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Design and Development of a Motivational Conversational Agent for Brain Injury Rehabilitation

By

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Contents

List of Figures

List of Tables

Summary

Adults with traumatic brain injury (TBI) can experience many symptoms including functional impairments, decreased memory, and low motivation. Recovery following TBI is possible due to the physiological mechanism of neuroplasticity – in which the brain is able to form new neuronal connections in response to rehabilitative training. Rehabilitation following TBI is supported through multi-disciplinary rehabilitation, in which client-centred goals are set and then pursued. However, rehabilitation care is time limited. Novel care approaches which leverage service provision and are motivational for clients, are needed.

Conversational Agents (CAs) provide a personal, human-computer conversation interface and can be designed to engage the user in a focused task with motivational content. Specific motivational behaviour change approaches can be applied to CA design: Motivational Interviewing (MI) has been integrated into CAs for users without cognitive impairment; and Self-Determination Theory (SDT) has been recommended for human-centred design for digital technologies including CAs. Additionally, both MI and SDT have been recommended for brain injury rehabilitation.

This thesis outlines the development of a motivational embodied CA (ECA) for brain injury rehabilitation. This type of ECA for this purpose has not previously been developed. Key considerations for developing the ECA were: addressing the clinical needs of clients with TBI: contextualizing the ECA to the clinical setting, and incorporating SDT and MI within the conversation dialogues. Living Laboratory design methodology was utilised for this project: including co-design with clinicians and clients and testing of the ECA in the real-life setting (two ambulatory care clinics, and the client's home environment).

The three phases of development of the ECA – called RehabChat – were conducted to optimise the feasibility and acceptability of this ECA. The phases were in-house development and testing, co-design workshops, and a mixed methods feasibility pilot trial. The initial ECA prototype was developed in-house, and then tested. Testing incorporated alpha testing to check thoroughly for glitches as well as general usability; and beta testing to detect any glitches and appraise usability more closely. For the co-design workshops and the feasibility pilot trial, full ethics approval was gained, and clients and clinicians of the collaborating clinics were recruited.

The co-design workshops comprised three cohorts (current clients, discharged clients and clinicians) and four rounds of co-design workshops. Separate meetings were conducted for each cohort for the first three rounds of meetings, followed by one final fourth workshop meeting comprising all cohorts. Iterative changes were made to the ECA during these workshops. The ECA was then thoroughly checked by completing second alpha testing. The refined stable model ECA was then used in the feasibility pilot trial.

For the mixed methods feasibility pilot trial, client-clinician dyads completed a two-week intervention using RehabChat alongside usual rehabilitation care. As well, clinician-participants, for whom no clients could be recruited, participated in a mock client-clinician session to use the ECA and then provide feedback. Results which revealed that participants thought RehabChat was motivational and that it was easy to use alongside usual care, are discussed and recommendations for future research and development of RehabChat are presented.

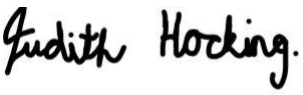
DECLARATION

I certify that this thesis:

1. does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university

2. and the research within will not be submitted for any other future degree or diploma without the permission of Flinders University; and

3. to the best of my knowledge and belief, does not contain any material previously published or written by another person except where due reference is made in the text.

Signed: 

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These acknowledgements include an initial statement of gratitude to people who have supported me personally during my PhD journey, followed by details for the very helpful input received from a number of people which enabled my PhD to be conducted.

Firstly, I am very grateful to my immediate and extended family members who provided encouragement, humour, and, particularly in the final months, reminders that I could indeed finish this PhD and that in fact it was very worthwhile to do so. I am also very appreciative of good friends and colleagues checking in on my progress and saying 'hi' at regular points during my candidature.

Secondly, there are a number of people who provided essential and invaluable input for my PhD, and to whom I am very thankful, as presented hereafter.

I am delighted to thank the four supervisors for my PhD, each of whom is mentioned below along with highlights of their supervision.

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- Prof Anthony Maeder as principal supervisor for just over the first half of my candidature (now adjunct supervisor), for providing guidance on considerations for designing a novel digital health tool; advising on synthesizing the disparate literature domains of conversational agents (CAs), positive behaviour change, and brain injury rehabilitation; and co-authoring two publications and one submitted manuscript.
- Prof David Powers as associate supervisor, for expert perspectives on how to prioritise what to include in the CA's design in reference to the literature, the software's capabilities, and to participant feedback; for trouble-shooting technical issues; and assistance in completing changes to the CA's customised style sheet (CSS).
- Dr Lua Perimal-Lewis as associate supervisor, for coaching me in the use of Living Laboratory methodology generally, and for its specific application to the clinical context of brain injury rehabilitation and designing a CA to be used alongside usual care; and advising on auditing and testing approaches for the CA.

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- Dr Maggie Killington (Research Co-ordinator, South Australian Brain Injury Rehabilitation Services (SABIRS)) for organising stakeholder consultation to confirm the relevance and acceptance of the project for the clinical setting; advising on contextualisation of the project for the ambulatory rehabilitation settings; and for being a co-investigator and site-contact person for both the co-design workshops and the feasibility pilot trial projects.
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Publications arising from this PhD

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- Hocking J, Maeder A. Motivational Embodied Conversational Agent for Brain Injury Rehabilitation. In: Maeder A, Higa C, van den Berg M, Gough C, editors. Ebook: Telehealth Innovations in Remote Healthcare Services Delivery Global TeleHealth 2021; 277:37-46.
- Hocking J, Oster C, Maeder A. Use of conversational agents in rehabilitation following brain injury, disease, or stroke: a scoping review protocol. JBI Evid Synth. 2021;19(6):1369-1381.

Submitted manuscript currently under review by journal:

- Hocking J, Oster C, Maeder A, Lange B. The use of conversational agents in rehabilitation following brain injury, disease, or stroke: a scoping review. 48 pages. Submitted to JBI Evidence Synthesis journal https://journals.lww.com/jbisrir/pages/default.aspx on 27-1-22.

Conference presentations

- Australian-Japan Joint Neurodegenerative Disease Symposium, Jun 2019. Presentation
    - https://flinders-my.sharepoint.com/:b:/g/personal/hock0136_flinders_edu_au/EQDu8CZq1kBJvuKW-bX3L9QBDiI_eNTk-ikK3yOleNcrAw?e=eIkkNO

- Australian Physiotherapy Association Conference, Oct 2019 – TRANSFORM 2019. Presentation
    - https://flinders-my.sharepoint.com/:u:/g/personal/hock0136_flinders_edu_au/EXaCT5R0ontLqiKGHwYVSfwBA-kOGPLXVX5qblB0S7qI1Q?e=iqB10e

- G-I-N & JBI (Guidelines International Network & Joanna Briggs Institute) Conference, Oct-Nov 2019 – Trustworthy evidence for questions that matter. Presentation
    - https://flinders-my.sharepoint.com/:u:/g/personal/hock0136_flinders_edu_au/EWOjNtC5C8FIu5doC-X_M1UBErYq3ZBoqLZuT1BbpeOC2Q?e=5IDStl

- Australian Institute of Digital Health: Emerging SA talent presentation, Sep 2020. Presentation.
    - https://flinders-my.sharepoint.com/:b:/g/personal/hock0136_flinders_edu_au/Ef-w_DD4uIhGvCxjuiKaYsQBTw4yvx9vZVk6OVql4kEecg?e=PhGIqH

- Australian Living Laboratory Innovation Network (ALLIN) conference Feb 2021 – 'Living Labs- the Human Heart of innovation; building back better. Co-presentation
    - https://flinders-my.sharepoint.com/:w:/g/personal/hock0136_flinders_edu_au/EVii7ZgWg3VGvTp4KwmnAa0BmG-0UZymIvO1wcDTZwG1nQ?e=GUoP2y

- Australian Research Council Industrial Transformation Research Hub for Digital Enhanced Living PhD Student Symposiums, Dec 2019 and Sep 2021: presentations for both
- Flinders University DocFest, Aug 2019. Poster

Personal perspectives statement

It is necessary to present my personal perspectives relevant to this project due to the qualitative aspects of this research. My previous work experience as a physiotherapist, and my current and previous studies have helped form my perspectives regarding motivation and digital health interventions for brain injury rehabilitation. The risk of any unintended bias that may occur due to my pre-conceived views on this project's topic and purpose have been countered by the rigorous way that the methodology for this project has been constructed. My personal perspectives are outlined below.

I have over 20 years' experience working as a physiotherapist. Much of this work has involved working with clients with brain injury and/or cognitive impairment. I have previously worked as a Senior Physiotherapist and Senior Clinical Educator at the South Australian Brain Injury Rehabilitation Services SABIRS. Through my previous work at SABIRS, I gained experience providing therapy for clients with moderate-severe traumatic brain injury (TBI) and other types of acquired brain injury (ABI) within an interdisciplinary team setting. During my work, I attended training for Motivational Interviewing (MI), and learnt that I would need to modify the approach of MI to suit the cognitive needs of the clients. I used simplified MI approaches in my clinical work, and with this found that even for clients with severe memory or concentration challenges, the clients were able to identify a personally meaningful goal that helped to motivate them in their rehabilitation sessions, and then focus on this more readily during therapy appointments. Additionally, I found that if I used the client's words for describing their goal during subsequent therapy sessions, the client was able to engage in the rehabilitation processes more readily. From this, I have developed a positivist view of the potential benefits of supporting motivation for clients with ABI including TBI: that supporting motivation in these clients will improve their recovery in one or more domains.

In my readings and learning as a PhD candidate, I found literature reporting research findings or expert opinions that confirmed my personal perspectives. Additionally, although motivational support as a means to improving rehabilitation recovery is a small field of research, it is nonetheless based upon sound theoretical paradigms, and has revealed no safety issues. Thus, it appears safe to pursue. My previous Honours and Master's degrees focussed upon intellectual disability. This provided me with insight into the health challenges and unique needs of this cohort, of which the principles can be applied to other clinical cohorts of clients with cognitive needs, such as adults with TBI.

Below are key topics I have clarified during my PhD:

- motivation to participate in rehabilitation is higher if the client is given opportunity to express what is their important goal to work towards in their rehabilitation

- it is important to use the client's wording of their goal, because it likely represents the client's cognitive and language abilities to form the goal, as well as the client's intrinsic motivation attaching meaningfulness to the goal
- client-centred approaches – such as Motivational Interviewing and Self-Determination Theory – are relevant for TBI rehabilitation.

Given my positivist approach, and the careful methodology utilised in my PhD, I expected that results of my research would provide comprehensive feedback for developing RehabChat into a tool that was feasible, usable and acceptable to clients and clinicians; as well as providing 'sign-posts' for its future research development.

Glossary

The abbreviations, acronyms and proper nouns used in this thesis are presented below with their full wording and/or explanation.

Abbreviations, acronyms and proper nouns	Full wording and/or explanation
ABI	acquired brain injury
ACSH	American Council on Science and Health
ADME	acronym for four researcher-developed Likert questions for: Anxiety, Depression, Motivation and Energy (used in feasibility pilot trial (see Appendix XVII))
ALL	all cohorts – in co-design workshops
Audacity	free, open source, cross-platform audio software for editing audio recordings; downloaded as App on Flinders University desktop computer (used in this project) (2)
BMQ-R	Brain Injury Rehabilitation Trust Motivation Questionnaire (BMQ) for carer or clinician use (3)
BMQ-S	Brain Injury Rehabilitation Trust Motivation Questionnaire (BMQ) for client use (3)
C	Client (client-participant in feasibility pilot trial)
CA	conversational agent
CALHN	Central Adelaide Local Health Network
CC	current client (cohort in co-deign workshops)
CL	clinician (cohort in co-design workshops)
Clevertar	Clevertar Pty Ltd.: Adelaide-based ECA software company
CNC	Clinician with No Client (clinician-participant in feasibility pilot trial who did not supervise a client using RehabChat)
CNHS	College of Nursing and Health Sciences (the Flinders University College in which the FDHRC is situated)
CONSORT	Consolidated Standards of Reporting Trials (4)
COVID-19	the illness caused by the coronavirus SARS-CoV-2 virus
CSS	Customised Style Sheet
CTO	Chief Technical Officer
CVA	cerebro-vascular accident
CWC	Clinician with Client (clinician-participant in feasibility pilot trial who supervised a client using RehabChat)

Abbreviations, acronyms and proper nouns	Full wording and/or explanation
DARN CAT’	(aspects of Motivational Interviewing) Desire, Ability, Reasons, Need, Commitment, Actuation, and Taking Steps (5)
DC	discharged clients (cohort in co-design workshops)
DEI	Data Extraction Instrument
DHI	digital health intervention
ECA	embodied conversational agent
EndNote	EndNote X9 (2018, Clarivate Analytics, PA, USA)
ET	education tutor
Excel	Microsoft 365 Excel software, used in this project (6)
F	female
FDHRC	Flinders Digital Health Research Centre (the Flinders University research centre in which this project was conducted)
GCS	Glasgow Coma Scale (7)
HADS	Hospital Anxiety and Depression Scale (8, 9),
HBC	health behaviour change
HCI	human-computer interface
HCP	health care professional
Healthdirect	Healthdirect was the video-conferencing platform (10) used by the collaborating clinics
HEP	home exercise program
HREC	human research ethics committee
Living Lab	Living Laboratory (co-design methodology used in this project)
LOC	loss of consciousness
M	male
MCI	mild cognitive impairment
MI	Motivational Interviewing (11)
Microsoft Transcribe	Microsoft AI-based software which transcribes digital audio recording to a word.docx format; used in this project (12)
MOT-Q	Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (3, 13)
mTBI	mild Traumatic Brain Injury

Abbreviations, acronyms and proper nouns	Full wording and/or explanation
n	number of participants (e.g. n=2 indicates 2 participants)
NLP	Natural Language Processing
NVivo	QSR International Pty Ltd qualitative research analysis software (14)
OT	occupational therapist
PC	personal computer
PCC	Population, Context, and Context
PD	Parkinson Disease
PhD	Doctor of Philosophy
PRISMA-ScR	Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping reviews
PT	Persuasive Technology
PTA	Post-Traumatic Amnesia
PwD	Person with Dementia
PwP	Person with Parkinson Disease
RCT	Randomized Controlled Trial
RehabChat	name of the ECA developed in this project
RTES	Rehabilitation Therapy Engagement Scale (15):
SCD	Single Case Design
SciTE	Scintilla based Text Editor (16)
SD	Standard Deviation
SDT	Self-Determination Theory
SMART	Specific, Measurable, Achievable, Relevant, Time-bound goal-setting framework (17)
SP	speech pathologist
SUS	System Usability Scale (18)
TBI	traumatic brain injury
UI	user interface
UX	user experience

Abbreviations, acronyms and proper nouns	Full wording and/or explanation
UTAUT	Unified Theory for Acceptance and Use of Technology (19)
VAS	visual analogue scale
WCAG	Website Content Accessibility Guidelines (20)
WHO	World Health Organization
WoZ	Wizard of Oz (a technology development approach)

1 Introduction

This chapter presents each of the main paradigms for this project, which are: brain injury rehabilitation for traumatic brain injury (TBI), motivational health behaviour change (HBC), and Embodied Conversational Agents (ECAs). Each of these paradigms will be presented separately, and then discussed in relation to each other. It should be noted that TBI is the diagnosis of client-participants in this study. However, additional clinical diagnoses are considered in this thesis to augment discussion at points where TBI literature is scant. These additional diagnoses include the broader diagnostic umbrella term of acquired brain injury (ABI) (of which TBI is one specific diagnosis), stroke or cerebro-vascular accident (CVA), brain diseases such as dementia or Parkinson Disease (PD), and disability more broadly. The reasons for including these additional diagnoses where relevant were that they incur a similar functional impact upon the client, for example cognitive and memory challenges, physical limitations, and difficulty completing daily activities; and that functional improvement is possible through the physiological process of neurogenesis (21) (see Section 1.1.3). A significant amount of literature is dedicated specifically to stroke. Stroke has been defined as a distinct diagnosis by the American Heart Foundation (24). However, it is also an identified cause of ABI (22) and is included in ABI research literature at least at times (25, 26). Accordingly, for the purposes of this PhD, specific research about stroke and/or other ABI diagnoses, PD and disability in general is considered, particularly when there is insufficient research pertinent to TBI. Similarly, where literature for ECAs was insufficient for the purposes of this project, reference to other related areas of literature for non-embodied conversational agents (CAs) and digital health in general is included where needed.

1.1 Traumatic brain injury

1.1.1 Aetiology of Acquired Brain Injury and Traumatic Brain Injury

Acquired Brain Injury (ABI) occurs when a person sustains an insult to their brain resulting in tissue injury (22). The causes of ABI are varied and include aneurysm bleed, surgery, traumatic brain injury and stroke (22). Traumatic Brain Injury (TBI) occurs when a person suffers an injury to their brain from an external force (23): either a direct force (such as head strike onto an object or surface, or object strike to the head) or an indirect force (for example, the shear forces on the brain associated with severe whiplash). A closely related diagnosis of cerebro-vascular accident (CVA), or stroke, occurs when the blood supply to the brain is interrupted due to blood vessel blockage or haemorrhage (24). ABI including TBI and CVA

result in an array of symptoms negatively affecting communication, physical ability, motivation, daily functional independence, and may cause cognitive challenges involving memory, insight or self-perception, and apathy (25, 26).

There are different levels of severity of TBI, ranging from mild to moderate or severe (27). The level of severity is determined by assessing three domains: how long the person experienced a loss of consciousness (LOC) (28); the Glasgow Coma Scale (GCS) score (7) (an assessment score of the level of brain arousal); and the duration of post-traumatic amnesia (PTA) in which memory is disrupted following TBI (28). For example, mild TBI has a LOC for less than an hour, a GCS of 13-15, and PT for less than 24 hours; whereas severe TBI has LOC for more than 24 hours, a GCS of 3-8, and PTA of at least 7 days (27).

1.1.2 Symptoms following Traumatic Brain Injury

Adults with TBI can experience a range of clinical symptoms affecting physical, psychological, memory and reasoning domains (22). These symptoms include decreased balance, mood changes, lethargy, dizziness, pain including headache, disordered insight and executive reasoning, difficulties with movement control, weakness, and sensory impairments including vision problems (28). Because of these symptoms, the individual may have reduced functional independence, be unable to do many of their usual life activities and suffer psychosocial issues that impact negatively upon family relationships and community participation, including usual work roles (28).

1.1.3 Recovery following brain injury

The primary mechanism for recovery following brain injury is through neuroplasticity, which is a process by which the brain forms new neural circuits (neurogenesis) which allow for learning of skills and improved functional abilities throughout the lifespan (21). More recent advances in neuroimaging of the brain have enabled a deeper understanding of the processes supporting neuroplasticity, for example, of increased neuroplasticity occurring following exercise (21). During rehabilitation for ABI and CVA, the level of adherence to, and engagement in, rehabilitation affects neuroplasticity and overall recovery made (29, 30). Research has also identified barriers to recovery following the level of severity of TBI (31). For moderate and severe TBI, injury severity and complexity relate directly to recovery, and are the main barriers to recovery (31). In mild TBI full recovery is possible, but psychological distress, reduced hope for recovery and compensation factors can inhibit recovery (31).

Recovery following brain injury is optimised through multi-disciplinary rehabilitation care provides a supportive care framework for a client with TBI. During rehabilitation, client-centred goals are chosen (22, 26, 32), and goal-attainment is supported (33). Client involvement in goal-setting during brain injury rehabilitation should commence in the early stages of care (34). A Cochrane quantitative review (33) of effectiveness of using goal setting and goal pursuit strategies in adults with acquired disabilities identified that clients should set personally meaningful, overarching goals, and under these set more functional goals and specific tasks to practice (33). Goal-setting is comprised of client-centred discussion and multi-disciplinary input (35). The components of successful goal-setting have been annotated using an acronym of SMART – Specific, Measurable, Achievable, Relevant, Time-bound (17). The SMART approach has been integrated into rehabilitation care (17), including brain injury rehabilitation (36). Following a SMART framework ensures that clear parameters for the rehabilitation goal are set with input by both the client and the clinician. The client can give particular input for the Specific and Relevant aspects, and the clinician can advise on the Measurable, Achievable and Time-bound aspects.

Attainment of rehabilitation goals can be optimised through ensuring that the set goals relate to the client's personal needs and experience (37), that motivation is supported (38, 39), that the clinician can tailor the goal-setting approach to the client's needs and the client and clinician have effective communication (40). In contrast, barriers to goal setting in rehabilitation include a lack of clinician and/or client ability or understanding of goal setting (40). Similarly, research has focused on therapy adherence and its impact upon improving rehabilitation outcomes after stroke, noting also that therapies which improve adherence can also increase motivation (26).

1.1.4 Motivational deficits in individuals with brain injury

Motivational deficits in clients with ABI have been described in regard to the aspect of motivation affected, such as intrinsic and extrinsic motivation (3, 13, 39), and to having a lack of motivation which is described as apathy (41, 42). A review of apathy following TBI describes this symptom as an impairment of goal-directed behaviour, resulting from impairment to the usual brain processes of emotion-related learning and reward-feedback learning (26). The neuroanatomy of apathy has been studied using neuro-imaging, the results of which found that irrespective of brain diagnosis, there were common regions of brain damage that were affected in individuals with low motivation and with varied brain conditions including dementia and stroke (43). These authors highlight the value of

understanding the anatomy of apathy as a basis for the development of effective therapies (43). These findings have been echoed in a review of neuroimaging for apathy in adults with CVA or dementia: specific areas of the brain are more commonly affected within each condition (for CVA the basal ganglia, and for dementia the anterior cingulate cortex) (44). This review's authors similarly emphasize that contextual influences impacting upon the clinical presentation of apathy need to be considered, and that apathy is not yet well defined (44). Low motivation in people with brain injury has also been attributed to emotional sequelae occurring following injury alongside the neuroanatomical changes (25). The need for the rehabilitation team to consider extrinsic factors influencing motivation such as the support being provided during a client's recovery has been highlighted (25).

Decreased motivation in adults with TBI can negatively impact their rehabilitation outcomes (13). Low motivation impedes participation in therapy programs, and overall progress in rehabilitation (3, 30, 38, 39). It has been noted in a qualitative review that decreased motivation can have a direct effect on the amount of self-directed exercise undertaken by clients with CVA (45). A specific focus upon supporting the motivational need of clients with brain injury has been discussed in the literature (38, 39). Motivation can be affected following TBI due to factors relating to how the client is thinking, and to the area of brain impacted by the injury. Self-limiting beliefs impact the manner in which an individual will approach opportunities to try new, more expansive activities, with such opportunities less likely to be attempted and the person thus having less potential to learn new skills (46).

1.2 Positive behaviour change and human motivation

Positive behaviour change refers to the study of human potential for change, actualisation of change, and facilitators and barriers to successfully achieving change in one's behaviour. Positive behaviour change describes an approach by which a person identifies and works towards achieving personally meaningful goals for change in their own life. Many theories exist regarding behaviour change: in the area of public health and social and behavioural sciences, 82 theories have been identified in this field alone (47). Given the plethora of options to choose from, attempts have been made to codify approaches to critically examining and rating different theorems (47).

