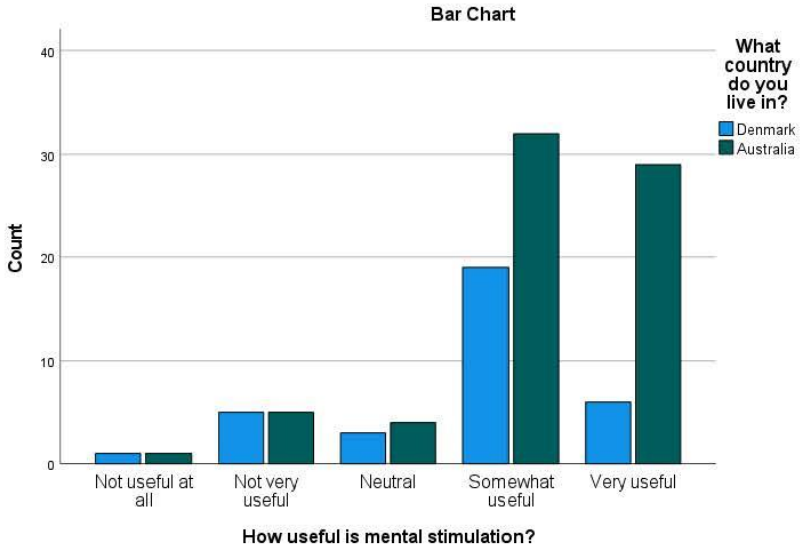
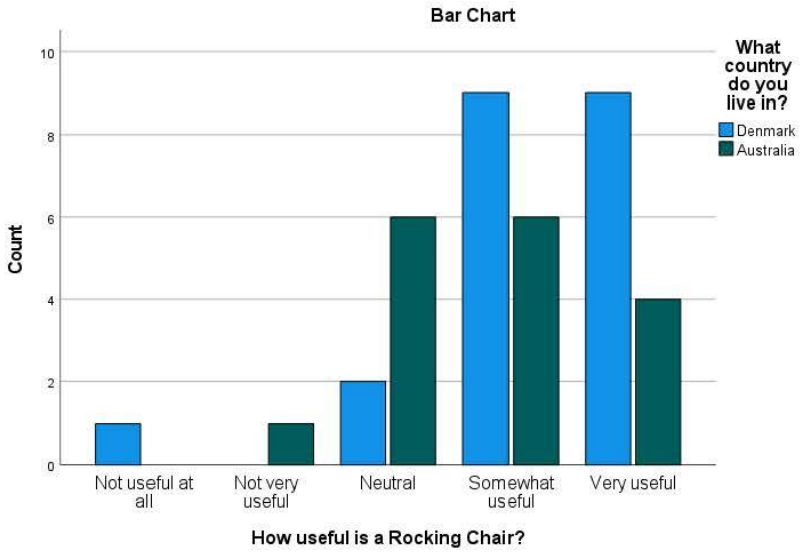
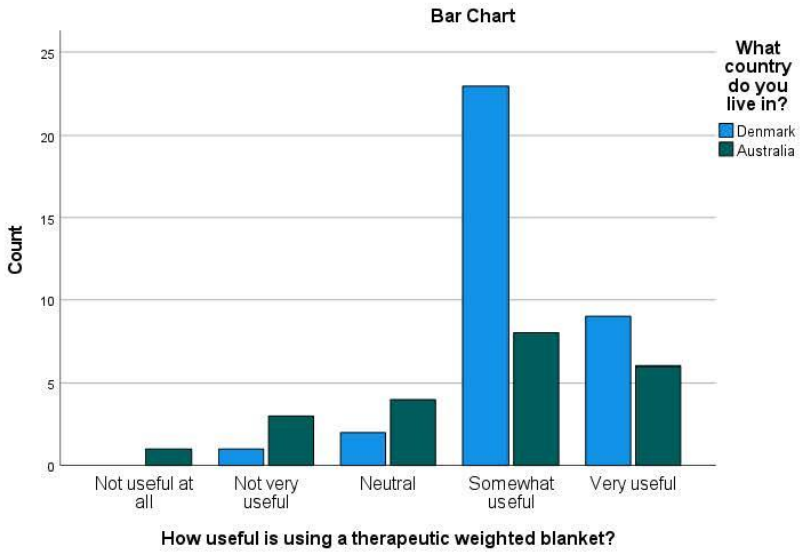
| Item | | Denmark | | Australia | |
|---|---|---|---|---|---|
| | | Sample size total | Somewhat useful or very useful | Sample size total | Somewhat useful or very useful |
| **18.03** | How useful is mental stimulation? | 34 | 73.5% | 71 | 85.9% |



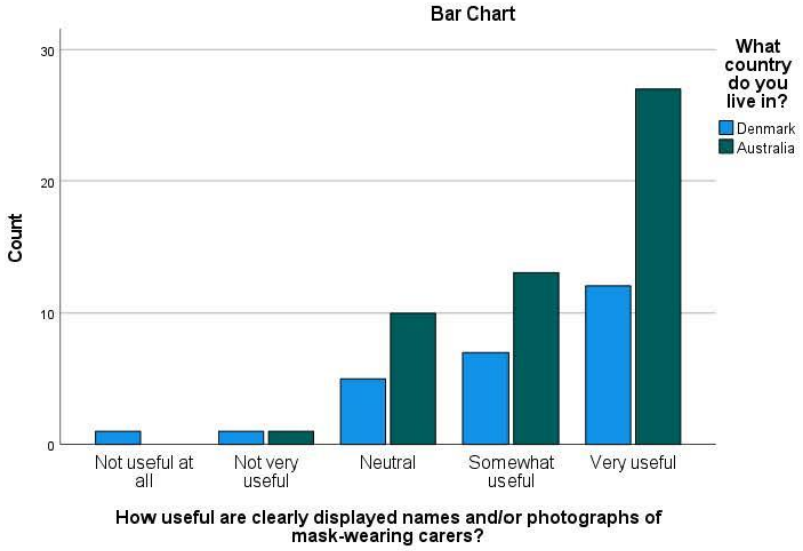
| Item | | Denmark | | Australia | |
|---|---|---|---|---|---|
| | | Sample size total | Somewhat useful or very useful | Sample size total | Somewhat useful or very useful |
| **13.03** | How useful is a Rocking Chair? | 21 | 85.7% | 17 | 58.8% |



| Item | | Denmark | | Australia | |
|---|---|---|---|---|---|
| | | Sample size total | Somewhat useful or very useful | Sample size total | Somewhat useful or very useful |
| **18.05** | How useful is using a therapeutic weighted blanket? | 35 | 91.4% | 22 | 63.6% |



| Item | | Denmark | | Australia | |
|---|---|---|---|---|---|
| | | Sample size total | Somewhat useful or very useful | Sample size total | Somewhat useful or very useful |
| **15.09** | How useful are clearly displayed names and/or photographs of mask-wearing carers? | 26 | 73.1% | 51 | 78.4% |



# Appendix 28 Feedback comprehensive version after first Delphi round

**First Delphi round Feedback, comprehensive version, 22/03/22. Unpublished material - not to be shared.**

## Results from the first Delphi survey

**Characteristics of the expert panel**

| | Denmark | Australia | Total |
|---|---|---|---|
| **Invited** | 45 | 81 | 126 |
| Completed first Delphi round | 40 | 74 | 114 |
| Response rate | 89% | 91% | 90% |
| Stakeholder group | | | |
| Previous patient | 1 | 2 | 3 |
| Previous family/next of kin | 2 | 6 | 8 |
| Physician | 6 | 4 | 10 |
| Nurse | 21 | 51 | 72 |
| Researcher | 4 | 2 | 6 |
| Physiotherapist | 5 | 3 | 8 |
| Occupational therapist | 1 | 3 | 4 |
| Manager | 0 | 2 | 2 |
| ICU chaplain | 0 | 1 | 1 |

## Items excluded from the guideline

Ten items (plus three modified items – see below) did not reach consensus and are now excluded from the guideline.

| Item | | Total[a] | Count[b] | Agreement %[c] | M | SD | Median | IQR |
|---|---|---|---|---|---|---|---|---|
| **12.04** | How useful is using earplugs at night time? | 83 | 54 | 65.1% | 3.8 | 0.93 | 4 | 0 |
| **18.01** | How useful is massage? | 79 | 50 | 63.3% | 3.67 | 0.96 | 4 | 1 |
| **18.09** | How useful is Guided Imagery? | 48 | 34 | 70.8% | 3.65 | 1.20 | 4 | 1 |
| **18.07** | How useful are Felicia Affolter methods? | 24 | 12 | 50.0% | 3.58 | 1.1 | 3.5 | 1.75 |
| **18.06** | How useful are nature-based sounds? | 79 | 46 | 58.2% | 3.53 | 0.95 | 4 | 0 |
| **17.01** | How useful is explaining to the patient what are and what are not acceptable behaviours? | 112 | 68 | 60.7% | 3.52 | 1.12 | 4 | 2 |
| **12.03** | How useful is using an eye mask at night-time? | 59 | 28 | 47.5% | 3.41 | 1.00 | 3 | 1 |
| **18.10** | How useful is aromatherapy? | 42 | 21 | 50.0% | 3.33 | 1.2 | 3.5 | 1.25 |
| **18.12** | How useful is reflexology? | 35 | 14 | 40.0% | 2.94 | 1.33 | 3 | 2 |
| **18.13** | How useful is acupuncture? | 25 | 4 | 16.0% | 2.56 | 1.19 | 3 | 1.5 |

a Total people rating the item
b Total rating somewhat or very useful
c Percentage rating somewhat or very useful
M: mean, SD: standard deviation, IQR: interquartile range

# Items to be re-rated in the second Delphi survey

Nine items reached agreements in only one country. Six will be re-rated. Three were modified into two new items. In total, eight items continue to the next round.

### Recommendations

| Item | | Denmark | | Australia | | Modifed to |
|---|---|---|---|---|---|---|
| | | Sample size total | Agree or strongly agree | Sample size total | Agree or strongly agree | |
| **7.02** | It is a good idea to rotate staff who care for and treat agitated patients (e.g., during a shift or between shifts). | 37 | 56.8% | 66 | 86.4% | **Item 15.10** The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care |
| **10.03** | Physical restraints should never be used to enable staff to leave the patient. | 40 | 90% | 73 | 61.6% | **Item 10.04** Physical restraints should not be used as a substitute for direct observation |

### Usefulness of interventions

| Item | | Denmark | | Australia | | Modified to |
|---|---|---|---|---|---|---|
| | | Sample size total | Somewhat useful or very useful | Sample size total | Somewhat useful or very useful | |
| **13.02** | How useful is using a bed-bike? | 36 | 91.7% | 36 | 69.4% | |
| **18.16** | How useful is Basal Stimulation at preventing or managing agitation? | 27 | 88.9% | 21 | 61.9% | |
| **15.04** | How useful is allocation of the same staff to care for the patient? | 40 | 92.5% | 73 | 63% | **Item 15.10** The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care |
| **18.03** | How useful is mental stimulation? | 34 | 73.5% | 71 | 85.9% | |

| | | | | | |
|---|---|---|---|---|---|
| **13.03** | How useful is a Rocking Chair? | 21 | 85.7% | 17 | 58.8% |
| **18.05** | How useful is using a therapeutic weighted blanket? | 35 | 91.4% | 22 | 63.6% |
| **15.09** | How useful is it for clinicians to use name tags and/or photographs of themselves when wearing facemasks? | 26 | 73.1% | 51 | 78.4% |

## New items

Sixteen new items (plus two new from modified items – see above) have been developed based on the open-ended responses in the first Delphi survey. These will be rated in the second Delphi survey.

### Recommendations

| Item | Recommendations |
|---|---|
| 3.02 | Non-drug approaches for the prevention of agitation should be an integrated part of standard care |
| 7.04 | Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift. |
| 9.04 | Clinicians caring for agitated patients should have access to immediate help if required. |
| 9.05 | Clinicians should be trained to use de-escalation techniques |
| 9.06 | Clinicians should check that aggressive agitated patients do not have access to potential weapons |
| 16.04 | Non-drug interventions must be adjusted to the individual patient (e.g. patient needs and preferences, level of agitation, patient history, observed effects/reactions). |

### Usefulness of interventions

| Item | Interventions |
|---|---|
| 9.07 | How useful is the BBAUM approach? BBAUM involves calming interventions for challenging behaviours. |
| 9.08 | How useful are the principles of "Gentle Violence Prevention" described by Leah Tranhold? |
| 12.09 | How useful is it to preserve patients' usual sleep-wake cycle? |
| 18.18 | How useful are relaxing breathing exercises? |
| 12.08 | How useful is it to minimise unnecessary stimuli (stimuli can be auditory (e.g. sounds), visual (e.g. lights, moving objects), tactile (e.g. lines, equipment), social (e.g. interacting people) etc? |
| 16.06 | How useful is to offer patients access to a Spiritual Support/Pastoral Care person? |
| 18.17 | How useful is it to sing or hum for or with a patient? |

| | |
|---|---|
| 16.07 | How useful is providing Trauma-Informed Care (TIC)? TIC is an approach to caring for individuals with a history of trauma. |
| 16.08 | How useful are patient diaries? |
| 16.09 | How useful is neuropaedagogy? |

## Items continuing to the last Delphi survey

Fifty-two items reached consensus in both countries and will be rated for inclusion in the guideline in the third and last Delphi survey. The list below describes items ranging from the highest rated to the lowest rated (according to Means).

### Agreement of Statements

| Item | | Total[a] | Count[b] | Agreement %[c] | M | SD | Median | IQR |
|---|---|---|---|---|---|---|---|---|
| 2.01 | Clinicians should identify and, when possible, treat causes of agitation. | 103 | 103 | 100.0% | 4.97 | 0.16 | 5 | 0 |
| 4.01 | Clinicians should support patients' fundamental care needs to reduce and manage agitation. | 103 | 102 | 99.0% | 4.93 | 0.35 | 5 | 0 |
| 5.01 | The multi-disciplinary team should collaborate to reduce and manage patient agitation. | 103 | 102 | 99.0% | 4.92 | 0.54 | 5 | 0 |
| 9.01 | The safety of patients, staff and family/next of kin should be given high priority when managing agitation. | 114 | 111 | 97.4% | 4.89 | 0.49 | 5 | 0 |
| 8.01 | Ongoing staff education about agitation and methods to reduce agitation should be provided. | 102 | 100 | 98.0% | 4.88 | 0.43 | 5 | 0 |
| 19.03 | Clinicians should offer family members information about agitation. | 114 | 112 | 98.2% | 4.85 | 0.50 | 5 | 0 |
| 10.01 | Intensive care units should have clear guidelines for the use of physical restraints. | 102 | 97 | 95.1% | 4.78 | 0.75 | 5 | 0 |
| 1.01 | ICU patients should be regularly and systematically assessed for agitation. | 103 | 100 | 97.1% | 4.78 | 0.64 | 5 | 0 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 7.01 | Additional staffing should be considered when there is an agitated patient in the ICU | 103 | 98 | 95.1% | 4.75 | 0.54 | 5 | 0 |
| 6.01 | Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation. | 103 | 96 | 93.2% | 4.64 | 0.83 | 5 | 0 |
| 9.02 | Clinicians should consider keeping a safe physical distance from a violent patient. | 112 | 99 | 88.4% | 4.54 | 0.79 | 5 | 1 |
| 19.04 | Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation. | 113 | 100 | 88.5% | 4.52 | 0.80 | 5 | 1 |
| 11.01 | Clinicians should consider using several non-drug strategies for agitated patients simultaneously. | 114 | 101 | 88.6% | 4.52 | 0.92 | 5 | 1 |
| 9.03 | The intensive care unit should be laid out in a way that makes observing agitated patients easier. | 103 | 88 | 85.4% | 4.47 | 0.94 | 5 | 1 |
| 7.03 | Staff caring for agitated patients should be offered debriefing. | 103 | 89 | 86.4% | 4.47 | 0.87 | 5 | 1 |
| 12.02 | Clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients | 102 | 89 | 87.3% | 4.46 | 0.94 | 5 | 1 |
| 3.01 | Non-drug approaches should be considered first when managing agitation | 113 | 100 | 88.5% | 4.46 | 0.94 | 5 | 1 |
| 10.02 | Clinicians should use physical restraints only as a last resort to ensure patient and staff safety. | 114 | 97 | 85.1% | 4.38 | 1.10 | 5 | 1 |

a Total people rating the item
b Total rating agree or strongly agree
c Percentage rating agree or strongly agree
M: mean, SD: standard deviation, IQR: interquartile range

## Usefulness of interventions

| Item | | Total[a] | Count[b] | Agreement %[c] | M | SD | Median | IQR |
|---|---|---|---|---|---|---|---|---|
| 12.01 | How useful is minimising interruptions at night? | 114 | 114 | 100.0% | 4.94 | 0.24 | 5 | 0 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 17.04 | How useful are hearing aids in the hearing impaired patient? | 106 | 106 | 100.0% | 4.92 | 0.28 | 5 | 0 |
| 15.02 | How useful is knowing about the patient's background? | 113 | 112 | 99.1% | 4.86 | 0.38 | 5 | 0 |
| 15.03 | How useful is ensuring patient dignity? | 113 | 112 | 99.1% | 4.83 | 0.40 | 5 | 0 |
| 17.05 | How useful are visual aids in the vision impaired patient? | 106 | 103 | 97.2% | 4.83 | 0.45 | 5 | 0 |
| 13.01 | How useful is supporting capable patients to be physically active | 113 | 112 | 99.1% | 4.78 | 0.44 | 5 | 0 |
| 14.04 | How useful is appropriate lighting adjusted according to the time of the day? | 109 | 106 | 97.2% | 4.77 | 0.63 | 5 | 0 |
| 15.01 | How useful is developing a relationship with the patient based on empathy, respect and trust? | 114 | 108 | 94.7% | 4.73 | | | 0 |
| 12.06 | How useful is it to group several care and treatment activities, rather than disturbing the patient several times? | 113 | 108 | 95.6% | 4.72 | 0.61 | 5 | 0 |
| 12.05 | How useful is offering quiet surroundings for the patient, for example a single-bed room? | 112 | 106 | 94.6% | 4.71 | 0.61 | 5 | 0 |
| 12.07 | How useful is respecting patients' need for personal space? | 112 | 105 | 93.8% | 4.69 | 0.59 | 5 | 0 |
| 17.02 | How useful is using clear and concise language? | 114 | 109 | 95.6% | 4.65 | 0.68 | 5 | 1 |
| 14.05 | How useful is it to have a clock and calendar visible to the patient? | 111 | 103 | 92.8% | 4.62 | 0.64 | 5 | 1 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 17.03 | How useful is using "active listening"? | 113 | 105 | 92.9% | 4.61 | 0.67 | 5 | 1 |
| 16.02 | How useful are care plans based on patient preferences and values? | 105 | 96 | 91.4% | 4.61 | 0.74 | 5 | 0 |
| 18.14 | How useful is taking the patient outdoors? | 105 | 97 | 92.4% | 4.52 | 0.80 | 5 | 1 |
| 15.08 | How useful is creating familiar surroundings? | 111 | 104 | 93.7% | 4.5 | 0.65 | 5 | 51 |
| 16.01 | How useful is involving patients in personal care activities? | 111 | 102 | 91.9% | 4.49 | 0.72 | 5 | 1 |
| 19.01 | How useful is teaching family members/next of kin to use non-drug strategies? | 109 | 99 | 90.8% | 4.48 | 0.74 | 5 | 1 |
| 17.01 | Irrespective of how much the patient appears to understand, how useful is explaining to them their circumstances? | 113 | 107 | 94.7% | 4.48 | 0.72 | 5 | 0 |
| 17.06 | How useful are alternative communication methods? | 109 | 103 | 94.5% | 4.47 | 0.75 | 5 | 1 |
| 15.07 | How useful is reassuring the patient that they are safe? | 114 | 107 | 93.9% | 4.46 | 0.61 | 5 | 0 |
| 16.03 | How useful is debriefing the capable patient after an episode of agitation? | 85 | 75 | 88.2% | 4.46 | 0.81 | 5 | 0 |
| 18.02 | How useful are comfortable surroundings | 106 | 89 | 84.0% | 4.41 | 0.80 | 5 | 1 |
| 14.01 | How useful is informing the patient about the plan for the day? | 113 | 99 | 87.6% | 4.4 | 0.80 | 4 | 1 |
| 19.05 | How useful is involving family members/next of kin in care? | 114 | 103 | 90.4% | 4.39 | 0.76 | 5 | 1 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 14.02 | How useful is using a personalised fixed daily schedule with familiar activities? | 105 | 93 | 88.6% | 4.38 | 0.89 | 5 | 1 |
| 15.06 | How useful is holding a patient's hand? | 114 | 101 | 88.6% | 4.3 | 0.80 | 4 | 1 |
| 18.15 | How useful is pet therapy? | 79 | 68 | 86.1% | 4.29 | 0.95 | 5 | 1 |
| 18.08 | How useful is classical or relaxing music, preferably adjusted to patient preferences? | 99 | 88 | 88.9% | 4.23 | 0.81 | 4 | 1 |
| 19.02 | How useful is using telephone and/or video conferencing when family members/next of kin are unable to visit the patient in person? | 96 | 80 | 83.3% | 4.19 | 1.03 | 4 | 1 |
| 16.05 | How useful is involving a psychologist or psychiatrist in the treatment plan? | 91 | 70 | 76.9% | 4.13 | 0.96 | 4 | 1 |
| 18.04 | How useful is using a fiddle toy? | 80 | 66 | 82.5% | 4.11 | 0.87 | 4 | 1 |
| 15.05 | How useful is using therapeutic touch? | 102 | 84 | 82.4% | 4.09 | 0.91 | 4 | 1 |

a Total people rating the item
b Total rating somewhat or very useful
c Percentage rating somewhat or very useful
M: mean, SD: standard deviation, IQR: interquartile range

# Appendix 29 Categorisation Matrix with coding rules



### Categorisation Matrix and coding rules for analysing qualitative data in Delphi study

This codebook or categorisation matrix is based on directed content analysis. The codebook is developed from survey 1, including 20 main categories and 71 subcategories, also called survey items.

The survey free text will be coded deductively into existing subcategories/items. Codes that do not fit into the existing matrix will be pooled, and similar codes will fall into new categories.

**Codes should be applied to areas that answer these questions:**

- Why did participants rate the way they did?
- Should items be reworded, and if so, to what?
- Are there any recommendations that should not be in a guideline?
- Are there any recommendations or interventions that should be added?

**Development of new items, modification of items, and removal of items**

Throughout the coding process, the researcher will consider if comments suggest removing, modifying, or developing new items. New items can be identified throughout the survey, as the throughout the survey participants are encouraged to mention new interventions. New items must be developed as close to the participants' wording as possible. For a new item to be developed, it needs to:

- reflect a new idea;
- be unambiguous;
- demonstrate an explicit action and not simply be a comment or a statement;
- fall inside the scope of the study (for example, items involving medication will be removed);
- build from participants' experiences. For example, if a participant states, "I've heard this is useful", it will not be developed into a new item.