The study of human ability to achieve positive changes in personal behaviour has gained considerable strength since the turn of this millennium (48). Prior to this, clear concepts of self-efficacy and social connectedness were presented in psychological research. Self-

efficacy theory (49, 50) focuses upon intrinsic thought-processes integral to undertaking and persisting in achieving a [new] task or behaviour: that this is more likely to occur when a person has higher self-efficacy, and that self-efficacy can be improved with experience of success even in completion of tasks which were challenging. Modern social psychological research has also presented solid theoretical framing regarding the human need for social connectedness (51). Social connectedness is a need that is inherent in humans which when deprived of fulfilment, results in negative repercussions for health and personal relationships (51). This concept is reflected in a related theorem: Self-Determination Theory by Ryan and Deci (2000) (52). Self-Determination Theory (SDT) encompasses a positive framework for enabling autonomous decision making, fulfilment in personal choice making through adherence to one's beliefs and needs, and supported enabling of a person forming and pursuing goals which are derived from authentic motivation.

Human motivation is a desire to perform a meaningful activity based on intrinsic or internal factors, and/or extrinsic or external drivers (52). Intrinsic and extrinsic motivation describe two aspects of the experience of motivation (53). Intrinsic motivation is the experience of being moved to do something because of one's interest in, value of, or belief in the worth of the action (53). Extrinsic motivation arises from outside influence of suggested or imposed priorities, which a person may happily accede to or begrudgingly obey (53). Intrinsic motivation carries a stronger ability to move the person to enacting a specific behaviour.

Human motivation can be optimised through supportive therapeutic approaches (11). Self-Determination Theory (SDT) – a behavioural theory –(52) and Motivational Interviewing (MI) – a counselling technique – (11, 54) are two such approaches which focus on supporting intrinsic motivation for behaviour change. Both are discussed in more detail below. Of note, MI has been aligned to SDT as the theory which closely matches the intent of MI as a therapy, and is able to explain why MI is effective (55). Both MI and SDT also share similar emphases of client-centred goal-setting and supporting resilience in pursuing goals and overcoming barriers (57). An example illustrating this is a comprehensive discussion chapter regarding physical activity and rehabilitation and motivation (56). This chapter describes the relevance of key behaviour change theories (including SDT) and MI for understanding how to best support motivation in clients to undertake needed physical activity to support their recovery goals (56).

1.2.1 Self-Determination Theory

Self-Determination Theory (SDT) identifies that motivation is improved when three inherent human needs are met: autonomy in decision-making, a sense of competency in achieving set tasks, and social connectedness with meaningful others (52). Autonomy refers to making choices for oneself; competence is the sense of having sufficient ability to achieve a given task; and connectedness refers to the experience of freely having meaningful relationships with others (52). If these three needs are supported, then intrinsic motivation to pursue personally meaningful goals is improved (52, 53). Intrinsically motivating goals are more likely to be pursued by an individual, even following setbacks. In contrast, extrinsic motivation describes linking of a person's motivational drive to external sources, such as the need to earn an income, or the desire to be popular (52). Self-Determination Theory has been studied widely and found to be effective in varied contexts including education, promoting physical activity, and health care (57, 58).

1.2.2 Motivational Interviewing

Motivational support for positive behaviour change can be achieved using the counselling model of MI (11, 25, 38, 59). Motivational Interviewing is a therapeutic conversation approach designed to garner the client's intrinsic volition to identify a personal health need to change, to set meaningful goal/s and strategies to achieve this change, and to then pursue their goal/s (5). Motivational Interviewing traditionally has been applied in a one-to-one, face-to-face, human-to-human context. In MI, the client is supported to lead the goal-setting discussion and to explore their challenges and any areas of ambivalence towards change (60). Throughout, the therapist should empathetically enable this process, and support the client's innate ability to form meaningful goals intended for overcoming their challenges.

Key components of MI include identifying and overcoming ambivalence, which when achieved allows the client to progress to goal setting and pursuit, and incorporating the 'spirit' of MI of the client being affirmed and the therapist being non-judgemental. It is important to maintain the client's trust and confidence, and to avoid shutting this down. For identifying and overcoming ambivalence, it is imperative to allow the client to explore their challenges and areas of ambivalence towards, or resistance to, change. Key facilitators for overcoming ambivalence are for the client to lead the discussion, and for the therapist to 'roll with resistance' by not confronting any resistance to change which may be expressed by the client, and instead to reflect it, and encourage the client to explore their own perceptions (60). For incorporating the 'spirit' of MI, the therapist needs to be affirming and at all times to support and honour the autonomy of the client to make their own choices when ready (60).

1.2.3 Health behaviour change

Positive behaviour change which results in improved health status or wellbeing can be described as Health Behaviour Change (HBC) (61). HBC is relevant to health care delivery, particularly for interventions which seek to address long-term or chronic conditions, by the client making positive changes to their behaviour. Positive behaviour change theories can be applied specifically for health purposes. For example, SDT has been applied to varied health contexts and physical activity (57, 58) and for cardiac rehabilitation (62). Self-Determination Theory has also been incorporated within usual care principles for promoting self-efficacy and intrinsic goal-setting in stroke rehabilitation (29).

1.3 Motivational support in brain injury rehabilitation

A specific focus upon supporting the motivational needs of clients with brain injury has been discussed in the literature (38, 39). If motivation is low, then progress during rehabilitation and overall recovery can be reduced (13). There is increasing interest in the need to integrate motivational elements within therapy for CVA rehabilitation, with this approach being distinctly different to more historical approaches for CVA rehabilitation which focussed primarily upon task practice (63). An expert analysis of this for neurological rehabilitation has suggested that a specific focus upon self-efficacy be adopted in both clinical trials as well as clinical work for neuro-rehabilitation (64). Similarly, a review has considered how the environment and context of rehabilitation for acquired disability can affect outcomes (33). This review found that implementation of effective management practices and processes of therapy care can directly improve motivation in clients with acquired disability during structured rehabilitation (33).

Ways in which motivation can be supported during brain injury rehabilitation specifically include appraising contributors to motivation such as psycho-social factors, the environment, and neuro-cognitive abilities and challenges (25). Support can also be achieved by incorporating motivational counselling, such as carefully applying MI in a way that meets the client's needs (25, 38). For CVA rehabilitation, the use of behaviour change theory, including SDT, to design and deliver the intervention has been discussed (65). Findings from research which integrated additional motivational support within usual upper limb motor training therapy showed that intended movement improvements were achieved up to eight months earlier than the control group receiving usual care; however, at one year follow-up both groups were equivalent (66).

A parallel aspect to motivation is the client's ability to engage in goal-setting. It has been reported that clients with TBI who have higher levels of involvement in setting their rehabilitation goals are able to maintain gains made during rehabilitation for two months following therapy cessation, compared to clients with low involvement in goal-setting, for whom gains made during rehabilitation were lost by the two-month time (67). Additionally, improved levels of independence in pursing goals can sustain ongoing recovery beyond the provision of structured rehabilitation (3, 38, 39).

When motivational approaches are used in ABI and CVA rehabilitation, it is necessary to assess the impact and benefit of these for the client – not only in regard to clinical outcomes, but also regarding motivation and its opposite of apathy, and other aspects of HBC principles. Specific outcome measurements and approaches for assessing apathy have been validated for people with ABI (3, 44, 68). These tools include the Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q) for appraising extrinsic motivation (3, 13) and the Brain Injury Rehabilitation Trust Motivation Questionnaire (BMQ) for appraising intrinsic motivation, with the BMQ-S for client use, and the BMQ-R for carer or clinician use (3). It is recommended to use the MOT-Q and BMQ-S together (3).

1.3.1 Motivational Interviewing in brain injury and stroke rehabilitation

Various therapy approaches have been reported for supporting motivation in adults with ABI or CVA. These include the use of MI, a well-described, methodical approach for conducting client-centred discussions purposed to identify goals, and overcome ambivalence and barriers to achieving the goals (11). Motivational Interviewing has been recommended for improving therapy engagement and self-awareness in people with ABI (25, 38). Motivational Interviewing is able to achieve this through initially supporting the client to engage in the conversation, then assisting them to focus on their personally identified need, followed helping them to think through how to address this need, and finally making plans to achieve meeting this need (5). These same factors have been identified as those which help to intensify motivational change in clients (69).

It has been noted that when applying MI in brain injury rehabilitation, that the cognitive needs of the client be sensitively considered and the usual MI approach be modified as required (38). Motivation Interviewing paradigms should be contextualised to the needs of clients with cognitive impairment, due to the fact that traditional MI assumes that the recipient has intact cognitive processes which allow full, and perhaps more predictable, participation in

motivational goal-setting conversations (25). A review investigating the efficacy of MI for supporting goal-setting in CVA rehabilitation, described the most significant improvement was related to client well-being (40), indicating that improved mental well-being may improve motivation for and engagement in rehabilitation.

Despite the relevance of MI and motivational support for brain injury rehabilitation, a 2015 Cochrane review investigating the efficacy of MI for CVA rehabilitation, identified an overall lack of evidence (70). In this review, comprehensive and dynamic searching was completed, which revealed a paucity of randomised controlled trial (RCT) evidence, with only one paper being included. The review consequently stated that there was insufficient evidence to state the effectiveness of MI for CVA rehabilitation. It should be noted however, that this review precluded inclusion of other types of motivational approaches, for example the use of behaviour change theories. Nonetheless, the relative lack of research evidence for the use of motivational approaches for brain injury rehabilitation, despite the apparent clinical relevance, further supports the need for the current research project to be conducted.

1.3.2 Self-Determination Theory in brain injury and stroke rehabilitation

Motivational support can be provided by integrating Self-Determination Theory (SDT) (52) during brain injury rehabilitation (39). The three inherent human needs identified in SDT of autonomy, connectedness and competency (52) are relevant for clients with ABI or CVA (39). In an overview of qualitative reviews investigating the experiences of clients following CVA and their carers, it was found that the key experiences which enhanced recovery included autonomy, social relations and engagement (71), which closely align to SDT tenets (52). This review also identified SDT has been previously identified as being highly relevant for supporting motivation in CVA rehabilitation (63, 71). The principles of SDT can be used to shape how the rehabilitation care is delivered. For example, staff interactions can focus upon client-centred autonomy for choice-making and goal-setting; and key loved ones can be involved in the client's therapy (39).

1.4 Designing Digital Health Interventions

This section will present key considerations for designing human-centred digital health interventions (DHIs), considering factors related to health purposes, and also to positive behaviour change more generally. These considerations are relevant also to the design of conversational agents (CAs) – which is discussed in the following section (see Section 1.6).

1.4.1 Overview

Digital health interventions incorporate the use of any digital technology within health care delivery. These technologies may either be designed specifically for health care use, such as tele-rehabilitation, or be designed for more general application and then adopted for use within health settings, for example, the use of step-trackers to incentivise physical activity (72). An expert consensus paper by Michie et al (2017) (73) recommends that development of digital health behaviour change interventions should be done cautiously given the dynamically changing sector of digital technology, and should focus on promoting end-user engagement. Additionally, the World Health Organization (WHO) in 2020 stated that usability and safety assessment is needed in the development of digital health interventions: that emphasis should be given to user experience, and that barriers to implementation should be identified and addressed (74).

Two main approaches have been reported for integrating human-centred design principles into DHIs for increasing user engagement with, and use of, the DHI, and for changing the user's views or behaviour. These are positive behaviour change (see Section 1.2), and persuasive technology (PT) (75). Below is a discussion of PT and of how PT as well as positive behaviour change can be integrated into the design of DHIs.

1.4.2 Persuasive Technology

Persuasive Technology (PT) (75) refers to the aspect of technology design concerned with influencing the user in order to change the user's choices and behaviour, without using deceit (75). Persuasive Technology is founded upon the principle that human users will be affected in some way when they interact with communication technology (75). The persuasive aspect of PT aims to form, alter, or reorganise the user's attitudes, behaviours or act of complying (76). Its founding protagonist BJ Fogg (1999) highlighted the need for considering the purposes of, and the means for applying, PT design principles (75). Fogg (1999) promulgated the need for defining principled guidelines to help ensure the ethical implementation of PT (75). The need for this rallying call was to help ensure that potential negative effects of PT would be avoided. Such negative effects included the technology not clearly stating its limited capabilities and purpose, and unethical coercive or seductive qualities being enabled within the experience of using the technology (75).

Persuasive Technology incorporates a functional triad comprising: a tool type (such as a calculator); a medium to enable or provide experiences (for example, virtual reality); and a social actor (a character which creates relationship, for example a digital pet). Fogg in 2002 (77) further expanded on details of PT as ultimately a design approach for increasing user engagement and user satisfaction with computer technologies. Fogg also explained the phenomenon of human users tending to apply a personality to the computer programme, even when it is not an intended goal of the programme designer (77). Such known outcomes, as well as unintended consequences, of user experience (UX) when using a DHI should be carefully considered when designing the DHI.

The need to clearly define the purposes of PT in technology design has been previously highlighted in a critique of Fogg's Persuasive Technology paradigm (78). This critique highlights the need for careful use of terminology in technology design, for example the distinction between engaging and persuading the user, and the premise of technology provides social stimulation rather than a social actor: the computer does not act in a social dialogue (as Fogg indicates) but rather has been designed by a person to promote persuasion (78). Further critique of PT (79) candidly appraises the negative effects of persuasive systems including technostress, anxiety, and different types of addiction. A 2014 review of the literature regarding PT design (76) found that many persuasively designed technologies do indeed persuade, but that there is a lack of actual assessment of how the user's general attitudes are more substantially changed. These authors highlight two pathways of persuasion evident in PT which are to persuade toward a behaviour change if the user is already interested in changing, for example a health behaviour; or to persuade toward a priority of a business, such purchasing behaviour to support a marketing goal (76). Key aspects of how PT design is able to persuade a user include the tool providing primary task support, dialoguing with the user, having a level of credibility, and using social influence to increase engagement (76). These aspects illustrate the intersect between the human interacting with the technology device, and this being connected to the real-world in regard to the behavioural task being achieved, or the social perception around using the tool. Fogg in 2019 described a Behaviour Design model that integrates with PT to further facilitate user engagement with using the technology tool (80). This Behaviour Design model includes two main tenets of supporting the user to change something they are already interested in, and providing the user with a sense of success (80). Notably, these two tenets accord closely with MI and SDT.

Recommendations have been proposed for overcoming the limitations of PT. These recommendations include implementing user-centred design, improving system usability, and carefully appraising intended versus unintended outcomes (78). Improved system usability can be achieved by ensuring the technology will avoid errors, perform as promised, and not demand too much effort from users (79). Interestingly, social features of systems have been found to not only relate to positive outcomes (for example, to help reduce loneliness), but also to several negative outcomes (stress, envy (of other users) and addiction). Such risks should be mitigated in the design of any interactive computing tool and assessed during evaluation of such tools (79).

In summary, PT offers many options for increasing user engagement and trust in the digital technology tool. If managed well, this could support optimal use of a DHI to support improved health or therapy engagement. Importantly, any unintended or negative sequelae of PT should be avoided both in how the tool is designed, and through monitoring for these sequelae during implementation of the tool.

1.4.3 Behaviour change principles in the design of digital interventions

There is increasing interest for integrating health behaviour change principles within the design of DHIs (73, 81) and also in appraising the effectiveness of these interventions (82). Michie et al (73) present expert recommendations for digital behaviour change interventions, which include the integration of behaviour change theory within both the design and trial of digital health technologies as well as in the ongoing monitoring of them so as to ensure optimal outcomes (73). Recent literature highlights the need for development of a methodological approach for choosing and applying a HBC approach to DHIs (73, 83). This has been proposed for the application of SDT to the design of digital behaviour change interventions (84): the tenets of SDT can be integrated both in the way in which the user interacts with the tool, and in the choice of the wellbeing outcome for which the tool is designed to support (84). An emphasis on supporting positive behaviour change in DHIs has also been recommended for supporting self-management for neurological clients: suggestions include in the integration of self-management approaches into mobile-Health and other digital health interventions, with an emphasis on supporting long-term self-management (64).

1.4.4 Comparing persuasive technology and positive behaviour change

There are apparent differences as well as some similarities between the purposes of PT compared to the integration of positive behaviour change principles in the design of digital technologies. The similarities are that both approaches help to enable user engagement and user of the tool, for an intended behavioural outcome. The differences are in relation to the theoretical basis for each approach. For example, SDT has a broad base for proven effectiveness in human care interventions (57, 85), whereas PT is inherently a design approach just for technologies. In a much-needed discussion outlining the different perspectives of technology designers (focussing on PT) and health professionals (focussing on behaviour change theory) within the context of behaviour change Apps for physical activity, a number of challenges facing this point of intersection were highlighted (83). These challenges included there being fragmented application of behaviour change theories and also of PT intents with a related lack of pragmatic methods and guidelines for PT (83). Additionally, diversity in user needs and preferences relating to behaviour change theories and PT approaches has been identified (83). Indeed, the persuasive design elements in and of themselves may fail at their intended purpose unless backed up by a relevant behaviour change theory (83). The authors also emphasize though that with careful design of both the flow and presentation of positive behaviour change content and of the persuasive design elements, that the latter can help to maintain immersive interaction by the user so as to optimally benefit the user in regard to the behaviour change content (83). These considerations align with the concept of behaviour change theory being used as a way to framework the design of persuasive technologies for supporting HBC (81). It appears that emerging trends in the literature point to technologists and health clinicians being able to come together to formulate a new integrated theoretical paradigm for DHIs (73, 83).

1.4.5 Assessing digital health interventions

There is a need to thoroughly test novel DHIs prior to and whilst implementing into care (86). However, usual health research approaches of robust and lengthy studies are not keeping pace with DHI development, which underscores a recent recommendation for more pragmatic approaches to testing of DHIs (86). Similarly, an earlier 2016 discussion paper outlines considerations for designing research for assessing DHIs, and acknowledges that the traditional health-oriented RCT model does not match the needs of DHI research which comprises diverse specialties of computing, health, behavioural and engineering sciences (87). The challenge is how to best appraise new and emerging digital technologies which are at varied levels of development, and hence which need different approaches for testing (86).

In response to this dilemma, distinct phases of testing of a DHI have been proposed (88). These phases include an initial phase to conceptualise and produce a relevant and acceptable prototype, and a second phase for completing feasibility testing of the refined model (88). Attention should be given to assessing usability, safety, privacy, personalisation, and adherence when designing and testing the DHI, whilst also considering potential barriers to uptake, including end-user characteristics, workforce issues, user expectations, funding and professional regulations, all of which should be appraised during testing (88). The WHO in 2020 released its recommendations for the design of DHIs – and similarly included the need for DHI design to focus on acceptability, usability, and user experience, whilst also identifying and overcoming barriers to uptake (74). These recommendations acknowledge both the patient and health provider as key end-users, and that the DHI use is situated in a broader context of health measures, established practices and safety requirements (74).

The need to assess not only the user's interaction with the DHI and the facilitators and barriers to this, but also the user's amount of intended behaviour change has also been highlighted (89), with the former influencing the latter. The amount of intended behaviour change enacted by the user could have direct impact upon their health outcomes. Results for assessment of this would be of great relevance for clinicians when appraising a DHI.

Clinicians may have specific preferences and needs when choosing and implementing a digital health technology into care provision. A study investigating a therapists' intention to use serious gaming in brain injury rehabilitation, identified that clinicians needed the game to support rehabilitation goals, provide meaningful training, be tailored to the client's needs, and be motivating to the client (90). Additional requirements included the need for clarity regarding the amount of clinical supervision required, for database functionality to incorporate personalisation features, and the ability to gather quantitative measures regarding patient's progress (90). This example illustrates the need for DHI design and testing to consider not only the user's engagement with the tool, and the intended behaviour change outcome, but also the clinician's requirements and how the tool is to be integrated into usual care structures.

1.4.6 Use of digital health interventions in rehabilitation for brain injury or stroke

A range of DHIs have been researched for brain injury and CVA rehabilitation, including: immersive videogames for upper limb training (91), virtual reality to support cognitive

challenges (92) including with an avatar integrated into the virtual reality (93), and avatar-based simulation technology to educate families how to support veterans to seek help for medical needs including TBI (94). As well, serious gaming has been shown to have very good acceptability with users, and good acceptability to therapists when utilised in brain injury rehabilitation for supporting cognitive recovery (90). These examples illustrate that DHIs can be used within rehabilitation for clients with a brain injury or stroke.

It is possible to embed positive behaviour change approaches into DHIs (84). This focus has been identified as a high priority for CVA rehabilitation (63) and brain injury rehabilitation (39). Self-Determination Theory specifically has been used as the framework for assessing the usefulness of video-games in CVA rehabilitation in regard to their ability to improve intrinsic or extrinsic motivation as well as clinical outcomes (95). Similarly, self-efficacy and long-term self-management approaches have been highlighted for the development of DHIs and of therapy approaches that use such DHIs for CVA rehabilitation (64). Examples of these include a customizable exercise App for increasing exercise in participants with CVA with therapist input via tele-rehabilitation if required (96), and use of varied affordable technology devices (including personal Apps chosen specifically for each participant) with rehabilitation clients (49% of cohort with neurological conditions); (97). That study found that clients continued using the device with technical and coaching support to their support rehabilitation goals for up to six months, including post discharge (97). These examples illustrate that digital health devices which emphasise health behaviour change or support can be used within rehabilitation for clients with a brain injury or stroke.

1.5 Conversational agents

1.5.1 Overview

Conversational agents (CAs) – or chatbots – are computer technology tools which provide a responsive, human-computer interface (HCI) with which a person can have a conversation (98). The first CA developed was ELIZA in 1966 (99). ELIZA was developed to have a turn-taking conversation which utilised natural language processing (NLP) to identify key words from the user's input and integrate them to relevant counselling type responses relevant to psychiatric care (99).

The user's mode of interaction with a CA is by written or spoken conversation dialogues. There is a lack of consensus regarding terminology used to refer to the many types of CAs,

including ECA (100), virtual agent or coach, intelligent agent, or virtual human (101). It has been suggested that soon CAs will replace Apps as the most common digital communication device (68). In contrast however, research for CAs is an emerging field. It has been noted for research of CAs that application and testing of complex CAs is more difficult, whereas implementation of simpler CAs accords with more research opportunities (102). Conversational agents have been reported as effective tools for education interventions (103) and health interventions, (104-107). Previous reviews have appraised the use of E/CAs for a range of health purposes (100) and psychology interventions (102).

Conversational agents may incorporate a virtual, humanoid character who embodies the computer dialogues – an embodied CA (ECA) (105, 108, 109). The humanoid avatar is able to speak (auditory output), and can provide facial expressions and gesturing functions (visual outputs) (109). The presence of an avatar in an ECA facilitates user engagement and understanding (109). The audio-visual display of the avatar can be modified, or more specifically personalised, to suit user preferences. The personality – or persona – of the avatar should be developed to match the purposes of the ECA: a scoping review of ECAs in psychology describes a range of avatar persona styles including tutor, coach, clinician and social interaction partner (102).

1.5.2 Conversation design: structure and style of responses

Key choices need to be made when designing a CA, regarding its overall conversation structure and the style of its responses to the user's input. Design of a CA should also optimise the capabilities of the software platform. These factors are discussed below.

1.5.2.1 Overall structure

Options for the overall structure of the CA conversation relate closely to the capabilities of the software used, and should be carefully considered. Different software options can allow for either a simple or complex CA structure. For example, a more complex approach to the conversation development and delivery can be facilitated by using NLP (the computer capability of recognising and parsing content from the user and then creating appropriate and relevant replies based on this (110)). Data input from wearable sensor devices which is processed in real-time can also be used to impact upon the CAs decision making (111). As well, large online public repositories of information can be utilised, or alternatively the researchers can develop and incorporate a large-scale language repository relevant to the

content and purpose (112, 113). The latter requires longer development time and involves training the computer system in two steps: first, gathering an appropriate library of words, phrasing, and dialogue decision-making, collectively referred to as the ECA language database; and second, using this language database to train the CA to understand the communication variations which will commonly occur in conversations with users for the relevant topic (112).

An alternate option is to structure the CA conversation using a simpler approach; for example, using a tree algorithm for decision making in response to user input, in which pre-developed CA replies are utilised (111). Use of a constrained model for structuring a CA conversation has been suggested by Fadhil (2018) (111) within which a 'Pipeline Design' provides a unidirectional branching tree construction for the conversation, comprising a definite start and multiple end-points. Within this design, a relevant HBC theory should be incorporated and user experience testing undertaken in order to inform refinements to the system. Fadhil (2019) has also suggested that for CAs used alongside usual clinical care, that the more mundane, repetitious aspects of care can be integrated into the CA (114), thus leaving the more complex aspects of care to be managed by a human expert. This interaction between client, clinician and CA should be carefully addressed when designing a CA for health purposes.

1.5.2.2 Respond to user's input

A CA conversation is significantly made up of how it responds to the user's input which creates the interactive experience that influences the user's overall experience. Responses made by the CA seeks to mimic natural human-to-human conversation as far as possible, and to focus on specific human needs and interests. Designing a CA conversation should consider factors which improve its flow from start to finish, including using engaging strategies near the start, and wrapping-up strategies towards the end (115). Careful attention should be given to designing a CA which is perceived by the user as being empathetic, as this has been shown to be more important than the goal being focused on in behaviour change CA for smoking cessation (116). Similarly, a well-designed conversation for a health CA should seek to mimic the human-human experience of the clinician-client therapeutic alliance which is paramount to supporting effective health outcomes (117). Aligned to this, the CA's style can be developed to offer variety in expression: computer modelling has been used to enable varied expression in a CA (109).

The options for how the CA responds to and interacts with the user's input relate to the complexity of the CA's reasoning algorithms for categorising and processing the user's input. Natural Language Processing enables the CA to identify and prioritise words within the user's utterances to enable the CA to generate a simple or multi-faceted output (e.g. provision of language alone, or an additional output of health information or offering to link the user with a human health professional (118)). Additionally, the proposed ways in which the CA will respond to user input can be initially trialled with human control, prior to finalising the approaches within the CA software. This is achieved by an expert researcher working remotely to compose contextualised responses provided of the CA to the user in real-time as the user interacts with the CA – called the Wizard of Oz (WoZ) approach. The WoZ approach enables proposed models of interaction to be tested before refining and committing these to be entered into the software. This approach has been used successfully in a CA designed to promote increased levels of exercise (119) and in a CA purposed to assist a client with severe TBI (120).

1.5.3 Incorporating Persuasive Technology principles into the design of a conversational agent

Persuasive Technology (PT) expounds a triad of components which are a tool, a medium, and a social actor (75). An example of all three in combination is an ECA (75): an ECA is used on a computing device such as an iPad; the user interface provides the medium for an interactive experience, and the humanoid avatar builds rapport with the user (75). Key PT attributes which can be integrated into the design of a CA to improve social engagement include friendly language, turn-taking, positive feedback, focussing on a goal that is relevant to the user and having a pleasant looking user interface (75).

The design of a CA may also incorporate a number of PT principles which help to improve the usability of the CA (111). These include the use of social dialogue, and personalisation of the discourse for example by using the user's name and referring back to previous conversations (81). Easy usability of the CA is important, specifically in regard to ease of navigation to use the tool, and the tool performing as anticipated (81). Attention to how the conversation itself is managed and delivered is also highly rated by users (121), in regard to areas such as the naturalness of the CA dialogues, clear turn-taking, the CA to be adept at resolving miscommunications, and use of polite approaches for wrapping up conversations (121). A discussion paper highlights examples of PT approaches which can be implemented to optimise user engagement and use of a CA through the design of the conversation (111).

These faciliatory approaches include the CA functioning as a virtual coach (mimicking a human coach), and providing interspersed prompts for motivation and relevant information (111). As well, the CA conversation structure can be designed to increase the user's insight regarding the need to change health behaviours (diet habits addressed in the paper) (111).

Interestingly, the context and purpose for the CA can affect the user's perspective on the usefulness or appropriateness of PT aspects. For example, participant feedback for a CA designed for physical activity promotion, revealed that social dialogue decreased user engagement and physical activity, which was likely because the users wanted a purposeful interaction with the CA rather than a social one (119). Similarly, CA user feedback has included that the CA should use minimal clichés and less often direct the user to say something (115). All of these findings indicate the complexity of CA content to not only ensure an easy, comfortable experience for the user, but to also engage the user in a purposeful way to achieve the CAs intended purpose.

1.5.4 Assessing conversational agents

It has been recommended that CAs should be assessed at each of the main development stages of design and development, piloting, evaluation, and implementation/clinical appraisal (102). Successful design of a CA is measured through assessing not only outcomes relating to the intended purpose of the CA such as health promotion, but also outcomes that demonstrate effective implementation and use of the CA (such as safety, acceptability, and feasibility). Specific non-clinical aspects of user experience (UX) and usability can be assessed to help inform about and optimise how much a client uses the CA and therefore how much they benefit from the content and purpose of the ECA (89). To ensure optimal outcomes in UX and usability, designers need to ask users what they are looking for in CAs (122). Consulting with potential end-users should occur during the design and development of the ECA as well as regarding the final stable model CA product developed. Assessment should also integrate the phenomenon that user needs will change with more CA use, such that what were the results of testing at an earlier point of use, may change over time, with different follow-up required (122).

1.6 Safety considerations for designing conversational agents

Specific safety considerations relating to the design of CAs have been reported. Risks arising from using a CA include stress and anxiety and even forms of addiction (79). Bickmore et al (2018) (123) have investigated the risk of mis-understanding by personal assistant CAs which use NLP (123). They found that these CAs which provide information founded upon general knowledge online content models are poor at providing advice for health conditions, including that they can provide information that is potentially dangerous (123). There are clear limitations for using NLP CAs, but safety can be improved with a clinician involved to monitor the client's CA use and being available to support the client as needed (124), and for the client to be referred back to the clinician at appropriate junctures rather than just relying on CA advice (118).

Conversational agents are at risk of failing to understand user input, or alternatively of misunderstanding or demonstrating non-understanding. This risk can be increased when there is lack of ability in implicature and presupposition knowledge in the CA. This can be due to the difficulty for the designer of ensuring that the CA dialogue management system is sufficiently complex to follow the user's conversational inputs. A safety mechanism is for the CA to clarify meaning with the user and/or alternatively to use constrained language, closed-ended questions to ensure accurate clarification particularly in emergency situations (117). Additional ways to address mis-understanding errors can include educating the user regarding optimal ways to talk to the CA to ensure clear understanding, for example regarding the types of grammar and vocabulary to use (117). However this has in practice been shown to be difficult to achieve (117).

Some risks however are unknown. An overview commentary on the emergence of CAs worldwide (122) highlights that even though people open up more easily to a CA, it is unknown if in the long-term this will have a negative effect. There is consequently an ethical responsibility of CA designers to ensure that the intended impact of the CA is beneficial, that potential, unintended negative impacts have been ameliorated so as to produce an overall neutral effect for the user. The CA can be in-built with an ability to identify out-of-domain questions, particularly those of significant safety concern, and a corpus of responses relevant to any emergency data input that would link the user to more appropriate help (117), including follow-up with a clinician. Bickmore et al (2018) (117) advise that the type of language processing should match the intended level of accuracy required for user interactions. Specifically, when higher degrees of accuracy are required, then constrained language should be used. Otherwise, if unconstrained language is used, then thorough

inbuilt mechanisms for identifying errors and checking for and correcting misunderstandings is required. Safety challenges can be clarified and mitigated through ongoing assessment of CA use and prompt redesign in response to assessment findings. These management approaches would help improve UX, and help avoid user disengagement with the CA.

1.7 User disengagement, and promoting longer term use

The literature reports on the challenge of user disengagement with CAs, as well as the potential benefit of promoting longer term CA use. The high drop-off rate of users with CAs inherently raises a risk of users not receiving enough support to achieve successful behaviour change (111). Incorrect user expectations of the CA, for example the user thinking that the CA is not performing as it should can negatively impact user engagement and use of the CA (122). This can be managed through the CA specifically stating its purpose: either as preliminary statements of a conversation, or as clarifying statements if user input deviates from the CAs main purpose.

The level of trust that a user has in the CA also affects their engagement. It has been recommended that future research could consider ways to increase the transparency and proactive representation of factors unique to HCIs within CAs. Suggestions for how this could be achieved include explicitly highlighting the data-processing and history-managing capabilities of CAs, and optimising human oversight of the use of CAs (particularly in more complex areas such as health scenarios) to nuance and optimise the degree of sensitivity and specificity to which the use of the CA can be implemented in care (102). In this way, users could remain satisfied that the CA was collating and managing their information well, the user would feel comfortable in telling the CA the needed data, and the CA use would likely be less intrusive in the clinical context and more sensitively applied to the user's needs.

Longer-term interviewing by a CA can provide more comprehensive data for the clinician overseeing the users care (125) and more opportunity for the user to be supported to practice the intended behaviour change. Long-term user engagement can be optimised by ensuring clearly defined purposes for the interaction, and the CA demonstrating empathy and understanding of the user's cognitive state (125). Embodied Conversational Agents may achieve more easily this due to their visual features which help enable a reduced cognitive load for users (125). This in turn could contribute to improved user adherence and satisfaction (125). Conversation length also affects cognitive effort and user engagement,

and should be appropriate to the purpose for which is its occurring. For example, for a finite task purpose, such as medication adherence, it should be short and efficient; and for an explorative discussion regarding symptoms, it should be a lengthier conversation (117). Nonetheless, it is important to note that the effects of long-term CA use are unknown and require further research (122).

1.8 Design considerations for health conversational agents

A range of design factors should be considered when developing a health CA. These factors include safety of the CA (117), and its ability to understand variability of the user's responses from (111). Additionally, health CA design should integrate HBC approaches, and also be appraised regarding how well the CA achieves its intended outcome such as HBC in, or meeting the specific needs of, the intended end-users (101). As well, at junctures where the client-user is dissatisfied with response of the CA, it should be planned that a health care professional (HCP) then becomes involved in the care of the client user, including providing any needed advice (126).

The design and development of a health CA should incorporate a multi-disciplinary design team – including computer science, speech and language, and neuroscience (101) – to provide input on human cognition and communication and match this to software capabilities. A range of approaches for developing the topic content for health CAs have been reported in the literature. These include consulting a multi-disciplinary team of experts regarding the content to be included for a mental health CA (118); using published best practice manuals, for example as content used in a behaviour change intervention CA (116); accessing content from online chat-site logs for example regarding weight loss (61); or identifying relevant themes and content from transcribed qualitative interviews with potential CA users to inform the conversation content for the CA (115).

The literature demonstrates that a variety of clinical needs and contexts can be reflected in the design and use of CAs. These mental health and psychology (102, 115, 127), and for health care more generally (100, 128). The conversation topic for a CA may include specific domains focussed upon specific tasks – for example, as used in a HBC CA to identify user language utterances which indicate stages of readiness for behaviour change (129). Previous research for HBC conversational agents (CAs) has describe how either a behaviour change theory and/or Motivational Interviewing has been integrated into the CA

content and design (61, 104, 105, 115). The content should reflect the dynamic nature of users' needs and preferences (122).

Finally, CAs have been developed for clients with brain disease, cognitive impairment, and memory loss for specific clinical purposes including speech training for people with PD (130) and dementia (131), and providing coping support to sufferers of PD (132). Conversational Agents have also been developed and researched for memory training for older adults (133, 134). When designing a tool for these client cohorts, there is a need to simplify the user interface so as to decrease the cognitive load of the user, so that users spend less time in just learning to use the functionalities of the program (125, 126). Please refer to Chapter 2 in this thesis which presents a scoping review of the use of CAs in rehabilitation for brain injury, disease and stroke, for a thorough appraisal of that field of research.

The needs of specific clinical cohorts and contexts can be met through using validated health counselling frameworks or behaviour change paradigms. Use of a psychology framework – covering personalised goal action intentions, education, planned tasks, progress review, utilising support resources, and feedback – has previously been (124) incorporated into a CA conversation structure. Other examples of integrating motivational aspects into CAs have been reported for the use of MI. These include incorporating MI along with other validated health counselling approaches (116), and using MI used as a stand-alone approach to address stress in tertiary students (115). The latter study demonstrated high user satisfaction and was able to support the user to perceive their need to change a behaviour and to commence working through a relevant change goal (115). A further example is a CA design for alleviating symptoms from anxiety and depression, used alongside therapist-led care, and for which the CA conversation was modelled on MI and focused on providing reminders and education (135). These examples illustrate that motivational HBC paradigms can be integrated into CA dialogue content.

1.8.1 Recommendations for designing health conversational agents

There currently is no agreed systematic approach for developing and reporting on health CAs (132). This is alarming, given that health care interventions are usually scaffolded with guidelines. There are however relevant expert design recommendations regarding the more general domains of DHIs and how to incorporate HBC principles within these. However, within these, there is a lack of cohesion in addressing the requirements of both clinicians and technology designers. For example, Michie et al 2017 (73) present expert panel

recommendations for HBC digital health interventions in regard to the development and evaluation of these tools – to determine why and how they work, and for whom, and in what context – and highlighting the need for development of an ontology that is used amongst researchers, but without referring to the many possibilities of technological options available (73). Fadhil et al 2019 (98) discuss the array of design possibilities for health CAs, but without referring to the need to integrate the requirements of registered clinical professions and regulated clinical settings into the CA design. In a review of healthcare CAs by Laranjo et al (2018) (100), clear reporting frameworks for the design CAs are recommended, but the review does not grapple with the complexities of integrating a CA within a real-life clinical setting.

1.8.2 Safety considerations for health conversational agents

Given that there are no best practice guidelines for the design of CAs for health care specifically (117, 123), it is important to consider the available literature on safety and risk mitigation for DHIs. The National Institute for Health and Care Excellence in the UK has produced a 2019 guideline document (136) which supports the UK governments commitment to ensuring that the digital health technologies commissioned by them are evidenced-based. No specific mention is made of CAs, but the document discusses the need to carefully consider CAs which utilise artificial intelligence due to their unique capacity to provide complex and inherently open-ended care to clients – which is in contrast to comparatively closed ended, more predictable systems, or systems which rely significantly on clinician input (136).

The literature also reports on key elements which help to optimise the safety of CA health interventions. These elements relate to the design of the CA conversation and include having expert consultation for clearly defining the intended clinical context, purpose, and conversation content of the CA (107), applying relevant evidenced-based HBC approaches (129), and modelling the CA conversation dialogues upon human-human clinical communication (109). Other key elements for improving CA safety include having ongoing access to clinical staff support during CA use (124), and conducting pilot testing of new devices when first developed (115, 129). Of note however, is that the level of complexity and time taken to develop a CA, will directly impact upon how long it will take to thoroughly assess the CA prior to it being ready for use in the real-life clinical setting. The level of complexity of design features chosen for the CA, for example the language style and conversation processing and decision-making, and the ability to personalise the CA function

to user profiles and needs will impact on the length of time required to develop and trial the CA to assess its clinical effectiveness and safety. Indeed, the greater the level of complexity, and 'naturalness' of the language, the more complex the risk mitigation and error avoidance strategies needing to be developed (117).

Safety is also optimised by thoroughly assessing a health CA for its safety and usability (see Section 1.5.4), as well as effectiveness, and for identifying areas requiring future research and development. However, the field of research for health CAs is still fairly small. In a review investigating CAs used for psychology (102) it was identified that the research literature focused primarily on development and piloting, with fewer studies dealing with evaluation (acceptability, usage), and minimal studies dealing with implementation (102). This highlights that health CA research is in its early stages, and that CAs are not yet widely tested for clinical effectiveness.

1.8.3 Data security in digital health relevant for conversational agents

Data security considerations for using CAs in health settings include the confidential collection and storage of data from user interactions, and also if any other digital technologies are used in an integrated way with the CA. Such considerations have been discussed more broadly for digital health technologies generally. The World Health Organization (WHO) guidelines for digital health interventions (137) offer broad advice regarding the design and implementation of digital health interventions, including the need for careful control of patient data security. The American Council on Science and Health (ACSH) (2019) (138) responded to these WHO 2019 guidelines (137), noting that a range of measures recommended in it are already in place in the USA, such as for telemedicine, but that some measures lack regulatory cohesion nationally, with issues of limitations of practitioner access to online information for practitioners, and needs to improve confidentiality and safety of data, and management of chronic health condition data. The ACSH discusses the new opportunities related to the monitoring of clients, for example through the use of wearable devices, and the related dilemma of how to choose when the data gathered is managed by a clinician or by computerised algorithmic processes. The ACSH commentary closes by stating that the development of digital formats for managing health care will become possible but requires careful planning to ensure high levels of clinical quality (138).

1.9 Key design and development considerations for this PhD

The current literature alludes to the need to carefully develop and assess CAs, but similarly does not offer explicit design and development guidelines. The potential benefit of PT design for improving immersive user engagement with a CA, which could in turn better support positive behaviour changes for improving health (83), has not been methodically structured regarding the design of health CAs. Similarly, PT and HBC paradigms have not been methodically co-integrated into digital behaviour change interventions generally (83). This is despite PT carrying a strong paradigm of achieving change in the user's thoughts and behaviours, and thus inherently having an impact upon behaviour change in the user (83). Ideally, CA design should adopt explicit approaches for integrating PT and HBC principles. A novel assessment paradigm has been recently published for assessing both behaviour change and user experience within digital health interventions (10), as these are two separate yet interrelated aspects of the user's experience; however, it does not recommend specific approaches for ECA design. Similarly, assessment tools for appraising Apps in regard to their ability to support behaviour change (11), and their quality (12, 13), also do not provide either best practice guidelines or specific application to CA design. Comprehensive digital technology design frameworks for accessibility (for example the Web Content Accessibility Guidelines (WCAG) (20, 139, 140)) and for acceptance and usability (such as the Unified Theory for Acceptance and Use of Technology (UTAUT) (19, 141, 142)) are important to consider whilst awaiting best practice design guidelines for health CAs.

A systematic review on the acceptability of technology use during brain injury rehabilitation (143) found an overall lack of theory driven frameworks for assessing acceptance and stated that

> "Future directions for research in this area include the use of theory-driven research designs to enhance our understanding of technology acceptance, to support the development of rehabilitation technologies that maximize functional outcomes for individuals with TBI" (Vaezipour et al 2019) (143).

This thesis will now proceed to demonstrate how these design challenges and opportunities were considered within the design and development of RehabChat – a motivational embodied conversational agent for brain injury rehabilitation. The following chapters will present: a scoping review investigating the use of CAs in rehabilitation for brain injury, disease, or stroke; a description of how Living Laboratory methodology has been applied as the overarching methodology for this project; the design and development processes used for RehabChat; outcomes from four rounds of co-design workshops for refining RehabChat; and finally, findings from the mixed methods feasibility pilot trial conducted in real-life clinical settings.

1.10 The research gap for this project

Rehabilitation for adults with TBI provides a supportive client-centred approach for goal-setting and pursuit. It is recommended that motivational paradigms be integrated into brain injury rehabilitation to enhance the client's therapy engagement and outcomes. Nonetheless, rehabilitation care for this cohort is time-limited, despite the potential for recovery being ongoing. Conversational agent technology can provide an appropriate basis for rehabilitation inputs for this context. Use of a motivational ECA for brain injury rehabilitation to support goal setting and pursuit could help to leverage care and improve client engagement in therapy, and hence also recovery. A motivational ECA to support brain injury rehabilitation goal-setting and goal-pursuit has not been previously developed.

1.11 Research hypotheses

Adults with a TBI may experience low motivation due to specific challenges arising from their TBI of decreased insight, memory, and executive planning. If motivation is low, then progress during rehabilitation and overall recovery can be thwarted. An ECA to support motivation, goal-setting and goal-pursuit may help to improve client engagement in therapy, and hence also recovery. This could be of considerable benefit for clients with a TBI.

There is no reported evidence for an ECA being researched or used to support motivation in brain injury rehabilitation. As a result, novel research hypotheses have been developed and clarified for this project. The main hypotheses underlying this research project is that use of an ECA in brain injury rehabilitation could improve client motivation to achieve goals, provide an extension to usual rehabilitation care, and enhance functional recovery. These hypotheses are premised upon that an ECA can provide iterative conversation dialogues which can be designed to support motivation and goal-setting; and that an ECA is highly accessible to the user outside of usual therapy interventions, which can leverage the amount of therapeutic support available to the client.

1.12 Research Aim

The overall aim of this project is to co-design a motivational ECA to support motivation during brain injury rehabilitation for adult clients with TBI in two ambulatory care clinics. This is the first time that a motivational ECA has been developed to support rehabilitation of

clients with TBI. This aim is expounded in the Research Questions and Research Objectives presented below.

1.13 Research Questions

The following research questions for this project reflect the theoretical paradigms presented above, the novel quality of this design and development research, the open exploratory approach used in co-design, and the more finite aspects of the feasibility pilot trial.

1.13.1 Main research question

How can an embodied conversational agent be used to support motivation and goal-setting in brain injury rehabilitation?

1.13.2 Research sub-question

1. What optimal ECA design can be developed using co-design in a real-life rehabilitation setting?
2. What are the key elements to be considered when developing a motivational ECA for brain injury rehabilitation?
3. What is the feasibility of using a motivational ECA in brain injury rehabilitation?

1.14 Research objectives

This PhD project undertook development and pilot trial of a motivational ECA for use in brain injury rehabilitation. The research project included in-house activities: a scoping review and development and initial testing of an ECA prototype. The ECA conversation dialogues were informed by HBC principles, specifically SDT and MI. A stable model ECA was subsequently developed in consultation with clinical stakeholders of two ambulatory care brain injury rehabilitation services using the Living Laboratory methodology. The refined ECA prototype was then tested in a feasibility pilot trial in the clinical settings.

1.14.1 Main research objective

Main objective: To design and pilot trial an ECA to support motivation in brain injury rehabilitation.

Planning for achieving this main objective was comprised of six sub-objectives, as listed below

1.14.2 Research sub-objectives 1 - 6

Sub-objective 1: Identify the reported literature for the use of CAs in brain injury, disease and stroke rehabilitation via a scoping review.

Sub-objective 2: Choose an appropriate ECA software platform for which ongoing technical support is provided.

Sub-objective 3: Develop an initial ECA prototype in-house

Sub-objective 4: Test and iteratively refine the initial ECA prototype through alpha testing and beta testing

Sub-objective 5: Conduct co-design workshops with clients and clinicians of the rehabilitation services, to develop the prototype ECA to a stable model ECA design.

Sub-objective 6: Complete a feasibility and usability pilot trial of the stable model ECA at the rehabilitation services.