Modifications can only be made to items that are not agreed upon (<75% agreement). Modifications to such items should be developed from comments that suggest alternative wording or alternative actions.

| Category | Coding rules | Item | Intervention |
|---|---|---|---|
| 1. Assessment | Any aspects related to assessment of agitation including how to assess, when and what to assess. | 1.01 | ICU patients should be regularly and systematically assessed for agitation |
| 2. Identifying causes | Any aspect related to identifying causes of agitation. This may also include examples of causes. | 2.01 | Clinicians should identify and, when possible, treat causes of agitation. |
| 3. When to treat | Any aspects that discuss the priority of nonpharmacological approaches and when they should be used. | 3.01 | Non-drug approaches should be considered first when managing agitation |
| | | 3.02 | Non-drug approaches for the prevention of agitation should be an integrated part of standard care |
| 4. Fundamental care needs | Any aspects related to fundamental care needs including physical, psychosocial and relational needs. | 4.01 | Clinicians should support patients' fundamental care needs to reduce and manage agitation. |
| 5. Team collaboration | Any aspects related to collaboration and communication between the multidisciplinary team members. | 5.01 | The multi-disciplinary team should collaborate to reduce and manage patient agitation. |
| 6. Leadership support | Any aspects related to leadership support to implement nonpharmacological interventions. | 6.01 | Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation |
| 7. Working conditions | Aspects related to staff wellbeing including staff allocation, debriefing etc. | 7.01 | Additional staffing should be considered when there is an agitated patient in the ICU |
| | | 7.02 | It is a good idea to rotate staff who care for and treat agitated patients (e.g., during a shift or between shifts). |
| | | 7.03 | Staff caring for agitated patients should be offered debriefing. |

| | | | |
|---|---|---|---|
| | | 7.04 | Clinicians caring for agitated patients should be offered frequent breaks during their shift |
| 8. Education | Aspects related to education of staff about agitation and using | 8.01 | Ongoing staff education about agitation and methods to reduce agitation should be provided. |
| 9. Safety | Any aspects discussing the safety of staff, patients and their family members | 9.01 | The safety of patients, staff and family/next of kin should be given high priority when managing agitation. |
| | | 9.02 | Clinicians should consider keeping a safe physical distance from a violent patient. |
| | | 9.03 | The intensive care unit should be laid out in a way that makes observing agitated patients easier. |
| | | 9.04 | Clinicians caring for agitated patients should have access to immediate help if required. |
| | | 9.05 | Clinicians should be trained to use de-escalation techniques |
| | | 9.06 | Clinicians should check that aggressive agitated patients do not have access to potential weapons |
| | | 9.07 | How useful is the BBAUM approach? BBAUM involves calming interventions for challenging behaviours. |
| | | 9.08 | How useful are the principles of "Gentle Violence Prevention" described by Leah Tranhold? |
| 10. Physical restraints | Any aspects that discuss physical restraints. | 10.01 | Intensive care units should have clear guidelines for the use of physical restraints. Physical restraints mean any manually applied method that reduces a patient's ability to move freely. |
| | | 10.02 | Clinicians should use physical restraints only as a last resort to ensure patient and staff safety. Physical restraints mean any manually applied method that reduces a patient's ability to move freely. |
| | | 10.03 | Physical restraints should never be used to enable staff to leave the patient. |
| | | 10.04 | Physical restraints should not be used as a substitute for direct observation |
| 11. Multiple interventions simultaneously | Any aspects discussing the use of several nonpharmacological interventions simultaneously. | 11.01 | Clinicians should consider using several non-drug strategies for agitated patients simultaneously * |
| 12. Sleep, rest and minimising stimuli | Any aspects related to the promotion of patient sleep and rest. | 12.01 | Minimising interruptions at night. |
| | | 12.02 | Minimise routine interventions and monitoring that are less important to the outcomes of patients. |
| | | 12.03 | Eye mask at night-time |
| | | 12.04 | Earplugs at night-time |
| | | 12.05 | Offering quiet surroundings |
| | | 12.06 | Group several care and treatment activities |
| | | 12.07 | Respecting patient's need for personal space |
| | | 12.08 | Minimising unnecessary stimuli |
| | | 12.09 | Preserve patients' usual sleep-wake cycle? |

| | | | |
|---|---|---|---|
| 13. Physical activity, stimulation and movements | Any aspects related to a type of planned, structured physical activity which could be undertaken by patients with the aim of increasing or maintaining their physical fitness and increasing their wellbeing. | 13.01 | Supporting capable patients to be physically active |
| | | 13.02 | Using a bed-bike |
| | | 13.03 | Rocking chair |
| 14. Orientation | Any aspects related to orientating the patient in terms of time, place, and situation. | 14.01 | Informing the patient about the plan for the day |
| | | 14.02 | Using a personalised fixed daily schedule with familiar activities |
| | | 14.03 | Irrespective of how much patients appear to understand how useful is explaining to them their circumstances |
| | | 14.04 | Appropriate lighting adjusted according to the time of the day |
| | | 14.05 | A clock and calendar visible to the patient. |
| 15. Feeling safe | Any aspects related to making the patient feel safe. | 15.01 | Developing a relationship with the patient |
| | | 15.02 | knowing about the patient's background |
| | | 15.03 | Ensuring patient dignity. |
| | | 15.04 | Allocation of the same staff. |
| | | 15.05 | Therapeutic touch. |
| | | 15.06 | Holding a patient's hand. |
| | | 15.07 | Reassuring the patient that they are safe? |
| | | 15.08 | Creating familiar surroundings. |
| | | 15.09 | Clearly displayed names and/or photographs. |
| | | 15.10 | The same staff should care for the same patient, as long as this is balanced with staff capacity and ability to sustain the required level of care |
| 16. Involving the patient in care activities | Any aspects related to the involvement of the patient in care activities. | 16.01 | Involving patients in personal care activities |
| | | 16.02 | Care plans based on patient preferences and values. |
| | | 16.03 | Debriefing the capable patient. |
| | | 16.04 | Non-drug interventions must be adjusted to the individual patient (e.g. patient needs and preferences, level of agitation, patient history, observed effects/reactions). |
| | | 16.05 | Involving a psychologist/psychiatrist |
| | | 16.06 | How useful is to offer patients access to a Spiritual Support/Pastoral Care person? |
| | | 16.07 | How useful is providing Trauma-Informed Care (TIC)? TIC is an approach to caring for individuals with a history of trauma. |
| | | 16.08 | Patient diary |
| | | 16.09 | How useful is neuropaedagogy? |
| 17. Communication | Any aspects related to communication with the patient. | 17.01 | Explaining to the patient what are and what are not acceptable behaviours |
| | | 17.02 | Clear and concise language |
| | | 17.03 | "active listening" |
| | | 17.04 | Hearing aids |
| | | 17.05 | Visual aids |
| | | 17.06 | Alternative communication methods? |
| 18. Comfort, relaxation and distraction | Any aspects related to making the patient feel comfortable, relaxed, and distracted. | 18.01 | Massage |
| | | 18.02 | Comfortable surroundings |
| | | 18.03 | Mental stimulation |
| | | 18.04 | Fiddle toy |

| | | | |
|---|---|---|---|
| | | 18.05 | Therapeutic weighted blanket? |
| | | 18.06 | Nature-based sounds |
| | | 18.07 | Felicia Affolter methods |
| | | 18.08 | Classical or relaxing music |
| | | 18.09 | Guided Imagery |
| | | 18.10 | Aromatherapy |
| | | 18.12 | Reflexology |
| | | 18.13 | Acupuncture |
| | | 18.14 | Taking the patient outdoors |
| | | 18.15 | Pet therapy |
| | | 18.16 | Basal Stimulation |
| | | 18.17 | How useful is it to sing or hum for or with a patient? |
| | | 18.18 | How useful are relaxing breathing exercises? |
| 19. Involvement of family/next of kin | Any aspects related to the involvement and communication of family/next of kin in order to support the patient. | 19.01 | How useful is teaching family members to use non-drug strategies |
| | | 19.02 | How useful is using telephone and/or video conferencing |
| | | 19.03 | Clinicians should offer family members information about agitation |
| | | 19.04 | Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation * |
| | | 19.05 | How useful is involving family members? |

# Appendix 30 Examples of how new Delphi items were developed

**Examples of how new items were developed**

| Category | New items (subcategory) | | Coded comments |
|---|---|---|---|
| Safety | 9.05 | Clinicians should be trained to use de-escalation techniques. De-escalation involves verbal and non-verbal techniques to calm down a patient. | Learning strategies around de-escalation, particularly regarding communication style and approach (AN).<br><br>They [psychiatry] have good experiences with de-escalation techniques and we have learnt a lot from their knowledge (DN).<br><br>Conflict management and de-escalation strategies are important to learn (AP).<br><br>Sadly, some staff seem only to be clinical and abrupt, and this can, in fact, escalate distress and agitation in patients (Afamily). |
| Safety | 9.07 | BBAUM approach | We have tried the BBAUM approach with good effect (DN).<br><br>I suggest BBAUM approach. BBAUM is a strategy where staff with their hands can calm down a patient. It is often used for patients with dementia (DN). |
| Sleep, rest and minimising stimuli | 12.09 | Preserve patients' usual sleep-wake cycle | Day/night routine is important in delirious or long term patients (AN).<br><br>There should be a great focus on maintaining circadian rhythm with activities during the day and (preferably) sleep during night time. It is difficult, but really good when it works (DP).<br><br>Sleep cycle must be protected (AN).<br><br>The main way of creating an environment conducive to rest and sleep is reducing unnecessary sound and interruptions at night. (AR). |
| Involving the patient in care activities | 16.04 | Non-drug interventions must be adjusted to the individual patient. | Moodiness and state of wellbeing on any one day could provide for a different response to these interventions (APatient).<br><br>The rocking chair may work one day but not the next (DN).<br><br>All of the above would depend on the type of patient and would need to be discussed with family members to determine suitability (Afamily).<br><br>All interventions really depend on how agitated the patient is and where in their critical illness they are (DN). |

# Appendix 31 CALHN Ethics Approval

Government of South Australia | Health
Central Adelaide Local Health Network

**Authorisation Date: 7 December 2021**

**Central Adelaide Local Health Network**
**Research Services**

Tel: 08 7117 2224

Postal Address:
Royal Adelaide Hospital
Clinical Trial Centre
Level 3, Wayfinder 3D460.02
Port Road
ADELAIDE SA 5000

Health.CALHNResearchLNR@sa.gov.au
www.health.sa.gov.au

ABN: 96 269 526 412

Ms Anne Mette Adams
College of Nursing and Health Sciences
Flinders University

Dear Ms Adams

**CALHN Reference Number:** 15710

**Project Title:** Non-pharmacological management of agitation in the intensive care unit – a Delphi study

Thank you for submitting the above proposal for review. This project has undergone ethics and governance review via the expedited processes of the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (HREC) and CALHN Research Services.

I am pleased to advise that your project has been granted full ethics approval and meets the requirements of the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007* incorporating all updates. The project is **authorised** by CALHN Research Services for conduct at the Royal Adelaide Hospital.

The CALHN HREC is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research* (2007).

Documents reviewed and approved:

| Document | Version | Date |
|---|---|---|
| Ethics and Governance Application (EGA) Form | - | 11 November 2021 |
| Protocol | 3 | 25 November 2021 |
| Participant Information Consent Form (PICF) – Patient | 3 | 25 November 2021 |
| Participant Information Consent Form (PICF) – Professionals | 3 | 25 November 2021 |
| Data Collection Sheet – Qualtrics Survey (Appendix 8) | 3 | 6 December 2021 |
| Recruitment through Webpage (Appendix 3) | 3 | 30 November 2021 |
| Flyer – Patient and Family Member (Appendix 4) | 4 | 3 December 2021 |
| Newsletter Advertisement – Patient and Family Member (Appendix 5) | 2 | 3 December 2021 |
| Newsletter Advertisement – Professionals (Appendix 6) | 4 | 3 December 2021 |
| PowerPoint Presentation (Appendix 9) | 2 | 30 November 2021 |
| Letter of Invitation (Appendix 12) | 2 | 30 November 2021 |

Sites covered by CALHN HREC approval:

| Site | State | Principal Investigator |
|---|---|---|
| the Royal Adelaide Hospital | SA | Anne Mette Adams |

Project authorisation is valid for **one (1) year** from **7 December 2021 to 7 December 2022**. An annual progress report requesting an extension must be submitted if the duration of the project continues beyond this period.

**GENERAL TERMS AND CONDITIONS OF PROJECT AUTHORISATION:**

1. The CALHN HREC is the South Australian (SA) 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by the CALHN HREC approval.

2. The study must be conducted in accordance with the standards outlined in the National Statement on Ethical Conduct in Human Research (2007), the Australian Code for the Responsible Conduct of Research (2018), and SA Health policies.
3. Adequate record keeping must be maintained in accordance with Good Clinical Practice, and the NHMRC, state, and national guidelines. The duration of record retention for all low risk research data is five years from the date of publication.
4. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability of the project and/or the site acceptability of the project must to be submitted to CALHN Research Services. Researchers are required to immediately report anything which might warrant review of ethical approval of the study, including:
   a) Adverse events which warrant protocol change or notification to research participants;
   b) Changes to the protocol;
   c) Changes to the safety or efficacy of the investigational product, device or method;
   d) Matters that may affect the conduct of the project;
   e) Premature termination of the study.
   5. Confidentiality of the research participants must be maintained at all times as required by law.
6. A report of the progress of the project at least annually, and related to the degree of risk to participants. The report is due on the anniversary of project authorisation. Continuation of approval is contingent on submission of this report, due within 14 days of the approval anniversary. Failure to comply may result in suspension of the project
7. A final report if the outcome of the project must be submitted on completion of the project. A copy of any published material must also be provided with the report, or following when available.
8. A copy of this letter should also be maintained on file by the Coordinating Principal Investigator as evidence of project authorisation.
9. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements. **A copy of compliance confirmation must be forwarded to CALHN Research Services upon receipt.**

***You are reminded that this letter constitutes ethical approval only and governance authorisation for CALHN sites.***

Should you have any queries about the consideration of your project, please contact Health.CALHNResearchLNR@sa.gov.au.

All future correspondence regarding this study must include the CALHN reference number in the subject header.

We wish you every success in your research.

Yours sincerely,

**Ian Tindall**
Chair, CALHN Human Research Ethics Committee

**Bernadette Swart**
Manager, CALHN Research Services

8 December 2021

# Appendix 32 Flinders University Cross-Institutional Ethics Approval

Dear Mrs Anne Mette Adams,

Please be advised that your request for cross-institutional approval has been approved for the below project:

**Project ID:** 4928

**Project Title:** NON-PHARMACOLOGICAL MANAGEMENT OF AGITATION IN THE INTENSIVE CARE UNIT – A DELPHI STUDY

**Expiry Date:** 07/12/2022

**Please note:**

- Any modification requests and annual or final reports must be submitted to the responsible Human Research Ethics Committee which has approved the original application.
- Extension of time requests must be submitted prior to the Ethics Approval Expiry Date listed in this email.
- Researchers must advise Flinders University's Research Ethics & Compliance Office immediately if:
    - any complaints regarding the research are received,
    - a serious or unexpected adverse event occurs that impacts participants, and
    - an unforeseen event occurs that may affect the ethical acceptability of the project.

Regards,

Mr Hendryk Flaegel

*on behalf of*

Human Research Ethics Committee (HREC)
Research Development and Support
human.researchethics@flinders.edu.au
Flinders University
Sturt Road, Bedford Park, South Australia, 5042
GPO Box 2100, Adelaide, South Australia, 5001

http://www.flinders.edu.au/research/researcher-support/ebi/human-ethics/human-ethics_home.cfm

ResearchNow
Ethics & Biosafety

Flinders University Research Development and Support
Proactively supporting our Research

# Appendix 33 Search Strategies June 2021

**Search strategies from all databases and registers 11th June 2021**

**Ovid MEDLINE**

| # | Ovid MEDLINE |
|---|---|
| 1 | Critical Illness/ or Critical Care/ or Intensive Care Units/ or Intensive Care/ or Respiration, Artificial/ |
| 2 | (ICU* or ((intensive or critical) adj3 (care or unit*))).tw,kw. |
| 3 | ((critical* adj3 ill*) or ((mechanical* or artificial) adj3 (respiration or ventilat*))).tw,kw. |
| 4 | Or/1-3 |
| 5 | Psychomotor Agitation/ |
| 6 | ("Hyperactive delirium" or agitat* or psychomotor).tw,kw. |
| 7 | Or/5-6 |
| 8 | randomized controlled trial/ or Random Allocation/ or Double Blind Method/ or Single Blind Method/ or clinical trial/ or Placebo/ or case control studies/ or cohort studies/ or cross-sectional studies/ or placebo/ |
| 9 | ("controlled clinical trial" or "multicenter study" or "randomi?ed controlled trial" or quasi-experiment* or (clinical adj3 trial*) or ((singl* or doubl* or treb* or tripl*) adj3 (blind* or mask*)) or placebo* or "randomly allocated" or (allocated adj3 random*) or "case control" or (cohort adj3 (study or studies)) or (observational adj3 (study or studies)) or (follow up adj3 (studies or study)) or longitudinal or retrospective or prospective or "pre-test" or "post-test" or "cross-sectional").tw,kw. |
| 10 | Or/8-9 |
| 11 | 4 and 7 and 10 |
| 12 | Intensive Care, Neonatal/ or Intensive Care Units, Pediatric/ |
| 13 | (neonatal or p?ediatric).ti,kw. |
| 14 | 12 or 13 |
| 15 | 11 not 14 |
| 16 | limit 15 to english language |

/: MeSH, tw.kf: Title or abstract, word in author provided keyword

**Emcare**

| # | EMCARE |
|---|---|
| 1 | critical illness/ or intensive care unit/ or intensive care/ or artificial ventilation/ |
| 2 | (ICU* or ((intensive or critical) adj3 (care or unit*))).tw,kw. |
| 3 | ((critical* adj3 ill*) or ((mechanical* or artificial) adj3 (respiration or ventilat*))).tw,kw. |
| 4 | Or/1-3 |
| 5 | restlessness/ |
| 6 | ("Hyperactive delirium" or agitat* or psychomotor).tw,kw. |
| 7 | Or/5-6 |
| 8 | clinical study/ or exp case control study/ or case report/ or exp clinical article/ or clinical trial/ or intervention study/ or exp longitudinal study/ or major clinical study/ or prospective study/ or retrospective study/ |
| 9 | ("controlled clinical trial" or "multicenter study" or "randomi?ed controlled trial" or (clinical adj3 trial*) or ((singl* or doubl* or treb* or tripl*) adj3 (blind* or mask*)) or placebo* or "randomly allocated" or (allocated adj3 random*) or "case control" or (cohort adj3 (study or studies)) or (observational adj3 (study or studies)) or (follow up adj3 (studies or study)) or longitudinal or retrospective or prospective or "pre-test" or "post-test" or "cross-sectional").tw,kw. |
| 10 | Or/8-9 |
| 11 | 4 and 7 and 10 |
| 12 | newborn intensive care/ |
| 13 | (neonatal or p?ediatric).ti,kw. |
| 14 | 12 or 13 |
| 15 | 11 not 14 |
| 16 | limit 15 to english language |

**CINAHL**

| # | CINAHL |
|---|---|
| S1 | (MH "Critical Illness") OR (MH "Critical Care") OR (MH "Intensive Care Units+") OR (MH "Respiration, Artificial+") |
| S2 | TI ( (ICU* OR ((intensive OR critical) N2 (care OR unit*))) ) OR AB ( (ICU* OR ((intensive OR critical) N2 (care OR unit*))) ) |
| S3 | TI ( ((critical* N2 ill*) OR ((mechanical* OR artificial) N2 (respiration OR ventilat*))) ) OR AB ( ((critical* N2 ill*) OR ((mechanical* OR artificial) N2 (respiration OR ventilat*))) ) |
| S4 | S1 OR S2 OR S3 |
| S5 | (MH "Psychomotor Agitation") OR (MH "Agitation") |
| S6 | TI ( ("Hyperactive delirium" OR agitat* OR psychomotor) ) OR AB ( ("Hyperactive delirium" OR agitat* OR psychomotor) ) |
| S7 | S5 OR S6 |
| S8 | (MH "Clinical Trials+") OR (MH "Case Control Studies+") OR (MH "Correlational Studies") OR (MH "Double-Blind Studies") OR (MH "Prospective Studies+") |
| S9 | TI ( ("controlled clinical trial" OR "multicenter study" OR "randomi#ed controlled trial" OR (clinical N2 trial*) OR ((singl* OR doubl* OR treb* OR tripl*) N2 (blind* OR mask*)) OR placebo* OR "randomly allocated" OR (allocated N2 random*) OR "case control" OR (cohort N2 (study OR studies)) OR (observational N2 (study OR studies)) OR (follow up N1 (studies OR study)) OR longitudinal OR retrospective OR prospective OR "pre-test" OR "post-test" OR "cross-sectional") ) OR AB ( ("controlled clinical trial" OR "multicenter study" OR "randomi#ed controlled trial" OR (clinical N2 trial*) OR ((singl* OR doubl* OR treb* OR tripl*) N2 (blind* OR mask*)) OR placebo* OR "randomly allocated" OR (allocated N2 random*) OR "case control" OR (cohort N2 (study OR studies)) OR (observational N2 (study OR studies)) OR (follow up N1 (studies OR study)) OR longitudinal OR retrospective OR prospective OR "pre-test" OR "post-test" OR "cross-sectional") ) |
| S10 | S8 OR S9 |
| S11 | S4 AND S7 AND S10 |
| S12 | (MH "Intensive Care Units, Pediatric") OR (MH "Intensive Care Units, Neonatal") |
| S13 | TI ( (neonatal OR p#ediatric) ) OR SU ( (neonatal OR p#ediatric) ) |
| S14 | S12 OR S13 |
| S15 | S11 NOT S14 |
| S16 | S11 NOT S14 (narrow by language: English) |

**Web of Science**

| # | Web of Science |
|---|---|
| 1 | TS=(ICU* or ((intensive or critical) NEAR/2 (care or unit*))) |
| 2 | TS=((critical* NEAR/2 ill*) or ((mechanical* or artificial) NEAR/2 (respiration or ventilat*))) |
| 3 | #1 OR #2 |
| 4 | TS=("Hyperactive delirium" or agitat* or psychomotor). |
| 5 | TS=("controlled clinical trial" or "multicenter study" or "randomi?ed controlled trial" or (clinical NEAR/2 trial*) or ((singl* or doubl* or treb* or tripl*) NEAR/2 (blind* or mask*)) or placebo* or "randomly allocated" or (allocated NEAR/2 random*) or "case control" or (cohort NEAR/2 (study or studies)) or (observational NEAR/2 (study or studies)) or (follow up NEAR/2 (studies or study)) or longitudinal or retrospective or prospective or "pre-test" or "post-test" or "cross-sectional") |
| 6 | #3 AND #4 AND #5 |
| 7 | TS=(neonatal or p?ediatric). |
| 8 | #6 NOT #7 and English (Languages) |

TS: title, abstract, author keywords, and keywords Plus

**PsycINFO**

| # | PsycINFO |
|---|---|
| 1 | intensive care/ or artificial respiration/ |
| 2 | (ICU* or ((intensive or critical) adj3 (care or unit*))).tw,id. |
| 3 | ((critical* adj3 ill*) or ((mechanical* or artificial) adj3 (respiration or ventilat*))).tw,id. |
| 4 | Or/1-3 |
| 5 | agitation/ |
| 6 | ("Hyperactive delirium" or agitat* or psychomotor).tw,id. |
| 7 | Or/5-6 |
| 8 | exp clinical trials/ or cohort analysis/ or followup studies/ or exp longitudinal studies/ or retrospective studies/ |
| 9 | ("controlled clinical trial" or "multicenter study" or "randomi?ed controlled trial" or (clinical adj3 trial*) or ((singl* or doubl* or treb* or tripl*) adj3 (blind* or mask*)) or placebo* or "randomly allocated" or (allocated adj3 random*) or "case control" or (cohort adj3 (study or studies)) or (observational adj3 (study or studies)) or (follow up adj3 (studies or study)) or longitudinal or retrospective or prospective or "pre-test" or "post-test" or "cross-sectional").tw,id. |
| 10 | Or/8-9 |
| 11 | 4 and 7 and 10 |
| 12 | Intensive Care, Neonatal/ or Intensive Care Units, Pediatric/ |
| 13 | (neonatal or p?ediatric).ti,id. |
| 14 | Or/12-13 |
| 15 | 11 not 14 |
| 16 | limit 15 to english language |

**SCOPUS**

| # | SCOPUS |
|---|---|
| 1 | ( ( TITLE-ABS-KEY ( icu* OR ( ( intensive OR critical ) W/2 ( care OR unit* ) ) ) OR TITLE-ABS-KEY ( ( ( critical* W/2 ill* ) OR ( ( mechanical* OR artificial ) W/2 ( respiration OR ventilat* ) ) ) ) ) AND TITLE-ABS-KEY ( "Hyperactive delirium" OR agitat* OR psychomotor ) AND TITLE-ABS-KEY ( "controlled clinical trial" OR "multicenter study" OR "randomi*ed controlled trial" OR ( clinical W/2 trial* ) OR ( ( singl* OR doubl* OR treb* OR tripl* ) W/2 ( blind* OR mask* ) ) OR placebo* OR "randomly allocated" OR ( allocated W/2 random* ) OR "case control" OR ( cohort W/2 ( study OR studies ) ) OR ( observational W/2 ( study OR studies ) ) OR ( follow AND up W/2 ( studies OR study ) ) OR longitudinal OR retrospective OR prospective OR "pre-test" OR "post-test" OR "cross-sectional" ) ) AND NOT TITLE-ABS-KEY ( neonatal OR p*ediatric ) AND ( LIMIT-TO ( LANGUAGE , "English" ) ) |

**ProQuest Dissertations and Thesis Global**

| # | ProQuest Dissertations & Theses Global |
|---|---|
| | (mainsubject("intensive care") OR mainsubject("critical care") OR noft((ICU* or ((intensive or critical) NEAR/2 (care or unit*)))) or noft(((critical* NEAR/2 ill*) or ((mechanical* or artificial) NEAR/2 (respiration or ventilat*))))) AND (noft(("Hyperactive delirium" or agitat* or psychomotor).)) AND (noft(("controlled clinical trial" or "multicenter study" or "randomi?ed controlled trial" or (clinical NEAR/2 trial*) or ((singl* or doubl* or treb* or tripl*) NEAR/2 (blind* or mask*)) or placebo* or "randomly allocated" or (allocated NEAR/2 random*) or "case control" or (cohort NEAR/2 (study or studies)) or (observational NEAR/2 (study or studies)) or (follow up NEAR/2 (studies or study)) or longitudinal or retrospective or prospective or "pre-test" or "post-test" or "cross-sectional"))) |

**Cochrane (Central)**

| # | Cochrane (Central) |
|---|---|
| | Trials matching ((ICU* or ((intensive or critical) NEAR/2 (care or unit*)))) OR (((critical* NEAR/2 ill*) or ((mechanical* or artificial) NEAR/2 (respiration or ventilat*)))) in Title Abstract Keyword AND "Hyperactive delirium" or agitat* or psychomotor in Title Abstract Keyword AND ("controlled clinical trial" or "multicenter study" or "randomi?ed controlled trial" or (clinical NEAR/2 trial*) or ((singl* or doubl* or treb* or tripl*) NEAR/2 (blind* or mask*)) or placebo* or "randomly allocated" or (allocated NEAR/2 random*) or "case control" or (cohort NEAR/2 (study or studies)) or (observational NEAR/2 (study or studies)) or (follow up NEAR/2 (studies or study)) or longitudinal or retrospective or prospective or "pre-test" or "post-test" or "cross-sectional") in Title Abstract Keyword - (Word variations have been searched) |

Cochrane only has MESH terms for the articles from Medline. This means that when you search Mesh terms in Cochrane, that search will only retrieve records from Medline. **If you have already searched Medline with Mesh terms, only search your keywords in Cochrane.**

**Trial registers and grey literature**

| | |
|---|---|
| **ClinicalTrials.gov** | Agitation, psychomotor |
| **Australian New Zealand Clinical Trials Registry** | Agitation |
| **World Health Organization International Clinical Trial Registry Platform** | Basic search: Agitation, completed studies |
| **EU Clinical Trials** | agitation |
| **Open grey** | agitation |

# Appendix 34 Reasons for excluding articles

| Excluded study | Explanation |
|---|---|
| Allak, Amir; Nguyen, Tam N; Shonka, David C Jr; Reibel, James F; Levine, Paul A; Jameson, Mark J *Immediate postoperative extubation in patients undergoing free tissue transfer.* The Laryngoscope / 2011;121(4):763-8<br>United States 2011 / | Interventions outside ICU |
| Chanques, Gerald; Jaber, Samir; Barbotte, Eric; Violet, Sophie; Sebbane, Mustapha; Perrigault, Pierre-Francois; Mann, Claude; Lefrant, Jean-Yves; Eledjam, Jean-Jacques<br>*Impact of systematic evaluation of pain and agitation in an intensive care unit.* Critical care medicine / 2006;34(6):1691-9<br>United States 2006 / | Involved pharmacology |
| Elay, G; Ozkaya, M *The Effect of Music and Massage on the Pain Scales and Vital Signs of ICU Patients with Hemodialysis Catheter* EUROPEAN JOURNAL OF THERAPEUTICS 2020;26(3):263-269 2020 | Agitation not an outcome |
| Morris, Stephanie M *The Experience of Music Therapy During the Weaning* Thesis, Augsburg University 2019 | Agitation not a clear outcome |
| Ozdemir L.; Karabulut E.<br>*Nurse education regarding agitated patients and its effects on clinical practice*<br>Contemporary Nurse / 2009;34(1):119-128<br>United Kingdom eContent Management Pty Ltd 2009 / | Agitation not measured |
| Kaur, Amandeep; Kumari, Vinay; Sharma, Manpreet<br>*Effect of Nature Based Sound's Intervention on Agitation and Anxiety of Patients Admitted in Intensive Care Units of MMIMS&R Hospital, Mullana, Ambala* International Journal of Health Sciences and research, vol 8, issue 11, 2019 | Authors call the scale Agitation Behavior Assessment Scale but has no references to support this. No contact information to the authors. |
| Khan, SH; Purpura, R; Durrani, S; Wang, S; Lindroth, H; Meeker, J; Hanneman, P; Xu, C; Khan, BA<br>*Decreasing delirium through music (DDM): a randomized controlled feasibility trial* American journal of respiratory and critical care medicine, 199( 9):<br>2019 | Conference abstract |
| Eghbali-Babadi, Maryam; Shokrollahi, Nasrin; Mehrabi, Tayebe *Effect of Family-Patient Communication on the Incidence of Delirium in Hospitalized Patients in Cardiovascular Surgery ICU.*<br>Iranian journal of nursing and midwifery research / 2017;22(4):327-331<br>India 2017 / | Agitation not an outcome |
| Gelogahi, Z. K., et al. (2018). *Effectiveness of nurse's intentional presence as a holistic modality on depression, anxiety, and stress of cardiac surgery patients* Holistic nursing practice **32**(6): 296-306. | Agitation not an outcome |
| McAndrew, Natalie S; Leske, Jane; Guttormson, Jill; Kelber, Sheryl T; Moore, Kaylen; Dabrowski, Sylvia<br>*Quiet time for mechanically ventilated patients in the medical intensive care unit.* Intensive & critical care nursing / 2016;35(bg4, 9211274):22-7<br>Netherlands 2016 / | Not using reliable and valid tool to measure agitation. Effect on agitation was measured through use of Haloperidol. |
| Nobahar, Monir; Fakhr-Movahedi, Ali; Ghorbani, Raheb<br>*Effects of touch on agitation in patients under mechanical ventilation*<br>Koomesh 2014;():325-333<br>2014 | Full-text not available in English |
| Trouillet, Jean-Louis; Luyt, Charles-Edouard; Guiguet, Marguerite; Ouattara, Alexandre; Vaissier, Elisabeth; Makri, Ralouka; | Agitation not an outcome (use of haloperidol was an outcome). |