2 Scoping review of the use of conversational agents in rehabilitation following brain injury, disease, or stroke

The contents for this chapter from Section 2.1 through to and including Section 2.7.1, and Appendices I, II, III and IV, are taken directly from the submitted manuscript for this review: 'Hocking J, Oster C, Maeder A, Lange B. The use of conversational agents in rehabilitation following brain injury, disease, or stroke: a scoping review. 48 pages.' submitted to JBI Evidence Synthesis journal on 27-1-22; with minor edits made to improve parsimony of the manuscript content for the purposes of this thesis. The co-authors for this submitted manuscript provided their permission for use of the manuscript in my PhD, and have completed the co-author permission form for this PhD.

This chapter presents the findings from a scoping review which investigated the use of conversational agents (CAs) in rehabilitation for brain injury, disease, or stroke. Conducting this review was seen as essential for this PhD project as it would provide a comprehensive overview of the best available literature relevant to helping inform the design and development of RehabChat. In this review, specific aspects regarding the use of CAs for these clinical populations and contexts were identified. These aspects were both clinical – purposes for using a CA, outcome measures used for appraising the benefit of CAs in rehabilitation, safety issues, different modes for implementing a CA in rehabilitation, and overall barriers and facilitators for CA use –, and technology related – technical design of the CA, usability, and design and development processes. Results for each of these aspects were all seen as potentially useful in informing the design of RehabChat, and potentially of any CA for rehabilitation care for these clinical populations.

The scoping review is included in full below. It was thought that including it in its entirety would best illustrate the breadth of literature considered, the diversity of the included studies, and the summary findings which contribute to defining this field of research. Results for each stage of this review's methodology help to illustrate the nature of this field of literature being new and emerging. The overall results also directly helped to inform the approach taken for this PhD project, as discussed in Section 2.7.2 below.

2.1 Introduction

Adults with brain injury, disease or stroke experience clinical challenges affecting physical, psychological, memory and reasoning domains (22). All of these diagnoses can be

rehabilitated to some degree, due to the physiological process of neuroplasticity. Neuro-plasticity is a process by which the brain forms new neural circuits allowing learning of skills and improved functional abilities (21). Recovery is optimised through multi-disciplinary rehabilitation, the gold-standard approach of care, in which client-centred goals are identified and pursued (22, 26, 32), and goal-attainment is supported (33). During rehabilitation for brain injury and stroke, the level of adherence to, and engagement in, rehabilitation affects neuroplasticity and overall recovery (29, 30). However, in clients with brain pathology, engagement and overall progress in rehabilitation can be reduced due to low motivation or apathy, leading to negative impact on rehabilitation and therapy outcomes (3, 13, 39), and also on engagement in self-directed exercise programs (45). Neuro-imaging has demonstrated that common regions of the brain are affected in individuals with varied brain conditions including dementia and stroke and who have decreased motivation (43). These authors highlight the value of understanding the anatomy of decreased motivation, or apathy, as a basis for the development of effective therapies (43). A specific focus upon supporting the motivational need of clients with brain injury has been discussed in the literature (38, 39). Due to the challenges of brain injury rehabilitation being time-limited, and the potential for clients to experience decreased engagement in therapy, the need for new, innovative approaches for rehabilitation care is warranted. Digital health technology has been proposed as an innovative option to support brain injury rehabilitation (39). Accordingly, understanding how use of a CA (98) during rehabilitation may benefit therapy adherence and/or engagement, and subsequently clinical outcomes, is warranted.

A well-managed CA conversation can better approach the human-human experience of the clinician-client interaction in which therapeutic alliance is paramount to supporting effective health outcomes (117). It is the level of success of this iterative communication pattern that will support optimal impact upon the user, and satisfaction by the user. Natural Language Processing (NLP) systems can use a range of approaches for managing the conversation relating to how the dialogue is managed. These approaches for dialogue management can include user or App initiative, directed or open-ended dialogue, whether purposed to complete a task such as a questionnaire, and if input and output is with written or spoken communication (100). The dialogue management can be finite (suitable for task specific purposes), or agent-based in which participants use language freely and are able to reason through responses, or a semi-directed frame-based dialogue in which the direction of the conversation rests upon the inputs by the user and the knowledge available in the CA (100).

Specific safety risks arising from the use of CAs include the user being misunderstood by the CA, and the CA providing at best annoying or irrelevant replies, or at worst dangerous replies (80). There is consequently an ethical responsibility of CA designers to ensure that the intended impact of the CA is beneficial, and that potential, unintended negative impacts have been ameliorated to produce an overall neutral effect for the user. Some risks however are unknown. An overview commentary on the emergence of CAs worldwide (122) highlights that even though people open up more easily to a CA, it is unknown if in the long-term this will have a negative effect. Such dilemmas will only be clarified through ongoing assessment of CA use. Bickmore et al (117) advise that the type of language processing should match the intended level of accuracy required for user interactions. Specifically, when higher degrees of accuracy are required, then constrained language should be used. If unconstrained language is used, then thorough inbuilt mechanisms for identifying errors and checking for and correcting misunderstandings is required. The high drop-off rate of users with CAs inherently raises a risk of users not receiving enough support to achieve the intended therapeutic outcome (111) such as for rehabilitation. Conversational Agent underuse has been attributed to the CA not doing what it was expected to do (122). It is important, therefore, to understand the potential benefits, as well as risks, of using CAs in any clinical context.

The use of CAs in health care has been reported in a number of previous synthesis reviews of the use of CAs in mental health (127), psychology (102), dementia (144, 145), and health care more generally (100, 128). Rampioni et al (2021) conducted a thematic analysis of ECAs for dementia clients, focusing on the research frameworks used to investigate the interactions between users and the ECA, and any barriers reported in the studies (145). As such, this review did not include CAs, and many of the objectives of our review were not included. A review by Ruggiano et al (2021) (144) focused on the CA technology itself: the authors sourced CAs through online repositories, and appraised them for their content and ease of use. No review has yet been conducted which investigates the use of CAs for brain injury, disease, or stroke by appraising the peer-reviewed and grey literature.

This review aims to inform the design, use, and reasons for using CAs in rehabilitation for brain injury, disease, or stroke, and provide an insight to this novel therapy as an emerging field of research. A scoping review methodology was deemed necessary due to its exploratory nature incorporating a wide range of publication types (including design and development papers, usability evaluations, early pilot trials, which is important when there is

a paucity of effectiveness studies) and also mulitiple clinical contexts. Brain injury, disease, and stroke are included due to there being limited literature regarding the use of CAs in any of these contexts separately. Stroke is similar to brain injury in that it happens suddenly, and results in varied neurological symptoms. Brain disease may have a gradual and progressive onset, resulting in evolving neurological symptoms.

A preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, and *JBI Evidence Synthesis* was conducted (4th May 2020) and no current or in-progress scoping reviews or systematic reviews on the topic were identified.

2.2 Review questions

Main review question: How are CAs designed for and used in rehabilitation for adults aged 18 years and older with brain injury, disease, or stroke?

The sub-questions of the review are as follows:

a) What types of CAs are used in rehabilitation for adults aged 18 years and older with brain injury, disease, or stroke?

b) For what purposes are CAs used in rehabilitation for adults aged 18 years and older with brain injury, disease, or stroke?

c) How are the needs of adult clients aged 18 years and older with brain injury, disease, or stroke integrated into the design of CAs used in rehabilitation care for this population?

d) How are CAs implemented in rehabilitation for adults aged 18 years and older brain injury, disease, or stroke?

e) What outcomes are used to assess the use of CAs in rehabilitation for adults aged 18 years and older with brain injury, disease, or stroke?

f) What safety issues have been identified with the use of CAs in rehabilitation for adults aged 18 years and older with brain injury, disease, or stroke?

g) What are the barriers to using CAs in adults aged 18 years or older with brain injury, disease, or stroke?

h) What are the facilitators to using CAs in adults aged 18 years or older with brain injury, disease, or stroke?

2.3 Inclusion criteria

2.3.1 Participants

This review considered studies that included adults aged 18 years or older with brain injury, disease, or stroke. The onset of the brain pathology needed to have occurred at 18 years or older.

Studies reporting research which was in an earlier stage of development and which involved either healthy participants, or no participants, but for which the intended eventual use was with this clinical participant cohort, were also considered.

Participants' diagnoses could be at any level of severity and include acquired brain injury (ABI) of any aetiology including traumatic brain injury (TBI), brain diseases including dementia, mild-cognitive impairment (MCI), and Parkinson Disease (PD), and cerebrovascular accident (CVA), or stroke.

2.3.2 Technological concept

This review considered studies that explored the design, development and/or use of CAs in rehabilitation following brain injury, disease, or stroke. Inclusion criteria were further clarified during the review process as follows. Studies were included if the CA: was presented in a 2-dimensional way on a computer device (personal computer (PC), laptop) or a mobile device (smart phone, iPad, or tablet); provided an interactive conversation experience with the user in which the CA content related to the user's input; and the content was directed to a clinical rehabilitation need of the clinical cohort. This is consistent with a previous review of ECAs for dementia care, where the inclusion criteria similarly contained the need for an interactive conversation, and content to be specifically related to the clinical focus (144). In another review of ECAs for psychology, the authors excluded studies in which the ECA output would be the same regardless of user usage (102).

Inclusion criteria were modified during the review process, specifically as follows. Studies were included if the CA had a 2-way conversation with the user, and were excluded it the CA only provided prompts or reminders, or asked questions in a pre-determined sequence

without specifically responding to the content of the user's input. Studies were included if the CA could be used on a two-dimensional computing device such as a smart phone or tablet, and excluded if it was integrated within a robot. These criteria changes improved the specificity of the type of CA being considered. Finally, studies did not have to report on outcome measures; this criteria change was helpful in ensuring a reasonable number of papers could be included in the review.

2.3.3 Clinical context

This review considered studies that were conducted as part of, or were developmental /preparation stages for, the intended clinical setting of rehabilitation following brain injury, disease, or stroke. The setting for the rehabilitation (intended or actual) could be centre-based or home-based, and incorporate single or multi-disciplinary care.

2.3.4 Types of evidence sources

Types of studies considered eligible were peer-reviewed publications, or academically published PhD and Master theses. Types of publications included quantitative, qualitative and/or mixed methods study designs; research protocols; peer-reviewed expert-opinion papers; clinical studies including pilot trials; systematic or scoping reviews; and peer-reviewed full conference papers (but not abstracts). For any included review, the list of papers for that review was searched for publications relevant for inclusion in this review. Grey literature sources in the form of theses, conference proceedings and design and development papers were considered for inclusion when the same research had not been presented as a peer-reviewed publication. Only studies published in English were considered due to resourcing constraints. Studies published with any date were considered. Research reports describing the design and development of a prototype CA intended for use in this review's target population, including reports that did not report any outcome results, were also considered. One deviation from the *a priori* protocol (146) was that recruitment did not need to be reported in the study.

2.4 Methods

This scoping review was conducted in accordance with the JBI methodology for scoping reviews (147). This review was conducted in accordance with an *a priori* protocol (146) excepting small modifications outlined in this Inclusion Criteria and Methods sections.

SUMARI software was not used as described in the *a priori* protocol (146), because title-abstract screening and full-text review could be conducted using EndNote X9 (2018, Clarivate Analytics, PA, USA) (EndNote).

Following completion of the search, all identified records were uploaded to EndNote for removing duplicates, and citation screening and management. The search results are presented according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping reviews (PRISMA-ScR) (148) in the PRISMA-ScR flow diagram (1) (see Figure 1).

2.4.1 Search strategy

A broad-ranging search strategy was utilised to identify available citations in a relatively novel field of research. Terminology for the CA aspect included a wide array of terms due to a lack of consensus in CA terminology, including dialogue systems, embodied CA (100), virtual agent, coach/tutor/clinician/social integration partner (102), intelligent agent, or virtual human (101).

The search strategy aimed to locate published primary studies, full conference papers, reviews, PhD and Masters theses, and opinion papers. An initial limited search of MEDLINE (Ovid) was undertaken to identify relevant articles on the topic from which key words were identified and used to develop a full search strategy. The search strategy was adapted for each included information source. The formal search of the information sources was undertaken in January 2021. The full search strategies are provided in Appendix I. The reference lists of included primary studies and secondary reviews were checked for additional papers.

The information sources searched were primary sourcing databases (MEDLINE (Ovid), Scopus, ProQuest, Web of Science) and grey literature sources including International Conference Proceedings Series and ProQuest Dissertations & Theses Global.

2.4.2 Study/Source of evidence selection

Following completion of the search all identified records were uploaded to EndNote X9 and then duplicates were removed using EndNote, and by manual checking. Prior to the formal screening process commencing, a pilot screening process was conducted as recommended in the JBI Manual of Evidence Synthesis (147). This comprised an initial screening of 25

titles/abstracts conducted by both co-reviewers independently followed by comparing the screening results, until at least 75% agreement occurred between the co-reviewers (147); this was achieved in the first round of pilot screening. Two independent reviewers with expertise in brain rehabilitation and CAs conducted the screening process, and any disagreements were resolved by discussion, or an objective arbitrator.

Potentially relevant papers were retrieved in full, and their citation details imported into EndNote. Full-text studies that did not meet the inclusion criteria were excluded, and reasons for their exclusion are provided in Appendix III. Any disagreements that arose between the reviewers were resolved through discussion or with a third reviewer.

2.4.3 Data extraction instrument

The Data Extraction Instrument (DEI) (see Appendix II) was iteratively developed in response to the nature of the included studies being more technical in nature than expected. The initial DEI (in the *a priori* protocol (146)) was focused more on traditional health journal style research articles, whereas the technical studies in this review were focused more on software design, and assessment of technical aspects and usability. Additional technical domains are based on the framework for describing CAs proposed in a systematic review of NLP ECAs incorporating NLP and used in health care by Laranjo et al (100) which includes: turns taken per task, task completions, rate of words inputted which are out-of-vocabulary, user perception of nature of virtual speech qualities, technical design, dialogue management, dialogue initiation, input modality, output modality, task-orientated, subjective experience by user, and any clinician determined outcome measures. This framework has been utilised and extended by Macedo et al (132), with additional categories including health domain and overall purpose (132). Our review has adopted these same domains, as represented in the DEI. The final version of the DEI has four main domains: Evidence source details and characteristics; Research design and health rationale; Technology description: and NLP related areas.

2.4.3.1 Data extraction

Data were extracted from the included papers using the DEI. An additional person was involved in data extraction (BL) due to being able to provide expert input regarding the included papers. The data extracted included specific details about the design and use of CAs in rehabilitation for adults with brain injury, disease, or stroke; the methodology

reported; outcomes measured; results; technical aspects; and safety considerations. Any disagreements that arose between the reviewers were resolved through discussion or with a third reviewer. Authors of papers were contacted to request missing or additional data, where required.

2.4.3.2 Data analysis and presentation

Data was presented in tables and discussed narratively. Findings have been tabulated according to the DEI categories, for ease of reader navigation of the tables. However, in order to answer the research questions, results are presented under headings reflecting the review's main question and sub-questions.

2.5 Results

2.5.1 Study inclusion

Searches were conducted across seven databases, identifying 7488 records. Duplicate records (n=438) and meeting announcements (n=197) were removed, leaving 6853 records for title-abstract screening. Following screening, 149 records were retrieved for full text review, from which 11 studies were finally included. No additional records were added from reference list checking of the included primary studies and additional reviews (n=2) (see Appendix IV). See the PRISMA ScR flowchart (Figure 1) for details.

The reasons for 138 papers being excluded following full-text review (see Appendix III) were: not reporting a CA (n=69); not a peer-reviewed paper (n=6); not having a 2-way conversation (n=37); not a rehabilitative focus (n=20); different cohort (n=5); and content reported in already included paper (n=2).

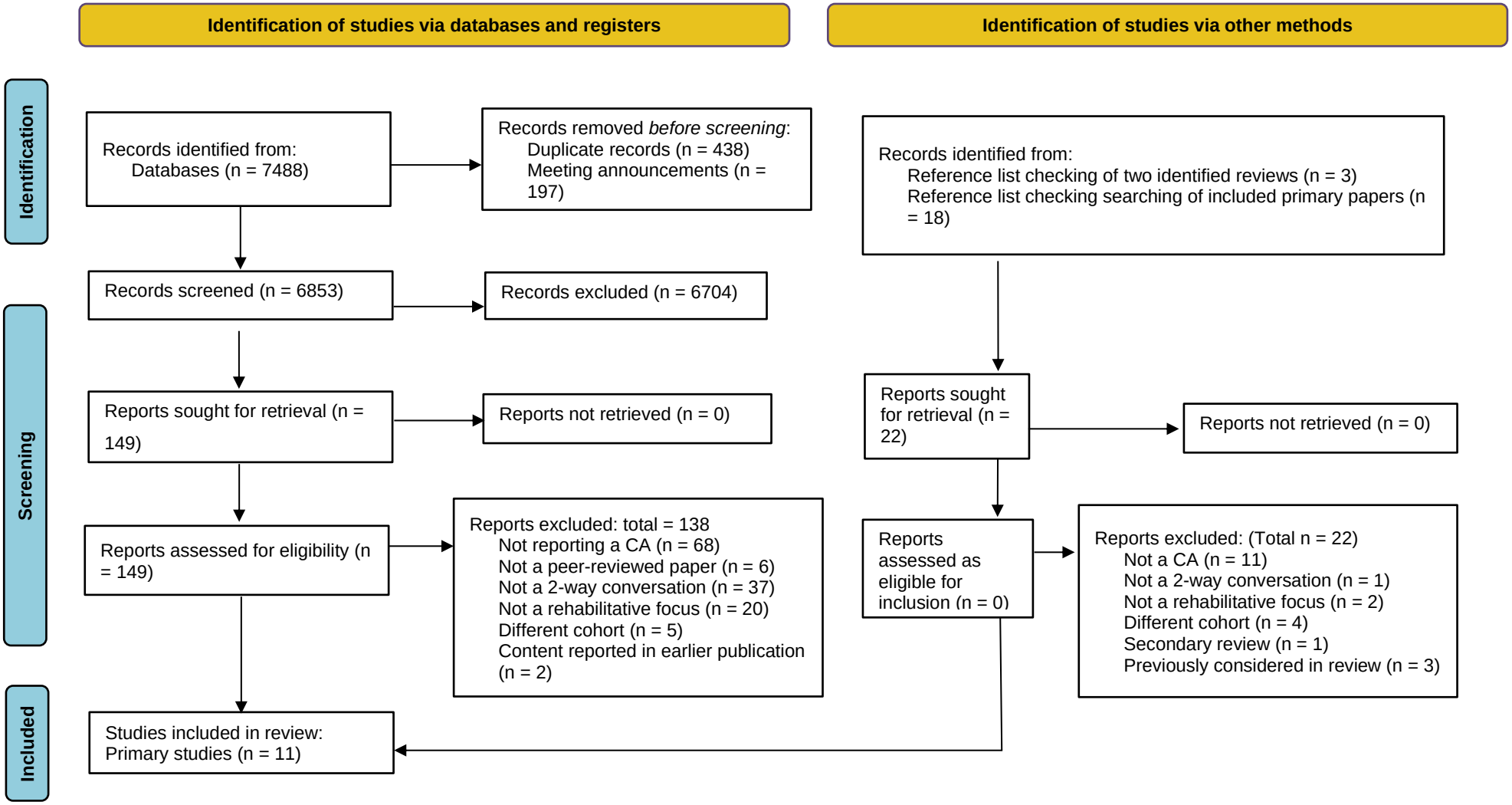


Figure 1: PRISMA ScR flow chart of search results and study selection and inclusion processes (1).

2.5.2 Characteristics of included studies

Ten articles from technological publications and one Masters thesis, published between 2012 and 2019 and reporting on seven CA prototypes, were included. For three of the CA prototypes presented, their iterative development was reported across either two or three papers (131, 149-154) (see Table 1). For the remaining four CAs presented, each was reported in a single study only. Clinical diagnoses considered were dementia (n=5) (150, 152-155), PD (n=2) (130, 132), stroke (n=1) (156), TBI (n=1) (120), mixed MCI and dementia cohort (n=1) (149), and mixed PD and dementia cohort (n=1) (131).

Most of the papers included a description of the technology prototype or proposed technology (n=9) and early user testing (n=6). Of those studies that included participant data (n=6), sample sizes ranged between 1 - 33 participants (120, 131, 149, 150, 153, 156). Four studies reported data on participants with a clinical diagnosis (120, 149, 150, 153), and two studies recruited only healthy participants (131, 156). Only one paper reported attrition, which was of one participant (153). The focus of user testing was either usability and conversation interactions (n=5) (120, 131, 149, 152, 156); or to gather feedback on the visual look of the avatar (n=1) (153).

Table 1: Evidence source details and characteristics

Citation	Country	Context: intended, actual*	Participants: intended, actual*	Recruitment process	Research methodology	Type of research activity
Huang et al 2012 (149)	Japan	Home-based care for MCI / early dementia	N=1 (72yo male, with MCI; a retired architect)	Not reported	Technology description; user testing	Technology description of ECA and 'memory vest' (incorporating sensors to record daily activity); initial user testing
Saito et al 2015 (150)	Japan	Lab-based research Intended context is home-based use with elderly with dementia	N=28 (PwD, (16M, 12F), av age 76.4 yrs)	Not reported	Technology description	ECA technology description and framework for analysing the user's language and attitude.
Ireland et al 2016 (131)	Australia	user testing with general public and older adults Intended cohorts: PwP, PwD	General public (online accessible version of app) Focus groups: N=33 ((17F, 16M), 27-87 yrs (mean: 66.5yrs); 70% owned smartphone)	For focus groups: community groups approached; participants given information forms provided; informed consent process	Technology description Real world use and focus groups	Technology description, brief description of focus group findings (limited)
Ireland et al 2015 (130)	Australia	Intended cohort: Community dwelling PwP	*(no data collected)*	N/A	Technology description	Technology description
Leo et al 2019 (155)	Italy	Intended: Hospital (long-term care) for early dementia	*(no data collected)* Intended: 10 elderly people with early onset dementia, their carers/family, health professionals	N/A Intended: MDT from research will recruit; voluntary participation	Technology description Research protocol	Technology description / prototype (ViTA) Protocol for proposed usability testing

Citation	Country	Context: intended, actual*	Participants: intended, actual*	Recruitment process	Research methodology	Type of research activity
Lohse 2019 (156)	Scotland	Intended: for stroke survivors	N=10 ('healthy' adults with tertiary degrees, (7F, 3M) mean age 32.9, SD=13.8; 9/10 participants had experience with CAs (e.g. Siri); 1/10 had experience with therapeutic CA)	In-house testing: not reported For usability testing: ethics approval; word-of-mouth recruitment; information form provided; informed consent process	Prototype development (data extracted from thesis Ch. 6 – Usability)	Prototype development, in-house testing, early usability testing
Macedo et al 2019 (132)	Portugal	not described	*(no data collected)* Intended cohort: triad of PwP, carer/family, health professional	N/A	Technology description Research protocol	Describes CA design, and how it is integrated on the ONParkinson mobile app – a previously developed platform used by PwP, carer and clinician
Nakatani et al 2019 (152)	Japan	Home-based care for PwD	Brief mention of user testing; no details provided for participant details nor of data collected	Not reported	Technology development and description	Development of how ECA would obtain personal ontology data from conversation with user, and then manage this as Linked Data conversation knowledge base for individual users: 'accumulate and manage' personalised data Initial testing (minimal details) – re: accuracy of data capture and error

Citation	Country	Context: intended, actual*	Participants: intended, actual*	Recruitment process	Research methodology	Type of research activity
						likelihood (no numerical data given) – to test if framework worked – which it did
Nakatani et al 2018 (153)	Japan	Long-term care setting for PwD	N=5 (PwD needing care/support (aged 74-99); 1 withdrew (disinterest in ECA)	Not reported	Basic evaluation on visual element Proposed development	Technology description and early development of 'look' of ECA virtual agent
Sakakibara et al 2017 (154)	Japan	Intended: PwD living at home	No data collected Intended: PwD	N/A	Technology description	Technology description of ECA – focused on development of conversation content
Wilks et al 2015 (120)	USA	Home (smart home technology); intentional design for specific client	N=1 (M with TBI and severe cognitive impairment, ex-serviceman) Feedback from spouse (re acceptability)	Not reported	Technology description and case study	Prototype description; usability, acceptability and safety testing by client and spouse

Legend: ASR = Automatic Speech Recognition; F = female; LOD = Linked Open Data; M = male; MTUAS = Media and Technology Usage and Attitude Scale; NLP = Natural Language Processing; OT = Occupational Therapist; PwD = People with Dementia; PwP = People with Parkinson Disease; RDF = Resource Description Framework; SUS = System Usability Scale; UPO = U=user, P=property, O=object; yo = years old; yrs = years. **Note:** The 11 included papers report on seven distinct CA prototypes. Where a prototype has been reported in two or more papers, the grouping of papers reporting on it are grouped together, separated by a black border.

Table 2: Research design and health rationale

Citation	Rehabilitation purpose*	Mode of use	Content of conversation	Content development	Outcomes measured	Results	Safety	Use barriers	Use facilitators
Huang et al 2012 (149)	Reminisce the day's activities	Converse with ECA at end of day Sensor 'memory vest' collates data on day's activities; database of sensor data will enhance ECA conversation	Activities and experiences of the day; physical wellbeing; meals; childhood memories; where they lived	Avatar design – based on feedback from hospital staff Conversation content – developed: 1. record & transcribe patient conversations; 2. key utterances collated; 3. nurses advised on response rules for key utterances; 4. keywords identified 5. content entered into Julius 6. key-word spotting & phoneme matching (to manage poor diction) 7. in-vivo memory vest	For ECA conversation: # of utterances; utterance duration; keywords; user responses; voice pitch Memory vest: user's movement (run, walk, bike, car, train); location when outside home	User willing to converse with ECA; better engagement when ECA providing backchannel feedback	Not reported	Not reported	Not reported

Citation	Rehabilitation purpose*	Mode of use	Content of conversation	Content development	Outcomes measured	Results	Safety	Use barriers	Use facilitators
				data to be used to enhance ECA conversation					
Saito et al 2015 (150)	Have conversation with ECA for PwD, – improve the quality of CA conversation experience: to avoid observed problem of VA utterance clashing with user speaking – through recognising user intent to pause outright or to pause and recommence speaking	User seated at desk, PC on desk, with video camera and microphone Approx. 10-minute conversation	Weather, family, health, food, hobby Binary tree structure for questions: yes/no questions asked by ECA until end of tree, when ECA then asks an open-ended question	Recorded (audio-visual recording of conversations (42) between PwD and ECA : video data – non-verbal data (gaze, pause) annotated, for machine learning model	Attitude recognition : user's intent to speak, and/or paused User's conversation : duration : topic frequency : utterances User's non-verbal data : gaze outside of display : pause +/- intent to speak again	Conversation duration, # of utterances, & pause duration likely useful indicators of user's attitude regarding speaking or pausing	Not reported	Not reported	Not reported
Ireland et al 2016 (131)	Analyse voice quality from voice sample; focus on gaining user	ECA 'Harlie' initiates phone call to user between 8a.m. –	Not clearly described; appears that any topic can be discussed	AIML for case-based reasoning & text pattern matching for varied topics,	Real-world use study: outcomes not reported Focus groups: usability; future	Focus groups: overall positive; some technical	Not reported	Issues from focus groups: technical issues (processing speed,	Not reported

Citation	Rehabilitation purpose*	Mode of use	Content of conversation	Content development	Outcomes measured	Results	Safety	Use barriers	Use facilitators
	voice sample (rather than on topic content)	8p.m.; or user can phone Harlie Converse on any topic user would like		situations & tasks System architecture : speech input : input control (detect utterance, pitch) : behaviour control (TTS, render animation) :output (speech & animation)	use suggestions Voice sample: articulation (vowels); vocabulary (range); mid-sentence pauses CA profile database of : utterances (#, duration), user responses (keywords, pitch)	issues (processing speed, problematic replies by CA); : in future – could provide company for aged care residents		'problematic' ECA responses, internet access)	
Ireland et al 2015 (130)	Engage PwP in conversation, monitor wellbeing & medications, obtain voice samples for analysis	Independent use	Questions on mental wellbeing, depressive symptoms; monitor medications & health status Information on support resources and exercise promotion	AIML – ECA can vary question structure / phrasing ECA can learn from poor answers	None	N/A	User may express depression or suicidal thoughts – if so, CA offers client to talk with support person/service	Not reported	Support needs in dexterity and/or speech limitations (provide options for voice and keyboard input)

Citation	Rehabilitation purpose*	Mode of use	Content of conversation	Content development	Outcomes measured	Results	Safety	Use barriers	Use facilitators
Leo et al 2019 (155)	Reminiscence therapy – storytelling of client's life	- initially, the CA asks the carer for input about the memories; the carer contributes to building stories by adding information - after this set-up phase, client initiates interactions through interactive speech-text interface, and listens to story recall ('map' of memory fragments)	personalised life stories / memories (minimal information)	1. client completes survey on personal photos (assisted by psychologist & family member) 2. Carer collates memory pieces onto ViTA into a memory framework 'map'	None collected Intended: for PwD – interview, demographic data, health history, record and medication review, comprehensive psycho-geriatric outcome assessments; SUS Intended: for carer – Care Burden Inventory; SUS	N/A	Not reported	Not reported	Not reported
Lohse 2019 (156)	Treat anxiety using TASK therapy protocol (internet-based CBT program)	Self-directed use to complete TASK exercises	TASK therapy protocol: education; self-monitoring; cognitive restructuring; exposure; response prevention;	1. Datasets of 18 clients completing 2 TASK activities : data cleaned (Python) : intents identified	MTUAS SUS Think-aloud evaluation Qual. interview	SUS median 78.8, mean 76.5 (SD17.7). General feedback : CA is more interactive	Not reported		Suggestions from user feedback: customised videos for different learning styles; videos in same stye as CA; use more emojis &

Citation	Rehabilitation purpose*	Mode of use	Content of conversation	Content development	Outcomes measured	Results	Safety	Use barriers	Use facilitators
	Education & information		relaxation training	(Watson Assistant) : CA trained 2. Two researchers did alpha testing; bugs resolved 3. Four post-grad students trialed it; bugs resolved; content refined 4. 10 graduates trialed it: main outcomes measured		that website or paper instructions : CA persona is friendly, positive, personal, formal : easy; clear cues; activities varied well; videos interesting Suggestions : talk through times of increased anxiety; give more feedback			GIFs; be able to change entered responses; more discussion – not just do exercises; describe exercises as stories
Macedo et al 2019 (132)	PD education	Used on ONParkinson website platform (which provides communication between triad of client, carer and therapist Limited detail on UI and	PD Minimal details.	1. prior survey (N=36 PwP) – information needs: main topics medication management & exercise) 2. health professionals developed content for both topics	None in this paper Intended / protocol: 1. evaluate tech performance (accuracy; recover from errors) 2. UX: preferences,	N/A	Not reported	Not reported	Not reported

Citation	Rehabilitation purpose*	Mode of use	Content of conversation	Content development	Outcomes measured	Results	Safety	Use barriers	Use facilitators
		user interactions Intended trial use: 1. 1/7 in controlled setting 2. 30/7 'in-the-wild' use		3. focus groups iteratively developed these & additional topics	satisfaction with speech & answers 3. health outcomes: intervention vs control group; interval measures				
Nakatani et al 2019 (152)	Increase amount of conversation that PwD has; make it easier for client to complete lengthy care profile questionnaire through doing this in conversation planning of CA conversation needed dynamic ability to respond to open field answers	Daily conversation CA asks questions on topics of interest to user	Reminiscence focus – profile, and life history Personal interest topics: e.g., life history, hobbies, favourite singer	1. Asks care profile questionnaire questions 2. extracts data using UPO model; convert data gathered to RDF format 3. uses LOD to enrich conversation topics	Ability for ECA to extract noun phrases from user input	ECA able to 'appropriately extract the noun phrase' (minimal detail)	Not reported	Not reported	Not reported

Citation	Rehabilitation purpose*	Mode of use	Content of conversation	Content development	Outcomes measured	Results	Safety	Use barriers	Use facilitators
	from clients (vs. developing pre-defined schema)								
Nakatani et al 2018 (153)	Regular conversation; promote user engagement through optimising ECA visual appeal	1. user chooses picture of preferred person they know 2. Avatar is styled on this 3. user has 3-minute conversation 4. user provides feedback	Not clearly described Focus is on visual details	Focus on developing visual presentation - based on chosen photo - multiple control points applied to image, software then stretches & moves these to form facial expressions	Acceptance of ECA Engagement with ECA Feedback on default vs. personalised ECA	Feedback : prefer personalised ECA; want to talk with familiar looking person : speech needs developing to accord with new style	Not reported	Not reported	Not reported
Sakakibara et al 2017 (154)	Increase conversation for PwD; to allay negative states (fear, sadness, anger) Decrease carer burden earlier ECA model used static script designed for	User speaks to ECA on PC screen	Life history; where lives; hobby LOD to enhance conversation content	1. Asks care profile questionnaire questions 2. extracts data using UPO model; convert data gathered to RDF format 3. uses LOD to enrich conversation topics	None	N/A	Not reported	Not reported	Not reported

Citation	Rehabilitation purpose*	Mode of use	Content of conversation	Content development	Outcomes measured	Results	Safety	Use barriers	Use facilitators
	each user (too burdensome for designers)								
Wilks et al 2015 (120)	develop rapport with client, to improve engagement; ECA to then provide reminders for daily tasks (brush teeth, call friend etc.)	Use at home (integrated into smart home set-up) 1. User had interview with researcher 2. User had interview with ECA 'Ava' – with support from OT 3. compared results from 1 and 2	Game of 20 questions Style : free-flowing, flexible and structured, not scripted	Not reported	Engagement (start, maintain & end conversation) Monitor : gaze to ECA, or away : if got up from conversation : duration of each conversation Feedback from spouse	ECA WOZ : 45-60 min : WOZ input focus on maintain conversation : user gaze most on ECA : minimal disengagement : wife reported answers more extensive cf. usual	OT supervised client use of ECA, to ensure minimal/no agitation or stress; & spouse present as standby support, not speaking. Wellbeing of spouse – authors describe that client responses could upset spouse	Not reported	Not reported

Legend: * indicates domains based on Macedo et al 2019 (132). **Note:** The 11 included papers report on seven distinct CA prototypes. Where a prototype has been reported in two or more papers, the grouping of papers reporting on it are grouped together, separated by a black border.

Table 3: Technology Description

Citation	*Task-oriented: yes/no*†	*Hardware*	*Software*	*Dialogue management*§	*Dialogue initiative: User, System, Mixed*	*Input modality*	*Output modality*	Appearance
Huang et al 2012 (149)	No	Not described	Avatar design: Poser 7 Animations: Adobe Flash Speech recognition: Julius Speech output: Google TTS	Frame - because asks a list of pre-determined questions, one-by-one	System	Speech	Speech Avatar animations (gestures: nodding, idling movements)	Young male doctor in white medical coat; head & trunk fill whole PC screen
Saito et al 2015 (150)	No	Desktop computer	Speech recognition: NLP & ASR Timing of speech outputs: detects audio-visual cues (minimal detail)	Finite-state then frame-based - yes-no questions to reach end of 'tree' at which point open-ended question is asked	System : asks questions in fixed order	Speech Video-recording of user's head & shoulders	Speech Avatar animation	Young male doctor in white medical coat; head & trunk fill whole PC screen
Ireland et al 2016 (131)	Yes	Smartphone	Android app using Google TTS & STT Animation rendering: Flash	Frame-based - uses stored AIML files and NLP, and a non-deterministic conversation	Mixed	Speech – user holds down green button when speaking	Text Speech	Speech bubbles, image of green robot next to CA's dialogues
Ireland et al 2015 (130)	Yes	Smartphone	Android operating system AIML Android app using Google TTS & STT	Frame-based - uses stored AIML files and NLP, and a non-deterministic conversation	Mixed	Speech	Text Speech	Speech bubbles: red (for bot); green (for human) No avatar character

Citation	*Task-oriented: yes/no*†	*Hardware*	*Software*	*Dialogue management*§	*Dialogue initiative: User, System, Mixed*	*Input modality*	*Output modality*	Appearance
Leo et al 2019 (155)	Yes	Intended for use on varied smart devices: tablet; smartphone; companion robot etc.	IBM Cloud cognitive platform, including TTS & STT NLP: ML trained to interpret 'intents and requests' related to entered memory content	Frame-based - completes a survey, ML trained to interpret 'intents and requests' related to entered memory content	Mixed	Speech Text Interactive touch-screen UI	Speech Images & icons	Not reported
Lohse 2019 (156)	Yes	Smartphone PC	IBM Watson; IBM Watson Assistant; Python	Frame-based - has the TRAK system of questions/information/exercises, linked with resources such as video or music. The client adheres to the program; some choice making allowed	System	Speech or text	Text Education resources such as diagrams, video, relaxing nature music	Text, video options (not shown)
Macedo et al 2019 (132)	No	Smartphone	IBM Watson Assistant Android Google TTS, STT	Agent-based	User	Text, speech (Portuguese)	Text, speech (Portuguese)	Speech bubbles, colour coded for CA & user; static avatar icon next to CA's bubbles
Nakatani et al 2019 (152)	No	PC or laptop	Web API (Java) with Apache Tomcat & Apache Axis2 MotionPortrait SDK for facial model. Bing speech API within	Frame-based - personal data enriched with LOD	System	Speech	Speech Animated avatar	Animated humanoid – friendly young lady – on LHS of screen; text bubbles & click

Citation	*Task-oriented: yes/no*†	*Hardware*	*Software*	*Dialogue management*§	*Dialogue initiative: User, System, Mixed*	*Input modality*	*Output modality*	Appearance
			Microsoft Azure for voice.					options on RHS
Nakatani et al 2018 (153)	No	PC or laptop	Same as Nakatani et al 2018	Not clearly described (as focus of article is on visual design)	Not clearly described (as focus of article is on visual design)	Speech	Speech, animated avatar	Animated design; friendly young lady – on LHS; text bubbles & click options on RHS
Sakakibara et al 2017 (154)	No	PC integrated with smart home technology and Cloud internet	Web API (Java) with Apache Tomcat & Jersey & Apache Axis2 LOD (DBPedia Japanese)	Frame-based - personal data enriched with LOD	System	Speech	Speech LOD content: text, image, movie	Animated design; friendly young lady – on LHS; text, LOD content on RHS
Wilks et al 2015 (120)	No	PC	No CA software described – used WOZ) Avatar design: www.sitepal.com	Not described	Mixed	Speech	Speech Animated avatar	Described that animated avatar presented on PC screen; minimal details

Legend: NLP = natural language processing; SLR = Sections in *italics* are based directly on recommendations for reporting on CAs from Laranjo et al (100); * indicates domains based on Macedo et al 2019 (132). † = Yes: to gather essential data, No: Not focused; instead provides conversation experience. § = Finite-state: pre-determined steps; Frame-based: need to complete a template. Unconstrained language; Agent-based: system intelligent behaviour; builds a conversation. PC = personal computer; TTS = text to speech; STT = speech to text. **Note:** The 11 included papers report on seven distinct CA prototypes. Where a prototype has been reported in two or more papers, the grouping of papers reporting on it are grouped together, separated by a black border.

2.5.3 Review findings

The review results are presented in tabular form in Tables 1, 2 and 3, according to the first three main domains of the DEI. The final DEI domain of NLP related areas is not presented, due to no study reporting on any of the areas for this domain.

2.5.3.1 Types of conversational agents

Of the seven prototypes reported, only two were distinctly described as incorporating an embodied humanoid avatar (149, 150, 152-154). One of these offered the option for personalizing the avatar design (153). For two CAs, text bubble content without an avatar was the primary design focus of the user interface (130-132) . For three of the CAs, insufficient detail was provided to know what the visual design was like (120, 155, 156). The reported CAs were used on a PC (n=2) (120, 150), PC or laptop (n=2) (152, 153), PC within a smart home set up (n=2) (120, 154), a smart phone (n=3), (130-132) on a PC or smartphone (n=1) (156), and one study stated the software was intended for use on a variety of smart devices (155). Wizard of Oz (WoZ) control of the CA (in which a human determines output of the CA during conversation with the user) was reported for one study (120).

2.5.3.2 Purposes for using conversational agent

Key purposes described for the CA presented included: to increase the amount of conversation the user has each day (n=4) (130, 152-154) including for the purposes of helping to minimize negative emotional states (154); reminiscence (n=2) (149, 155); and one study each for anxiety management and education (156), PD education (132), improve quality of conversation experience through analysing user intent to speak (150), build rapport prior to providing prompting for daily tasks (120), obtain and analyse a voice sample from PD client to help monitor their voice quality within their disease progression (131) and to combine this also with monitoring wellbeing (130).

2.5.3.3 How client needs integrated into design of conversational agent

The ways in which relevant coded content was obtained for developing the CA conversations varied across the studies and included: recording open-ended interviews with clients (n=2) (149, 150), using data from completed questionnaires (152, 154) or surveys (132, 155), or from user interactions with an online structured therapy intervention (156). Linked Open Data (online open-access repositories of information) was utilised to augment conversation content (n=2) (152, 154). A carer helped develop memory content for a CA (155). One of the projects developed a CA specific to the needs of a specific client with TBI study (120), whilst the remaining studies reported CA development and testing for an intended cohort more generally.

2.5.3.4 How implemented in rehabilitation

Recruitment processes were described for two of the six user testing studies (131, 156). The duration of the CA use was reported in three studies, and ranged from three minutes (153), to 10 minutes (150) and to 45-60min (120). The remaining studies did not provide details about duration or frequency of use. Two studies described support being provided by 1-2 persons (120, 155). Specific clinician oversight of the client using the CA was reported in one study in which an occupational therapist supervised the client using the ECA, to help ensure the client did not become agitated or stressed, and additionally, the spouse was present during the session to act as a standby support but did not provide any verbal input (120). The environments in which a CA was used included the user's home (131, 149, 154) integrated with smart home technology (120) and a residential care facility (155).

2.5.3.5 Outcomes measured

The outcomes included measures and feedback for system usability (156) (utilising the System Usability Scale (18)); preference for default or personalised avatar; engagement with ECA use (153); gaze to ECA or away, conversation duration), language detection (utterance number and duration, voice pitch (149); intent to speak or pause (150), voice sample for vowel articulation and mid-sentence pauses (131) and technological performance (CA ability to extract noun phrases (152); processing speed and problematic CA replies (131); CA speech audio (153)). No health or wellbeing outcomes were assessed.

2.5.3.6 Safety considerations

No adverse events were reported. Mental wellbeing safety considerations were reported in two studies in terms of whether the user expresses depressive or suicidal thoughts – in which case the CA offered the client to talk with support person or service (130) – , and the role of the OT supervising the client's use of the CA is to ensure that the client did not become agitated or stressed (120). The nine remaining papers did not report on safety.

2.5.3.7 Barriers to using conversational agents

One paper (131) reported barriers to use identified through focus group feedback, which were processing speed, 'problematic' ECA responses and internet access. The ten other papers did not discuss any barriers.

2.5.3.8 Facilitators to using conversational agents

Three studies reported facilitators for CA use (156) including ensuring that the client's spouse found the ECA acceptable (120), incorporating customised videos for different learning styles

(155), and providing options for both voice and keyboard input to support user needs in speech and dexterity (130).

2.6 Discussion

This scoping review adopted a very broad-ranging search strategy used with both health and technological databases, to optimise the likelihood of identifying all possible articles from peer-reviewed and grey literature sources. This approach identified many potential studies, of which only 11 were finally included. These 11 papers demonstrated creativity and diversity of approaches for providing a CA tool for use by the clinical cohorts and showed that this field of research is in its early stages, with papers reporting prototype development and early user testing. The papers also illustrated that the unique need of these cohorts can be represented in the design of CA technology, albeit effectiveness testing was not incorporated into the studies. It was of interest to note the three suites of papers each presenting the step-wise development of a CA – these presentations help to convey the rigour in which CA prototypes are developed, and in what ways specific functionalities are embedded into the software. It also demonstrates the potential flexibility of this research field in being able to incorporate design aspects in a manner responsive to client needs.

The included papers reported numerous factors regarding CA use relating to engagement in using the CA and in engaging in therapy, wellbeing, and leveraging care. Engagement with using the CA could be facilitated by incorporating reminiscence topics and stories of personal meaning to the client (155). Increased CA use enables the client to receive the intended benefits of having more conversation. Ways in which a CA was used to support engagement in existing care structures included integrating the CA in the following ways: with an existing online therapy package so as to support and facilitate meaningful interactions (156); and within an online platform for interaction between a client with PD, their carer and clinician (132), in which the CA supported completing an essential questionnaire regarding the client's life history and interests, results of which were used to model their care (152). Support for wellbeing was enabled by CA use through monitoring wellbeing in the conversation (130), and by enabling increased conversation experience which was seen as assisting in reducing negative mood (154). Finally, use of a CA leveraged usual care by providing a tool for obtaining voice samples to be analysed for voice quality and function for PD (130, 131), and a CA intended for prompting the client to do daily activities (120). Both of these examples enable therapeutic actions to be completed without human input.

The main types of methodology were technology description of prototype CAs and early user testing with low sample sizes, with focus on conversation content and management. These factors reflect the over-arching nature of the included papers being at the early development and testing stage. The main areas of under-reporting were the NLP-related areas. This was possibly due to

most of the studies having small participant numbers, and the focus for the testing was to check if the overall system worked reliably. Nonetheless, the lack of planned intention to assess the NLP domains including speech recognition, natural language generation and speech synthesis is a gap and should be addressed in future research. Without such evidence regarding these factors, it is difficult to appraise the reliability of the CA.

Barriers and facilitators to use and safety were poorly reported in the included studies. These domains are of key interest to health professionals when deciding the potential applicability of the tool for their clinical work. Given the novelty of CAs for rehabilitation, with their effectiveness not yet being-researched, it is paramount that safety particularly be prioritized in future research. Careful study of barriers and facilitators of CA use will assist ongoing research in streamlining trialling to relevant types of prototypes, and optimising CA usability and real-world uptake. Similarly, the lack of description of recruitment should be addressed in future research including at the earlier stages of feasibility testing (4), with unbiassed, voluntary recruitment utilising informed consent processes being implemented. For studies with just one participant, rationale should be stated for this including difficulty recruiting, or the study design warrants it.