1

| Excluded study | Explanation |
|---|---|
| Nieszkowska, Ania; Leprince, Pascal; Pavie, Alain; Chastre, Jean; Combes, Alain<br>*Early percutaneous tracheotomy versus prolonged intubation of mechanically ventilated patients after cardiac surgery: a randomized trial.*<br>Annals of internal medicine / 2011;154(6):373-83<br>United States 2011 / | |
| Tan, Carolyn M; Camargo, Mercedes; Miller, Franziska; Ross, Katie; Maximous, Ramez; Yung, Priscilla; Marshall, Carl; Fleming, Dimitra; Law, Madelyn; Tsang, Jennifer Ly<br>*Impact of a nurse engagement intervention on pain, agitation and delirium assessment in a community intensive care unit.* BMJ open quality / 2019;8(3):e000421<br>England 2019 / | Agitation not an outcome |
| Olson, DaiWai M; Perera, Anjali; Atem, Folefac; Wagner, Audra S; Zanders, Michael; Venkatachalam, Aardhra M; Stutzman, Sonja E<br>*Music in mechanically ventilated stroke patients.*<br>British Journal of Neuroscience Nursing 10/02/ 2019;15():S8-S13<br>Mark Allen Holdings Limited 2019 10/02/ | Wrong aim |
| Smonig, Roland; Magalhaes, Eric; Bouadma, Lila; Andremont, Olivier; de Montmollin, Etienne; Essardy, Fatiah; Mourvillier, Bruno; Lebut, Jordane; Dupuis, Claire; Neuville, Mathilde; Lermuzeaux, Mathilde; Timsit, Jean-Francois; Sonneville, Romain<br>*Impact of natural light exposure on delirium burden in adult patients receiving invasive mechanical ventilation in the ICU: a prospective study.*<br>Annals of intensive care / 2019;9(1):120<br>Germany 2019 / | Agitation not an outcome, sedation an outcome. |
| SOURI, LAKIE ABOUZAR; Bolhasani, Masomeh; Nobahar, Monir; FAKHR, MOVAHEDI ALI; Mahmoudi, Hosein *The effect of touch on the arterial blood oxygen saturation in agitated patients undergoing mechanical ventilation*<br>Iranian Journal of Critical Care Nursing, 5(3):<br>2012 | Agitation not an outcome |
| Spiva L.; Hart P.L.; Gallagher E.; McVay F.; Garcia M.; Malley K.; Kadner M.; Segars A.; Brakovich B.; Horton S.Y.; Smith N. *The effects of guided imagery on patients being weaned from mechanical ventilation*<br>Evidence-based Complementary and Alternative Medicine / 2015;2015((Spiva) | Agitation not an outcome |
| Arias-Rivera, S; Lopez-Lopez, C; Frade-Mera, M J; Via-Clavero, G; Rodriguez-Mondejar, J J; Sanchez-Sanchez, M M; Acevedo-Nuevo, M; Gil-Castillejos, D; Robleda, G; Cachon-Perez, M; Latorre-Marco, I; Equipo ASCyD<br>*Assessment of analgesia, sedation, physical restraint and delirium in patients admitted to Spanish intensive care units. Proyecto ASCyD.*<br>Enfermeria intensiva / 2020;31(1):3-18<br>2020 / | Not using reliable and valid tool to measure agitation. |
| Carraway J.S.; Carraway M.W.; Truelove C.A.<br>*Nursing implementation of a validated agitation and sedation scale: An evaluation of its outcomes on ventilator days and ICU length of stay*<br>Applied Nursing Research / 2020; | Agitation not an outcome |
| Perren, A; Corbella, D; Iapichino, E; Di Bernardo, V; Leonardi, A; Di Nicolantonio, R; Buschbeck, C; Boegli, L; Pagnamenta, A; Malacrida, R *Physical restraint in the ICU: does it prevent device removal?.*<br>Minerva anestesiologica / 2015;81(10):1086-95<br>Italy 2015 / | Agitation not an outcome |

# Appendix 35 Checklist for randomised controlled trials

## INTRODUCTION

JBI is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide, South Australia. JBI develops and delivers unique evidence-based information, software, education and training designed to improve healthcare practice and health outcomes. With over 70 Collaborating Entities, servicing over 90 countries, JBI is a recognised global leader in evidence-based healthcare.

### JBI Systematic Reviews

The core of evidence synthesis is the systematic review of literature of a particular intervention, condition or issue. The systematic review is essentially an analysis of the available literature (that is, evidence) and a judgment of the effectiveness or otherwise of a practice, involving a series of complex steps. JBI takes a particular view on what counts as evidence and the methods utilised to synthesise those different types of evidence. In line with this broader view of evidence, JBI has developed theories, methodologies and rigorous processes for the critical appraisal and synthesis of these diverse forms of evidence in order to aid in clinical decision-making in healthcare. There now exists JBI guidance for conducting reviews of effectiveness research, qualitative research, prevalence/incidence, etiology/risk, economic evaluations, text/opinion, diagnostic test accuracy, mixed-methods, umbrella reviews and scoping reviews. Further information regarding JBI systematic reviews can be found in the JBI Evidence Synthesis Manual.

### JBI Critical Appraisal Tools

All systematic reviews incorporate a process of critique or appraisal of the research evidence. The purpose of this appraisal is to assess the methodological quality of a study and to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. All papers selected for inclusion in the systematic review (that is – those that meet the inclusion criteria described in the protocol) need to be subjected to rigorous appraisal by two critical appraisers. The results of this appraisal can then be used to inform synthesis and interpretation of the results of the study. JBI Critical appraisal tools have been developed by the JBI and collaborators and approved by the JBI Scientific Committee following extensive peer review. Although designed for use in systematic reviews, JBI critical appraisal tools can also be used when creating Critically Appraised Topics (CAT), in journal clubs and as an educational tool.

# JBI CRITICAL APPRAISAL CHECKLIST FOR RANDOMIZED CONTROLLED TRIALS

Reviewer_____Date_____

Author_____Year_____ Record Number_____

| | Yes | No | Unclear | NA |
|---|---|---|---|---|
| 1. Was true randomization used for assignment of participants to treatment groups? | ☐ | ☐ | ☐ | ☐ |
| 2. Was allocation to treatment groups concealed? | ☐ | ☐ | ☐ | ☐ |
| 3. Were treatment groups similar at the baseline? | ☐ | ☐ | ☐ | ☐ |
| 4. Were participants blind to treatment assignment? | ☐ | ☐ | ☐ | ☐ |
| 5. Were those delivering treatment blind to treatment assignment? | ☐ | ☐ | ☐ | ☐ |
| 6. Were outcomes assessors blind to treatment assignment? | ☐ | ☐ | ☐ | ☐ |
| 7. Were treatment groups treated identically other than the intervention of interest? | ☐ | ☐ | ☐ | ☐ |
| 8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed? | ☐ | ☐ | ☐ | ☐ |
| 9. Were participants analyzed in the groups to which they were randomized? | ☐ | ☐ | ☐ | ☐ |
| 10. Were outcomes measured in the same way for treatment groups? | ☐ | ☐ | ☐ | ☐ |
| 11. Were outcomes measured in a reliable way? | ☐ | ☐ | ☐ | ☐ |
| 12. Was appropriate statistical analysis used? | ☐ | ☐ | ☐ | ☐ |
| 13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial? | ☐ | ☐ | ☐ | ☐ |

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

# EXPLANATION FOR THE CRITICAL APPRAISAL TOOL FOR RCTS WITH INDIVIDUAL PARTICIPANTS IN PARALLEL GROUPS

How to cite: *Tufanaru C, Munn Z, Aromataris E, Campbell J, Hopp L. Chapter 3: Systematic reviews of effectiveness. In: Aromataris E, Munn Z (Editors). JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global

Answers: Yes, No, Unclear or Not/Applicable

**Critical Appraisal Tool for RCTs (individual participants in parallel groups)**

1. **Was true randomization used for assignment of participants to treatment groups?**

   The differences between participants included in compared groups constitutes a threat to the internal validity of a study exploring causal relationships. If participants are not allocated to treatment and control groups by random assignment there is a risk that the allocation is influenced by the known characteristics of the participants and these differences between the groups may distort the comparability of the groups. A true random assignment of participants to the groups means that a procedure is used that allocates the participants to groups purely based on chance, not influenced by the known characteristics of the participants. Check the details about the randomization procedure used for allocation of the participants to study groups. Was a true chance (random) procedure used? For example, was a list of random numbers used? Was a computer-generated list of random numbers used?

2. **Was allocation to groups concealed?**

   If those allocating participants to the compared groups are aware of which group is next in the allocation process, that is, treatment or control, there is a risk that they may deliberately and purposefully intervene in the allocation of patients by preferentially allocating patients to the treatment group or to the control group and therefore this may distort the implementation of allocation process indicated by the randomization and therefore the results of the study may be distorted. Concealment of allocation (allocation concealment) refers to procedures that prevent those allocating patients from knowing before allocation which treatment or control is next in the allocation process. Check the details about the procedure used for allocation concealment. Was an appropriate allocation concealment procedure used? For example, was central randomization used? Were sequentially numbered, opaque and sealed envelopes used? Were coded drug packs used?

3. **Were treatment groups similar at the baseline?**

   The differences between participants included in compared groups constitute a threat to the internal validity of a study exploring causal relationships. If there are differences between participants included in compared groups there is a risk of selection bias. If there are differences between participants included in the compared groups maybe the 'effect' cannot

be attributed to the potential 'cause' (the examined intervention or treatment), as maybe it is plausible that the 'effect' may be explained by the differences between participants, that is, by selection bias. Check the characteristics reported for participants. Are the participants from the compared groups similar with regards to the characteristics that may explain the effect even in the absence of the 'cause', for example, age, severity of the disease, stage of the disease, co-existing conditions and so on? Check the proportions of participants with specific relevant characteristics in the compared groups. Check the means of relevant measurements in the compared groups (pain scores; anxiety scores; etc.). *[Note: Do NOT only consider the P-value for the statistical testing of the differences between groups with regards to the baseline characteristics.]*

4. **Were participants blind to treatment assignment?**

   If participants are aware of their allocation to the treatment group or to the control group there is the risk that they may behave differently and respond or react differently to the intervention of interest or to the control intervention respectively compared to the situations when they are not aware of treatment allocation and therefore the results of the study may be distorted. Blinding of participants is used in order to minimize this risk. Blinding of the participants refers to procedures that prevent participants from knowing which group they are allocated. If blinding of participants is used, participants are not aware if they are in the group receiving the treatment of interest or if they are in any other group receiving the control interventions. Check the details reported in the article about the blinding of participants with regards to treatment assignment. Was an appropriate blinding procedure used? For example, were identical capsules or syringes used? Were identical devices used? Be aware of different terms used, blinding is sometimes also called masking.

5. **Were those delivering treatment blind to treatment assignment?**

   If those delivering treatment are aware of participants' allocation to the treatment group or to the control group there is the risk that they may behave differently with the participants from the treatment group and the participants from the control group, or that they may treat them differently, compared to the situations when they are not aware of treatment allocation and this may influence the implementation of the compared treatments and the results of the study may be distorted. Blinding of those delivering treatment is used in order to minimize this risk. Blinding of those delivering treatment refers to procedures that prevent those delivering treatment from knowing which group they are treating, that is those delivering treatment are not aware if they are treating the group receiving the treatment of interest or if they are treating any other group receiving the control interventions. Check the details reported in the article about the blinding of those delivering treatment with regards to treatment assignment. Is there any information in the article about those delivering the treatment? Were those delivering the treatment unaware of the assignments of participants to the compared groups?

6. **Were outcomes assessors blind to treatment assignment?**

If those assessing the outcomes are aware of participants' allocation to the treatment group or to the control group there is the risk that they may behave differently with the participants from the treatment group and the participants from the control group compared to the situations when they are not aware of treatment allocation and therefore there is the risk that the measurement of the outcomes may be distorted and the results of the study may be distorted. Blinding of outcomes assessors is used in order to minimize this risk. Check the details reported in the article about the blinding of outcomes assessors with regards to treatment assignment. Is there any information in the article about outcomes assessors? Were those assessing the treatment's effects on outcomes unaware of the assignments of participants to the compared groups?

**7. Were treatment groups treated identically other than the intervention of interest?**

In order to attribute the 'effect' to the 'cause' (the treatment or intervention of interest), assuming that there is no selection bias, there should be no other difference between the groups in terms of treatment or care received, other than the manipulated 'cause' (the treatment or intervention controlled by the researchers). If there are other exposures or treatments occurring at the same time with the 'cause' (the treatment or intervention of interest), other than the 'cause', then potentially the 'effect' cannot be attributed to the examined 'cause' (the investigated treatment), as it is plausible that the 'effect' may be explained by other exposures or treatments occurring at the same time with the 'cause' (the treatment of interest). Check the reported exposures or interventions received by the compared groups. Are there other exposures or treatments occurring at the same time with the 'cause'? Is it plausible that the 'effect' may be explained by other exposures or treatments occurring at the same time with the 'cause'? Is it clear that there is no other difference between the groups in terms of treatment or care received, other than the treatment or intervention of interest?

**8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?**

For this question, follow up refers to the time period from the moment of random allocation (random assignment or randomization) to compared groups to the end time of the trial. This critical appraisal question asks if there is complete knowledge (measurements, observations etc.) for the entire duration of the trial as previously defined (that is, from the moment of random allocation to the end time of the trial), for all randomly allocated participants. If there is incomplete follow up, that is incomplete knowledge about all randomly allocated participants, this is known in the methodological literature as the post-assignment attrition. As RCTs are not perfect, there is almost always post-assignment attrition, and the focus of this question is on the appropriate exploration of post-assignment attrition (description of loss to follow up, description of the reasons for loss to follow up, the estimation of the impact of loss

to follow up on the effects etc.). If there are differences with regards to the loss to follow up between the compared groups in an RCT, these differences represent a threat to the internal

validity of a randomized experimental study exploring causal effects, as these differences may provide a plausible alternative explanation for the observed 'effect' even in the absence of the 'cause' (the treatment or intervention of interest). When appraising an RCT, check if there were differences with regards to the loss to follow up between the compared groups. If follow up was incomplete (that is, there is incomplete information on all participants), examine the reported details about the strategies used in order to address incomplete follow up, such as descriptions of loss to follow up (absolute numbers; proportions; reasons for loss to follow up) and impact analyses (the analyses of the impact of loss to follow up on results). Was there a description of the incomplete follow up (number of participants and the specific reasons for loss to follow up)? It is important to note that with regards to loss to follow up, it is not enough to know the number of participants and the proportions of participants with incomplete data; the reasons for loss to follow up are essential in the analysis of risk of bias; even if the numbers and proportions of participants with incomplete data are similar or identical in compared groups, if the patterns of reasons for loss to follow up are different (for example, side effects caused by the intervention of interest, lost contact etc.), these may impose a risk of bias if not appropriately explored and considered in the analysis. If there are differences between groups with regards to the loss to follow up (numbers/proportions and reasons), was there an analysis of patterns of loss to follow up? If there are differences between the groups with regards to the loss to follow up, was there an analysis of the impact of the loss to follow up on the results? [Note: Question 8 is NOT about intention-to-treat (ITT) analysis; question 9 is about ITT analysis.]

**9. Were participants analyzed in the groups to which they were randomized?**

This question is about the intention-to-treat (ITT) analysis. There are different statistical analysis strategies available for the analysis of data from randomized controlled trials, such as intention-to-treat analysis (known also as intent to treat; abbreviated, ITT), per-protocol analysis, and as-treated analysis. In the ITT analysis the participants are analyzed in the groups to which they were randomized, regardless of whether they actually participated or not in those groups for the entire duration of the trial, received the experimental intervention or control intervention as planned or whether they were compliant or not with the planned experimental intervention or control intervention. The ITT analysis compares the outcomes for participants from the initial groups created by the initial random allocation of participants to those groups. Check if ITT was reported; check the details of the ITT. Were participants analyzed in the groups to which they were initially randomized, regardless of whether they actually participated in those groups, and regardless of whether they actually received the planned interventions? *[Note: The ITT analysis is a type of statistical analysis recommended in the Consolidated Standards of Reporting Trials (CONSORT) statement on best practices in trials reporting, and it is considered a marker of good methodological quality of the analysis of results of a randomized trial. The ITT is estimating the effect of offering the intervention, that is, the effect of instructing the participants to use or take the intervention; the ITT it is not estimating the effect of actually receiving the intervention of interest.]*

**10. Were outcomes measured in the same way for treatment groups?**

If the outcome (the 'effect') is not measured in the same way in the compared groups there is a threat to the internal validity of a study exploring a causal relationship as the differences in outcome measurements may be confused with an effect of the treatment (the 'cause'). Check if the outcomes were measured in the same way. Same instrument or scale used? Same measurement timing? Same measurement procedures and instructions?

**11. Were outcomes measured in a reliable way?**

Unreliability of outcome measurements is one threat that weakens the validity of inferences about the statistical relationship between the 'cause' and the 'effect' estimated in a study exploring causal effects. Unreliability of outcome measurements is one of the different plausible explanations for errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Check the details about the reliability of measurement such as the number of raters, training of raters, the intra-rater reliability, and the inter-raters reliability within the study (not as reported in external sources). This question is about the reliability of the measurement performed in the study, it is not about the validity of the measurement instruments/scales used in the study. *[Note: Two other important threats that weaken the validity of inferences about the statistical relationship between the 'cause' and the 'effect' are low statistical power and the violation of the assumptions of statistical tests. These other two threats are explored within Question 12).]*

**12. Was appropriate statistical analysis used?**

Inappropriate statistical analysis may cause errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Low statistical power and the violation of the assumptions of statistical tests are two important threats that weaken the validity of inferences about the statistical relationship between the 'cause' and the 'effect'. Check the following aspects: if the assumptions of statistical tests were respected; if appropriate statistical power analysis was performed; if appropriate effect sizes were used; if appropriate statistical procedures or methods were used given the number and type of dependent and independent variables, the number of study groups, the nature of the relationship between the groups (independent or dependent groups), and the objectives of statistical analysis (association between variables; prediction; survival analysis etc.).

**13. Was the trial design appropriate for the topic, and any deviations from the standard RCT design accounted for in the conduct and analysis?**

Certain RCT designs, such as the crossover RCT, should only be conducted when appropriate. Alternative designs may also present additional risks of bias if not accounted for in the design and analysis.

Crossover trials should only be conducted in people with a chronic, stable condition, where the intervention produces a short term effect (i.e. relief in symptoms). Crossover trials should ensure there is an appropriate period of washout between treatments.

Cluster RCTs randomize groups of individuals, forming 'clusters.' When we are assessing outcomes on an individual level in cluster trials, there are unit-of-analysis issues, as individuals within a cluster are correlated. This should be taken into account by the study authors when conducting analysis, and ideally authors will report the intra-cluster correlation coefficient.

Stepped-wedge RCTs may be appropriate when it is expected the intervention will do more good than harm, or due to logistical, practical or financial considerations in the roll out of a new treatment/intervention. Data analysis in these trials should be conducted appropriately, taking into account the effects of time.

# Appendix 36 Checklist for Quasi-Experimental studies

## INTRODUCTION

JBI is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide, South Australia. JBI develops and delivers unique evidence-based information, software, education and training designed to improve healthcare practice and health outcomes. With over 70 Collaborating Entities, servicing over 90 countries, JBI is a recognised global leader in evidence-based healthcare.

### JBI Systematic Reviews

The core of evidence synthesis is the systematic review of literature of a particular intervention, condition or issue. The systematic review is essentially an analysis of the available literature (that is, evidence) and a judgment of the effectiveness or otherwise of a practice, involving a series of complex steps. JBI takes a particular view on what counts as evidence and the methods utilised to synthesise those different types of evidence. In line with this broader view of evidence, JBI has developed theories, methodologies and rigorous processes for the critical appraisal and synthesis of these diverse forms of evidence in order to aid in clinical decision-making in healthcare. There now exists JBI guidance for conducting reviews of effectiveness research, qualitative research, prevalence/incidence, etiology/risk, economic evaluations, text/opinion, diagnostic test accuracy, mixed-methods, umbrella reviews and scoping reviews. Further information regarding JBI systematic reviews can be found in the JBI Evidence Synthesis Manual.

### JBI Critical Appraisal Tools

All systematic reviews incorporate a process of critique or appraisal of the research evidence. The purpose of this appraisal is to assess the methodological quality of a study and to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. All papers selected for inclusion in the systematic review (that is – those that meet the inclusion criteria described in the protocol) need to be subjected to rigorous appraisal by two critical appraisers. The results of this appraisal can then be used to inform synthesis and interpretation of the results of the study. JBI Critical appraisal tools have been developed by the JBI and collaborators and approved by the JBI Scientific Committee following extensive peer review. Although designed for use in systematic reviews, JBI critical appraisal tools can also be used when creating Critically Appraised Topics (CAT), in journal clubs and as an educational tool.

# JBI CRITICAL APPRAISAL CHECKLIST FOR QUASI-EXPERIMENTAL STUDIES

Reviewer_____Date_____

Author_____Year_____ Record Number_____

| | Yes | No | Unclear | Not applicable |
|---|---|---|---|---|
| 1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)? | ☐ | ☐ | ☐ | ☐ |
| 2. Were the participants included in any comparisons similar? | ☐ | ☐ | ☐ | ☐ |
| 3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest? | ☐ | ☐ | ☐ | ☐ |
| 4. Was there a control group? | ☐ | ☐ | ☐ | ☐ |
| 5. Were there multiple measurements of the outcome both pre and post the intervention/exposure? | ☐ | ☐ | ☐ | ☐ |
| 6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed? | ☐ | ☐ | ☐ | ☐ |
| 7. Were the outcomes of participants included in any comparisons measured in the same way? | ☐ | ☐ | ☐ | ☐ |
| 8. Were outcomes measured in a reliable way? | ☐ | ☐ | ☐ | ☐ |
| 9. Was appropriate statistical analysis used? | ☐ | ☐ | ☐ | ☐ |

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

# EXPLANATION FOR THE CRITICAL APPRAISAL TOOL FOR QUASI-EXPERIMENTAL STUDIES

*How to cite: Tufanaru C, Munn Z, Aromataris E, Campbell J, Hopp L. Chapter 3: Systematic reviews of effectiveness. In: Aromataris E, Munn Z (Editors). JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global

**Critical Appraisal Tool for Quasi-Experimental Studies (Experimental Studies without random allocation)**

Answers: Yes, No, Unclear or Not/Applicable

### 1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?

Ambiguity with regards to the temporal relationship of variables constitutes a threat to the internal validity of a study exploring causal relationships. The 'cause' (the independent variable, that is, the treatment or intervention of interest) should occur in time before the explored 'effect' (the dependent variable, which is the effect or outcome of interest). Check if it is clear which variable is manipulated as a potential cause. Check if it is clear which variable is measured as the effect of the potential cause. Is it clear that the 'cause' was manipulated before the occurrence of the 'effect'?

### 2. Were the participants included in any comparisons similar?

The differences between participants included in compared groups constitute a threat to the internal validity of a study exploring causal relationships. If there are differences between participants included in compared groups there is a risk of selection bias. If there are differences between participants included in the compared groups maybe the 'effect' cannot be attributed to the potential 'cause', as maybe it is plausible that the 'effect' may be explained by the differences between participants, that is, by selection bias. Check the characteristics reported for participants. Are the participants from the compared groups similar with regards to the characteristics that may explain the effect even in the absence of the 'cause', for example, age, severity of the disease, stage of the disease, co-existing conditions and so on? *[NOTE: In one single group pre-test/post-test studies where the patients are the same (the same one group) in any pre-post comparisons, the answer to this question should be 'yes.']*

### 3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?

In order to attribute the 'effect' to the 'cause' (the exposure or intervention of interest), assuming that there is no selection bias, there should be no other difference between the groups in terms of treatments or care received, other than the manipulated 'cause' (the intervention of interest). If there are other exposures or treatments occurring in the same time with the 'cause', other than the intervention of interest, then potentially the 'effect' cannot be attributed to the intervention of interest, as it is plausible that the 'effect' may be explained by other exposures or treatments, other than the intervention of interest, occurring in the same time with the intervention of interest. Check the reported exposures or interventions received by the compared groups. Are there other exposures or treatments occurring in the same time with the intervention of interest? Is it plausible that the 'effect' may be explained by other exposures or treatments occurring in the same time with the intervention of interest?

### 4. Was there a control group?

Control groups offer the conditions to explore what would have happened with groups exposed to other different treatments, other than to the potential 'cause' (the intervention of interest). The comparison of the treated group (the group exposed to the examined 'cause', that is, the group receiving the intervention of interest) with such other groups strengthens the examination of the causal plausibility. The validity of

causal inferences is strengthened in studies with at least one independent control group compared to studies without an independent control group. Check if there are independent, separate groups, used as control groups in the study. *[Note: The control group should be an independent, separate control group, not the pre-test group in a single group pre-test post-test design.]*

### 5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?

In order to show that there is a change in the outcome (the 'effect') as a result of the intervention/treatment (the 'cause') it is necessary to compare the results of measurement before and after the intervention/treatment. If there is no measurement before the treatment and only measurement after the treatment is available it is not known if there is a change after the treatment compared to before the treatment. If multiple measurements are collected before the intervention/treatment is implemented then it is possible to explore the plausibility of alternative explanations other than the proposed 'cause' (the intervention of interest) for the observed 'effect', such as the naturally occurring changes in the absence of the 'cause', and changes of high (or low) scores towards less extreme values even in the absence of the 'cause' (sometimes called regression to the mean). If multiple measurements are collected after the intervention/treatment is implemented it is possible to explore the changes of the 'effect' in time in each group and to compare these changes across the groups. Check if measurements were collected before the intervention of interest was implemented. Were there multiple pre-test measurements? Check if measurements were collected after the intervention of interest was implemented. Were there multiple post-test measurements?

### 6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?

If there are differences with regards to the loss to follow up between the compared groups these differences represent a threat to the internal validity of a study exploring causal effects as these differences may provide a plausible alternative explanation for the observed 'effect' even in the absence of the 'cause' (the treatment or exposure of interest). Check if there were differences with regards to the loss to follow up between the compared groups. If follow up was incomplete (that is, there is incomplete information on all participants), examine the reported details about the strategies used in order to address incomplete follow up, such as descriptions of loss to follow up (absolute numbers; proportions; reasons for loss to follow up; patterns of loss to follow up) and impact analyses (the analyses of the impact of loss to follow up on results). Was there a description of the incomplete follow up (number of participants and the specific reasons for loss to follow up)? If there are differences between groups with regards to the loss to follow up, was there an analysis of patterns of loss to follow up? If there are differences between the groups with regards to the loss to follow up, was there an analysis of the impact of the loss to follow up on the results?

### 7. Were the outcomes of participants included in any comparisons measured in the same way?

If the outcome (the 'effect') is not measured in the same way in the compared groups there is a threat to the internal validity of a study exploring a causal relationship as the differences in outcome measurements may be confused with an effect of the treatment or intervention of interest (the 'cause'). Check if the outcomes were measured in the same way. Same instrument or scale used? Same measurement timing? Same measurement procedures and instructions?

### 8. Were outcomes measured in a reliable way?

Unreliability of outcome measurements is one threat that weakens the validity of inferences about the statistical relationship between the 'cause' and the 'effect' estimated in a study exploring causal effects. Unreliability of outcome measurements is one of different plausible explanations for errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment

('cause'). Check the details about the reliability of measurement such as the number of raters, training of raters, the intra-rater reliability, and the inter-raters reliability within the study (not to external sources). This question is about the reliability of the measurement performed in the study, it is not about the validity of the measurement instruments/scales used in the study. *[Note: Two other important threats that weaken the validity of inferences about the statistical relationship between the 'cause' and the 'effect' are low statistical power and the violation of the assumptions of statistical tests. These other threats are not explored within Question 8, these are explored within Question 9.]*

### 9. Was appropriate statistical analysis used?

Inappropriate statistical analysis may cause errors of statistical inference with regards to the existence and the magnitude of the effect determined by the treatment ('cause'). Low statistical power and the violation of the assumptions of statistical tests are two important threats that weakens the validity of inferences about the statistical relationship between the 'cause' and the 'effect'. Check the following aspects: if the assumptions of statistical tests were respected; if appropriate statistical power analysis was performed; if appropriate effect sizes were used; if appropriate statistical procedures or methods were used given the number and type of dependent and independent variables, the number of study groups, the nature of the relationship between the groups (independent or dependent groups), and the objectives of statistical analysis (association between variables; prediction; survival analysis etc.).

# Appendix 37 Data Extraction Template

**Data extraction template (additional data extraction to default template in Covidence)**

| Topic | Data Extraction |
|---|---|
| **Identification** | Publication year. Sponsorship source, country, setting, authors contact details. |
| **Methods** | Study aim<br>A summary of the authors' main conclusions and recommendations<br>Study limitations<br>Data Collection Period<br>Ethics approval?<br>Any adverse events reported? |
| **Population** | Sample size calculation<br>Have important populations been excluded from the study? (disadvantaged populations)<br>Inclusion Criteria<br>Exclusion Criteria<br>Group differences<br>Baseline Characteristics<br>n<br>Gender (m/f)<br>Age (mean ± SD)<br>Mechanical ventilated<br>current drug therapy<br>Length of stay in the intensive care unit before intervention<br>Glasgow Coma Scale<br>Primary medical diagnosis<br>Baseline leve of agitation |
| **Intervention** | Description of interventions (intervention group/control group)<br>Description of intervention (include sufficient detail for replication about experiment/ usual care)<br>Duration of treatment<br>Timing (frequency)<br>Providers (profession e.g. doctor, nurse, social worker, also did they need training to deliver the intervention?)<br>Intervention costs (intervention costs or changes in costs as result of intervention)<br>Resource requirements (staff numbers, equipment)<br>Time points when measurements were taken during the study<br>Time points reported? Yes/no<br>Patient acceptance and satisfaction |
| **Outcomes** | Outcome name, type, how it was reported, the scale used, range of scale, units of measurements, directions of measurements (lower is better/higher is better), data value (change from baseline, endpoint)<br><br>If only a figure is available then use webplotdigitizer https://apps.automeris.io/wpd/ to find correct values<br><br>Outcomes considered for this review:<br>Agitation mean/SD<br>Adverse events (number) add timepoints all and serious<br>Length of stay<br>Quality of life<br>Post-traumatic stress<br>Patient satisfaction<br>Family satisfaction<br>Workforce injuries<br>use of medication<br>use of physical restraints<br>staff confidence in managing agitation<br>family confidence in managing agitation |

# Appendix 38 Full list of searches and results

**Full list of searches 14th June 2021**

| Source | Citations imported |
|---|---|
| Databases | |
| MEDLINE | 816 |
| PUBMED | 63 |
| Emcare | 1096 |
| Scopus | 1474 |
| Web of Science | 940 |
| CINAHL | 485 |
| ProQuest Dissertations and Thesis | 23 |
| Cochrane (Central) | 497 |
| Total Databases | **5394** |
| Registers | |
| ClinicalTrials.gov https://clinicaltrials.gov/ | 247 |
| Australian New Zealand Clinical Trials Registry http://www.anzctr.org.au/TrialSearch.aspx | 20 |
| EU Clinical Trials Register(https://www.clinicaltrialsregister.eu/ | 93 |
| World Health Organization International Clinical Trial Registry Platform https://ictrptest.azurewebsites.net/ | 54 |
| ISRCTN registry https://www.isrctn.com/ | 108 |
| Total from registers | 522 |
| Ref. lists and websites | |
| Additional citations from references lists | 7 |
| Open Grey http://opengrey.eu/ | 77 |
| Total ref. lists and websites | **84** |
| Total all sources | **6000** |
| Duplicates removed | 2571 |
| Total without duplicates | **3429** |

# Appendix 39 Excluded papers due to low methodological quality

**Reasons for excluding studies**

**Akin et al.** (1): This RCT does not fulfil essential criteria as it does not describe true randomisation or appropriate allocation concealment threatening the external validity of the study. In addition, baseline information is missing (males/females). It is unclear if the AACNSAS scale is valid and reliable in measuring levels of agitation. The authors only describe personal experiences of how consistency between observers was ensured in a previous study, with no references provided. It is unclear who did the measurements and how inter-rater reliability was ensured. There is a lack of clarity about the frequency of the intervention.

**Ashlaghi et al.** (2): Major concerns about this quasi-experimental study. No description of the intervention. Impossible to tell the difference between intervention and usual care. No information about the duration and timing of treatment. No information about when the measurements were done, by whom and if interrater reliability was ensured. Measurements were not reported; this study only provided p values. Finally, the patients were not similar at baseline, with 7.5 years of difference between the two groups.

**Khalifezadeh** (3): This RCT does not fulfil essential criteria as it does not describe true randomisation or appropriate allocation concealment threatening the external validity of the study. In addition, we question the design of this study. Many of the interventions seem similar to usual care (emotional support, effective communication). Sixteen participants left the study, and it is unclear how this was considered during the analysis of data. It is unclear when measurements were done and if they were done at the same time for both groups. It is unclear who did the measurements and if inter-rater reliability was ensured. Inferential statistics were used due to the small sample size, and the Chi-square test for trend was not used.

**Sedghi et al.** (4): At the point of data extraction, it became clear that there were some errors in the reporting (Table 2, p. 6) with numbers that were impossible (for example RASS scores changed from -3.37 ± 0.89 on day 4 to 4 ± 30.85 on day 5). A request was sent to the authors. As we did not receive a reply and thus were unable to confirm the reporting error with the authors, it was decided to exclude the study.

**Quality assessment of methodological quality using JBIs checklist of randomised controlled trials**

| | Q 1 | Q 2 | Q 3 | Q 4 | Q 5 | Q 6 | Q 7 | Q 8 | Q 9 | Q1 0 | Q1 1 | Q1 2 | Q1 3 | **Tot al (%)** | **Methodologi cal quality** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Akin et al. 2014 (1), tUrk. | N | U | U | N A | N A | U | U | Y | Y | Y | U | U | Y | **33%** | **Low** |
| Khalifezade h, 2011 (3) Iran | U | U | Y | U | N A | N | U | U | Y | U | U | N | N | **17%** | **Low** |

Y = yes; N = no; U = Unclear; N/A = not applicable.
0 - 49%: low methodological quality; 50 - 69%: adequate methodological quality; 70 - 85: moderate methodological quality; 86 - 100: strong methodological quality.

Q1. Was true randomization used for assignment of participants to treatment groups?
Q2. Was allocation to treatment groups concealed?

1

Q3. Were treatment groups similar at baseline?
Q4. Were participants blind to treatment assignment?
Q5. Were those delivering treatment blind to treatment assignment?
Q6. Were outcomes assessors blind to treatment assignment?
Q7. Were treatment groups treated identically other than the intervention of interest?
Q8. Was follow-up complete and, if not, were differences between groups in terms of their follow-up adequately described and analyzed?
Q9. Were participants analyzed in the groups to which they were randomized?
Q10. Were outcomes measured in the same way for treatment groups?
Q11. Were outcomes measured in a reliable way?
Q12. Was appropriate statistical analysis used?
Q13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?

**Quality assessment of methodological quality using JBIs checklist of Quasi-experimental studies**

| | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | **Total (%)** | **Methodological quality** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Ashlaghi 2018, (2), Iran | Y | N | U | Y | N | Y | U | U | U | **33%** | **Low** |
| Sedghi (4) | Y | Y | U | Y | Y | Y | Y | U | N | **67%** | **Low due to data not reliable** |

Y = yes; N = no; U = Unclear; N/A = not applicable.
0 - 49%: low methodological quality; 50 - 69%: adequate methodological quality; 70 - 85: moderate methodological quality; 86 - 100: strong methodological quality.

Q1 = Is it clear in the study what is the 'cause' and what is the 'effect' (i.e., there is no confusion about which variable comes first)?
Q2 = Were the participants included in any comparisons similar?
Q3 = Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?
Q4 = Was there a control group?
Q5 = Were there multiple measurements of the outcome both pre and post the intervention/exposure?
Q6 = Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?
Q7 = Were the outcomes of participants included in any comparisons measured in the same way?
Q8 = Were outcomes measured in a reliable way?
Q9 = Was appropriate statistical analysis used?

**References:**


1. Korhan EA, Khorshid L, Uyar M. Reflexology: its effects on physiological anxiety signs and sedation needs. Holistic nursing practice. 2014;28(1):6-23.
2. Ashlaghi HA, Pourshirvani A, Zandi M, Nasiri M. The effect of familiar voices on levels of agitation in patients admitted to intensive care units. MEDICAL SCIENCE. 2018;22(91):328-34. PubMed PMID: WOS:000435720100011.
3. Khalifezadeh A, Safazadeh S, Mehrabi T, Mansour BA. Reviewing the effect of nursing interventions on delirious patients admitted to intensive care unit of neurosurgery ward in Al-Zahra Hospital, Isfahan University of Medical Sciences. Iranian journal of nursing and midwifery research. 2011;16(1):106-12.
4. Sedghi T, Ghaljeh M, Faghihi H, Sarani H. The Effect of Auditory and Tactile Stimulation by a Family Member on the Level of Agitation in Patients with Traumatic Brain Injury and Decreased Consciousness: A Quasi-Experimental Study. Medical-Surgical Nursing Journal. 2020;9(2).

# Appendix 40 Search Strategies Sep 2021

**Search strategies for Guidelines September 2021**

| # | Medline |
|---|---|
| 1 | Psychomotor agitation/ |
| 2 | ("Hyperactive delirium" or agitat* or psychomotor).tw,kw. |
| 3 | 1 or 2 |
| 4 | guideline/ or practice guideline/ or consensus/ |
| 5 | (guideline* or guidance* or statement or standards or "position paper").tw,kw. |
| 6 | 4 or 5 |
| 7 | 3 AND 6 |
| 8 | limit 7 to (english language and yr="2011 - 2021") |

| # | CINAHL |
|---|---|
| 1 | (MH "Psychomotor Agitation") OR (MH "Agitation") |
| 2 | TI (("Hyperactive delirium" OR agitat* OR psychomotor)) OR AB (("Hyperactive delirium" OR agitat* OR psychomotor)) |
| 3 | S1 or S2 |
| 4 | MH (guidelines or protocols or "practice guideline" or "clinical practice guideline") |
| 5 | AB (guideline* OR guidance* OR statement* OR standards) |
| 6 | S4 or S5 |
| 7 | S3 AND S6 |
| 8 | Published Date 2011-2021<br>Narrow by language: English |

| # | PsycInfo |
|---|---|
| 1 | Exp agitation/ |
| 2 | ("Hyperactive delirium" or agitat* or psychomotor).tw,id. |
| 3 | 1 or 2 |
| 4 | Exp Treatment Guidelines/ |
| 5 | (Guideline* or Guidance* or consensus or statement* or standards or "position paper" or "position stand" or recommendation*).tw. |
| 6 | 4 or 5 |
| 7 | 3 and 6 |
| 8 | limit 8 to (english language and yr="2011 - 2021") |

**Search strategies for Reviews September 2021**

| # | Medline |
|---|---|
| 1 | aggression/ or agonistic behavior/ or delusions/ or paranoid behavior/ or problem behavior/ or wandering behavior/ or confusion/ or delirium/ or emergence delirium/ or psychomotor agitation/ or anger/ or rage/ or anxiety/ or psychological distress/ or fear/ or panic/ or irritable mood/ or dangerous behavior/ |
| 2 | ((difficult or inappropriate or agonistic or problem* or aggressive or abusive or challenging or disturbed or disruptive or agonistic or inappropriate or repetitive or purposeless or non-specific or dangerous) adj1 (behavi?or*)).tw,kf. |
| 3 | ("hyperactive delirium" or agitat* or aggressi* or confus* or restless* or delirium or delirious or delusions or paranoid or anger or rage or anxiety or "psychological distress" or fear or panic or restless or "resist* care" or panic or irrit* or hyperactiv* or "excessive motor activity" or "psychomotor activity" or pacing or pushing or biting or grabbing or scratching or pulling or kicking).tw,kf. |

| | |
|---|---|
| 4 | 1 or 2 or 3 |
| 5 | meta-synthesis/ or "Systematic Review"/ or "Review"/ |
| 6 | Critical Illness/ or Critical Care/ or Intensive Care Units/ or Intensive Care/ or Respiration, Artificial/ |
| 7 | (ICU* or ((intensive or critical) adj3 (care or unit*))).tw,kw. |
| 8 | ((critical* adj3 ill*) or ((mechanical* or artificial) adj3 (respiration or ventilat*))).tw,kw. |
| 9 | 6 or 7 or 8 |
| 10 | 4 AND 5 AND 9 |
| 11 | Intensive Care, Neonatal/ or Intensive Care Units, Pediatric/ |
| 12 | ("neonatal" or "p?ediatric").tw,kf. |
| 13 | 11 AND 12 |
| 14 | Limit 10 to (english language and yr="2011 - 2021") |
| 15 | 14 NOT 13 |

| # | **CINAHL** |
|---|---|
| 1 | (MH "Aggression") OR (MH "Disruptive Behavior") OR (MH "Wandering Behavior") OR (MH "Compulsive Behavior") OR (MH agitation or aggression or anxiety) OR (MH Delirium) OR (MH "confusion") OR (MH psychological distress) |
| 2 | TI ((difficult OR inappropriate OR agonistic OR problem* OR aggressive OR abusive OR challenging OR disturbed OR disruptive OR agonistic OR inappropriate OR repetitive OR purposeless OR non-specific OR dangerous) N2 (behavi#OR*)) |
| 3 | TI ("hyperactive delirium" OR agitat* OR aggressi* OR confus* OR restless* OR delirium OR delirious OR delusions OR paranoid OR anger OR rage OR anxiety OR "psychological distress" OR fear OR panic OR restless OR "resist* care" OR panic OR irrit* OR hyperactiv* OR "excessive motor activity" OR "psychomotor activity" OR pacing OR pushing OR biting OR grabbing OR scratching OR pulling OR kicking) |
| 4 | S1 or S2 or S3 |
| 5 | MH systematic review or meta-analysis or literature review or review of literature |
| 6 | TI systematic review or meta-analysis or literature review or review of literature |
| 9 | 5 or 6 |
| 10 | (MH "Critical Illness") OR (MH "Critical Care") OR (MH "Intensive Care Units*") OR (MH "Respiration, Artificial*") |
| 11 | TI ((ICU* OR ((intensive OR critical) N2 (care OR unit*)))) OR AB ( (ICU* OR ((intensive OR critical) N2 (care OR unit*)))) |
| 12 | TI (((critical* N2 ill*) OR ((mechanical* OR artificial) N2 (respiration OR ventilat*)))) OR AB ( ((critical* N2 ill*) OR ((mechanical* OR artificial) N2 (respiration OR ventilat*)))) |
| 13 | 10 or 11 or 12 |
| 14 | 4 AND 9 AND 13 |
| 15 | Published Date 2011-2021<br>Narrow by language: English |

| # | **PsycINFO** |
|---|---|
| 1 | aggression/ or agonistic behavior/ or delusions/ or paranoid behavior/ or problem behavior/ or wandering behavior/ or confusion/ or delirium/ or emergence delirium/ or psychomotor agitation/ or anger/ or rage/ or anxiety/ or psychological distress/ or fear/ or panic/ or irritable mood/ or dangerous behavior/ |
| 2 | ((difficult or inappropriate or agonistic or problem* or aggressive or abusive or challenging or disturbed or disruptive or agonistic or inappropriate or repetitive or purposeless or non-specific or dangerous) adj2 (behavior* or behaviour)).tw,id. |

| | |
|---|---|
| 3 | ("hyperactive delirium" or agitat* or aggressi* or confus* or restless* or delirium or delirious or delusions or paranoid or anger or rage or anxiety or "psychological distress" or fear or panic or restless or "resist* care" or panic or irrit* or hyperactiv* or "excessive motor activity" or "psychomotor activity" or pacing or pushing or biting or grabbing or scratching or pulling or kicking).tw,id. |
| 4 | 1 or 2 or 3 |
| 5 | Systematic review/ OR meta-analysis/ |
| 6 | (review or meta-analysis).tw,id. |
| 7 | 5 or 6 |
| 8 | intensive care/ or artificial respiration/ |
| 9 | (ICU* or ((intensive or critical) adj3 (care or unit*))).tw,id. |
| 10 | ((critical* adj3 ill*) or ((mechanical* or artificial) adj3 (respiration or ventilat*))).tw,id. |
| 11 | 8 or 9 or 10 |
| 12 | 4 AND 7 AND 11 |
| 13 | limit 12 to (english language and yr="2011 - 2021") |

# Appendix 41 Overview of Searches, Sources and Results

**Search 8th September 2021: Guidelines**

| Source, country (website). | Results |
|---|---|
| MEDLINE | 774 |
| CINAHL | 791 |
| PsycInfo | 430 |
| Australian Clinical Practice Guidelines (NHMRC), Australia. | No results |
| National Institute for Health and Care Excellence (NICE), UK | 52 |
| Scottish Intercollegiate Guidelines Network, Scotland | No results |
| Worlds Health Organisation (WHO) | No results |
| BMJ Best Practice, UK | 10 |
| Centre for Kliniske Retningslinjer, Denmark | 50 |
| Guidelines International Network (GIN) library of guidelines | No results |
| Agency for Healthcare Research and Quality (archive for guidelines from previous National Guideline Clearinghouse), US. | No results |
| Canadian Medical Association CPG InfoBase, Canada. | 12 |
| turning research into practice (TRIP) database | 6 |
| New Zealand Guidelines Group, New Zealand. | No results |
| Total data bases | 1995 |
| Total registers | 130 |
| Duplicates removed | 439 |
| Total after duplicates removed | **1556** |
| Full texts retrieved | 93 |
| Final articles | 10 |

**Search 9th September 2021: Qualitative systematic reviews**

| Source, country (website). | Results |
|---|---|
| MEDLINE | 1477 |
| CINAHL | 499 |
| PsycInfo | 347 |
| Total databases | 2323 |
| Duplicates removed | 380 |
| Total after duplicates removed | **1945** |
| Full texts retrieved | 164 |
| Final articles | 3 |

# Appendix 42 Checklist for Systematic Reviews and Research Synthesis

## INTRODUCTION

JBI is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide, South Australia. JBI develops and delivers unique evidence-based information, software, education and training designed to improve healthcare practice and health outcomes. With over 70 Collaborating Entities, servicing over 90 countries, JBI is a recognised global leader in evidence-based healthcare.

### JBI Systematic Reviews

The core of evidence synthesis is the systematic review of literature of a particular intervention, condition or issue. The systematic review is essentially an analysis of the available literature (that is, evidence) and a judgment of the effectiveness or otherwise of a practice, involving a series of complex steps. JBI takes a particular view on what counts as evidence and the methods utilised to synthesise those different types of evidence. In line with this broader view of evidence, JBI has developed theories, methodologies and rigorous processes for the critical appraisal and synthesis of these diverse forms of evidence in order to aid in clinical decision-making in healthcare. There now exists JBI guidance for conducting reviews of effectiveness research, qualitative research, prevalence/incidence, etiology/risk, economic evaluations, text/opinion, diagnostic test accuracy, mixed-methods, umbrella reviews and scoping reviews. Further information regarding JBI systematic reviews can be found in the JBI Evidence Synthesis Manual.

### JBI Critical Appraisal Tools

All systematic reviews incorporate a process of critique or appraisal of the research evidence. The purpose of this appraisal is to assess the methodological quality of a study and to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. All papers selected for inclusion in the systematic review (that is – those that meet the inclusion criteria described in the protocol) need to be subjected to rigorous appraisal by two critical appraisers. The results of this appraisal can then be used to inform synthesis and interpretation of the results of the study. JBI Critical appraisal tools have been developed by the JBI and collaborators and approved by the JBI Scientific Committee following extensive peer review. Although designed for use in systematic reviews, JBI critical appraisal tools can also be used when creating Critically Appraised Topics (CAT), in journal clubs and as an educational tool.

# JBI CRITICAL APPRAISAL CHECKLIST FOR SYSTEMATIC REVIEWS AND RESEARCH SYNTHESES

Reviewer_____Date_____

Author_____Year_____ Record Number_____

| | | Yes | No | Unclear | Not applicable |
|---|---|---|---|---|---|
| 1. | Is the review question clearly and explicitly stated? | ☐ | ☐ | ☐ | ☐ |
| 2. | Were the inclusion criteria appropriate for the review question? | ☐ | ☐ | ☐ | ☐ |
| 3. | Was the search strategy appropriate? | ☐ | ☐ | ☐ | ☐ |
| 4. | Were the sources and resources used to search for studies adequate? | ☐ | ☐ | ☐ | ☐ |
| 5. | Were the criteria for appraising studies appropriate? | ☐ | ☐ | ☐ | ☐ |
| 6. | Was critical appraisal conducted by two or more reviewers independently? | ☐ | ☐ | ☐ | ☐ |
| 7. | Were there methods to minimize errors in data extraction? | ☐ | ☐ | ☐ | ☐ |
| 8. | Were the methods used to combine studies appropriate? | ☐ | ☐ | ☐ | ☐ |
| 9. | Was the likelihood of publication bias assessed? | ☐ | ☐ | ☐ | ☐ |
| 10. | Were recommendations for policy and/or practice supported by the reported data? | ☐ | ☐ | ☐ | ☐ |
| 11. | Were the specific directives for new research appropriate? | ☐ | ☐ | ☐ | ☐ |

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

_____

_____

_____

# JBI CRITICAL APPRAISAL CHECKLIST FOR SYSTEMATIC REVIEWS AND RESEARCH SYNTHESIS

How to cite: *Aromataris E, Fernandez R, Godfrey C, Holly C, Kahlil H, Tungpunkom P. Summarizing systematic reviews: methodological development, conduct and reporting of an Umbrella review approach. Int J Evid Based Healthc. 2015;13(3):132-40.*

When conducting an umbrella review using the JBI method, the critical appraisal instrument for Systematic Reviews should be used.

The primary and secondary reviewer should discuss each item in the appraisal instrument for each study included in their review. In particular, discussions should focus on what is considered acceptable to the aims of the review in terms of the specific study characteristics. When appraising systematic reviews this discussion may include issues such as what represents an adequate search strategy or appropriate methods of synthesis. The reviewers should be clear on what constitutes acceptable levels of information to allocate a positive appraisal compared with a negative, or response of "unclear". This discussion should ideally take place before the reviewers independently conduct the appraisal.

Within umbrella reviews, quantitative or qualitative systematic reviews may be incorporated, as well as meta-analyses of existing research. There are 11 questions to guide the appraisal of systematic reviews or meta-analyses. Each question should be answered as "yes", "no", or "unclear". Not applicable "NA" is also provided as an option and may be appropriate in rare instances.

1. **Is the review question clearly and explicitly stated?**

   The review question is an essential step in the systematic review process. A well-articulated question defines the scope of the review and aids in the development of the search strategy to locate the relevant evidence. An explicitly stated question, formulated around its PICO (Population, Intervention, Comparator, Outcome) elements aids both the review team in the conduct of the review and the reader in determining if the review has achieved its objectives. Ideally the review question should be articulated in a published protocol; however this will not always be the case with many reviews that are located.

2. **Were the inclusion criteria appropriate for the review question?**

   The inclusion criteria should be identifiable from, and match the review question. The necessary elements of the PICO should be explicit and clearly defined. The inclusion criteria should be detailed and the included reviews should clearly be eligible when matched against the stated inclusion criteria. Appraisers of meta-analyses will find that inclusion criteria may include criteria around the ability to conduct statistical analyses which would not be the norm for a systematic review. The types of included studies should be relevant to the review question, for example, an umbrella review aiming to summarize a range of effective non-pharmacological interventions for aggressive behaviors amongst elderly patients with dementia will limit itself to including systematic reviews and meta-analyses that synthesize quantitative studies assessing the various interventions; qualitative or economic reviews would not be included.