The clinical context of rehabilitation for brain injury, disease, or stroke is a complex one comprising the client, the multi-disciplinary therapy team, carers, and family. Each client's needs are unique, and may change dynamically, due to deterioration in their condition or through gaining positive recovery. Accordingly, any CA tool needs to be resilient to deal with these many dynamic aspects. There are potentially a wide range of indications for using CAs in this complex setting – memory assistance, goal setting and pursuit, education, and mood support. Some clients in this cohort need some degree of clinician oversight whilst using a CA. Therefore, it is an imperative that the research 'speaks' to the clinician – addressing effects that the clinician should know regarding testing in their cohort, risks, benefits, validity of content development, and the recommended duration of intervention to achieve the intended benefits.

This review has indicated the need for future translational research to progress to investigate feasibility, acceptability, and usability of the CAs for clients, carers and family, and clinicians, particularly to investigate which features and capabilities are needed and preferred by these consumers. Following these mid-stages of research and development, effectiveness testing of possible benefits of the CA on rehabilitation outcomes, as well as the risk for any unintended negative outcomes, should be undertaken. These areas of research are necessary for ensuring that novel technical developments in CA design and functionality can be thoroughly appropriated to clients' rehabilitation needs, clinicians' requirements, and clinical service constraints.

Our review has reported the development and evaluation of CAs from a peer-reviewed research perspective, regarding the technical description of the CAs, the ability of the CA to be integrated

into usual care, and the perspectives of client- and clinician- end users. This contrasts to a systematic review of commercially available CAs for dementia clients and caregivers (144) which analysed the CAs regarding functionality and the quality of interactions using a previously developed evaluation template (157) completed by the researchers, with no input from the intended end-users. It also contrasts to a thematic literature analysis focusing on end-user feedback regarding CAs used in dementia care, which highlighted the need for consulting with intended end-users and ensuring that the CAs functionalities meet the clinical needs; however, this review did not include description of the CAs being referred to (145). Finally, in a mapping study of CAs used for health (98), the main areas considered were user experience, the different options for user interactions, conversation structure, duration, and language understanding. It notably does not discuss particular health contexts nor the need for effectiveness testing needed to validate its use. Our review in comparison sought to discuss both the technical aspects and the health considerations.

The nature of this review's findings have been echoed in a much larger scoping review of ECAs (as stand-alone software or web based interventions utilising two-dimensional or robotic technology) used in psychology for which 54 papers were included (102). In that review, over half of the studies were for a single condition (autism), which parallels our review with dementia represented in five of the 11 studies. The psychology review identified that the research field was in early stages of development and piloting, with only five studies looking at evaluation (of user experience) and only one study was a RCT (102). Again, this is similar to our review, in that the predominant mode of assessment was of user experience (in six of the 11 papers).

This review's included articles all came from technological publications and no health journals. This finding has been discussed previously in a review of SMS text-based dialogue systems used for mental health (127). It has been noted that there is likely a number of these types of research reported as papers and conference proceedings in technology databases, but which do not become published in health databases, due to not achieving the required level of clinical consideration in how they are represented (127). This could be likely due to the computer technology and informatics audience being interested in algorithms and background software mapping, and health professionals being interested in clinical safety and efficacy.

2.7 Conclusion

This scoping review presents the results of a broad-ranging search investigating the design and use of CAs in rehabilitation for brain injury, disease, or stroke. The 11 included studies demonstrated that this field of research is in its early stages, with most papers presenting technology description and early prototype development. Nonetheless, this review's results demonstrate how the unique clinical needs of these cohorts have been integrated into CA

technology, and that these CAs were able to be used by the clinical participants as reported in initial usability testing. Given that CAs can be used on highly accessible PC and mobile technology devices, there is much value to be gained from further research in this field, with particular emphasis on careful translation of the technology into the real-life clinical setting, and progression to effectiveness and safety testing. Currently though, the evidence in this field is limited, and does not allow for any systematic review. The nature of the current evidence means that strong conclusions cannot be made. Accordingly, clinicians should be cautious when utilising CA technology in practice because of the lack of sufficient evidence reporting on their safety and effectiveness for clinical use. Nonetheless, this scoping review demonstrates sufficient indication for ongoing research in this field.

2.7.1 Implications for research

CA technological developments can occur at a rapid pace, faster than what can be thoroughly assessed from a health perspective and imbuing a somewhat fluid nature to this field of research. To help overcome this dilemma, clear reporting frameworks can be used to assist in ensuring that research is conducted and reported in ways that are common across the fields of technology development and rehabilitation. Future related research should include development of best practice guidelines for the reporting of health CAs generally, and also specific details for rehabilitation CAs. Developing and implementing recommendations for reporting on rehabilitation CAs would then provide basis for more rigorous clinical trials and systematic reviews in the future. It is those levels of evidence that will facilitate clinical acceptance and validity for use. The DEI used in this review offers one reporting framework option, as it covers both rehabilitation and technological domains. Other relevant frameworks include the World Wide Web Consortium's guidelines for cognitive accessibility (158) and WHO reporting recommendations for novel digital health technologies (159).

Future research should importantly report on domains of safety, barriers, and facilitators for use, and the accuracy of the CA in detecting user input and producing appropriate outputs. Co-design, or at least regular intervals of user testing, with comprehensive feedback being gathered and integrated into the design of the CA and its intended mode of use, is recommended. This will help to optimise the usability, feasibility, and acceptability of the CA. Overall, a cautious approach to the development and implementation of CAs for this setting is required due to client participants' cognitive vulnerability and susceptibility to stress or other negative outcomes, even with a stable model CA. The intended CA abilities need to be thoroughly determined and assured before being used by client-participants. Research should also consider the views and perspectives of clinicians and family members/carers, as their perspectives will help to improve the usability of a novel CA.

2.7.2 Relevance for the design and development of RehabChat

The implications for future research stated above relate directly to the design and development of RehabChat. Specifically, RehabChat should be developed with a cautious approach because there is a lack of any research precedent for developing a CA for brain injury rehabilitation, and because clients with TBI as the intended end-users for it have complex needs related to fatigue, memory, and cognitive challenges. As such, they are at greater risk of experiencing stress or frustration using an ECA, or for becoming unsure about the process for using the ECA alongside usual care, compared to a healthy cohort. As well, safety issues should be actively observed for, not only because of the clients' clinical needs, but also because the field of CA research is still in its relative infancy and does not yet offer a comprehensive appraisal of safety risks associated with CA use. Similarly, current research negligibly reports on the barriers and facilitators for CA use in this cohort. As such, these should be carefully appraised for RehabChat. Aligned with this is the lack of agreed standards or guidelines for the development of health CAs, thus requiring that RehabChat be developed with adherence to relevant broader guidelines for technology design.

This review helped to define the design of RehabChat regarding the style of language processing, and also the dialogue and conversation structure used. It was decided that NLP would not be used for RehabChat because resourcing and time did not allow for the development of this. In regard to dialogue and conversation structure, this review helped to confirm that simple language, use of affirmations, and a focus on what is meaningful for the client should indeed be incorporated. This review also inherently affirmed the approach taken for testing RehabChat of commencing with healthy participants then progressing to focus group type testing prior to a mixed methods feasibility pilot trial, paralleling the findings of this review that most of the included papers reported user testing in various forms.

Finally, this review's clear finding of a lack of reporting of this field of research in health journals, and the under-reporting of factors relating to health research themes of content validity and recruitment processes, underscores the imperative for the RehabChat project that it reports these factors transparently. These factors are presented in detail throughout the thesis, with much of RehabChat's development being focused on its content being changed in response to participant feedback and with reference to relevant literature.

The following chapters of this thesis will describe in detail the step-wise approach used for addressing the above considerations within the development stages of RehabChat – from in-house testing through co-design workshops and a final feasibility pilot trial – and the use of relevant guidelines, such as the Web Content Accessibility Guidelines (WCAG) (20, 139, 140), for 'auditing' RehabChat's design. These stages were deemed necessary to thoroughly prepare the ECA ready for a later future clinical trial.

At all of RehabChat's development stages, the complex clinical needs of clients were considered. and the high priority areas of safety, barriers and facilitators, and recommendations for improving the intended mode of use of RehabChat were appraised through participant feedback. After in-house testing and co-design workshops, changes were made in response to feedback. For feedback obtained from the pilot trial, this has informed the design of future research for RehabChat at the rehabilitation settings.

This review positions the RehabChat project in the current literature landscape and indirectly illustrates that the RehabChat project addresses the relevant requirements for adequately reporting the step-wise development of a CA for brain injury rehabilitation.

3 Overarching methodology: Living Laboratory

This chapter presents the overarching methodology for this project which is Living Laboratory (Living Lab), a description of why Living Lab was chosen for this project, and details of how Living Lab has been practically applied in each stage of this project.

3.1 Choosing a project methodology: Living Laboratory

The choice of a co-design methodology for this project was based upon three factors: able to accommodate the unique needs of participants with a brain injury; accord with the underlying motivational frameworks for this project of Motivational Interviewing (MI) (11) and Self-Determination Theory (SDT) (52) (see Chapter 1); and to have been successfully used previously for technology design projects with people with brain injury or cognitive impairment. To accommodate the clinical needs of client participants in this PhD, the project methodology also needed to be conducted in a way that supported participants being able to extrapolate their experience participating in the project to their real-life context. Ways this could be achieved were for participants to have sufficient time and repeated opportunity for reflection and clarification of ideas through iterative engagement. As well, in order to avoid increased cognitive effort, the methodology needed to allow the participant to use the prototype artefact in their familiar setting (such as a clinic, or their home). In contrast, if the participant used the artefact in a research setting, it would take increased cognitive effort to imagine using it in their real-life context and to provide meaningful feedback. For the methodology to align with MI and SDT, it needed to facilitate a client-centred approach, in which the focus of the research artefact was to meet client needs, and also that the client was central to determining the focus of design.

The Living Laboratory methodology (160) (Living Lab) met these requirements in the following ways: it integrates consultation with both client and professional end-users (161); highlights the need to understand the perspectives, experiences and environment of the end-users (162); and enables the research approaches to be conducted in ways that sensitively meet the needs of clients with traumatic brain injury (TBI) (162) including helping to reduce cognitive fatigue. Indeed, there are specific aspects of Living Lab that are highly relevant for brain injury rehabilitation research. It allows participants repeated opportunity to provide iterative feedback during the design project and enables them to use the artefact in their environments. This approach is helpful for clients with TBI who have memory challenges, and/or who require extra time to understand a novel concept. Living Lab can also include a focus of observing participants using the artefact as intended and obtaining their feedback (user testing), with active inclusion of participants in the actual design and creation process (participatory design) (163). Conducting iterative cycles of consultation regarding the development of the project's artefact, and contextualising the research

to the end-user's world, helps to minimise participant's effort in envisioning the novel tool being developed.

Living Lab also has clear affinity with the motivational support paradigms for brain injury rehabilitation – MI (11) and SDT (52) – in which the client's needs and perspectives are understood and supported within their real-life setting. Living Lab similarly seeks to understand end-user needs and perspectives, and the real-life context of the user's experience. Living Lab is inherently responsive, explorative, and open-ended in its approach. At the start of a Living Lab project, it is unknown how the project will finish (16). This approach enables iterative development of a novel product in response to evolving consultation and feedback: this ensures the participants can express candid priorities and personal views and opinions (17). Finally, Living Lab has been used for the design of technology solutions for adults with brain injury and cognitive impairment, specifically with clients with TBI living in community housing for designing smart-home technology solutions (162), and also for development of a memory assistant for older adults with memory loss (164). It is also the preferred co-design methodology for the Flinders Digital Health Research Centre (FDHRC) which is the academic setting for this project. In contrast, the Delphi co-design methodology focuses upon consensus being achieved between the participating experts (165) without practical, integrated testing in the real-life setting.

It is important to note that whilst Living Lab includes use of qualitative research methods to engage with participants and to achieve the defined project goals (166), it is not a qualitative methodology. Living Lab is explicitly a methodology which seeks to reach an end-point with the design and development of a tool. This contrasts with qualitative research which seeks to explore phenomena of interest (167).

3.2 Overview of Living Laboratory's five key tenets applied to this project

Living Laboratory provides a comprehensive framework for conducting research in a real-life context (168) through implementation of its five key tenets (160). These tenets are end-user engagement; testing in a real-life setting; multi-stakeholder consultation; multi-method-approach; and co-creation (160). Living Lab has been found to be the only design methodology that includes such a comprehensive array of methodological domains (161). The approach recommends that for stakeholder consultation, that both public and private sector entities, university academics, as well as intended end-users are engaged (160, 163). Additionally, Living Lab emphasizes that for effective end-user engagement, researchers should take time to thoroughly learn about and understand the priorities of the end-users (160).

This project was comprised of progressive stages: ideation, initial prototype development, in-house testing, co-design workshops, and a mixed methods feasibility pilot trial. Living Lab was incorporated at each of these stages and allowed for iterative end-user consultation, and subsequent responsive changes being made to RehabChat. This approach was achieved through applying the five Living Lab tenets interconnectedly (see Figure 2) as described below.

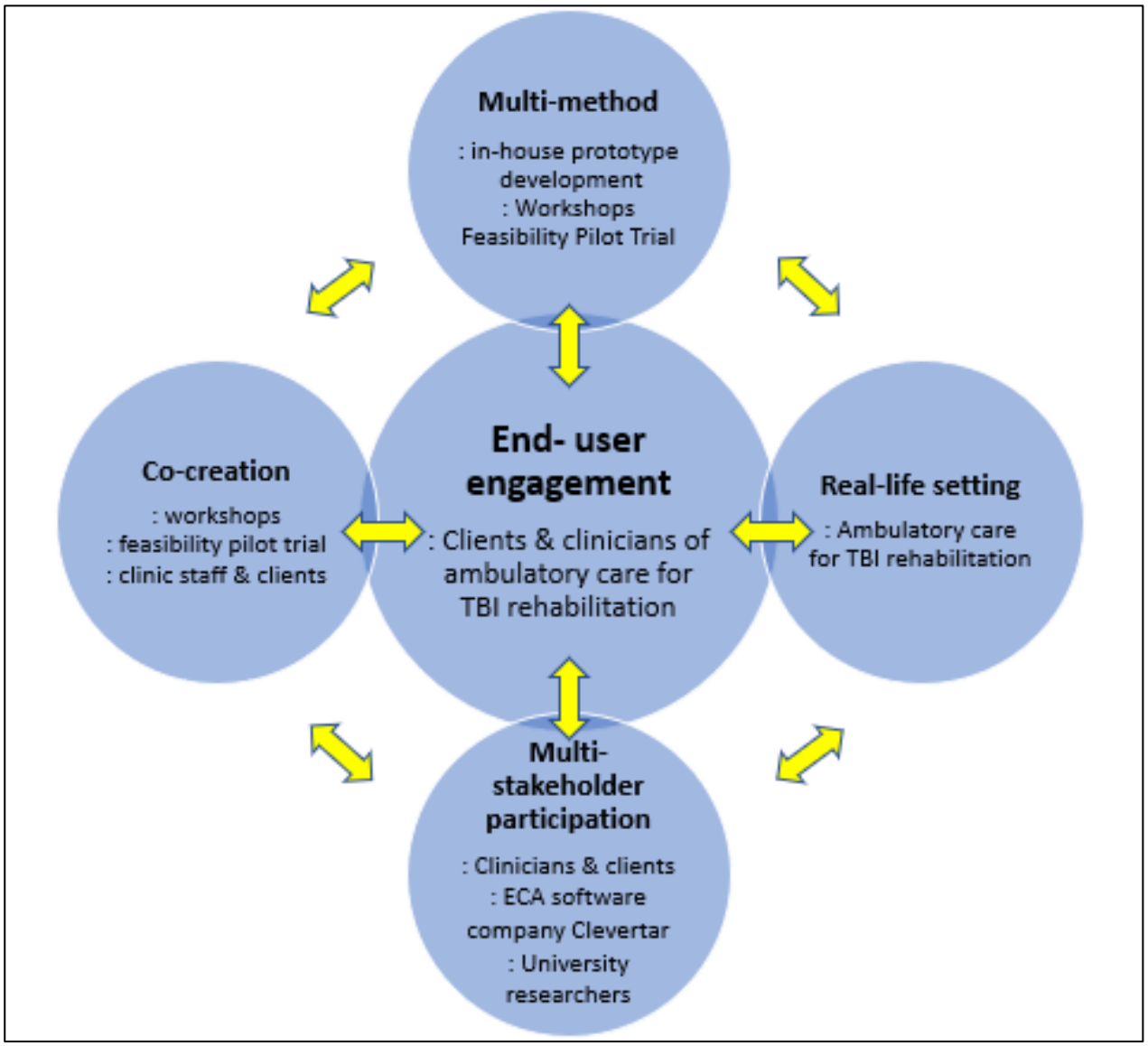


Figure 2: Living Lab five main tenets applied to this project

Early ideation was based on not only literature review and discussion with academic staff, but through also through stakeholder consultation with senior clinic staff. Three ideation meetings with senior clinicians, managers, and the research coordinator of the TBI rehabilitation ambulatory care services were conducted in 2019. During these meetings, the relevance and viability of this project was discussed, and it was confirmed that the project would be relevant and achievable to conduct, and that the ECA software was overall appropriate in its design. Following these consultations, in-house prototype development commenced, in which the ECA conversation structure and content was initially developed with consideration given to known clinical needs of clients with TBI. During

the next stage of in-house development, alpha and beta testing were conducted during which the healthy participants were asked to consider the perspectives of clients with TBI and their rehabilitation clinicians. Finally, direct consultation with clients and clinicians was achieved in the co-design Workshops and the feasibility pilot trial. Following each stage of consultation in this project, design changes were made to RehabChat, with these changes being reviewed in the subsequent stage of testing. This multi-layered approach to iteratively gaining input to RehabChat's development helped to optimise its relevance for ambulatory care TBI rehabilitation, and acceptability to the end-users, both of which are important factors contributing to the uptake and implementation of RehabChat more broadly (169). The way in which each of the five Living Lab tenets have been implemented practically in this project are discussed in detail below, and also presented in Table 4 below.

Table 4: Applying the five tenets of Living Lab to this project

Living Lab tenets	Project activities	Details
Co-creation	Ideation meetings	Regular ideation meetings conducted with university researchers and brain injury rehabilitation research coordinator.
	Co-creation Workshops	Iterative co-creation Workshops with clinicians and clients (see Figure 2)
	Feasibility wilot trial	Conduct 2-week intervention: RehabChat used alongside usual care by client-therapist dyads
Multi stakeholder participation *(see Table 5 for details)*	In-house development of initial ECA prototype	University academic staff specialist in digital health and PhD candidate; Clevertar P/L
	In-house alpha testing	University academic staff specialist in digital health
	In-house beta testing	University academic staff and PhD candidates working in digital health
	Co-creation workshops	Participants from both clinics: current and discharged clients with TBI; clinicians
	Feasibility pilot trial	Participants from both clinics: current clients with TBI; clinicians
Real-life setting	Recruitment	Specific screening process developed in consultation with clinicians
	Feasibility pilot trial	RehabChat used in end-users' environment: in clinic appointments; and client's home
Active user engagement	Co-creation workshops	Iterative cycles of consultation with clients and clinicians, and ECA prototype development
	Feasibility pilot trial	Client-clinician dyads used ECA alongside usual care; mixed methods results inform further ECA development
Multi-method approach	Multiple, varied stages of testing and development	In-house development of initial prototype (170): identify appropriate software platform; alpha testing; beta testing
		Co-creation workshops (see Figure 3)
		Feasibility pilot trial: client-clinician dyads used ECA alongside usual clinical care
	Use established guidelines for assessing the ECA	WCAG (158) domains of Perceivability, Operability, Usability and Robustness used to construct assessment approaches for co-creation workshops and feasibility pilot trial
		UTAUT (142) used to devise the question guide for semi-structured interviews for feasibility pilot trial
	Qualitative-type* research design	Qualitative data collection for co-creation workshops and feasibility pilot trial. Analysis utilised the Framework Analysis approach (171). Data managed using NVivo qualitative data analysis software (14)
	Mixed methods research design	Mixed methods data collation and analysis used for feasibility pilot trial: quantitative data included the SUS (18), standardised quantitative questionnaires for rehabilitation engagement, motivation and system usability (see Section 6.4); qualitative data as above.
	Adapting methodology to specific needs of clients with TBI	Specific requirements of the brain injury rehabilitation clinics and of the clients' clinical needs have were integrated into the project's methodology (see Table 6)

Legend: * = Whilst Living Lab may utilise qualitative research methods to achieve defined project goals (166, 172), it is not a qualitative methodology exploring a phenomena of interest, but instead seeks to reach an end-point with the design and development of a tool (167). WCAG = Web Content Accessibility Guidelines. UTAUT = The Unified Theory of Acceptance and Use of Technology assessment framework. SUS = System Usability Scale

3.2.1 Real-life setting

The real-life setting of the clinics has been incorporated into the two main stages of development for RehabChat: in the co-design workshops by recruiting clients and clinicians from both clinics, and into the feasibility pilot trial by situating it in the actual clinic setting and client's home setting. The clinical settings for this research project were two brain injury rehabilitation services, both part of the state-wide public rehabilitation services. Both services provide inter-disciplinary rehabilitation for adults with brain injury (ABI), offering tele-rehabilitation and in-person clinic and/or community appointments. One service provides care to adults with moderate-severe ABI (ABI arising from any cause including TBI), and the other provides care to adults with mild TBI (173). The research co-ordinator for these state-wide services consulted on finer points of methodology relating to the clinical application of the project within the real-life clinic settings was the site contact person for this project. This project was also conducted in the client's home environment: the client-participants in the feasibility pilot trial used RehabChat at home in-between their clinic appointments.

In regard to applying the research to the real-life setting, this project takes the testing to the participants' context. This is in contrast to the alternative Living Lab approach of creating a purpose-built setting which mimics the user's setting and to which the intended end-user must enter and experience (162). This latter alternative approach, although allowing researchers to control for variables more easily, would be less supportive of clients with TBI when providing context-specific feedback.

3.2.2 Multi-methodology

Multiple and distinct methodologies were carefully chosen and implemented in this project using the Living Lab approach. These methodologies can be grouped under in-house development, the co-design workshops, and the feasibility pilot trial. All methodologies needed to meet both the clinical needs of clients (see Table 6) as well as technological recommendations for digital technology development such as the Web Content Accessibility Guidelines (WCAG) (20, 139). Additionally, specific approaches were chosen for appraising the relevant peer-reviewed literature: a broad-ranging literature review to gather sufficient rationale for this PhD (see Chapter 1), and a more focussed scoping review to consider the green field of the use of CAs for rehabilitation for people with brain injury, disease, or stroke (see Chapter 3).

In-house development included iterative testing through alpha and beta cycles of testing, with changes made to RehabChat following each round. For the co-design workshops, three rounds of consultation meetings were held separately for each of three sub-cohorts (current clients, discharged clients, clinicians), followed by a final fourth meeting incorporating all three groups (see Figure 12 in Chapter 5). Following each meeting, audio recordings were taken, and a transcription

finalised for each recording. This qualitative feedback was analysed using a Framework Analysis approach (171). Framework Analysis is used in qualitative research including for research conducted by multi-disciplinary teams (171). It enables data analysis to proceed in a transparent way to a pre-defined purpose (for this project it was to identify feedback that would directly impact upon the design of RehabChat) and can be done for studies involving 1:1 interviews or focus groups (in this study these are called co-design workshops) (171). Iterative changes were made to the ECA in response to findings of the data analyses.