3. **Was the search strategy appropriate?**

   A systematic review should provide evidence of the search strategy that has been used to locate the evidence. This may be found in the methods section of the review report in some cases, or as an appendix that may be provided as supplementary information to the review publication. A systematic review should present a clear search strategy that addresses each of the identifiable PICO components of the review question. Some reviews may also provide a description of the approach to searching and how the terms that were ultimately used were derived, though due to limits on word counts in journals this may be more the norm in online only publications. There

should be evidence of logical and relevant keywords and terms and also evidence that Subject

Headings and Indexing terms have been used in the conduct of the search. Limits on the search should also be considered and their potential impact; for example, if a date limit was used, was this appropriate and/or justified? If only English language studies were included, will such a language bias have an impact on the review? The response to these considerations will depend, in part, on the review question.

### 4. Were the sources and resources used to search for studies adequate?

A systematic review should attempt to identify "all" the available evidence and as such there should be evidence of a comprehensive search strategy. Multiple electronic databases should be searched including major bibliographic citation databases such as MEDLINE and CINAHL. Ideally, other databases that are relevant to the review question should also be searched, for example, a systematic review with a question about a physical therapy intervention should also look to search the PEDro database, whilst a review focusing on an educational intervention should also search the ERIC. Reviews of effectiveness should aim to search trial registries. A comprehensive search is the ideal way to minimize publication bias, as a result, a well conducted systematic review should also attempt to search for grey literature, or "unpublished" studies; this may involve searching websites relevant to the review question, or thesis repositories.

### 5. Were the criteria for appraising studies appropriate?

The systematic review should present a clear statement that critical appraisal was conducted and provide the details of the items that were used to assess the included studies. This may be presented in the methods of the review, as an appendix of supplementary information, or as a reference to a source that can be located. The tools or instruments used should be appropriate for the review question asked and the type of research conducted. For example, a systematic review of effectiveness should present a tool or instrument that addresses aspects of validity for experimental studies and randomized controlled trials such as randomization and blinding – if the review includes observational research to answer the same question a different tool would be more appropriate. Similarly, a review assessing diagnostic test accuracy may refer to the recognized QUADAS[1] tool.

### 6. Was critical appraisal conducted by two or more reviewers independently?

Critical appraisal or some similar assessment of the quality of the literature included in a systematic review is essential. A key characteristic to minimize bias or systematic error in the conduct of a systematic review is to have the critical appraisal of the included studies completed independently and in duplicate by members of the review team. The systematic review should present a clear statement that critical appraisal was conducted by at least two reviewers working independently from each other and conferring where necessary to reach decision regarding study quality and eligibility on the basis of quality.

### 7. Were there methods to minimize errors in data extraction?

Efforts made by review authors during data extraction can also minimize bias or systematic errors in the conduct of a systematic review. Strategies to minimize bias may include conducting all data extraction in duplicate and independently, using specific tools or instruments to guide data extraction and some evidence of piloting or training around their use.

### 8. Were the methods used to combine studies appropriate?

A synthesis of the evidence is a key feature of a systematic review. The synthesis that is presented should be appropriate for the review question and the stated type of systematic review and evidence it refers to. If a meta-analysis has been conducted this needs to be reviewed carefully.

Was it appropriate to combine the studies? Have the reviewers assessed heterogeneity statistically and provided some explanation for heterogeneity that may be present? Often, where heterogeneous studies are included in the systematic review, narrative synthesis will be an appropriate method for presenting the results of multiple studies. If a qualitative review, are the methods that have been used to synthesize findings congruent with the stated methodology of the review? Is there adequate descriptive and explanatory information to support the final synthesized findings that have been constructed from the findings sourced from the original research?

### 9. Was the likelihood of publication bias assessed?

As mentioned, a comprehensive search strategy is the best means by which a review author may alleviate the impact of publication bias on the results of the review. Reviews may also present statistical tests such as Egger's test or funnel plots to also assess the potential presence of publication bias and its potential impact on the results of the review. This question will not be applicable to systematic reviews of qualitative evidence.

### 10. Were recommendations for policy and/or practice supported by the reported data?

Whilst the first nine (9) questions specifically look to identify potential bias in the conduct of a systematic review, the final questions are more indictors of review quality rather than validity. Ideally a review should present recommendations for policy and practice. Where these recommendations are made there should be a clear link to the results of the review. Is there evidence that the strength of the findings and the quality of the research been considered in the formulation of review recommendations?

### 11. Were the specific directives for new research appropriate?

The systematic review process is recognized for its ability to identify where gaps in the research, or knowledge base, around a particular topic exist. Most systematic review authors will provide some indication, often in the discussion section of the report, of where future research direction should lie. Where evidence is scarce or sample sizes that support overall estimates of effect are small and effect estimates are imprecise, repeating similar research to those identified by the review may be necessary and appropriate. In other instances, the case for new research questions to investigate the topic may be warranted.

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# Appendix 43 AGREE II Critical Appraisal of included guidelines

**AGREE II Critical Appraisal of included guidelines***

| Domains | Baldacara et al. (2) | Devlin et al. (3) | Donato et al. (4) | Garriga et al. (5) | Gillings et al. (6) | Hospitals of Leicester NHS (7) | Luaute et al. (8) | Patel et al. (9) | Richmond et al. (10) | Vieta et al. (1) |
|---|---|---|---|---|---|---|---|---|---|---|
| **1. SCOPE AND PURPOSE** | | | | | | | | | | |
| The overall objective(s) of the guideline is specifically described. | Y | Y | Y | Y | Y | Y | Y | U | Y | Y |
| The health question(s) covered by the guideline is specifically described. | Y | Y | U | Y | N | U | U | Y | N | Y |
| The population is specifically described. | U | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| **Score** | **2/3:67%** | **3/3=100%** | **2/3=67%** | **3/3=100** | **2/3=67%** | **2/3=67%** | **2/3=67%** | **2/3=67%** | **2/3=67%** | **3/3=100** |
| **2. STAKEHOLDER INVOLVEMENT** | | | | | | | | | | |
| The guideline development group includes individuals from all relevant professional groups. | N | Y | N | U | U | U | Y | Y | U | Y |
| The views and preferences of the target population (patients, public, etc.) have been sought. | N | Y | U | N | N | N | N | N | N | N |
| The target users of the guideline are clearly defined. | N | Y | U | U | Y | Y | N | N | U | U |
| **Score** | **0/3=0%** | **3/3=100%** | **0/3=0%** | **0/3=0%** | **1/3=33%** | **1/3=33%** | **1/3=33%** | **1/3=33%** | **0/3=0%** | **1/3=33%** |

1

| Domains | Baldacara et al. (2) | Devlin et al. (3) | Donato et al. (4) | Garriga et al. (5) | Gillings et al. (6) | Hospitals of Leicester NHS (7) | Luaute et al. (8) | Patel et al. (9) | Richmond et al. (10) | Vieta et al. (1) |
|---|---|---|---|---|---|---|---|---|---|---|
| **3. RIGOUR OF DEVELOPMENT** | | | | | | | | | | |
| Systematic methods were used to search for evidence. | Y | Y | N | Y | N | N | Y | N | U | Y |
| The criteria for selecting the evidence are clearly described. | | | | | | | | | | |
| The criteria for selecting the evidence are clearly described. | Y | Y | N | Y | N | n | Y | Y | N | N |
| The strengths and limitations of the body of evidence are clearly described. | Y | Y | N | N | N | N | N | N | N | N |
| The methods for formulating the recommendations are clearly described | Y | Y | N | N | N | N | Y | Y | N | N |
| The health benefits, side effects, and risks have been considered in formulating the recommendations. | U | Y | Y | Y | N | N | Y | Y | N | N |
| There is an explicit link between the recommendations and the supporting evidence. | Y | Y | N | Y | N | N | Y | Y | N | N |
| The guideline has been externally reviewed by experts prior to its publication. | N | Y | Y | N | N | Y | Y | N | N | N |
| A procedure for updating the guideline is provided. | N | U | N | N | Y | Y | N | N | N | N |
| **Score** | **5/8=63%** | **7/8=88%** | **2/8=25%** | **4/8=50%** | **1/8=13%** | **2/8=25%** | **6/8=75%** | **4/8=50%** | **0/8=0** | **1/8=13%** |

| Domains | Baldacara et al. (2) | Devlin et al. (3) | Donato et al. (4) | Garriga et al. (5) | Gillings et al. (6) | Hospitals of Leicester NHS (7) | Luaute et al. (8) | Patel et al. (9) | Richmond et al. (10) | Vieta et al. (1) |
|---|---|---|---|---|---|---|---|---|---|---|
| **4. CLARITY OF PRESENTATION** | | | | | | | | | | |
| The recommendations are specific and unambiguous | Y | Y | Y | Y | Y | Y | N | Y | Y | N |
| The different options for management of the condition or health issue are clearly Presented | Y | Y | U | Y | N | Y | Y | Y | Y | Y |
| Key recommendations are easily identifiable. | N | Y | U | Y | N | Y | Y | Y | Y | Y |
| **Score** | **2/3=67%** | **3/3=100%** | **2/3=67%** | **3/3=100** | **2/3=67%** | **2/3=67%** | **1/3=33%** | **3/3=100** | **3/3=100** | **1/3=33%** |
| **5. APPLICABILITY** | | | | | | | | | | |
| **The guideline** | | | | | | | | | | |
| Describes facilitators and barriers to its application | N | U | N | N | N | N | N | N | N | N |
| The guideline provides advice and/or tools on how the recommendations can be put into practice. | N | Y | U | Y | N | Y | N | N | Y | Y |
| The potential resource implications of applying the recommendations have been considered | N | Y | N | Y | N | N | N | N | Y | N |
| The guideline presents monitoring and/or auditing criteria. | N | Y | Y | Y | N | Y | Y | N | N | Y |
| **Score** | **0/4=0%** | **3/4=75%** | **1/4=25%** | **3/4=75%** | **0/4=0** | **2/4=50%** | **1/4=25%** | **0/4=0** | **2/4=50%** | **2/4=50%** |

| Domains | Baldacara et al. (2) | Devlin et al. (3) | Donato et al. (4) | Garriga et al. (5) | Gillings et al. (6) | Hospitals of Leicester NHS (7) | Luaute et al. (8) | Patel et al. (9) | Richmond et al. (10) | Vieta et al. (1) |
|---|---|---|---|---|---|---|---|---|---|---|
| **6. EDITORIAL INDEPENDENCE** | | | | | | | | | | |
| The views of the funding body have not influenced the content of the guideline | U | Y | U | Y | U | U | U | Y | U | U |
| Competing interests of guideline development group members have been recorded and addressed. | Y | Y | Y | U | Y | U | Y | Y | Y | U |
| **Score** | 1/2=50% | 2/2=100% | 1/2=50% | 1/2=50% | 1/2=50% | 0/2=0 | 1/2=50% | 2/2=100 % | 1/2=50% | 0/2=0 |
| **Overall score of the six domains** | 247/600= 41% | 563/600= 94% | 234/600= 39% | 375/600= 63% | 230/600= 38% | 242/600= 40% | 317/600= 53% | 350/600= 58% | 267/600= 45% | 229/600= 38% |

Y=Yes, N=No, U=Unclear.

COI: conflicts of interest

**Calculation Key:** There are six domains. Each domain can give up to 100 score. The maximum score is therefore 600. The scores of each domain are added together to give an overall score of 600.

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# Appendix 44 Endorsed recommendations with linked evidence

## Appendix 44 Final set of recommendations with linked evidence

The summary of judgements and type of recommendations is based on the GRADE methodology and by the Evidence to Decision Framework (1, 2))

**Is the problem a priority?**

According to the existing literature and stakeholder consultation, it is of very high priority to identify nonpharmacological strategies to prevent, minimise or manage agitation in the ICU.

**Is there important uncertainty about or variability in how much people value the main outcomes?**

According to stakeholder consultation, the answer is no.

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| 1.1.1 | The safety of patients, staff and family/next of kin should be given high priority when managing agitation. | (3, 4). | | Very high | Very high | Very high (14) | ⊕◯◯◯ Very low[a] | Weak |
| 1.1.2 | Clinicians caring for and treating agitated patients should always have access to immediate practical support[b]. | (5) | | Very high | Very high | Very high (10) | ⊕◯◯◯ Very low[a] | Weak |
| 1.1.3 | Clinical staff should check that aggressive and violent agitated patients do not have access to objects that can be used to injure others (e.g. sharp objects, weapons, hard objects that can be thrown)[b] | (5) | Staff may not have authority to look through a patient's belongings. | Very high | Very high | Very high (8) | ⊕◯◯◯ Very low[a] | Weak and conditional |

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| 1.1.4 | Clinicians should consider keeping a safe physical distance from a violent patient. | (3, 4). | It may be necessary to get close to the patient to reduce agitation or keep patient safe (e.g. give drugs, avoid extubation). | High | Very high<br><br>(Danish clinicians rated less feasible). | Very high (30) | ⨁◯◯◯<br>Very low[a] | Weak and conditional |
| 1.1.5 | The intensive care unit should be laid out in a way that makes observing agitated patients easier. | (6) | | High | Medium | Very high (26) | ⨁◯◯◯<br>Very low[a] | Weak and conditional as seen as less feasible. |
| 1.2.1 | Non-drug approaches should be considered first when managing agitation | (3, 4, 7). | Some situations may require prompt medical treatment to keep patients and staff safe. | High | Very high | Very high (5) | ⨁◯◯◯<br>Very low[a] | Weak and conditional |
| 1.2.2 | Non-drug approaches for the prevention of agitation should be an integrated part of standard care[b] | (5) | | Very high | Very high | Very high (2) | ⨁◯◯◯<br>Very low[a] | Weak |
| 1.3.1 | Clinicians should consider using several non-drug strategies for agitated patients simultaneously. | (8, 9) | | High | High | Very high (43) | ⨁◯◯◯<br>Very low [b,c,d] | Weak |
| 1.4.1 | Clinicians should use physical restraints only as a last resort to ensure patient and staff safety. | (3, 4, 10-14) | | High | High | Very high (45) | ⨁◯◯◯<br>Very low[a] | Weak |
| 1.4.2 | Physical restraints should not be used as a substitute for direct observation[c]. | (5) | Recommendation may not be appropriate in Danish context. | Very high | High | Very high (22) | ⨁◯◯◯<br>Very low[a] | Weak and conditional. |

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| | | | Australian participants stated how this recommendation could create safety issues when needing to walk away to get medication, facilitate breaks etc. | | | | | |
| 1.4.3 | Intensive care units should have clear guidelines for the use of physical restraints. | (3, 4, 6). | | Very high | Very high | Very high (9) | ⊕◯◯◯ Very low[a] | Weak |
| 2.1.1 | ICU patients should be regularly and systematically assessed for agitation. | (3, 4, 6, 13, 15). | ICUs may not have appropriate assessment tools. Assessment should not disturb the patient. | Very high | Very high | Very high (20) | ⊕◯◯◯ Very low[a] | Weak and conditional |
| 3.1.1 | Clinicians should support patients' fundamental care needs to reduce and manage agitation. | (6) | | Very high | Very high | Very high (13) | ⊕◯◯◯ Very low[a] | Weak |
| 3.1.2 | Clinicians should identify and, when possible, treat causes of agitation. | (3, 4, 6, 7, 13, 16) | | Very high | High | Very high (20) | ⊕◯◯◯ Very low[a] | Weak |
| 4.1.1 | Develop a relationship with the patient based on empathy, respect and trust. | (3, 6, 13-15, 17, 18). | | Very high | Very high | Very high (12) | ⊕◯◯◯ Very lowa | Weak |
| 4.1.2 | Become familiar with the patient's background (e.g., likes, dislikes, culture, history, | (6) | | Very high | Very high | Very high (35) | ⊕◯◯◯ Very low[a] | Weak |

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| | values, fears and routines). | | | | | | | |
| 4.2.1 | Clinicians should be trained to use de-escalation techniques[b]. | (3-7, 13, 15) | | Very high | Very high | Very high (15) | ⨁◯◯◯ Very low[a] | Weak |
| 4.2.2 | Use clear and concise language. | (3, 13, 15). | | Very high | Very high | Very high (11) | ⨁◯◯◯ Very low[a] | Weak |
| 4.2.3 | Use "active listening". | (3, 6, 13, 15). | | Very high | Very high | Very high (25) | ⨁◯◯◯ Very low[a] | Weak |
| 4.2.4 | Use alternative communication methods. | (17) | | Very high | Very high | Very high (34) | ⨁◯◯◯ Very low[a] | Weak |
| 5.1.1 | Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation | (6) | | High | Very high | Very high (32) | ⨁◯◯◯ Very low[a] | Weak |
| 5.1.2 | Clinicians should offer family members information about agitation | (6, 7) | | Very high | Very high | Very high (31) | ⨁◯◯◯ Very low[a] | Weak |
| 5.2.1 | Teach family members/next of kin to use non-drug strategies. | (6) | | Very high | High | Very high (52) | ⨁◯◯◯ Very low[a] | Weak |
| 5.2.2 | Involve family members/next of kin in care. | (6, 14, 17, 18) | Families need to have capacity to be involved and must be safeguarded from feeling responsible for care. Dignity of patient must be protected. | Very high | High (less feasible in Denmark) | High (55) | ⨁◯◯◯ Very low[a] | Weak and conditional |
| 5.2.3 | Use telephone and/or video conferencing when | (6) | | High | High | Very high (50) | ⨁◯◯◯ Very low[a] | Weak |

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| | family members/next of kin are unable to visit the patient in person. | | | | | | | |
| 6.1.1 | Reassure the patient that they are safe. | (12, 14, 15, 17, 18). | | Very high | Very high | Very high (28) | ⊕◯◯◯ Very low[a] | Weak |
| 6.1.2 | Hold a patient's hand. | (6, 17) | | High | Very high | High (58) | ⊕◯◯◯ Very low[a] | Weak |
| 6.2.1 | Involve patients in personal care activities. | (6, 12-15, 17-19) | | Very high | Very high | Very high (44) | ⊕◯◯◯ Very low[a] | Weak |
| 6.2.2 | Debrief the capable patient after an episode of agitation. | (3, 13, 15). | | High | High | High (51) | ⊕◯◯◯ Very low[a] | Weak |
| 6.2.3 | Use neuropaedagogy[b]. | (5) | | High | Medium | Medium (62) (less important in Australian). | ⊕◯◯◯ Very low[a] | Weak and conditional (less feasible, and less imporant in Australia) |
| 6.2.4 | Involve a psychologist or psychiatrist in the treatment plan. | (6, 7) | | High | Medium | Medium (63) | ⊕◯◯◯ Very low[a] | Weak and conditional (less important and less feasible). |
| 6.2.5 | Respect patients' need for personal space. | (3, 4, 12, 15) | Must be done in safe ways. | Very high | High | Very high (39) | ⊕◯◯◯ Very low[a] | Weak and conditional |
| 6.2.6 | Ensure patient dignity. | (12) | | Very high | Very high | Very high (6) | ⊕◯◯◯ Very low[a] | Weak |
| 6.3.1 | Ensure comfortable surroundings (i.e. by optimising room temperature, ventilation and/or design). | (3, 4, 6, 15) | | High | Medium | Very high (36) | ⊕◯◯◯ Very low[a] | Weak and conditional as less feasible. |
| 6.3.2 | Offer a fidget toy. | (6) | Staff should be aware of hygiene and a risk of the toy being thrown. | High | Medium | Medium (61) | ⊕◯◯◯ Very low[a] | Weak and conditional as less feasible and less important. |

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| 6.3.3 | Play classical or relaxing music, preferably adjusted to patient preferences. | (20, 21) | | High | High | High (59) (less important in Denmark) | ⨁◯◯◯ Very low [d,e,f,g] | Weak and conditional as less important in Denmark. |
| 6.3.4 | Take the patient outdoors. | (6) | Patient should be in stable condition and not exhibiting behaviours posing a risk to staff. | Very high | Medium | High (53) | ⨁◯◯◯ Very low[a] | Weak and conditional as less feasible. |
| 6.3.5 | Use pet therapy. | (6) | Infection risks. Risk of allergies among other patients and staff. | High | Medium | High (60) | ⨁◯◯◯ Very low[a] | Weak and conditional as less feasible. |
| 6.3.6 | Use therapeutic touch. | (17, 18, 22) | | High | High | High (56) | ⨁◯◯◯ Very low[a] | Weak |
| 6.4.1 | Inform the patient about the plan for the day. | (6) | | High | Very high | Very high (42) | ⨁◯◯◯ Very low[a] | Weak |
| 6.4.2 | Use a personalised fixed daily schedule with familiar activities. | (6) | Schedule needs to be flexible and adaptable to patient needs. | High | High | High (57) | ⨁◯◯◯ Very low[a] | Weak |
| 6.4.3 | Irrespective of how much the patient appears to understand, explain to them their circumstances. | (6, 14, 15, 17, 18) | | Very high | Very high | Very high (40) | ⨁◯◯◯ Very low[a] | Weak |
| 6.4.4 | Use hearing aids in the hearing-impaired patient. | (6) | | Very high | Very high | Very high (3) | ⨁◯◯◯ Very low[a] | Weak |
| 6.4.5 | Use visual aids in the vision-impaired patient. | (6) | | Very high | Very high | Very high (7) | ⨁◯◯◯ Very low[a] | Weak |
| 6.4.6 | Use appropriate lighting adjusted according to the time of the day. | (3, 6) | | Very high | Very high | Very high (29) | ⨁◯◯◯ Very low[a] | Weak |

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| 6.4.7 | Create familiar surroundings (e.g. with pictures or other items from the patient's home). | (6) | | Very high | Very high | Very high (48) | ⊕◯◯◯ Very low[a] | Weak |
| 6.4.8 | Have a clock and calendar visible to the patient. | (3) | | Very high | Very high | Very high (33) | ⊕◯◯◯ Very low[a] | Weak |
| 7.1.1 | Support capable patients to be physically active (e.g. by supporting patients to sit on the edge of the bed or take small walks) | (6) | | Very high | Very high | Very high (16) | ⊕◯◯◯ Very low[a] | Weak |
| 7.2.1 | Minimise unnecessary stimuli[b]. | (5) | | Very high | High | Very high (23) | ⊕◯◯◯ Very low[a] | Weak |
| 7.2.2 | Group care and treatment activities, rather than disturbing the patient several times. | (6) | | Very high | Very high | Very high (21) | ⊕◯◯◯ Very low[a] | Weak |
| 7.2.3 | Clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients (stimuli can be auditory, e.g. sounds, visual, e.g. lights or moving objects, tactile, e.g. lines or equipment, social, e.g. interacting with people) | (6) | Must be based on professional judgement by experienced and knowledgeable clinician. | High | Very high | Very high (41) | ⊕◯◯◯ Very low[a] | Weak and conditional |

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| 7.2.4 | Offer quiet surroundings for the patient, for example a single bed room. | (6) | Can be dangerous to move an agitated patient. | Very high | High | Very high (38) | ⊕◯◯◯ Very low[a] | Weak and conditional |
| 7.2.5 | Use mental stimulation such as Lego, jigsaws, radio, TV, internet, magazines, pictures[c] | (6) | | High | High | High (54) | ⊕◯◯◯ Very low[a] | Weak |
| 7.3.1 | Preserve patients' usual sleep-wake cycle[b]. | (5, 7) | | Very high | High (less feasible in Denmark) | Very high (24) | ⊕◯◯◯ Very low[a] | Weak and conditional as less feasible in Denmark |
| 7.3.2 | Minimise interruptions at night from noise, light and activities. | (6, 14) | | Very high | Very high | Very high (4) | ⊕◯◯◯ Very low[a] | Weak |
| 8.1.1 | Develop care plans based on patient preferences and values. | (6, 12, 13, 15, 19) | | Very high | High | Very high (46) | ⊕◯◯◯ Very low[a] | Weak |
| 8.1.2 | Non-drug interventions must be adjusted to the individual patient (e.g. patient needs, history and preferences, level of agitation, previous experiences with interventions)[b] | (5) | | Very high | Very high | Very high (27) | ⊕◯◯◯ Very low[a] | Weak |
| 9.1.1 | Additional staffing should be considered when there is an agitated patient in the ICU. | (6, 7, 15) | | Very high | Medium | Very high (17) | ⊕◯◯◯ Very low[a] | Weak and conditional as less feasible |
| 9.1.2 | Staff caring for agitated patients | (3, 6, 13-15) | By trained staff in safe environments | High | High | High (51) | ⊕◯◯◯ Very low[a] | Weak and conditional |

| Item | Recommendation | Origin of evidence (ref. list below) | Undesirable effects/comments | Delphi consensus* | Feasibility* | Importance* (ranked) | Quality/certainty of the evidence ** | Strength of recommendation*** |
|---|---|---|---|---|---|---|---|---|
| | should be offered debriefing. | | | | | | | |
| 9.1.3 | Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift[b]. | (5) | | Very high | Medium | Very high (19) | ⊕◯◯◯ Very low[a] | Weak and conditional as less feasible |
| 9.1.4 | Ongoing staff education about agitation and methods to reduce agitation should be provided. | (3, 4, 6, 7, 15, 17). | | Very high | High | Very high (37) | ⊕◯◯◯ Very low[a] | Weak |
| 9.2.1 | Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation. | (6) | | Very high | Very high | Very high (47) | ⊕◯◯◯ Very low[a] | Weak |
| 9.3.1 | The multi-disciplinary team should collaborate to reduce and manage patient agitation. | (6) | | Very high | Very high | Very high (18) | ⊕◯◯◯ Very low[a] | Weak |

***Consensus, feasibility and importance:**
Very high: 90-100% rating *somewhat* or *strongly/very (useful, agree, importance, feasible)*.
High: 75-89% rating *somewhat* or *strongly/very (useful, agree, importance, feasible)*.
Medium: 50-75% rating *somewhat* or *strongly/very (useful, agree, importance, feasible)*.

[a]: Limitations of study design (consensus statements or qualitative research which usually warrant downgrading to very low (23))

[b]: serious risk of bias (differences between intervention and usual care unclear).

[c]: serious indirectness (psychoactive drugs received before/during the intervention is unclear).

[d]: serious imprecision (related to small sample size/ short intervention/ short term follow-up).

[e]: serious indirectness (different intervention components between studies).

[f]: serious risk of bias (unclear if true randomization was used).

[g]: Serious risk of bias (control and intervention groups not similar at baseline).

### **Certainty of the evidence (23)

**High certainty**: We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty**: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty**: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty**: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

### ***Strength of recommendation (23)

**Strong recommendation:** A strong recommendation is one for which guideline panel is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention). A strong recommendation implies that most or all individuals will be best served by the recommended course of action.

Note: Strong recommendations are not necessarily high priority recommendations.

**Weak recommendation:** A weak recommendation is one for which the desirable effects probably outweigh the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists. A weak recommendation implies that not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual the individual patient's circumstances, preferences, and values. When there are weak recommendations caregivers need to allocate more time to shared decision making, making sure that they clearly and comprehensively explain the potential benefits and harms to a patient.

**Conditional recommendation**: According to the GRADE working group a weak and a conditional recommendation is the same. In this thesis, all recommendations were weak recommenations. **A recommendation was described as weak and conditional if there were qualitative comments suggesting important limitations to the recommendation or if a recommendation was seen as less feasible or important.**

NOTE: no recommendations were judged to be good practice recommendations. Good Practice recommendations represent common-sense practice, are supported by indirect evidence and are associated with assumed large net benefit. These should not be graded (23). However, as discussed in the supervisory group, it was challenging to determine what constitutes common-sense strategies.

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# Appendix 45 List of all endorsed recommendations

**Endorsed recommendations with corresponding levels of consensus, feasibility and importance**

| Theme 1: Care Principles | | | | | |
|---|---|---|---|---|---|
| **Category** | **Item** | **Recommendation** | **Consensus[a]** | **Feasibility[d]** | **Importance[e] (ranked)** |
| Safety should be a high priority | 1.1.1 | The safety of patients, staff and family/next of kin should be given high priority when managing agitation. | 97 | 93 | 94 (14) |
| | 1.1.2 | Clinicians caring for and treating agitated patients should always have access to immediate practical support[b]. | 99 | 82 | 99 (10) |
| | 1.1.3 | Clinical staff should check that aggressive and violent agitated patients do not have access to objects that can be used to injure others (e.g. sharp objects, weapons, hard objects that can be thrown)[b] | 99 | 94 | 98 (8) |
| | 1.1.4 | Clinicians should consider keeping a safe physical distance from a violent patient. | 88 | 78 | 98 (30) |
| | 1.1.5 | The intensive care unit should be laid out in a way that makes observing agitated patients easier. | 85 | 64 | 96 (26) |
| Think NPS first | 1.2.1 | Non-drug approaches should be considered first when managing agitation | 89 | 92 | 90 (5) |
| | 1.2.3 | Clinicians should support patients' fundamental care needs to reduce and manage agitation. | 99 | 95 | 100 (13) |
| | 1.2.4 | Non-drug approaches for the prevention of agitation should be an integrated part of standard care[b] | 100 | 98 | 97 (2) |
| Use multiple NPS | 1.3.1 | Clinicians should consider using several non-drug strategies for agitated patients simultaneously. | 89 | 89 | 91 (43) |
| Physical restraints should be a last resort | 1.4.1 | Clinicians should use physical restraints only as a last resort to ensure patient and staff safety. | 85 | 85 | 91 (45) |
| | 1.4.2 | Physical restraints should not be used as a substitute for direct observation[c]. | 93 | 89 | 94 (22) |

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|---|---|---|---|---|---|
| | 1.4.3 | Intensive care units should have clear guidelines for the use of physical restraints. | 95 | 93 | 98 (9) |
| Theme 2: Assess for agitation | | | | | |
| Assessment | 2.1.1 | ICU patients should be regularly and systematically assessed for agitation. | 97 | 100 | 96 (20) |
| Theme 3: Identify and treat causes | | | | | |
| Causes of agitation | 3.1.1 | Clinicians should identify and, when possible, treat causes of agitation. | 100 | 89 | 99 (20) |
| Theme 4: Caregiver behaviours and developing trusting relationships | | | | | |
| Relationships | 4.1.1 | Develop a relationship with the patient based on empathy, respect and trust. | 95 | 98 | 99 (12) |
| | 4.1.2 | Become familiar with the patient's background (e.g., likes, dislikes, culture, history, values, fears and routines). | 99 | 94 | 98 (35) |
| Caregiver behaviours | 4.2.1 | Clinicians should be trained to use de-escalation techniques[b]. | 99 | 92 | 97 (15) |
| | 4.2.2 | Use clear and concise language. | 96 | 99 | 98 (11) |
| | 4.2.3 | Use "active listening". | 93 | 96 | 96 (25) |
| | 4.2.4 | Use alternative communication methods. | 95 | 93 | 94 (34) |
| Theme 5: Family involvement | | | | | |
| Communication with families | 5.1.1 | Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation | 89 | 95 | 97 (32) |
| | 5.1.2 | Clinicians should offer family members information about agitation | 98 | 99 | 95 (31) |
| Family in care | 5.2.1 | Teach family members/next of kin to use non-drug strategies. | 91 | 80 | 92 (52) |
| | 5.2.2 | Involve family members/next of kin in care. | 90 | 77 | 86 (55) |
| | 5.2.3 | Use telephone and/or video conferencing when family members/next of kin are unable to visit the patient in person. | 83 | 89 | 94 (50) |
| Theme 6: Psychosocial comfort | | | | | |
| Help patients to feel safe | 6.1.1 | Reassure the patient that they are safe. | 94 | 99 | 96 (28) |
| | 6.1.2 | Hold a patient's hand. | 89 | 94 | 83 (58) |

| | | | | | |
|---|---|---|---|---|---|
| Empower the patient | 6.2.1 | Involve patients in personal care activities. | 92 | 91 | 95 (44) |
| | 6.2.2 | Debrief the capable patient after an episode of agitation. | 88 | 85 | 89 (51) |
| | 6.2.3 | Use neuropaedagogy[b]. | 82 | 72 | 69 (62) |
| | 6.2.4 | Involve a psychologist or psychiatrist in the treatment plan. | 77 | 51 | 70 (63) |
| | 6.2.5 | Respect patients' need for personal space. | 94 | 85 | 95 (39) |
| | 6.2.6 | Ensure patient dignity. | 99 | 97 | 99 (6) |
| Comfort and relaxation | 6.3.1 | Ensure comfortable surroundings (i.e. by optimising room temperature, ventilation and/or design). | 84 | 73 | 94 (36) |
| | 6.3.2 | Offer a fidget toy. | 83 | 73 | 74 (61) |
| | 6.3.3 | Play classical or relaxing music, preferably adjusted to patient preferences. | 89 | 85 | 84 (59) |
| | 6.3.4 | Take the patient outdoors. | 92 | 70 | 86 (53) |
| | 6.3.5 | Use pet therapy. | 86 | 42 | 78 (60) |
| | 6.3.6 | Use therapeutic touch. | 82 | 89 | 81 (56) |
| Re-orientation | 6.4.1 | Inform the patient about the plan for the day. | 88 | 95 | 95 (42) |
| | 6.4.2 | Use a personalised fixed daily schedule with familiar activities. | 89 | 82 | 87 (57) |
| | 6.4.3 | Irrespective of how much the patient appears to understand, explain to them their circumstances. | 95 | 96 | 94 (40) |
| | 6.4.4 | Use hearing aids in the hearing-impaired patient. | 100 | 98 | 99 (3) |
| | 6.4.5 | Use visual aids in the vision-impaired patient. | 97 | 100 | 98 (7) |
| | 6.4.6 | Use appropriate lighting adjusted according to the time of the day. | 97 | 93 | 98 (29) |
| | 6.4.7 | Create familiar surroundings (e.g. with pictures or other items from the patient's home). | 94 | 94 | 93 (48) |
| | 6.4.8 | Have a clock and calendar visible to the patient. | 93 | 94 | 98 (33) |
| Theme 7: Physical comfort | | | | | |
| Mobilise patients | 7.1.1 | Support capable patients to be physically active (e.g. by supporting patients to sit on the edge of the bed or take small walks) | 99 | 92 | 99 (16) |

| | | | | | |
|---|---|---|---|---|---|
| Ensure the right level of stimuli | 7.2.1 | Minimise unnecessary stimuli[b]. | 97 | 80 | 98 (23) |
| | 7.2.2 | Group care and treatment activities, rather than disturbing the patient several times. | 96 | 92 | 97 (21) |
| | 7.2.3 | Clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients (stimuli can be auditory, e.g. sounds, visual, e.g. lights or moving objects, tactile, e.g. lines or equipment, social, e.g. interacting with people) | 87 | 92 | 90 (41) |
| | 7.2.4 | Offer quiet surroundings for the patient, for example a single bed room. | 95 | 83 | 95 (38) |
| | 7.2.5 | Use mental stimulation such as Lego, jigsaws, radio, TV, internet, magazines, pictures[c] | 88 | 80 | 85 (54) |
| Promote sleep | 7.3.1 | Preserve patients' usual sleep-wake cycle[b]. | 98 | 80 | 97 (24) |
| | 7.3.2 | Minimise interruptions at night from noise, light and activities. | 100 | 91 | 100 (4) |
| Theme 8: Provide individualised care | | | | | |
| Importance of individualised care | 8.1.1 | Develop care plans based on patient preferences and values. | 91 | 88 | 93 (46) |
| | 8.1.2 | Non-drug interventions must be adjusted to the individual patient (e.g. patient needs, history and preferences, level of agitation, previous experiences with interventions)[b] | 100 | 94 | 97 (27) |
| Theme 9: Interventions related to the context | | | | | |
| Staff support | 9.1.1 | Additional staffing should be considered when there is an agitated patient in the ICU. | 95 | 64 | 96 (17) |
| | 9.1.2 | Staff caring for agitated patients should be offered debriefing. | 86 | 79 | 89 (51) |
| | 9.1.3 | Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift[b]. | 99 | 60 | 94 (19) |
| | 9.1.4 | Ongoing staff education about agitation and methods to reduce agitation should be provided. | 98 | 88 | 97 (37) |

| | | | | | |
|---|---|---|---|---|---|
| Leadership support | 9.2.1 | Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation. | 93 | 99 | 98 (47) |
| Multidisciplinary team collaboration | 9.3.1 | The multi-disciplinary team should collaborate to reduce and manage patient agitation. | 99 | 99 | 100 (18) |

[a] Percentage rating *somewhat agree* or *strongly agree*, or *somewhat useful* or *very useful*
[b] New recommendation developed during the Delphi study
[c] Re-rated recommendation.
[d] percentage rating *somewhat feasible* or very feasible
[e] Percentage *rating somewhat important* or *very important*

Very high (≥90%) level of consensus, feasibility and importance.
High (≥75) level of consensus, feasibility and importance.
Medium (≤75%) level of consensus, feasibility and importance.

Significant difference ($p<0.05$) in ratings between countries AND one country rating below 75%

# Appendix 46 Recommendations with levels of consensus

## Recommendations with their levels of consensus

## Included recommendations

**For recommendations rated twice, this table only includes results from the last rating.**

| Item | Recommendation | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Recommendation | All participants | | | Australia (n=74)* | Denmark (n=40)* | Patient/ family (n=11)*, ** | Allied Health (incl 1 chaplain) (n=13)* | Physician( n=10)* | Researcher (n=6)* | Nurse (incl 2 NUMs) (n=72)* |
| | | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| 2.1.1 | Assess for agitation | 97.1 | 4.75 ± .46 | 5 (1) | 98.5 | 94.6 | | 92.3 | 90 | 100 | 98.6 |
| 3.1.2 | Clinicians should identify and, when possible, treat causes of agitation. | 100 | 5 ± 0 | 5 (0) | 100 | 100 | | 100 | 100 | 100 | 100 |
| 1.2.1 | NPS should be considered first | 88.5 | 4.75 ± 0.46 | 5 (1) | 91.8 | 82.5 | 80 | 100 | 80 | 83.3 | 89.2 |
| 1.2.2 | Support fundamental care needs | 99 | 5 ± 0 | 5 (0) | 100 | 97.3 | | 100 | 100 | 100 | 98.6 |
| 9.3.1 | The multi-disciplinary team should collaborate | 99 | 4.88 ± 0.35 | 5 (0) | 100 | 98.5 | | 100 | 100 | 100 | 98.6 |
| 9.2.1 | Nursing and medical leaders should support the use of non-drug interventions | 93.2 | 4.63 ± 1.06 | 5 (0) | 93.9 | 91.9 | | 100 | 90 | 83.3 | 93.2 |
| 9.1.1 | Additional staffing should be considered | 95.1 | 4.75±0.46 | 5 (1) | 93.9 | 97.3 | | 76.9 | 100 | 100 | 97.3 |
| 9.1.2 | Staff caring for agitated patients | 86.4 | 4.63 ±0.74 | 5 (1) | 90.9 | 78.4 | | 76.9 | 60 | 83.3 | 100 |

| Item | Recommendation | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Recommendation | All participants | | | Australia (n=74)* | Denmark (n=40)* | Patient/ family (n=11)*, ** | Allied Health (incl 1 chaplain) (n=13)* | Physician( n=10)* | Researcher (n=6)* | Nurse (incl 2 NUMs) (n=72)* |
| | | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| | should be offered debriefing. | | | | | | | | | | |
| 9.1.4 | Ongoing staff education about agitation and methods | 98.0 | 4.88 ±0.35 | 5(0) | 98.4 | 96.6 | | 100 | 100 | 100 | 97.3 |
| 1.1.1 | Safety of patients, staff and family | 97.4 | 5 ± 0 | 5 (0) | 97.3 | 97.5 | 81.8 | 100 | 100 | 83.3 | 100 |
| 1.1.4 | Safe physical distance | 88.4 | 4.75 ± 0.46 | 5 (1) | 91.7 | 82.5 | 77.8 | 100 | 70 | 66.7 | 91.9 |
| 1.1.5 | ICU layout | 85.5 | 4.75 ± .71 | 5 (0) | 90.9 | 75.7 | | 84.6 | 90 | 83.3 | 85.1 |
| 1.4.3 | Clear guidelines for physical restraints | 95.1 | 5 ± 0 | 5 (0) | 100 | 86.5 | | 92.3 | 90 | 100 | 95.9 |
| 1.4.1 | Physical restraints as a last resort | 85.1 | 4.75 ± 0.46 | 5 (1) | 86.5 | 82.5 | 72.7 | 92.3 | 80 | 50 | 89.2 |
| 1.3.1 | Use multiple NPS | 88.6 | 5 ± 0 | 5 (0) | 87.8 | 90 | 81.8 | 84.6 | 100 | 100 | 87.8 |
| 7.3.2 | Minimising interruptions at night. | 100 | 4.88±0.35 | 5 (0) | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| 6.3.4 | Taking the patient outdoors | 92.4 | 4.5±0.76 | 5(1) | 95.7 | 85.7 | 100 | 92.3 | 90 | 100 | 90 |
| 7.2.4 | Offering quiet surroundings | 94.7 | 4.63±0.74 | 5(1) | 91.6 | 100 | 100 | 100 | 100 | 100 | 91.8 |
| 7.2.2 | Group several care and treatment activities | 95.6 | 4.5±0.54 | 4.5(1) | 96.4 | 92.5 | 100 | 84.6 | 100 | 100 | 95.9 |

| Item | Recommendation | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Recommendation | All participants | | | Australia (n=74)* | Denmark (n=40)* | Patient/ family (n=11)*, ** | Allied Health (incl 1 chaplain) (n=13)* | Physician( n=10)* | Researcher (n=6)* | Nurse (incl 2 NUMs) (n=72)* |
| | | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| 6.2.5 | Respecting patient's need for personal space | 93.8 | 4.75±0.46 | 5(1) | 94.5 | 92.3 | 100 | 100 | 66.7 | 100 | 94.5 |
| 7.2.3 | Clinicians should minimise routine interventions and monitoring | 87.3 | 4.88 ± .35 | 5 (0) | 86.3 | 88.9 | | 92.3 | 80 | 83.3 | 87.7 |
| 7.1.1 | Supporting capable patients to be physically active | 99.2 | 4.75±0.46 | 5(1) | 98.6 | 100 | 100 | 100 | 100 | 100 | 98.6 |
| 6.4.1 | Informing the patient about the plan for the day | 87.7 | 4.5±0.54 | 4.5(1) | 93.3 | 76.9 | 100 | 84.6 | 70 | 83.3 | 89 |
| 6.4.2 | Using a personalised fixed daily schedule with familiar activities | 88.6 | 4.5±0.54 | 4.5(1) | 87.9 | 89.7 | 100 | 92.3 | 88.9 | 66.7 | 87.6 |
| 6.4.3 | Explaining to them their circumstances | 94.7 | 4.5±0.76 | 5(1) | 94.5 | 95 | 100 | 93.2 | 100 | 100 | 93.2 |
| 6.4.6 | Appropriate lighting adjusted according to the time of the day | 97.3 | 4.75±0.46 | 5 (1) | 98.7 | 94.4 | 100 | 100 | 90 | 100 | 97.2 |
| 6.4.8 | A clock and calendar visible to the patient. | 92.8 | 4.5±0.76 | 5(1) | 91.6 | 94.9 | 90.9 | 100 | 90 | 83.3 | 93 |
| 4.1.1 | Developing a relationship with the patient | 94.8 | 4.38±0.92 | 5(0) | 94.6 | 95 | 100 | 100 | 80 | 100 | 94.6 |

| Item | Recommendation | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Recommendation | All participants | | | Australia (n=74)* | Denmark (n=40)* | Patient/ family (n=11)*, ** | Allied Health (incl 1 chaplain) (n=13)* | Physician( n=10)* | Researcher (n=6)* | Nurse (incl 2 NUMs) (n=72)* |
| | | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| 4.1.2 | knowing about the patient's background | 99.1 | 4.88±0.35 | 5(0) | 98.6 | 100 | 100 | 100 | 100 | 100 | 98.6 |
| 6.2.6 | Ensuring patient dignity. | 99.1 | 4.88±0.35 | 5(0) | 100 | 97.4 | 100 | 100 | 90 | 100 | 100 |
| 6.3.6 | Therapeutic touch. | 82.4 | 3.75±1.28 | 4(1) | 80.9 | 85.3 | 100 | 100 | 62.5 | 75 | 79.4 |
| 6.1.2 | Holding a patient's hand. | 88.6 | 4.13±1.36 | 4.5(1) | 87.8 | 90 | 100 | 100 | 90 | 100 | 83.8 |
| 6.1.1 | Reassuring the patient | 93.8 | 4.63±0.74 | 5(1) | 94.6 | 92.5 | 100 | 92.3 | 90 | 100 | 93.2 |
| 6.4.7 | Creating familiar surroundings. | 93.7 | 4.5±0.93 | 5(1) | 95.7 | 90 | 100 | 92.3 | 80 | 80 | 95.8 |
| 6.2.1 | Involving patients in personal care activities | 91.9 | 4.5±0.76 | 5(1) | 95.9 | 84.6 | 90 | 84.6 | 87.5 | 100 | 93.2 |
| 8.1.1 | Care plans based on patient preferences and values. | 91.4 | 4.63±0.74 | 5(1) | 94.2 | 85.8 | 100 | 100 | 75 | 66.7 | 92.8 |
| 6.2.2 | Debriefing the capable patient | 88.3 | 4.38±0.92 | 5(1) | 86.2 | 92.6 | 100 | 78.8 | 77.8 | 100 | 88.9 |
| 4.2.2 | Clear and concise language | 95.6 | 4.88±0.35 | 5(0) | 93.2 | 100 | 100 | 100 | 100 | 100 | 93.2 |
| 4.2.3 | "active listening" | 92.9 | 4.63±0.52 | 5(1) | 90.5 | 97.5 | 100 | 100 | 90 | 100 | 90.5 |
| 6.4.4 | Hearing aids | 100 | 5±0 | 5(0) | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| 6.4.5 | Visual aids | 97.1 | 5±0 | 5(0) | 98.6 | 94.3 | 100 | 100 | 90 | 100 | 97.1 |

| Item | Recommendation | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Recommendation | All participants | | | Australia (n=74)* | Denmark (n=40)* | Patient/ family (n=11)*, ** | Allied Health (incl 1 chaplain) (n=13)* | Physician( n=10)* | Researcher (n=6)* | Nurse (incl 2 NUMs) (n=72)* |
| | | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| 4.2.4 | Alternative communication methods? | 94.5 | 4.63±0.52 | 5(1) | 97.2 | 89.1 | 100 | 100 | 90 | 83.3 | 94.4 |
| 6.3.1 | Comfortable surroundings | 84 | 4.38±1.19 | 5(2) | 81.8 | 88.6 | 100 | 100 | 57.1 | 60 | 82.9 |
| 6.3.2 | Fidget toy | 82.6 | 3.88±1.36 | 4.5(3) | 83.9 | 79.1 | 100 | 100 | 57.1 | 100 | 79.2 |
| 6.3.3 | Classical or relaxing music | 88.9 | 4±1.31 | 4(1) | 92.2 | 82.9 | 100 | 91.7 | 88.9 | 83.3 | 87.3 |
| 6.2.4 | Involving a psychologist/psychiatrist | 76.9 | 4.13±1.13 | 4.5(2) | 77.2 | 76.5 | 88.9 | 83.3 | 55.6 | 66.7 | 78.2 |
| 6.3.5 | Pet therapy | 86.1 | 3.63±1.19 | 4(3) | 86.2 | 85.7 | 100 | 100 | 71.4 | 100 | 81.3 |
| 5.2.2 | Involving family members | 90.3 | 4.25±1.04 | 4.5(1) | 94.6 | 82.5 | 100 | 76.9 | 80 | 100 | 91.9 |
| 5.2.1 | Teaching family members | 90.8 | 4.75±0.46 | 5(1) | 93 | 86.8 | 100 | 100 | 90 | 80 | 88.7 |
| 5.2.3 | Telephone and/or video conferencing | 83.3 | 4.38±0.74 | 4.5(1) | 83.8 | 82.3 | 100 | 100 | 62.5 | 75 | 81 |
| 5.1.2 | Clinicians should offer family members information about agitation | 98.2 | 4.88 ± 0.35 | 5 (0) | 97.5 | 100 | 90.9 | 100 | 100 | 100 | 98.6 |
| 5.1.1 | Establish how much the family would like to and are able to be involved | 88.5 | 4.75 ± 0.71 | 5 (0) | 86.5 | 92.3 | 90.9 | 91.7 | 70 | 83.3 | 90.5 |

| Item | Recommendation | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Recommendation | All participants | | | Australia (n=74)* | Denmark (n=40)* | Patient/ family (n=11)*, ** | Allied Health (incl 1 chaplain) (n=13)* | Physician( n=10)* | Researcher (n=6)* | Nurse (incl 2 NUMs) (n=72)* |
| | | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| 7.2.5 | Mental stimulation | 88 | 4.21±0.78 | 4(1) | 82.4 | 91 | 100 | 84.6 | 62.5 | 80 | 90.8 |
| 1.2.3 | NPS as a part of standard care | 100 | 4.89±0.32 | 5(0) | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| 7.3.1 | Preserve patients' usual sleep-wake cycle | 98 | 4.68±0.55 | 5(1) | 100 | 94.4 | 100 | 100 | 100 | 80 | 98.6 |
| 7.2.1 | Minimise stimuli | 97 | 4.68±0.60 | 5(1) | 98.5 | 94.7 | 88.9 | 100 | 100 | 100 | 97.1 |
| 1.1.3 | Patient access to objects | 99 | 4.93±0.29 | 5(0) | 100 | 98.5 | 100 | 100 | 100 | 100 | 98.5 |
| 1.1.2 | Immediate practical support | 99.1 | 4.91±0.33 | 5(0) | 100 | 98.5 | 100 | 92.3 | 100 | 100 | 100 |
| 4.2.1 | Clinicians should be trained to use de-escalation techniques. | 99.1 | 4.89±0.40 | 5(0) | 100 | 97.4 | 100 | 100 | 100 | 100 | 98.6 |
| 8.1.2 | Non-drug interventions must be adjusted to the individual patient | 100 | 4.89±0.32 | 5(0) | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| 9.1.3 | Clinicians should be offered frequent breaks during their shift. | 99.1 | 4.82±0.41 | 5(0) | 98.5 | 100 | 100 | 100 | 100 | 100 | 98.6 |
| 1.4.2 | PR not a substitute for direct observation | 93.3 | 4.64±0.79 | 5(0) | 100 | 89.6 | 100 | 100 | 88.9 | 100 | 91.2 |
| 6.2.3 | Neuropaedagogy | 82 | 4.24±0.96 | 5(1) | 82.6 | 81.8 | 100 | 100 | 25 | 0 | 81.5 |

* n=total sample of stakeholders involved in the first Delphi round. Not all would have experience with an intervention, meaning this total sample does not reflect how many answered each individual question. Contact the primary author for more details.