In the feasibility pilot trail, client-clinician dyads used the ECA alongside usual rehabilitation care. The clinician provided clinical oversight for their client during the trial to ensure client safety and wellbeing, and that rehabilitation goals and practice activities were suited to the client's needs (see Figure 4 in Chapter 3, and Figure 11 in Chapter 4). A single-case series A-B-A research model was used due to the likelihood of low numbers of recruited clients. This research design has been used previously in stroke rehabilitation research (174). Each of the 'A' phases lasted for one week, and the 'B' phase for two weeks. The client-clinician dyads used the ECA for two weeks, alongside usual multi-disciplinary rehabilitation care. The feasibility pilot trial included mixed methods data collection and analyses comprising semi-structured interviews, and completion of quantitative outcome measure questionnaires related to rehabilitation and validated for this cohort, and the System Usability Scale (SUS) which, although not validated for use in this cohort, has simple wording and is short (18).

3.2.3 Active engagement by intended end-users

The primary end-users for this project were clients with TBI of either clinic. The eligibility criteria were having a diagnosis of TBI, able to give own consent, and able to use an iPad. The auxiliary end-users were clinicians of either clinic. The unique clinical needs of clients with TBI were considered closely when designing this project's methodology, rather than clinicians' needs, due to clients having specific clinical needs regarding communication, memory, and cognitive fatigue (see Table 6). Nonetheless, clinicians' needs were also considered and addressed by designing the feasibility pilot trial to be minimally invasive upon their work-time and upon how they usually provided care. This was achieved through designing the content of RehabChat to match established rehabilitation approaches of goal-setting and progress review (33, 67), which is further described in Chapter 4 and has also been reported previously (170).

3.2.4 Multi-stakeholder participation

Consultation with multiple stakeholders has occurred during all of this project's stages. Consultations were held with intended end-users to achieve co-creation of RehabChat (see next section) and with multiple other stake-holders. These other stakeholders included the PhD supervision team comprising expert academics from the fields of Living Laboratory, computer

science, rehabilitation, and/or digital health. Regular consultation was held with the PhD supervisors throughout the whole project. A key stakeholder was the Research Co-ordinator for the collaborating brain injury rehabilitation services, who was consulted during all project stages except for alpha and beta testing. Clients and clinicians were consulted during the co-design workshops and feasibility pilot trial. Early ideation meetings were held in 2019 with senior clinical and management staff of the collaborating brain injury rehabilitation services (formal meetings firstly with the Research Co-ordinator, and later with senior administrative and clinical management; and a semi-formal discussion with middle management, senior clinicians, and staff clinicians).

Table 5: Stakeholders' participation in project

Stakeholders	**Stage of project**				
	IDENTIFY PROBLEM (need to leverage care)	**SOLUTION CONCEPT** (motivational ECA)	**SOLUTION DESIGN** (alpha & beta testing)	**PROTOYPE SOLUTION** (co-creation workshops)	**REFINED SOLUTION** (feasibility pilot trial)
PROJECT TEAM MEMBERS: university academic PhD supervisors & PhD candidate	√	√	√	√	√
ACADEMIC STAKEHOLDERS: other academic staff and PhD candidates			√		
PUBLIC EXTERNAL STAKEHOLDER: Senior clinicians and managers from collaborating clinics	√				
PUBLIC EXTERNAL STAKEHOLDER: clients and clinicians from collaborating clinics				√	√
PUBLIC EXTERNAL STAKEHOLDER: Information Technology, & administrative staff from collaborating clinics					√
PRIVATE EXTERNAL STAKEHOLDER: Clevertar Pty Ltd (175), Chief Technical Officer		√	√	√	√
SOLUTION DOMAIN EXPERT: Research Coordinator for brain injury rehabilitation clinics	√	√		√	√
END-USER POPULATION: Clients with TBI – current clients				√	√
END-USER POPULATION: Clients with TBI - discharged clients				√	
END-USER COMMUNITY REPRESENTATIVE: Clinicians of collaborating clinics				√	√

Legend: TBI = traumatic brain injury

Technical aspects of the project were discussed with the Chief Technical Officer (CTO) of the software company Clevertar Pty Ltd (175) (Clevertar) who provided the Clevertar Virtual Human

software for this project. Clevertar was not involved in conceptualising or assessing RehabChat. Clevertar provided pro bono use of the ECA software for this project as well as free technical support. Formal annual meetings were held with Clevertar's CTO to advise on the project's overall purpose and progress and to clarify how RehabChat would be presented in the thesis. Additional email communication was also had with the Clevertar CTO from In-house testing stage through to the end of the project, to enquire about technical capabilities of the ECA software, and to resolve occasional software glitches.

Further stakeholders were involved for determining how to integrate RehabChat into the clinic setting for the pilot trial. These people included the senior service manager, administration staff, electronic case-note managers, and Information Technology staff. Through consulting with these professionals, a streamlined way was organised for how RehabChat could be accessed alongside usual care, both via tele-conferencing and by being loaded onto clinic iPads, and for automated summary e-record entries.

3.2.5 Co-creation

Co-creation – or co-design – in Living Lab refers to how input from participants directly informs the design of the project's artefact, which can occur iteratively throughout the project's duration (163). Participants in this project included the intended end-users and the multiple stakeholders (see sections above).

A considerable aspect of Living Lab is co-design with intended end-users. Co-design with intended end-uses should be conducted when developing a novel digital health tool – such as an embodied conversational agent (ECA) for rehabilitation – to optimise the tool's usefulness and improve its acceptability (176). Co-design enables the researchers to identify the unique needs and perspectives of the intended end-users, which is particularly relevant when working with adults with traumatic brain injury (TBI) in order to accommodate participants' needs including cognitive fatigue and memory challenges. Co-design has previously been implemented in brain injury rehabilitation research for varied purposes. Examples of this include creating solutions relating to employment (177) and strategies for self-management (178), and for developing telerehabilitation services (179). A range of co-design approaches previously used with participants with learning disabilities (172) are also relevant for participants with TBI. These approaches include acknowledging and acting upon participant choices and feedback, thus empowering participants to perceive themselves as active influencers in the project; and ensuring that the materials and content delivered in co-design sessions match participants' abilities incorporate using cognitively similar approaches across different sessions (172).

Co-design in this project was achieved through recruiting clients and clinicians from the clinics, and having regular consultation with the site research coordinator throughout the project. Co-design

helped ensure that iterative design changes to both RehabChat, and also to how the project was being conducted, could be implemented in a responsive manner. The multi-disciplinary supervision team for this PhD project have experience in computer science, Living Lab methodology, rehabilitation, digital health technologies, and in implementing research in clinical settings, and provided expert guidance for the whole project. Input from all of these participants has influenced how RehabChat has been created, with particular emphasis on meeting the clinical needs of clients in both the purpose and content of RehabChat, and in how the project was conducted (see following section).

3.2.5.1 Addressing the clinical needs of end-users

In order to achieve effective co-design with client end-users in this project, it was necessary to address their clinical needs in how the methodology was designed. The process for this is presented below. This project contextualised the development of RehabChat within the real-life clinical setting so as to best ensure it will meet the needs of both clients and clinicians. This aligns to Living Lab's tenet of focussing on the real-life setting and the needs of the intended end-users.

Using a Living Lab approach has meant that the specific requirements of the clinical setting were closely considered and integrated into the project activities. This was achieved through responding to feedback from ideation discussions with stakeholders and responding to feedback from beta testing (see Chapter 4). This feedback identified specific clinical requirements needing to be accommodated in the design of the project activities (see Table 6). Integrating these considerations was essential to ensuring that client participation was optimally supported. Optimising participant support was important for improving feedback quality, which in turn better informed the usability and acceptability of RehabChat.

Table 6: Design of project activities to integrate clinical considerations - client needs; requirements of brain injury rehabilitation settings

Project activity	Clinical considerations	How considerations integrated into design of each activity
Screening & recruitment	Eligible clients may have other issues (e.g. social stressors, other health challenges) precluding their participation	Clinicians who know clients' needs decide on client's eligibility, suitability
	Client's trust of project improved if clinic staff, rather than research staff, make initial contact	Screening clinician contacts client
	Client may forget to reply to initial information provided	Screening clinician to do follow-up phone call if no reply by RSVP date
Co-creation workshops	Three sub-cohorts have unique perspectives	1st, 2nd 3rd rounds of workshops conducted with each cohort in separate meetings
	Inherent power differential between clinicians and clients	
	All sub-cohorts together - reassures participants that feedback has been treated equally and collectively	4th workshop conducted with all cohorts together
	Clients use ECA on the intended device (iPad) so better able to imagine use in clinic	Use ECA on iPad at each Workshop
	Using ECA is a new and cognitively demanding experience for clients	First, the training module practised by participants, then parts of the rehabilitation module
Feasibility pilot trial	Clients may require simple, repeated cues for how to use ECA	Participants first complete ECA training module and assessment
	Clinician aware of their specific role in providing oversight	Clinicians receive additional training about their role
	Possible challenges recruiting clients with TBI; likely small Ss	Statistical model: single case series design, A-B-A model
	Client made aware ECA being tested, and not a proven treatment	Explain in recruitment. Short ECA testing phase of two weeks;
	Monitor variations in well-being in clients	Pre-trial, during and post-trial repeated measures to assess anxiety, depression, energy, and motivation
	Clients with TBI can experience fatigue	Clinicians educated to screen for this. Client can take rest breaks when using ECA
	Outcome measures should match needs of clients	Outcome questionnaires validated for cohort, except SUS (18) which has simple wording and is short
	Usual clinical care ongoing to ensure optimal clinical outcomes	ECA to be used alongside usual care in usual clinic service delivery model

Legend: ECA = embodied conversational agent; TBI = traumatic brain injury; SUS = System Usability Scale

3.2.5.2 Specific approaches for screening and recruitment

Client needs were specifically considered when designing the Screening and Recruitment process for both the co-design workshops, and the feasibility pilot trial. The screening process was developed iteratively through consulting with the research coordinator of the collaborating brain injury rehabilitation services, and staff champions. Key aspects decided for the screening process were that the clinicians conducted eligibility screening of the clients as they would have insight about each client's needs and social situation because factors apart from eligibility criteria may determine if the client will be suitable for participating in the study (for example, if the client was experiencing other considerable demands related to managing their home life or returning to work). Results of the screening and recruitment processes were collected according to the Consolidated Standards of Reporting Trials (CONSORT) recommendations for feasibility studies regarding criteria to be reported for screening and recruitment (4). See Chapter 4 for details of the screening and recruitment process.

Specific aspects of the recruitment process were also designed to meet client needs. Establishing trust with potential client-participants was prioritised as it was identified that trust affects the client's openness towards considering participation in the study. To help establish trust about the study, a familiar clinic staff person contacted each eligible client to invite their interest in participating and ask if they would like an information brochure emailed to them. The staff person would also follow up with the client following this regarding if they would like to speak with the research person regarding participation. To facilitate a supportive approach when recruiting client-participants, a separate participant information and consent form was developed for clients (see Appendix X). This used simpler language compared to the version for clinicians (see Appendix IX).

3.2.6 Use of Living Laboratory for in-house development, co-design workshops and feasibility pilot trial

The methods developed for in-house development, co-creation workshops and the feasibility pilot trial, as well as for the associated elements of eligibility screening and recruitment, and for appraising usability of the ECA, are presented in Table 6. Details are provided in Table 6 on how these activities were designed to accommodate and support the complex setting of brain injury rehabilitation, and the specific clinical needs of clients with TBI. These methods were developed through consideration of beta feedback, working within the technical

capabilities of the Clevertar Virtual Human software, and having ongoing consultation with academic stakeholders and the research coordinator for the ambulatory care brain injury rehabilitation services involved in this project.

The five main tenets of Living Lab were used more comprehensively in the co-design workshops and feasibility pilot trial, than during the earlier in-house work. This was because the latter two larger parts of the study were conducted directly with end-users. Nonetheless, end-user needs and the intended real-life setting were closely considered during in-house development and testing by both the researchers and the healthy participants.

Below is an overview of how Living Lab has been applied for the in-house testing, co-design workshops, and the feasibility pilot trial. For each of these projects, a description of how each of the five main tenets of Living Lab are implemented is provided.

3.2.7 In-house development

In-house development, including details of alpha and beta testing, has been previously reported in (170), and is presented in detail in Chapter 4.

3.2.7.1 Alpha testing

Active involvement of end-users: Academic supervisors were the participants: whilst completing the testing, they were asked to consider the perspective of clients and clinicians of brain injury rehabilitation setting.

Real-life setting: The real-life setting was indirectly represented through the participants considering brain injury rehabilitation whilst completing the testing. This approach is defensible because alpha testing is focused on identifying technical issues rather than on nuancing the clinical contextualization of the product.

Multi-methodology: The purpose of alpha testing was to identify and resolve any technical glitches, and to gather preliminary feedback on its clarity, user experience, and potential fit-for-use. Modifications to RehabChat would be made in response to this feedback.

Multi-stakeholder engagement: Academic PhD supervisors participated. Clevertar provided technical input if required.

Co-creation: Client and clinician end-users were not engaged in alpha testing. Feedback from the academic participants resulted in changes being made to RehabChat.

3.2.7.2 Beta testing

End-user engagement: Client and clinician end-users were not engaged in this sub-project; however, their perspectives were considered by participants: participants asked to adopt the perspective of either a clinician or a client

Real life setting: Participants were asked to consider the context of a brain injury rehabilitation service

Multi-methodology: User Experience testing with healthy participants (this has been previously reported for a CA for stroke rehabilitation (156). Participant feedback was analysed using the Framework Analysis approach (171).

Multi-stakeholder consultation: Participants for beta testing were PhD candidates and academic staff with experience in digital health and/or neuro-rehabilitation. Clevertar provided technical support if required.

Co-creation: Findings of data analysis of participant feedback resulted in substantial changes to RehabChat, including clarifying the purpose and content of RehabChat, and also the mode of use intended for it in the real-life clinic setting (see Chapter 4).

3.2.8 Co-design workshops

Co-creation: The co-creation workshops were designed to ensure that the unique perspectives of the three sub-cohorts (current clients, discharged clients, and clinicians) would be clearly expressed, by conducting separate meetings for these groups in the first three rounds of workshops (see Figure 3). This model ensured that inherent power differences between the clinicians and clients could be managed. The final fourth workshop was conducted with all participants together to demonstrate that all feedback was considered equally in informing the design of RehabChat (see Figure 3).

During each of the workshop meetings, participants used the ECA on an iPad. The participants were first taught to use the ECA by practising the training module. Following this, they could ask any questions whilst using parts of the rehabilitation module. Using this supportive approach created an immersive, and less cognitively demanding experience

rather than if the researcher merely demonstrated ECA use on an iPad or through an audio-visual presentation. It also facilitated participants being able to express their responses in real-time , which in turn allowed for more open and thorough feedback and discussion amongst participants. The workshops allowed participants time to contemplate what they thought, to express their views, and compare with other's views. This is different to answering a questionnaire independently of others input (17).

Active end-user involvement: Clients and clinicians from both clinics participated in all four workshops. Both current and discharged clients were recruited, in order to allow people who had already completed their care to look back and see if their perspectives had changed from when they were a current client, and to also consider the discharge time period of their rehabilitation journey in which they transitioned from the support of a therapy team.

A guide for conducting the workshops was developed which enabled the researchers to respond to the participants' feedback in real-time and to ensure the workshop discussions were user-centred rather than researcher centred.

Real-life setting: The focus areas for the semi-structured discussions in the workshops were motivation in rehabilitation, user preferences for the design of RehabChat and its content, and how best to integrate RehabChat alongside usual rehabilitation care. In this way, the real-life setting was considered.

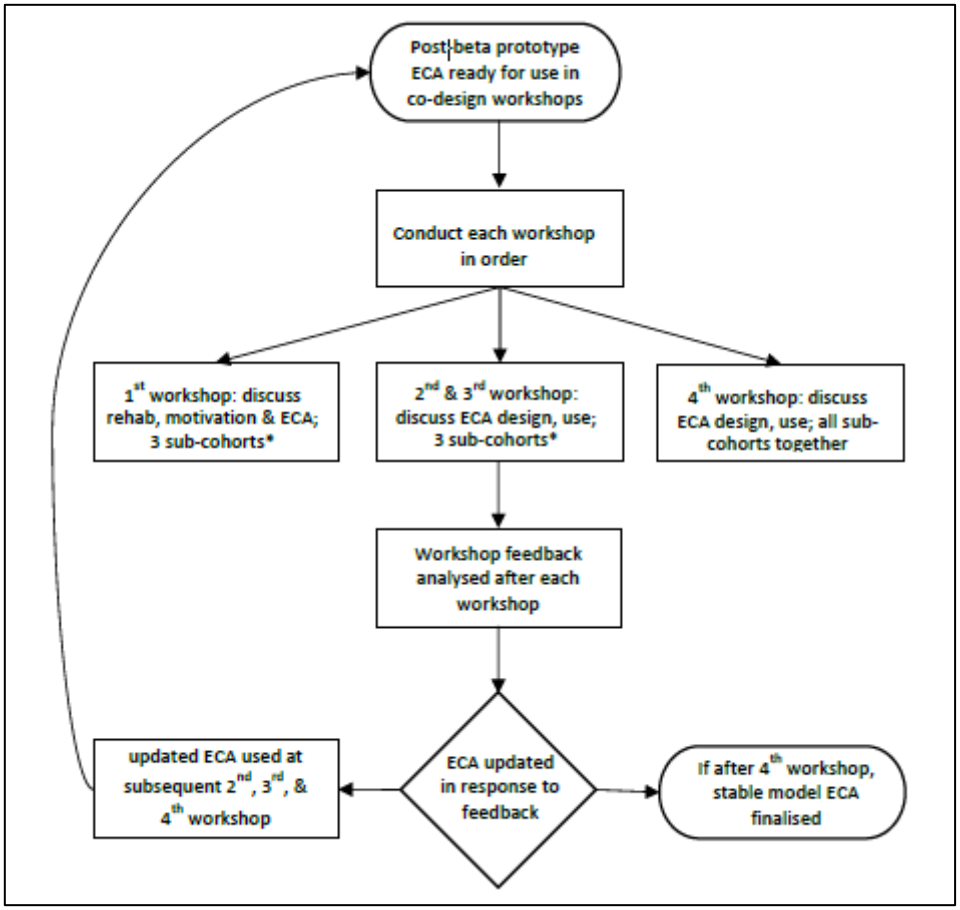


Figure 3: Series of four co-design workshops with current clients, discharged clients, and clinicians

3.2.9 User experience testing – the preliminary part of the feasibility pilot trial

A specific approach was implemented for user testing of the refined prototype developed at the end of the co-design workshops. Clinicians recruited to the feasibility pilot trial received initial training in how to use RehabChat, and also about their role as a supervising clinician. They then participated in user testing during which they used RehabChat freely, gave open-ended feedback about their experience and opinions, and answered semi-structured questions. This approach to user testing enabled the prototype to be checked for obvious usability issues or design problems in a contextualised but time-efficient way. Feedback for user testing resulted in a small number of important changes to RehabChat (see Chapter 6, Section 6.5.2).

Real-life setting: Participants were clinicians of the two clinics.

End-user engagement: Clinician using RehabChat and providing feedback

Real-life setting: Clinician considers use of RehabChat in their clinical work

Multi-stakeholder consultation: Clinicians, Clevertar, clinic I.T. staff

Multi-methodology: User testing; iterative approach to prototype development

Co-creation: Clinician feedback is integrated into RehabChat; and this refined prototype is used in the pilot trial.

3.2.10 Mixed methods feasibility pilot trial

The mixed methods feasibility pilot trial was focussed on testing feasibility, usability, and acceptability (see Chapter 6). Figure 4 below shows how the RehabChat ECA was integrated alongside usual care. Participants received initial one-to-one training to use RehabChat with support of the researcher. This training incorporated each participant receiving a user guide, completing the ECA training module and being able to ask questions. This approach promoted ease of learning for participants, and in particular reduced cognitive demand for clients in the lead up to using RehabChat during clinical care. Client needs were further supported through ensuring that the dyad clinician received further training for their role of providing clinical oversight regarding ensuring that the set goals were meaningful for the client and comprised the SMART aspects (17), and in monitoring the client's well-being.

Active user involvement: Clients and clinicians involved as dyads

Real-life setting: Integrated for use alongside usual rehabilitation care.

Multi-methodology: Real-world use; qualitative 1:1 semi-structured interviews; quantitative data obtained from questionnaires for clinical outcomes and usability.

Multi-stakeholder engagement: Clevertar, clients, clinicians, clinic I.T. staff

Co-creation: Feedback from client and clinician participants has helped design a blueprint for future testing and development of RehabChat.

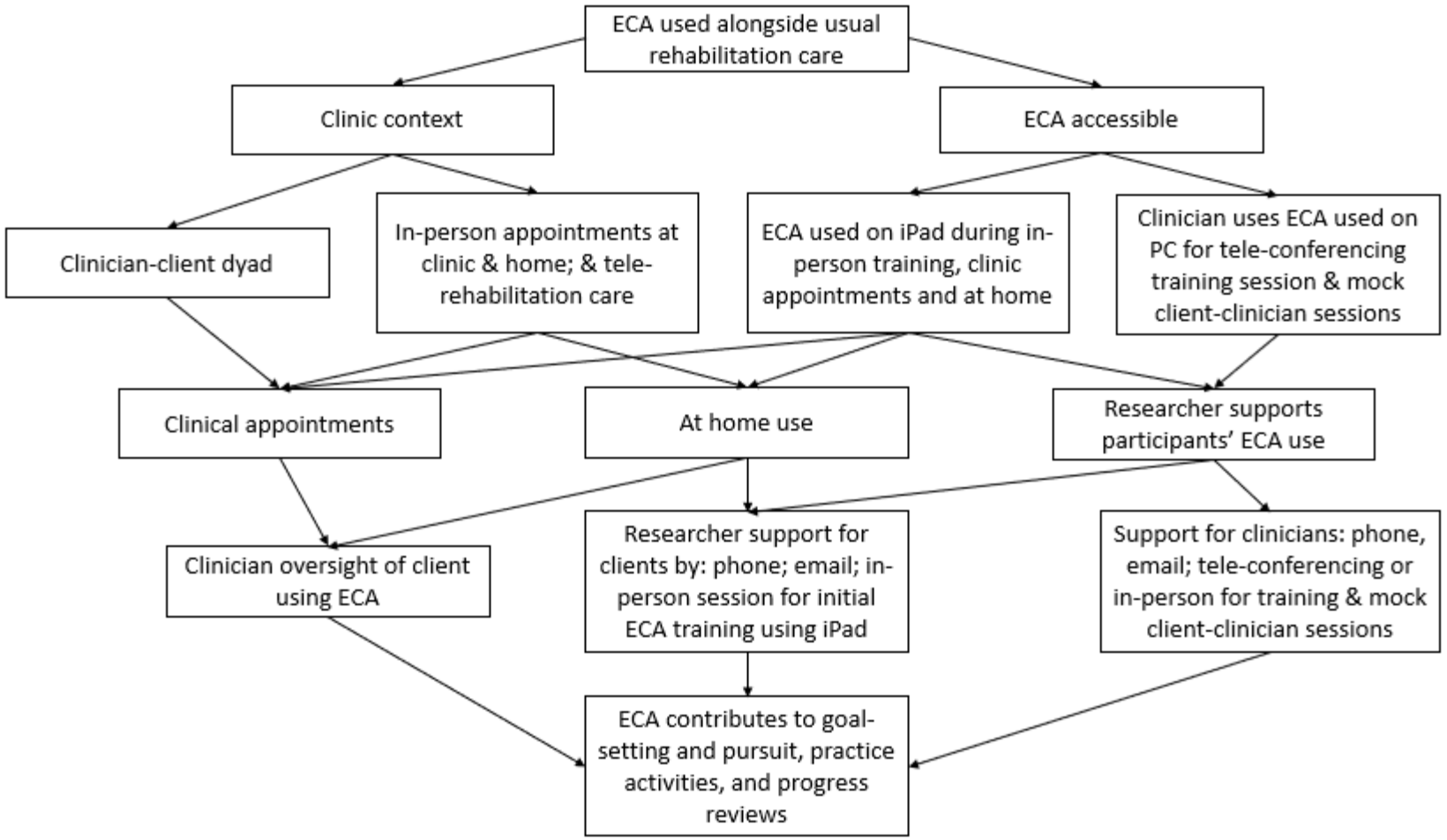


Figure 4: ECA integrated alongside usual care

3.3 Appraising this PhD project alongside relevant Living Laboratory literature for brain injury, disease, and stroke

This section will present an overview of relevant Living Lab research relating to rehabilitation for brain injury, disease, stroke, and physical disabilities, and highlight from these studies factors which are relevant to the current PhD project. It is useful to appraise this literature so as to identify Living Lab approaches that may assist in future developments of RehabChat, particularly as this cohort has unique preferences in how to be engaged during research participation (180). In Living Lab, all participants are respected and seen as actual co-creators in the design process (181). It is through effective consultation with participants that client need cans be optimally addressed in the design and content of a novel device (164).