** Questions not asked patients and family members,

NUM Nurse Unit Manager, SD standard deviation, IQR interquartile range,

## Excluded recommendations

**For recommendations rated twice, this table only includes results from the last rating.**

| Recommendations | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Australia (n=74) | Denmark (n=40) | Patient/family (n=11) | Allied Health (incl 1 chaplain) (n=13) | Physician (n=10) | Researcher (n=6) | Nurse (incl 2 NUMs) (n=72) |
| | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| Eye mask at night-time | 47.5 | 3.5±1.2 | 3.5(1) | 52.2 | 30.8 | 50 | 40 | 66.7 | 50 | 44.7 |
| Earplugs at night-time | 65.1 | 3.5±1.2 | 3.5(1) | 68.3 | 56.5 | 77.8 | 33.3 | 75 | 40 | 67.3 |
| Massage | 63.3 | 3.38±1.41 | 3.5(1) | 59.2 | 70 | 83.3 | 84.6 | 25 | 50 | 59.6 |
| Nature-based sounds | 58.2 | 3±1.07 | 3(1) | 68.7 | 39.3 | 88.9 | 33.3 | 50 | 33.3 | 60 |
| Felicia Affolter methods | 50 | 2.88±0.99 | 3(2) | 38.5 | 63.7 | 100 | 75 | 0 | 100 | 40 |
| Guided Imagery | 70.8 | 3.38±1.3 | 4(1) | 74.3 | 55.5 | 100 | 100 | 33.3 | 50 | 62.1 |
| Aromatherapy | 50 | 2.63±0.92 | 3(2) | 52.9 | 37.5 | 62.5 | 20 | 0 | 50 | 56 |
| Reflexology | 40 | 2.75±1.04 | 3(2) | 38.4 | 43.4 | 83.3 | 20 | 25 | 50 | 33.3 |
| Acupuncture | 16 | 2.75±1.17 | 3(1.5) | 13.3 | 20 | 60 | 0 | 0 | 0 | 9.1 |
| Explaining to the patient what are and what are not acceptable behaviours | 60.7 | 3.63±1.19 | 4(2) | 68.5 | 46.2 | 90 | 46.2 | 50 | 50 | 61.6 |

| Recommendations | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Australia (n=74) | Denmark (n=40) | Patient/family (n=11) | Allied Health (incl 1 chaplain) (n=13) | Physician (n=10) | Researcher (n=6) | Nurse (incl 2 NUMs) (n=72) |
| | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| It is a good idea to rotate staff | 75.8 | 4.5 ± 1.07 | 5 (1) | 86.3 | 56.7 | | 61.5 | 30 | 33.3 | 87.8 |
| Physical restraints should never be used to enable staff to leave the patient. | 71.7 | 4.75 ± 0.71 | 5 (2) | 61.6 | 90 | 72.7 | 84.6 | 80 | 100 | 65.8 |
| Bed bike | 70 | 3.88±0.92 | 4(2) | 50 | 81.3 | 50 | 66.7 | 71.4 | 100 | 71 |
| Rocking Chair | 55 | 3.45±1.21 | 4(1) | 36.4 | 65 | 50 | 100 | 0 | 100 | 47.1 |
| Allocation of the same staff | 73.4 | 3.88±1.55 | 4.5(2) | 66.2 | 97.4 | 100 | 100 | 100 | 83.3 | 60.3 |
| Clearly displayed names and/or photographs | 75 | 4.05±1.01 | 4(2) | 82.7 | 59.3 | 100 | 70 | 62.5 | 33.3 | 76 |
| Therapeutic weighted blanket | 83 | 3.98±0.86 | 4(0.5) | 73.3 | 91.4 | 100 | 100 | 71.4 | 100 | 78 |
| Basal Stimulation | 83 | 4.13±0.87 | 4(1) | 74.2 | 90.6 | 100 | 75 | 66.7 | 100 | 81.4 |
| Trauma informed care | 82.9 | 4.27±0.87 | 4(1) | 93.5 | 50 | 100 | 75 | 50 | 100 | 85.5 |
| Access to a spiritual/pastoral care person | 72.3 | 4.03±0.90 | 4(1) | 75.9 | 64 | 80 | 90.9 | 44.4 | 60 | 72.9 |

| Recommendations | All participants | | | Countries | | Stakeholder Groups | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Australia (n=74) | Denmark (n=40) | Patient/family (n=11) | Allied Health (incl 1 chaplain) (n=13) | Physician (n=10) | Researcher (n=6) | Nurse (incl 2 NUMs) (n=72) |
| | Consensus (%) | Mean (± SD) | Median (IQR) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) | Consensus (%) |
| Diary | 75 | 4.08±0.76 | 4(1) | 74.4 | 75.9 | 90.9 | 71.4 | 57.1 | 40 | 78.6 |
| "Gentle Violence Prevention" | 63 | 3.89±0.94 | 4(2) | 54.5 | 74.4 | 100 | 100 | 0 | 0 | 60 |
| BBAUM approach | 60 | 3.88±1.01 | 4(2) | 60 | 60 | 80 | 100 | 33.3 | 0 | 56.3 |
| Relaxing breathing | 67 | 3.70±0.95 | 4(1) | 73 | 53.3 | 85.7 | 66.7 | 55.6 | 60 | 66.7 |
| Sing or hum | 63 | 3.63±0.96 | 4(1) | 66.7 | 60.4 | 71.4 | 60 | 50 | 75 | 62.7 |
| The same staff should care for the same patient | 77.4 | 3.92±1.28 | 4(1) | 66.2 | 97.4 | 90 | 92.3 | 100 | 100 | 68.1 |

* n=total sample of stakeholders involved in the first Delphi round. Not all would have experience with an intervention, meaning this total sample does not reflect how many answered each individual question. Contact the primary author for more details.

** Questions not asked patients and family members,

NUM Nurse Unit Manager, SD standard deviation, IQR interquartile range,

# Appendix 47 Recommendations ranked for importance

**Recommendations ranked of importance according to the mean score**

| Recommendation | Importance | Rank |
|---|---|---|
| Clinicians should identify and, when possible, treat causes of agitation. | 4.98 | 1 |
| Non-drug approaches for the prevention of agitation should be an integrated part of standard care. | 4.95 | 2 |
| Use hearing aids in the hearing impaired patient. | 4.93 | 3 |
| Minimise interruptions at night from noise, light and activities. | 4.92 | 4 |
| Non-drug approaches should be considered first when managing agitation | 4.91 | 5 |
| Ensure patient dignity. | 4.9 | 6 |
| Use visual aids in the vision-impaired patient. | 4.89 | 7 |
| Clinical staff should check that aggressive and violent agitated patients do not have access to objects that can be used to injure others (e.g. sharp objects, weapons, hard objects that can be thrown). | 4.89 | 8 |
| Intensive care units should have clear guidelines for the use of physical restraints. Physical restraints mean any manually applied method that reduces a patient's ability to move freely. | 4.89 | 9 |
| Clinicians caring for and treating agitated patients should always have access to immediate practical support. | 4.88 | 10 |
| Use clear and concise language. | 4.86 | 11 |
| Develop a relationship with the patient based on empathy, respect and trust. | 4.86 | 12 |
| Clinicians should support patients' fundamental care needs to reduce and manage agitation. | 4.85 | 13 |
| The safety of patients, staff and family/next of kin should be given high priority when managing agitation. | 4.84 | 14 |
| Clinicians should be trained to use de-escalation techniques. De-escalation involves verbal and non-verbal techniques to calm down a patient. | 4.84 | 15 |
| Support capable patients to be physically active (e.g. by supporting patients to sit on the edge of the bed or take small walks) | 4.83 | 16 |
| Additional staffing should be considered when there is an agitated patient in the ICU | 4.82 | 17 |
| The multi-disciplinary team should collaborate to reduce and manage patient agitation. | 4.79 | 18 |
| Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift. | 4.79 | 19 |
| ICU patients should be regularly and systematically assessed for agitation | 4.78 | 20 |
| Group care and treatment activities, rather than disturbing the patient several times. | 4.78 | 21 |
| Physical restraints should not be used as a substitute for direct observation. | 4.77 | 22 |
| Minimise unnecessary stimuli. Stimuli can be auditory (e.g. sounds), visual (e.g. lights, moving objects), tactile (e.g. lines, equipment), social (e.g. interacting people) etc | 4.77 | 23 |
| Preserve patients' usual sleep-wake cycle. | 4.77 | 24 |
| Use "active listening". Active listening means listening carefully and demonstrating an interest in what a person has to say. | 4.76 | 25 |
| The intensive care unit should be laid out in a way that makes observing agitated patients easier. | 4.76 | 26 |
| Non-drug interventions must be adjusted to the individual patient (e.g. patient needs, history and preferences, level of agitation, previous experiences with interventions). | 4.75 | 27 |
| Reassure the patient that they are safe. | 4.75 | 28 |
| Use appropriate lighting adjusted according to the time of the day. | 4.75 | 29 |
| Clinicians should consider keeping a safe physical distance from a violent patient. | 4.75 | 30 |
| Clinicians should offer family members information about agitation | 4.73 | 31 |
| Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation | 4.72 | 32 |

1

| | | |
|---|---|---|
| Have a clock and calendar visible to the patient. | 4.7 | 33 |
| Use alternative communication methods. Alternative communication methods may include pen and paper, boards with icons and pictures, alphabet boards, computer communication systems. | 4.69 | 34 |
| Become familiar with the patient's background (e.g. likes, dislikes, culture, history, values, fears and routines). | 4.68 | 35 |
| Ensure comfortable surroundings (i.e. by optimising room temperature, ventilation and/or design)? | 4.67 | 36 |
| Ongoing staff education about agitation and methods to reduce agitation should be provided. | 4.66 | 37 |
| Offer quiet surroundings for the patient, for example a single bed room. | 4.66 | 38 |
| Respect patients' need for personal space. | 4.64 | 39 |
| Irrespective of how much the patient appears to understand, explain to them their circumstances. | 4.6 | 40 |
| Clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients (e.g., avoid unnecessary glucose monitoring, endotracheal suctioning, neurological checks). | 4.6 | 41 |
| Inform the patient about the plan for the day. | 4.56 | 42 |
| Clinicians should consider using several non-drug strategies for agitated patients simultaneously. | 4.55 | 43 |
| Involve patients in personal care activities. | 4.55 | 44 |
| Clinicians should use physical restraints only as a last resort to ensure patient and staff safety. Physical restraints mean any manually applied method that reduces a patient's ability to move freely. | 4.55 | 45 |
| Develop care plans based on patient preferences and values. | 4.53 | 46 |
| Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation | 4.52 | 47 |
| Create familiar surroundings (e.g. with pictures or other items from the patient's home). | 4.5 | 48 |
| Staff caring for agitated patients should be offered debriefing. | 4.5 | 49 |
| Use telephone and/or video conferencing when family members/next of kin are unable to visit the patient in person. | 4.47 | 50 |
| Debrief the capable patient after an episode of agitation. | 4.46 | 51 |
| Teach family members/next of kin to use non-drug strategies. | 4.44 | 52 |
| Take the patient outdoors. | 4.37 | 53 |
| Use mental stimulation. Mental stimulation can involve activating the patient with Lego, jigsaws, radio, TV, internet, magazines, pictures etc | 4.36 | 54 |
| Involve family members/next of kin in care. | 4.31 | 55 |
| Use therapeutic touch. Therapeutic touch means using hands to touch and calm a patient. | 4.26 | 56 |
| Use a personalised fixed daily schedule with familiar activities. | 4.24 | 57 |
| Hold a patient's hand. | 4.23 | 58 |
| Play classical or relaxing music, preferably adjusted to patient preferences. | 4.2 | 59 |
| Use pet therapy. Pet therapy involves an animal, often a dog or cat, visiting the patient in the intensive care unit | 4.14 | 60 |
| Offer a fidget toy. A fidget toy is an object designed to be touched, squeezed or pulled to keep restless hands occupied. | 4.09 | 61 |
| Use neuropaedagogy. Neuropaedagogy builds on knowledge of how the brain works and focuses on patient strengths rather than weaknesses | 4.05 | 62 |
| Involve a psychologist or psychiatrist in the treatment plan. | 3.96 | 63 |

# Appendix 48 Feasibility of recommendations

**Feasibility of recommendations**

| Recommendation | Somewhat feasible | | Very feasible | | Total rating item | Total rating somewhat or very | | M | Md | SD | IQR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Count | Percentage | Count | Percentage | Count | Percentage | Count | | | | |
| ICU patients should be regularly and systematically assessed for agitation. | 19 | 21.6% | 69 | 78.4% | 88 | 100% | 88 | 4.78 | 5 | 0.414 | 0 |
| Clinicians should identify | 30 | 33.7% | 57 | 64.0% | 89 | 98% | 87 | 4.62 | 5 | 0.533 | 1 |
| Non-drug approaches should be considered first | 31 | 35.2% | 50 | 56.8% | 88 | 92% | 81 | 4.48 | 5 | 0.678 | 1 |
| Non-drug standard care. | 30 | 34.1% | 56 | 63.6% | 88 | 98% | 86 | 4.61 | 5 | 0.535 | 1 |
| Clinicians should support patients' fundamental care needs | 37 | 42.0% | 47 | 53.4% | 88 | 95% | 84 | 4.47 | 5 | 0.66 | 1 |
| The multi-disciplinary team should collaborate to reduce and manage patient agitation. | 34 | 38.2% | 54 | 60.7% | 89 | 99% | 88 | 4.6 | 5 | 0.516 | 1 |
| Nursing and medical leaders should support the use of non-drug interventions | 36 | 41.4% | 50 | 57.5% | 87 | 99% | 86 | 4.55 | 5 | 0.566 | 1 |
| Additional staffing should be considered when there is an agitated patient in the ICU | 39 | 44.3% | 17 | 19.3% | 88 | 64% | 56 | 3.5 | 4 | 1.184 | 2 |
| Staff caring for agitated patients should be offered debriefing. | 43 | 49.4% | 26 | 29.9% | 87 | 79% | 69 | 3.94 | 4 | 1.004 | 1 |
| frequent breaks during their shift | 39 | 44.3% | 14 | 15.9% | 88 | 60% | 53 | 3.48 | 4 | 1.104 | 1.75 |
| Ongoing staff education | 35 | 39.3% | 43 | 48.3% | 89 | 88% | 78 | 4.33 | 4 | 0.78 | 1 |
| safety of patients, staff and family/next of kin | 33 | 36.7% | 51 | 56.7% | 90 | 93% | 84 | 4.47 | 5 | 0.722 | 1 |
| keeping a safe physical distance from a violent patient. | 37 | 42.0% | 32 | 36.4% | 88 | 78% | 69 | 4 | 4 | 1.028 | 1 |
| ICU laid out in a way that makes observing agitated patients easier. | 37 | 41.1% | 21 | 23.3% | 90 | 64% | 58 | 3.63 | 4 | 1.136 | 1 |

| Recommendation | Somewhat feasible | | Very feasible | | Total rating item | Total rating somewhat or very | | M | Md | SD | IQR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Count | Percentage | Count | Percentage | Count | Percentage | Count | | | | |
| Clinicians caring for and treating agitated patients should always have access to immediate practical support. | 48 | 53.9% | 25 | 28.1% | 89 | 82% | 73 | 4.04 | 4 | 0.796 | 1 |
| Clinicians should be trained to use de-escalation | 48 | 54.5% | 33 | 37.5% | 88 | 92% | 81 | 4.25 | 4 | 0.747 | 1 |
| aggressive and violent agitated patients do not have access to objects | 24 | 27.3% | 59 | 67.0% | 88 | 94% | 83 | 4.6 | 5 | 0.635 | 1 |
| clear guidelines for the use of physical restraints. | 14 | 16.3% | 66 | 76.7% | 86 | 93% | 80 | 4.65 | 5 | 0.763 | 0 |
| physical restraints only as a last resort | 33 | 37.5% | 42 | 47.7% | 88 | 85% | 75 | 4.25 | 4 | 0.925 | 1 |
| Physical restraints should not be used as a substitute for direct observation. | 19 | 21.6% | 59 | 67.0% | 88 | 89% | 78 | 4.45 | 5 | 0.982 | 1 |
| several non-drug strategies for agitated patients simultaneously. | 34 | 37.8% | 46 | 51.1% | 90 | 89% | 80 | 4.37 | 5 | 0.771 | 1 |
| Minimise interruptions at night | 54 | 60.0% | 28 | 31.1% | 90 | 91% | 82 | 4.16 | 4 | 0.763 | 1 |
| Clinicians should minimise routine interventions | 48 | 53.3% | 35 | 38.9% | 90 | 92% | 83 | 4.27 | 4 | 0.731 | 1 |
| Offer quiet surroundings for the agitated patient | 43 | 47.8% | 32 | 35.6% | 90 | 83% | 75 | 4.06 | 4 | 0.976 | 1 |
| Group care and treatment activities, rather than disturbing the patient several times. | 47 | 52.2% | 36 | 40.0% | 90 | 92% | 83 | 4.26 | 4 | 0.787 | 1 |
| Respect patients' need for personal space. | 41 | 46.1% | 35 | 39.3% | 89 | 85% | 76 | 4.15 | 4 | 0.936 | 1 |
| Minimise unnecessary stimuli. | 48 | 54.5% | 22 | 25.0% | 88 | 80% | 70 | 3.93 | 4 | 0.894 | 0.75 |
| Preserve patients' usual sleep-wake cycle. | 58 | 64.4% | 14 | 15.6% | 90 | 80% | 72 | 3.79 | 4 | 0.942 | 0 |
| Support capable patients to be physically active | 43 | 47.8% | 40 | 44.4% | 90 | 92% | 83 | 4.34 | 4 | 0.69 | 1 |
| Inform the patient about the plan | 24 | 27.3% | 60 | 68.2% | 88 | 95% | 84 | 4.61 | 5 | 0.651 | 1 |

| Recommendation | Somewhat feasible | | Very feasible | | Total rating item | Total rating somewhat or very | | M | Md | SD | IQR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Count | Percentage | Count | Percentage | Count | Percentage | Count | | | | |
| Use a personalised fixed daily schedule with familiar activities. | 34 | 39.1% | 37 | 42.5% | 87 | 82% | 71 | 4.13 | 4 | 1.009 | 1 |
| explain to them their circumstances | 21 | 23.6% | 64 | 71.9% | 89 | 96% | 85 | 4.66 | 5 | 0.602 | 1 |
| Use appropriate lighting adjusted according to the time of the day. | 37 | 42.5% | 44 | 50.6% | 87 | 93% | 81 | 4.38 | 5 | 0.796 | 1 |
| clock and calendar visible | 23 | 25.8% | 61 | 68.5% | 89 | 94% | 84 | 4.58 | 5 | 0.736 | 1 |
| Develop a relationship with the patient based on empathy, respect and trust. | 32 | 36.0% | 55 | 61.8% | 89 | 98% | 87 | 4.58 | 5 | 0.58 | 1 |
| Become familiar with the patient's background | 37 | 41.6% | 47 | 52.8% | 89 | 94% | 84 | 4.46 | 5 | 0.641 | 1 |
| Ensure patient dignity. | 18 | 20.5% | 67 | 76.1% | 88 | 97% | 85 | 4.72 | 5 | 0.566 | 0 |
| Use therapeutic touch | 29 | 35.4% | 44 | 53.7% | 82 | 89% | 73 | 4.43 | 5 | 0.685 | 1 |
| Hold a patient's hand. | 32 | 36.0% | 52 | 58.4% | 89 | 94% | 84 | 4.53 | 5 | 0.605 | 1 |
| Reassure the patient that they are safe. | 14 | 15.7% | 74 | 83.1% | 89 | 99% | 88 | 4.82 | 5 | 0.415 | 0 |
| Create familiar surroundings | 33 | 37.5% | 50 | 56.8% | 88 | 94% | 83 | 4.5 | 5 | 0.643 | 1 |
| Involve patients in personal care activities. | 47 | 52.8% | 34 | 38.2% | 89 | 91% | 81 | 4.25 | 4 | 0.743 | 1 |
| Develop care plans based on patient preferences and values. | 35 | 41.7% | 39 | 46.4% | 84 | 88% | 74 | 4.3 | 4 | 0.818 | 1 |
| Debrief the capable patient | 40 | 47.6% | 31 | 36.9% | 84 | 85% | 71 | 4.17 | 4 | 0.804 | 1 |
| interventions must be adjusted to the individual patient | 40 | 45.5% | 43 | 48.9% | 88 | 94% | 83 | 4.42 | 4 | 0.638 | 1 |
| Involve a psychologist or psychiatrist | 30 | 38.0% | 10 | 12.7% | 79 | 51% | 40 | 3.23 | 4 | 1.176 | 2 |
| access to a Spiritual Support/Pastoral Care person. | 34 | 42.5% | 22 | 27.5% | 80 | 70% | 56 | 3.81 | 4 | 1.045 | 2 |
| Provide TIC | 16 | 41.0% | 9 | 23.1% | 39 | 64% | 25 | 3.69 | 4 | 1.055 | 1 |

| Recommendation | Somewhat feasible | | Very feasible | | Total rating item | Total rating somewhat or very | | M | Md | SD | IQR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Count | Percentage | Count | Percentage | Count | Percentage | Count | | | | |
| Keep a patient diary. | 27 | 38.0% | 21 | 29.6% | 71 | 68% | 48 | 3.75 | 4 | 1.13 | 2 |
| Use neuro pedagogy. | 14 | 38.9% | 12 | 33.3% | 36 | 72% | 26 | 4 | 4 | 0.894 | 2 |
| Use clear and concise language | 21 | 23.3% | 68 | 75.6% | 90 | 99% | 89 | 4.73 | 5 | 0.515 | 0.25 |
| Use "active listening". | 26 | 29.2% | 59 | 66.3% | 89 | 96% | 85 | 4.58 | 5 | 0.704 | 1 |
| Use hearing aids | 27 | 30.3% | 60 | 67.4% | 89 | 98% | 87 | 4.65 | 5 | 0.524 | 1 |
| Use visual aids | 24 | 27.0% | 65 | 73.0% | 89 | 100% | 89 | 4.73 | 5 | 0.446 | 1 |
| Alternative communication methods | 27 | 30.7% | 55 | 62.5% | 88 | 93% | 82 | 4.55 | 5 | 0.659 | 1 |
| Ensure comfortable surroundings | 36 | 40.4% | 29 | 32.6% | 89 | 73% | 65 | 3.92 | 4 | 1.014 | 2 |
| Mental stimulation | 37 | 43.0% | 32 | 37.2% | 86 | 80% | 69 | 4.1 | 4 | 0.882 | 1 |
| Offer a fidget toy | 28 | 35.4% | 30 | 38.0% | 79 | 73% | 58 | 3.99 | 4 | 1.044 | 2 |
| Play classical or relaxing music | 32 | 36.8% | 42 | 48.3% | 87 | 85% | 74 | 4.29 | 4 | 0.834 | 1 |
| Take the patient outdoors. | 46 | 52.3% | 16 | 18.2% | 88 | 70% | 62 | 3.65 | 4 | 1.073 | 1 |
| Pet therapy | 23 | 29.5% | 10 | 12.8% | 78 | 42% | 33 | 3.04 | 3 | 1.243 | 2 |
| Teach family members/next of kin to use non-drug strategies. | 49 | 55.7% | 21 | 23.9% | 88 | 80% | 70 | 3.99 | 4 | 0.78 | 0 |
| Use telephone and/or video conferencing | 51 | 58.6% | 26 | 29.9% | 87 | 89% | 77 | 4.15 | 4 | 0.708 | 1 |
| Offer family members information | 33 | 37.1% | 55 | 61.8% | 89 | 99% | 88 | 4.61 | 5 | 0.514 | 1 |
| Establish how much the family would like to and are able to be involved | 31 | 35.2% | 53 | 60.2% | 88 | 95% | 84 | 4.56 | 5 | 0.584 | 1 |
| Involve family members/next of kin in care. | 33 | 37.9% | 34 | 39.1% | 87 | 77% | 67 | 4.11 | 4 | 0.868 | 1 |

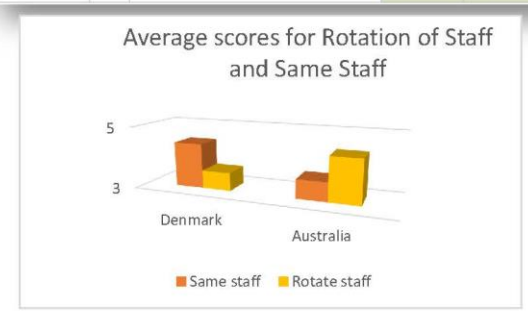
| | Somewhat feasible | | Very feasible | | Total | Somewhat or very | | M | Md | SD | IQR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Count | Row N % | Count | Row N % | Count | % | Count | | | | |
| Use "active listening". | 26 | 29.2% | 59 | 66.3% | 89 | 96% | 85 | 4.58 | 5 | 0.704 | 1 |
| Use hearing aids | 27 | 30.3% | 60 | 67.4% | 89 | 98% | 87 | 4.65 | 5 | 0.524 | 1 |
| Use visual aids | 24 | 27.0% | 65 | 73.0% | 89 | 100% | 89 | 4.73 | 5 | 0.446 | 1 |
| Alternative communication methods | 27 | 30.7% | 55 | 62.5% | 88 | 93% | 82 | 4.55 | 5 | 0.659 | 1 |
| Ensure comfortable surroundings | 36 | 40.4% | 29 | 32.6% | 89 | 73% | 65 | 3.92 | 4 | 1.014 | 2 |
| Mental stimulation | 37 | 43.0% | 32 | 37.2% | 86 | 80% | 69 | 4.1 | 4 | 0.882 | 1 |
| Offer a fidget toy | 28 | 35.4% | 30 | 38.0% | 79 | 73% | 58 | 3.99 | 4 | 1.044 | 2 |
| Play classical or relaxing music | 32 | 36.8% | 42 | 48.3% | 87 | 85% | 74 | 4.29 | 4 | 0.834 | 1 |
| Take the patient outdoors. | 46 | 52.3% | 16 | 18.2% | 88 | 70% | 62 | 3.65 | 4 | 1.073 | 1 |
| Pet therapy | 23 | 29.5% | 10 | 12.8% | 78 | 42% | 33 | 3.04 | 3 | 1.243 | 2 |
| Teach family members/next of kin to use non-drug strategies. | 49 | 55.7% | 21 | 23.9% | 88 | 80% | 70 | 3.99 | 4 | 0.78 | 0 |
| Use telephone and/or video conferencing | 51 | 58.6% | 26 | 29.9% | 87 | 89% | 77 | 4.15 | 4 | 0.708 | 1 |
| Offer family members information | 33 | 37.1% | 55 | 61.8% | 89 | 99% | 88 | 4.61 | 5 | 0.514 | 1 |
| Establish how much the family would like to and are able to be involved | 31 | 35.2% | 53 | 60.2% | 88 | 95% | 84 | 4.56 | 5 | 0.584 | 1 |
| Involve family members/next of kin in care. | 33 | 37.9% | 34 | 39.1% | 87 | 77% | 67 | 4.11 | 4 | 0.868 | 1 |

# Appendix 49 Joint Displays

| Meta-inference one: The provision of NPS to reduce agitation depends on the establishment of a trusting relationship and staff behaviours related to patient relational needs | |
|---|---|
| Phase one: Stakeholder Consultation | Stakeholders described the importance of developing a trusting relationship (by listening, showing respect, calm behaviours, empathy) with the patient (n=16/51) and knowing (likes, dislikes, culture, fears, history) the patient (n=12/51). Ensuring continuity of care (n=4) by allocating the same staff to look after the patient helped staff to know the patient and their needs and helped patients to feel safer. Rotation of staff to avoid burnout (n=5). |
| Phase two: Systematic Reviews | The systematic review of interventions of effectiveness did not identify any interventions that included a trusting relationship. Three guidelines outside the ICU described the importance of the relationship (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017). This was related to acknowledging patient suffering, being able to identify patient needs and collaborate with patients. The three qualitative systematic reviews all emphasised the importance of the relationship (Boehm et al., 2021; Fetters, Curry, & Creswell, 2013; Samantha Freeman, Yorke, & Dark, 2022; Gaete Ortega, Papathanassoglou, & Norris, 2020). A trusting relationship helped the patient through a frightening time and supported a need for human connection. Having the same staff was described as essential. The systematic review of effectiveness did not identify any interventions that considered staff behaviours. Guidelines from outside the ICU described how staff needed to consider their communication styles when attempting to reduce agitation. The non-threatening, empathetic, reassuring and clear language was described as important. Setting clear limits for acceptable behaviours was also described as important. The qualitative reviews emphasised the importance of effective communication and reassurance and mentioned alternative communication methods. |
| Phase three: Delphi | **Quantitative data:** |

**Table 48 Theme 4: Caregiver behaviours and developing trusting relationships**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Relationships | 4.1.1 | Develop a relationship with the patient based on empathy, respect and trust. | 95 | 98 | 99 (12) |
| | 4.1.2 | Become familiar with the patient's background (e.g., likes, dislikes, culture, history, values, fears and routines). | 99 | 94 | 98 (35) |
| Caregiver behaviours | 4.2.1 | Clinicians should be trained to use de-escalation techniques[b]. | 99 | 92 | 97 (15) |
| | 4.2.2 | Use clear and concise language. | 96 | 99 | 98 (11) |
| | 4.2.3 | Use "active listening". | 93 | 96 | 96 (25) |
| | 4.2.4 | Use alternative communication methods. | 95 | 93 | 94 (34) |

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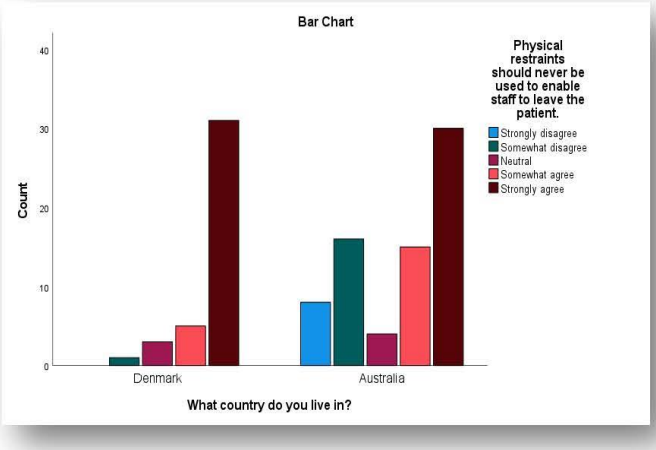



**Qualitative data**

NPS were more likely to work if patients trusted staff. Developing a trusting relationship required staff to acknowledge human suffering and humanise care in the ICU. Knowing the patient was a major category that helped staff to understand patient needs and triggers of agitation and provide individualised care. Agitation was described as complex, and patients reacted differently on different NPS.

> Building a rapport and a relationship based on trust, respect and kindness is absolutely fundamental to my role" (Australian nurse, ID 1082)

The qualitative data, from both Danish and Australian participants, described the importance of having the same staff to care for the patient to develop a trusting relationship and make patients feel safer.

> Allocation of same staff is very useful if the staff member shows personal empathy and connection. This provides a point of stability and continuity of care, giving reassurance to the patient (and the family), helping to reduce confusion, disorientation and agitation (Australian family, ID 1063)

However, there were also several arguments, Danish and Australian, for why staff should rotate. These were strongly linked to staff burnout and exhaustion.

> Dealing with an agitated patient can be very draining and if you have that patient for 12 hour shift it's very exhausting mentally and emotionally and the nurse is more likely to go for pharmacological options rather than non pharmacological options. Nurses should rotate after 6 hours for best patient outcomes (Australian nurse, ID 1028).

How staff behaved seem to have a major impact on patient agitation. Related to communication, staff needed to consider how they could approach patients in a non-threatening and respectful manner

> We can benefit from thinking about our communication style to these patients. I find that we don't always do this well (Danish nurse, ID 2013).

Related to reassurance, it was described how 'just being there' and showing care and compassion helped patients who felt alone and afraid.

> We often experience that agitated patients, if they are intubated, calm down and accept treatment if there is a person present with them all the time. Someone to hold their hand, calm them and explain what is going on (Danish physician ID 2033)

Explaining to the patient what were and were not acceptable behaviours was not seen as helpful. This was explained by patients often not understanding corrections due to confusion and not being able to change their behaviours due to the medical cause of their agitation.

> This recommendation risks adding guilt and shame to the patient over the agitated episode. Instead, health professionals should express acceptance and ability to accommodate the agitated behaviours (Danish researcher, ID 2031).

Related to physical restraints:

> Physical restraints should be a last resort, where psychiatrists are involved and where both pharmacological and nonpharmacological interventions are insufficient, and there is a risk of harm towards staff" (Danish nurse, ID 1022)
>
> Wrist restraints were very upsetting for my mother, who had had a stroke and was very confused (Australian family member, ID 1065)
>
> Sometimes due to staff breaks or needing two staff to check medications you may need [physical] restraints for safety (Australian nurse, ID 1054).

Meta-inference

Developing a trusting relationship in the ICU is about respecting the patient as a person, acknowledging the patient's suffering and getting to know the patient in order to provide individualised care. It is essential that patients do not feel threatened by staff but are met with care, acknowledgement, clear communication and empathy. When trusting relationships are established, staff are more likely to identify patient needs, patients are more likely to collaborate, and NPS are more likely to be effective. This study found that discontinuity of care and PR were two threats to the establishment of a trusting staff-patient relationships.

Meta-inference two: The provision of NPS to reduce agitation depends on engagement with family

Phase one: Stakeholder Consultation

Family presence and support (n=12), family participation in care (n=1), family information and training (n=4), family empowerment (n=3). Family can also hinder effective management of agitation (n=3).

Phase two: Systematic Reviews

Family involvement was not mentioned by the first systematic review of effectiveness of interventions in ICU, and only briefly mentioned in existing guidelines. However, all three qualitative reviews described the importance of involving the family who could provide protection, comfort, guidance and orientate the patient (Boehm et al., 2021; Samantha Freeman et al., 2022; Gaete Ortega et al., 2020). Family members could engage patients in a meaningful way, for instance, by bringing in familiar items, newspapers, cards or books (Boehm et al., 2021). Nurses could also encourage family members to be involved in personal hygiene, such as brushing the patient's hair or performing oral care (Boehm et al., 2021). Involving family members in clinical rounds and decision-making was seen as important (Boehm et al., 2021).

Phase three: Delphi

**Quantitative data:**

**Table 49 Theme 5: Family Involvement**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Communication with families | 5.1.1 | Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation | 89 | 95 | 97 (32) |
| | 5.1.2 | Clinicians should offer family members information about agitation | 98 | 99 | 95 (31) |
| Family in care | 5.2.1 | Teach family members/next of kin to use non-drug strategies. | 91 | 80 | 92 (52) |
| | 5.2.2 | Involve family members/next of kin in care. | 90 | 77 | 86 (55) |
| | 5.2.3 | Use telephone and/or video conferencing when family members/next of kin are unable to visit the patient in person. | 83 | 89 | 94 (50) |

**Qualitative data:**

Providing information to family is important.

> "Families can be incredibly traumatised by patient agitation. Offering education and information about it would help. Espically in written form so they can take it home and re read about it. I believe they should also be offered debriefing if needed" (Australian nurse, ID 1048).

Family knows the patient.

> "But if they had talked to my husband and asked what I was like as a person, then they would have known that I have difficulties with such things" (Danish patient, ID 2003)

Telephone and video conference useful when family is unable to come in

> "It is a good idea with telephone or video meetings with relatives. I experienced an episode where I was very sad and confused. I missed my husband and our children. It helped me to hear my husbands voice, even though it was just a few minutes. It was difficult for me to speak, but I just needed to hear his voice. It helped me a lot" (Danish patient, ID 2003)

There are also some important risks involved related to emotional wellbeing

> It's not always appropriate for families to be involved or see their family members so agitated. When helpful with a good outcome I definitely agree, however, not if there is an emotional risk to the family (Nurse Manager, ID 1057).

And feelings of guilt and stress

> It is easy to put undue stress on the family who may feel that they are 'letting the patient down' if they feel they can't do what is asked. This sort of guilt may resonate for a long time after the admission if not managed properly (Australian nurse, ID 1012)

> The family needed to be hyper vigilant, present 24/7 and ready to physically prevent my mother from tearing out her IV central line and feeding tubes or injuring herself (Australian family member, 1066).

Some participants described how family should not be involved in personal care activities, this came from Danish participants

> Generally, I would recommend that relatives are not included in the care, but have the primary purpose of being relatives when they are visiting (Danish physiotherapist, ID 2043).

> Culturally, we, in Denmark, do not have a tradition for involving relatives in personal care. This is related to the patient's dignity and integrity in the long term (Danish physiotherapist, ID 2029).

Meta-inference

It is crucial to always take into account the role of the family and their potential for involvement in care when aiming to reduce agitation. As ICU patients often cannot adequately express their needs, family members who know the individual patient's preferences and reactive behaviours are vital for identifying these needs. Families can also be helpful in calming an agitated patient. However, the family needs appropriate education about agitation and ways in which they can support their agitated loved one. Clinicians must also be equipped to facilitate appropriate family member input to prevent a paradoxical increase in patient agitation and family member feelings of stress and guilt.

| Meta-inference three: The provision of NPS to reduce agitation must consider of causes of agitation and patient needs | |
|---|---|
| Phase one: Stakeholder Consultation | Supporting patient physical needs was related to:<br>- Optimising comfort (related to elimination, mouthcare, hydration, nutrition, change of position) (n=18)<br>- Promoting sleep (n=16)<br>- Mobilisation (n=15)<br><br>Psychosocial needs were related to:<br>- The need to feel safe, respected and cared for.<br>- The need to cope, feel empowered and in control.<br>- The need to feel understood and to understand.<br>- The need for meaning and predictability.<br><br>Psychosocial need included familiar surroundings (n=5), patient involvement in care (n=3), patient information (n=1), communication tools (n=3), reorientation (n-13).<br><br>Need for stimulation was also emphasised for example including basal stimulation (n=4) and cognitive stimulation (n=4), music (n-11). |
| Phase two: Systematic Reviews | The systematic reviews of effectiveness included several studies focusing on patients' physical needs All interventions showed a significant effect, but our confidence in the results was very low. One guideline outside the ICU suggested supporting patient sleep. This was supported by the qualitative systematic reviews suggesting patients entered a vicious cycle of sleep deprivation and agitation. Three guidelines outside the ICU also emphasised the importance of comfortable surroundings (temperature, light, ventilation and colours) (Baldaçara et al., 2018; Garriga et al., 2016; Richmond et al., 2012).<br><br>The systematic review of effectiveness did not identify any interventions that considered psychosocial needs. Guidelines outside ICU suggested debriefing patients after episode of agitation (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017), orientating patients and providing explanations (Baldaçara et al., 2018; Richmond et al., 2012) and involving and empowering patients (Garriga, Pacchiarotti, Bernardo, & Vieta, 2017; Patel et al., 2018; Richmond et al., 2012; Vieta et al., 2017). One qualitative systematic reviews also described the importance of talking to patients about their episodes of agitation (Ortega, Papathanassoglou, & Norris, 2020), orientating patients (Gaete Ortega et al., 2020), involving patients in care due to their overwhelming sense of powerlessness and dependence (Boehm et al., 2021; Samantha Freeman et al., 2022; Gaete Ortega et al., 2020), using therapeutic touch to connect with patients (Samantha Freeman et al., 2022; Gaete Ortega et al., 2020) and finally to involve family as a way of calming and orientating patients (Boehm et al., 2021; Samantha Freeman et al., 2022; Gaete Ortega et al., 2020) |

Phase three: Delphi

**Quantitative data:**

**Table 50 Theme 6: Psychosocial Needs**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Help patients to feel safe | 6.1.1 | Reassure the patient that they are safe. | 94 | 99 | 96 (28) |
| | 6.1.2 | Hold a patient's hand. | 89 | 94 | 83 (58) |
| Empower the patient | 6.2.1 | Involve patients in personal care activities. | 92 | 91 | 95 (44) |
| | 6.2.2 | Debrief the capable patient after an episode of agitation. | 88 | 85 | 89 (51) |
| | 6.2.3 | Use neuropaedagogy[c]. | 82 | 72 | 69 (62) |
| | 6.2.4 | Involve a psychologist or psychiatrist in the treatment plan. | 77 | 51 | 70 (63) |
| | 6.2.5 | Respect patients' need for personal space. | 94 | 85 | 95 (39) |
| | 6.2.6 | Ensure patient dignity. | 99 | 97 | 99 (6) |
| Comfort and relaxation | 6.3.1 | Ensure comfortable surroundings (i.e. by optimising room temperature, ventilation and/or design). | 84 | 73 | 94 (36) |
| | 6.3.2 | Offer a fidget toy. | 83 | 73 | 74 (61) |
| | 6.3.3 | Play classical or relaxing music, preferably adjusted to patient preferences. | 89 | 85 | 84 (59) |
| | 6.3.4 | Take the patient outdoors. | 92 | 70 | 86 (53) |
| | 6.3.5 | Use pet therapy. | 86 | 42 | 78 (60) |
| | 6.3.6 | Use therapeutic touch. | 82 | 89 | 81 (56) |
| Re-orientation | 6.4.1 | Inform the patient about the plan for the day. | 88 | 95 | 95 (42) |
| | 6.4.2 | Use a personalised fixed daily schedule with familiar activities. | 89 | 82 | 87 (57) |
| | 6.4.3 | Irrespective of how much the patient appears to understand, explain to them their circumstances. | 95 | 96 | 94 (40) |
| | 6.4.4 | Use hearing aids in the hearing-impaired patient. | 100 | 98 | 99 (3) |
| | 6.4.5 | Use visual aids in the vision-impaired patient. | 97 | 100 | 98 (7) |
| | 6.4.6 | Use appropriate lighting adjusted according to the time of the day. | 97 | 93 | 98 (29) |
| | 6.4.7 | Create familiar surroundings (e.g. with pictures or other items from the patient's home). | 94 | 94 | 93 (48) |
| | 6.4.8 | Have a clock and calendar visible to the patient. | 93 | 94 | 98 (33) |

**Table 51 Theme 7: Physical Needs**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Mobilise patients | 7.1.1 | Support capable patients to be physically active (e.g. by supporting patients to sit on the edge of the bed or take small walks) | 99 | 92 | 99 (16) |
| Ensure the right level of stimuli | 7.2.1 | Minimise unnecessary stimuli[b]. | 97 | 80 | 98 (23) |
| | 7.2.2 | Group care and treatment activities, rather than disturbing the patient several times. | 96 | 92 | 97 (21) |
| | 7.2.3 | Clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients (stimuli can be auditory, e.g. sounds, visual, e.g. lights or moving objects, tactile, e.g. lines of equipment, social, e.g. interacting with people) | 87 | 92 | 90 (41) |
| | 7.2.4 | Offer quiet surroundings for the patient, for example a single bed room. | 95 | 83 | 95 (38) |
| | 7.2.5 | Use mental stimulation such as Lego, jigsaws, radio, TV, internet, magazines, pictures[c] | 88 | 80 | 85 (54) |
| Promote sleep | 7.3.1 | Preserve patients' usual sleep-wake cycle[b]. | 98 | 80 | 97 (24) |
| | 7.3.2 | Minimise interruptions at night from noise, light and activities. | 100 | 91 | 100 (4) |

**Qualitaitve data:**

Physical activity was seen as important for sleep, comfort and self-awareness.

> "Movement wherever possible is "critical". It provides a small sense of self control and patient contribution to a patient's experience in ICU. Being left to

lie in bed without any attempts to assist movements can make patients feel frustrated and controlled, increasing agitation" (Australian Family, ID 1063).

Minimising stimuli was important for sleep and relaxation.

> There should be a major focus on maintaining a circadian rhythm with activities during the day and (preferably) sleep at night. It's hard to implement but is really good when it works (Danish researcher, ID 1033)

Several interventions aiming to increase patient comfort reached agreement.

> Take them out to an open space and get some sun exposure during the morning will help improve their mood and somehow calm patients down and improve their behaviours". (Australian nurse, ID 1044)

Mental stimulation was also seen as important, as long as this did not irritate or hyper stimulate a patient leading to agitation. Sensory deficits can make patients disorientated and agitated. Reorientating patients calm them down:

> Schedules, clocks, lighting adjusted to time of day are all things which provide balance, rhythm and stability to a patient when everything else is out of their control, and sometimes also understanding. Being told the plan for the day (having it written somewhere for the patient (and family) to see provides reassurance and a sense of control/ understanding regarding their care, helping to reduce frustration and agitation (Australian family member, ID 1063)

> From my experience staff can't provide too much information or too many explanations. If staff had informed me better I would have avoided all the frustrations/agitation I experienced (Danish patient, ID 2003)

Involving patients in their care through different means can be helpful. For example involving a psychologist or psychiatrist:

> Ideally we should have psychology services available to these patients, because very often we see untreated mental illness or poorly supported neurodiversity as being a key reason for their situation in ICU. Psychology services could help to provide these patients with key tools to get them through their stay in ICU and hospital, without escalating agitation and the consequences of these incidents (physically restraining the patient, forcibly injecting them) and related trauma (Australian nurse, ID 1082)

| | |
|---|---|
| Meta-inference | Care must consider patients' unique needs when attempting to prevent, minimise or manage agitation. This meta-inference is closely related to identifying causes of agitation, as these are often related to unmet psychosocial or physical (incl biomedical) needs. |

| Meta-inference four: The provision of NPS to reduce agitation depends on the ICU culture and staff support. | |
|---|---|
| Phase one: Stakeholder Consultation | Adequate resources (n=7), supportive leadership n=2), multidisciplinary collaboration (n=4), education of staff (n=6), emotional support of staff (n=2).<br>An outcome they wanted to see was increased staff confidence in managing agitation. Rotation of staff to avoid burnout. |
| Phase two: Systematic Reviews | The systematic review of interventions of effectiveness did not identify any articles related to the context. The guidelines outside the ICU suggested debriefing staff (Baldaçara et al., 2018; Richmond et al., 2012; Vieta et al., 2017), ensuring adequate staff (Richmond et al., 2012; Vieta et al., 2017), training staff (Baldaçara et al., 2018; Garriga et al., 2016; Luauté, Plantier, Wiart, & Tell, 2016; Richmond et al., 2012) and promoting interdisciplinary collaboration (Baldaçara et al., 2018; Luauté et al., 2016; Patel et al., 2018; Richmond et al., 2012). Safety should be of high priority (Baldaçara et al., 2018; Garriga et al., 2016). |

One ICU guideline emphasised the importance of one to one nursing (Whitehouse et al., 2014).

One qualitative systematic review supported staff education about agitation in the ICU (Samantha Freeman et al., 2022).

Phase three: Delphi

**Quantitative data:**

**Table 53 Theme 9: Interventions related to the context**

| Category | Item | Recommendation | Consensus[a] | Feasibility[d] | Importance[e] (ranked) |
|---|---|---|---|---|---|
| Staff support | 9.1.1 | Additional staffing should be considered when there is an agitated patient in the ICU. | 95 | 64 | 96 (17) |
| | 9.1.2 | Staff caring for agitated patients should be offered debriefing. | 86 | 79 | 89 (51) |
| | 9.1.3 | Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift[b]. | 99 | 60 | 94 (19) |
| | 9.1.4 | Ongoing staff education about agitation and methods to reduce agitation should be provided. | 98 | 88 | 97 (37) |
| Leadership support | 9.2.1 | Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation. | 93 | 99 | 98 (47) |
| Multidisciplinary team collaboration | 9.3.1 | The multi-disciplinary team should collaborate to reduce and manage patient agitation. | 99 | 99 | 100 (18) |

**Qualitative data**

Related to resources:

> Staffing ratios are perhaps the most important aspect of management as without adequate staffing, there is no ability to deliver nonpharmacological interventions. (Australian physician, ID 1052)
>
> It is very physically and mentally draining to care for a hyperactive delirious patient and one's energy and strength quickly gets depleted. Breaks and perhaps change of staff is important (Danish nurse, ID 2018).

Aggressive patients and staff safety

> I have had a patient wake from cardiac surgery, we did not know the past history. The patient ripped drains from self. Attacked staff and other patients with carving knife. Then escaped the unit (Australian nurse, ID 1027)

Patient centred care and/or staff wellbeing

> Depends on staffing levels at hospital and whether or not frequent breaks would result in the patient being left alone - as was the case for my mother when she was in ICU. (Australian Family, ID 1066)

Effectivity and/or safety

> Sometimes bedside staff are just kept told you just need to manage even though the patient behaviour is escalating to an unsafe point (Australian nurse, ID 1019)

Related to prioritisation

> My personal experience in regard to this recommendation is that bad or junior nurses are allocated the confused/agitated ICU patient when in reality it should be the most senior nurse caring for these patients as they have a myriad of care planning capabilities (nurse manager, ID 1040)
>
> Perhaps because the delirious and agitated patient is not interesting to ICU nurses. They want the ECMO [extracorporeal membrane oxygenation], the sick ventilated patient with a TOF [assessment of neuromuscular block] of 0 or the tamponade post CABG [coronary artery bypass graft] x4 that requires a chest reopening. From the perspective of the manager, this is ever prevalent

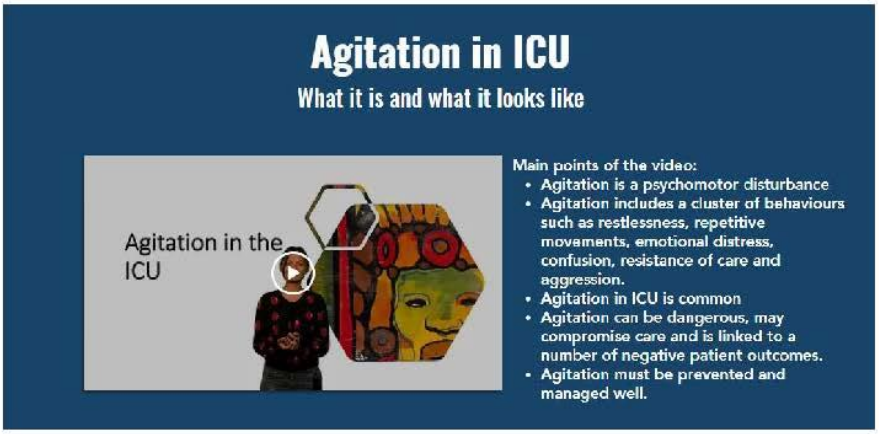
# Appendix 50 A webpage in two languages

## A webpage developed for stakeholders

Navigation panel with an opportunity to choose either Danish or English:


Multiple videos, including an introduction to the topic:


Description of what agitation is:



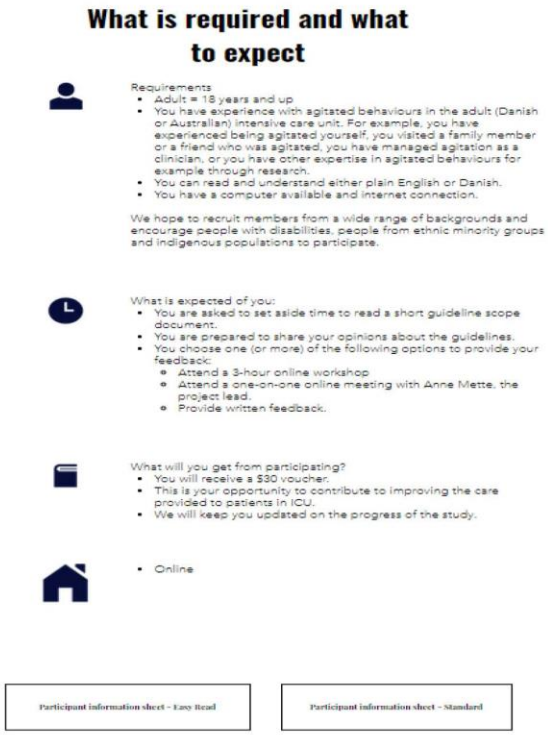
**Everything translated into Danish:**


**A geographical overview of where the primary researcher is situated, opportunities to get in contact with the researchers and an overview of affiliations:**


The primary investigator is the recipient of an Australian Government Research Training Program Scholarship and is a Flinders University-Aalborg University Inaugural Erik Elgaard Sørensen PhD scholar.

This project is supported by a research seeding grant from the Australian College of Critical Care Nurses (ACCCN)

**Information about the purpose of the research and what it means to be involved :**



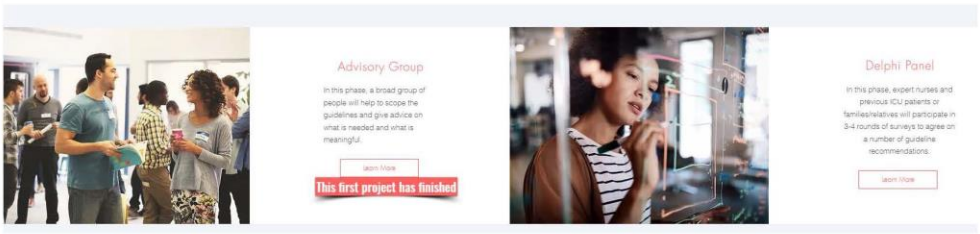


Registration into Workshops


Participant information sheet – Easy Read

Participant information sheet – Standard

**An opportunity to register interest online:**




**Information about Ethics:**


**Getting to know the researchers:**

## Meet Our Research Team

**Anne Mette Adams**

Principle Investigator

Anne Mette is a PhD candidate and lecturer at Flinders University in South Australia. She is a critical care nurse and has worked with critically ill patients in Denmark, Australia and Norway on healthcare settings.

Read more here

**Tiffany Conroy**

Professor

Tiffany is the Deputy Dean for Nursing Leadership and Innovation and the Academic Lead for Nursing in the College of Nursing and Health Sciences at Flinders University. She is a registered nurse and an experienced educator in nursing, knowledge translation, evidence-based healthcare, and systematic reviews.

Read more here

**Diane Chamberlain**

Professor

Diane is the Dean of Graduate Research at Flinders University. She is also the coordinator and educational designer of Postgraduate Acute Care and Critical Care Topics at Flinders University.

Read more here

**Mette Grønkjær**

Professor

Mette is the Head of Research at the Clinical Nursing Research Unit, Aalborg University Hospital. Department of Clinical Medicine, Aalborg University.

Read more here

**Charlotte Brun Thorup**

Postdoctoral Researcher

Charlotte holds a postdoctoral position in clinical nursing at Aalborg University Hospital.

An overview of publications:

## Publications

This page will be updated as we publish our findings.

**Our first publication is out!**

Click here to access the article. If the link does not work for you, please contact Anne Watts, and she will forward you the article.

**A systematic review and meta-analysis on the evidence of nonpharmacological interventions for agitation in ICU**

Click here to access the article. If the link does not work for you, please contact Anne Watts, and she will forward you the article.

**A methodology paper on stakeholder engagement**

Click here to access the article. If the link does not work for you, please contact Anne Watts, and she will forward you the article.

**A page only for Delphi study participants:**

# Delphi Study

## - feedback and instructions for participants

This page is developed for our Delphi participants. Below you will find information that will support you when filling out the Delphi round surveys.

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### Results from the first Delphi Round and instructions for the second Delphi round.

In this video Anne Mette gives an overview of the three Delphi rounds and gives a brief description of our findings so far. This presentation also describes the aim of the second Delhi round.

### Results from the second Delphi Round and instructions for the third and last Delphi round.

**News and Updates:**