3.3.1 Living Laboratory research for participants with acquired brain injury, stroke, or physical disabilities

A large-scale, ongoing Living Lab project in Victoria, Australia investigating the optimal design of stroke rehabilitation facilities – NOVELL – was launched in 2020 (182, 183). NOVELL comprises a multi-disciplinary team of researchers – clinicians, neuroscience researchers and architects – working to produce virtual designs which can be trialled by participants – clients, family. NOVELL uses in-depth consultation and rigorous testing as outlined on their web-site (182, 183). This study is similar to the RehabChat project in that it included a non-clinical profession in the stakeholders (architecture) similarly to the current project which collaborated with Clevertar Pty Ltd and the clinics' information technology and management staff.

A current Canadian Living Lab study – BRILLIANT Rehab – (184) is a large Living Lab project design to improve community mobility for people with acquired brain injury. The website for this project promotes that it engages closely with end-users and seeks to deeply understand their needs and expectations (185). This parallels the RehabChat project in which end-user consultation explored the clients' experiences of motivation and goal-achievement in during rehabilitation. Another Canadian Living Lab study (162) reports on a 14-year project for a purpose-built residential unit for clients with brain conditions including TBI. Cognition-supporting technologies for enabling community living are designed in consultation with clients, clinical researchers, and care givers for implementation in the unit (162). This paper also describes the two key approaches to designing a Living Lab testing environment – having a more controlled, purpose-developed living environment such as described in this paper; or utilising a more open-ended environment for testing a product

such as in the client's own home. The authors also comment that factors such as the manner in which the tool is implemented, and the rate of progression it goes through in the testing cycles should be well considered (162). This parallels the considerations for the current project, in that testing was done in the more open-ended contexts of rehabilitation clinics and the client's home, because it needed to be tested alongside the variability of both settings. As well, this project took a stepwise approach to developing RehabChat, allowing for iterative feedback to be provided by participants during the four rounds of co-design workshops, prior to then testing in the real-life settings. Another large Canadian study investigating ways to optimise social inclusion across the lifespan of people with physical disabilities in a shopping mall environment (186) engaged with a range of community stakeholders. This aligns with the RehabChat project consulting with a large range of stakeholders.

3.3.2 Living Laboratory research with older adults with cognitive impairment

There appears to be increasing interest and recognition in the use of Living Laboratory to solve the unique needs of older adults living with dementia. A recent scoping review (2021) (187) identified Living Lab projects focused on developing health and well-being products or services, including for example an assistant robotic, dance therapy, and a personal reminder calendar (187). This review identified that the design of the Living Labs included broad stakeholder consultation – with clients, family, researchers, entrepreneurs, and clinical professionals. In the included studies, testing was done in the real-life setting (community or care facilities) including with multiple sensor and data collection tools, or in specially-developed Living Lab living environments. The review focuses on the studies' outcomes and results, noting that favourable results were generally achieved. However, it also notes that this area of research is small, with this likely being because of the difficulties of involving clients with cognitive impairment in co-creation activities (187). For the current RehabChat project, the involvement of clients with TBI was supported through providing regular cues and extra time for when clients were using the ECA during the co-design workshops, and also during each 1:1 training session at the start of the feasibility pilot trial. As well, during the pilot trial, ongoing clinical oversight and twice weekly researcher phone calls were provided as additional support to accommodate any concerns or difficulties encountered by the participants.

In another recent Australian Living Laboratory study by Pedell et al (2019) (181) involving people with dementia (PwD) to co-create an interactive app for social interactions, the authors note that more creative approaches to designing the methodology are warranted in

order to accommodate participants' cognitive needs. In this study, they developed the app so that participants could interact with content that is aligned to their interests not just with aspects to do with dementia. They also recruited dyads of a person with dementia and their support person (181). These factors were similarly represented in the RehabChat study: the ECA allowed for personalised content to be entered into it, and client-clinician dyads were recruited for the feasibility pilot trial.

Previous research has focussed on how best to engage older adults with dementia when participating in a Living Lab design project (180). Key aspects include keeping participants informed on the progress of the study, and how their input has contributed to the project outcomes. As well, participants' needs should be considered: for example, the need to accommodate or avoid fatigue, and to adjust for the cognitive ability of participants. It was also found that participant motivation for being in the study was related to valuing the importance of contributing to a research project, and that the topic being researched was meaningful to them personally (180). These findings align with the current PhD project in that both the co-design workshops were conducted at a pace that suited the client participants, and that for the feasibility pilot trial clients were able to focus the ECA content on rehabilitation goal that was meaningful to them. As well, feedback included that a client participant valued being able to participate in the project and contribute to its outcomes.

Similar findings were highlighted in a 2020 scoping review on how Living Lab research with older adults for developing assistive tools for daily living and well-being including digital technologies (Knight-Davidson et al 2020) (188). This review recommends that researchers should be aware of the motivations and emotional experiences of participants during the co-design process, and adopt a flexible approach to conducting the research in order to accommodate fluctuating or decreasing abilities such as in communication (188). This is similar to the RehabChat research in that the use of clinician oversight and twice-weekly researcher phone calls were incorporated which accommodated the potentially fluctuating clinical needs of clients, including their well-being status.

In a recent Living Lab protocol (2019) (189) for co-creating assistive solutions for people living with dementia, the study design included monthly co-creation meetings to identify needs and solutions, and to review products being iteratively designed in response to feedback (189). This protocol also proposed that participants could take the prototype home to use in their own environment. For the current project, the co-design workshop meetings were similarly held at two-three weekly intervals, and during the feasibility pilot trial the ECA was taken home by the client to use for completing the practice activities.

A recent paper (2020) (190) reports on a 20-year Living Lab project which has focused on older adults with dementia living in residential care. This project incorporated multi-stakeholder (clients, family, clinicians, and education and policy professionals) consultation comprising a network of collaborators across a region inclusive of 110 care facilities (southern area of The Netherlands), rather than being based around a focus site. Consultation feedback was considered and applied to the local setting through to the policy level [vertically], and between the stakeholders and scientific experts for development of identified needed products and services [horizontally]. This project also influenced health policy legislation, hosted student placements, and conducted public forums (190). Despite this 20-year project being very much larger than the current study, there are some parallels. The RehabChat study collaborated with two brain injury rehabilitation which provided services across a broad region of the whole state. Also, consultation for this project involved a wide array of stakeholders as needed including senior management, information technology, and case-note administration staff, as well as clients and clinicians from the rehabilitation services.

Finally, a Living Lab project conducted by the Flinders Digital Health Research Centre (FDHRC) for designing a memory enhancement application (164) utilised similar research approaches to those being used in the current RehabChat study including: clarifying the design and content of the application to meet the needs of a specific user cohort – community-dwelling older adults with early memory loss –; conducting co-design focus groups with caregivers to refine the design of the app; and then implementing user testing of the tablet-based app with the five participants with early memory loss (164). User feedback was positive and provided input to the iterative design approach used for the application. This project demonstrates the application of living Lab for a smaller project in which testing is done in the user's home setting. As such it accords with the methodology for the RehabChat project. It also important to note that at the FDHRC the preferred design methodology is Living Lab. This factor was another key consideration when choosing Living Lab for this RehabChat project which was also conducted at the FDHRC.

3.4 Conclusion

Using Living Lab in this project provided the necessary framework for appraising and addressing the complex clinical needs of clients and aligning the design of RehabChat and its intended mode of use to the clinical setting. Living Lab importantly enabled an iterative approach for developing RehabChat which included close consultation with end-users and necessary engagement with multiple other stakeholders. By implementing the overarching

foci of Living Lab of close attention to end-user needs and contextualising RehabChat's development to the real-life setting, this project has optimised that RehabChat would more be a relevant, usable, and acceptable tool for the brain injury rehabilitation setting.

4 Design and development processes

The in-house development of RehabChat has been reported in a previous publication (170) (Hocking J, Maeder A. Motivational Embodied Conversational Agent for Brain Injury Rehabilitation. In: Maeder A, Higa C, van den Berg M, Gough C, editors. Telehealth Innovations in Remote Healthcare Services Delivery. Global TeleHealth 2020 [Internet]. 2021(277). p. 37-46. DOI: 10.3233/SHTI210026). The following sections of this chapter include content from the approved pre-publication manuscript version of this publication, with some small editing changes made to improve parsimony:

- *Section 4.4.1.1 Feedback received in alpha testing*
- *Table 10: Alpha Testing Alpha testing feedback and design changes made in response*
- *4.4.1.2 Changes made to alpha prototype*
- *4.4.2. Beta testing*
- *Table 11: Beta testing feedback – main themes*

This chapter presents the key processes and considerations for designing and developing RehabChat. The theoretical frameworks that have informed the design of RehabChat including the ECA itself and its intended mode of use, are explained. The specific stages of development of RehabChat are also presented. These stages included: choosing appropriate software, initial prototype development, alpha testing to assess general workability of the ECA, and beta testing to appraise the clinical relevance and potential usefulness of the ECA. These stages of development provided the basis for refining an ECA model ready to be tested by clients with traumatic brain injury (TBI) and brain injury rehabilitation clinicians in the subsequent co-design workshops and feasibility pilot trial. The remainder of this thesis demonstrates further how the design and development considerations presented in this chapter were applied to the co-design workshops and mixed methods feasibility pilot trial.

The RehabChat ECA prototype was developed in-house at the Flinders Digital Health Research Centre (FDHRC), Flinders University. The overall concept for this project was based upon the results of the background literature review (see chapter 1). It was also discussed with and agreed upon by key stakeholders (senior clinical and management staff of the collaborating clinics, and the chief technical officer of Clevertar Pty Ltd who supplied the ECA software) during 2019.

4.1 Introducing RehabChat

RehabChat is an embodied conversational agent (ECA) designed for brain injury rehabilitation. RehabChat was developed using the Virtual Human software platform by the Adelaide-based company Clevertar Pty Ltd (175) (Clevertar). This ECA software can be downloaded onto a laptop or desktop computer, mobile phone, or tablet. For this project, the software was loaded onto an iPad or personal computer using the Chrome internet browser. RehabChat's user interface (UI) comprises an avatar on the left side and the dialogue text bubbles on the right side. The avatar speaks and then the spoken content is displayed in a text dialogue bubble on the right side. The user can enter responses using typing and clicking on choice options (see Figure 6 and Appendix V). Appendix V includes screen shot images demonstrating key aspects of RehabChat including the management portal and the UI and the ECA being used. Each of the images is headed by brief explanatory notes which highlight key points included in it.

4.1.1 Visual display of RehabChat

This section presents the how RehabChat is visually displayed including the ECA launch button, the functionalities and layout of RehabChat's UI, and the way in which the ECA conversation progresses. RehabChat was deployed on a personal computer or iPad: on the participant's personal computer for alpha and beta testing, university iPads for the co-design workshops, and on clinic iPads for the feasibility pilot trial. The software's UI shows a human-like speaking avatar, and speech bubbles showing the text of what the avatar has just spoken as well as the answers that the user enters (see Figure 6). The RehabChat avatar demonstrated subtle gesturing, and facial expressions. The human user responds to questions and comments from RehabChat by clicking on buttons or typing in responses. Each set of bubbles was separately colour coded to indicate content by the ECA or from the user. The upper right corner of the UI included a minimise button to use for closing the software, and in the lower left corner a mute button which could be used at any time the user wanted to just read the content as text (see Figures 6 and 7).

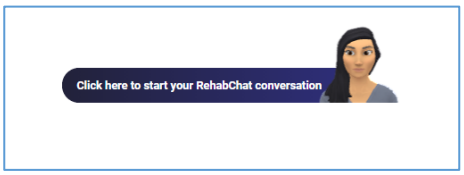
Used in co-design workshops	Used in feasibility pilot trial
	

Figure 5: ECA launch button

The visual display and conversation content of RehabChat evolved through the various development stages of RehabChat in response to participant feedback and

recommendations. For example, the ECA launch button was significantly simplified for the feasibility pilot trial (see Figure 5). As well, the design of the user interface (UI) was updated from a 50 – 50 display as used in the co-design workshops (see Figure 6) to a one-third – two-thirds display for the feasibility pilot trial (see Figure 7).

The opening dialogues of the ECA conversation were developed to be welcoming and to establish rapport through the avatar and the user both sharing their names (see Figure 6 screenshot 1). These opening dialogues were also developed to require only simple engagement by the user (see Figure 6 screenshot 2.). The user could also choose to skip over listening to the avatar speaking, and progress to just reading the dialogue content.

The ECA dialogue structure offered different options for user input. These included free text entry in response to an avatar question, with cues written just above the text entry box (see Figure 6, screenshot A.); and being able to click a response from multiple choice options (see Figure 6, screenshot B). The way in which the ECA conversation was designed was to be easy to navigate, and to incorporate content from the user's entered responses within subsequent dialogues (see Figure 6 screenshots A. and B.).

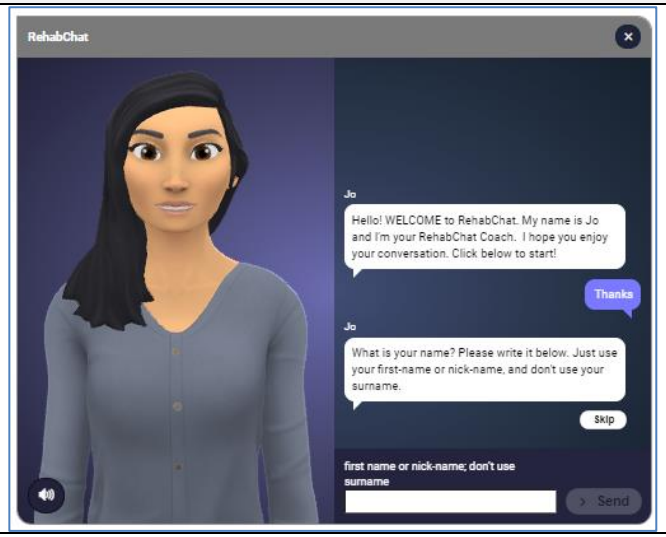
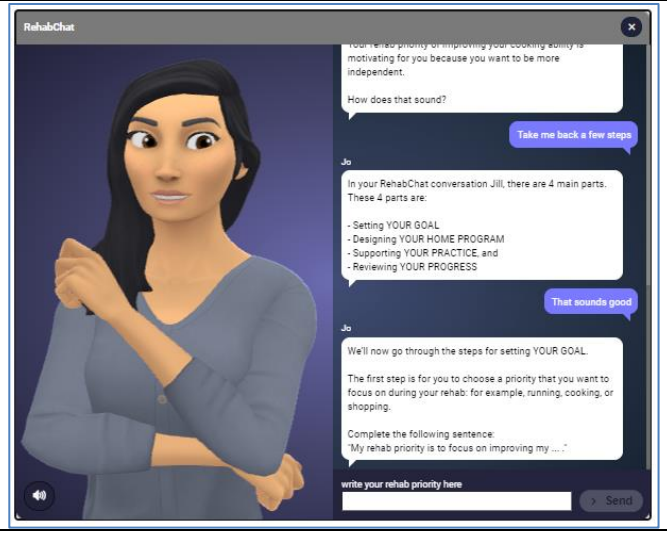
<table>
<tr><th colspan="2">Opening dialogues: two screenshots showing progression of of conversation in initial interactions</th></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td>1. Opening screen</td><td>2. Text entry for user's first or nickname; button to skip speaking & go to next dialogue</td></tr>
<tr><th colspan="2">Goal-setting conversation: two screenshots showing progression of conversation in setting rehab prioritiy</th></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td>A. Early example showing overall conversation structure; free text entry</td><td>B. Use of entered text content in subsequent dialogues; multiple-choice options</td></tr>
</table>

Figure 6: ECA user interface functions – version used in co-design workshops

Components of the UI display include the button for minimising the avatar which, when clicked, minimises the UI to the launch button (see Figure 5) the response panel where the user enters their response, and options for silencing the avatar (see Figure 7). The design of the UI for RehabChat was focused on improving visual comfort and intuitive use for the user.

Figure 7: ECA user interface layout – version used in feasibility pilot trial

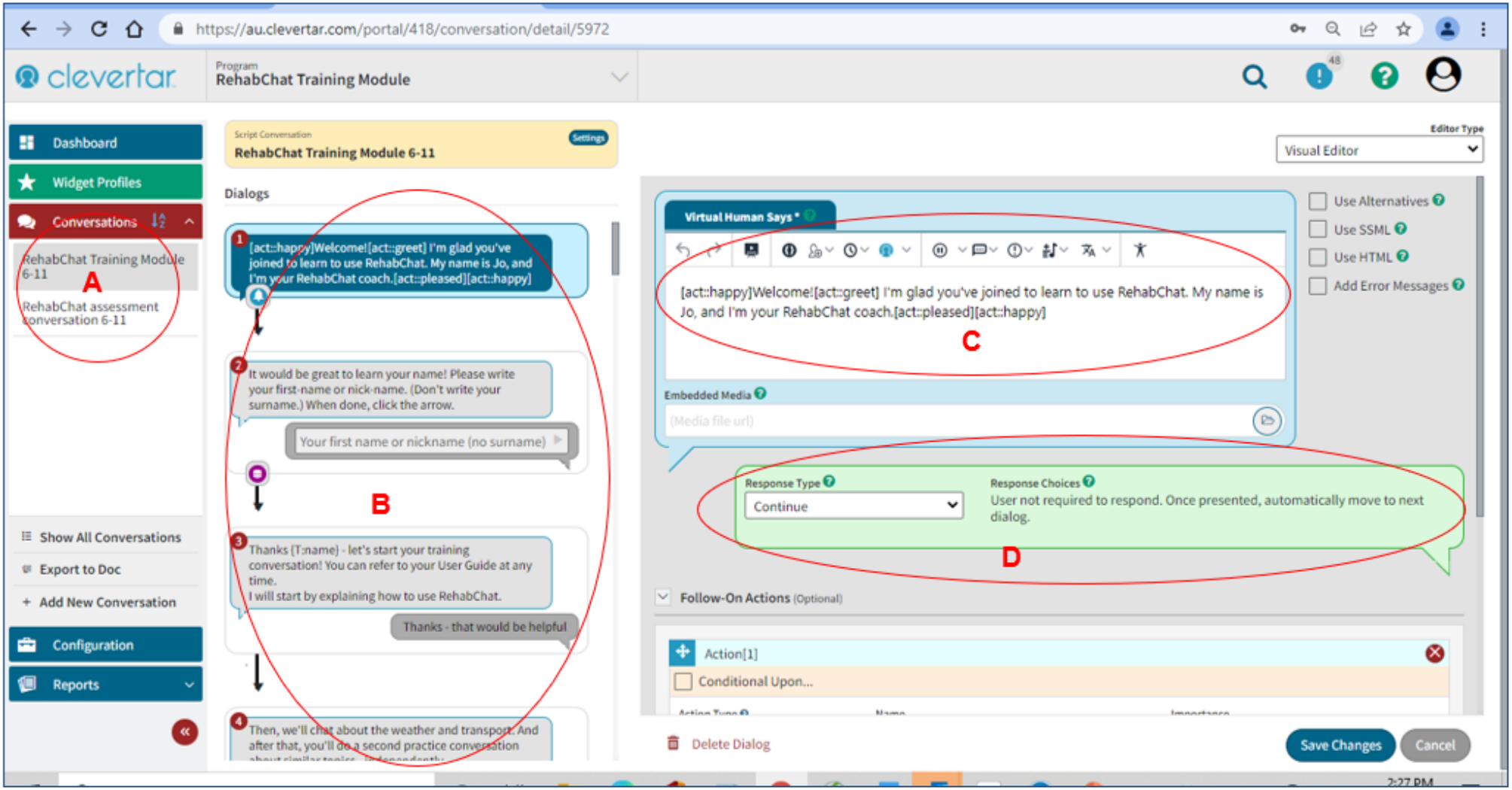
4.1.2 Clevertar Virtual Human software platform

This section will describe the ECA software platform used in this study. Also see Section 4.3.3.1 for a summary of the reasons for choosing this ECA software.

The Clevertar Virtual Human software platform (175) used for RehabChat contains a content management interface comprising a script editor, a profile editor, and the dashboard (191) (see Appendix V). The content management portal allows the dialogue content to be edited, and the required user response to each dialogue to be chosen (see Figure 8). The script editor allows the designer to configure the content for the dialogue text, dialogue progression rules (either requiring a response from the user or not), conversation decision points, and to set usage notification alerts (e.g. when user has completed specific stages of the conversation). The designer can create sections which allow the use to enter freeform text, and for these to be saved as individual variables which can be programmed to be used in subsequent dialogues at relevant points. Choices can be made as to whether the user will enter their response either as text or click options. The profile editor enables design of the UI including the launch button style, avatar's visual persona and accent, and the capabilities available to the user such as ability to change an entered response, or to reload the whole conversation. The dashboard displays quantitative usage data including number of users, number of visits, usage time, and triggered alerts.

All usage data is collected and stored by Clevertar. Clevertar abides by Australian national standards for data security. Clevertar's privacy statement can be found at https://www.clevertar.com/privacy-policy/ . Clevertar's terms of use can be found at https://www.clevertar.com/wp-content/uploads/2018/10/Clevertar-App-User-Terms-October-2018.pdf . Clevertar provided *pro bono* access to the software and consultative technical support for use of the software during this project. The Chief Technical Officer of Clevertar provided *pro-bono* technical support when requested during this project. Clevertar did not provide any input to the content development and designed purpose of RehabChat. Additionally, no clinical data or confidential identifying information was shared with Clevertar.

The capabilities and functionalities of the software enabled the ECA to be specifically designed to support brain injury rehabilitation, including the conversation content being developed to reflect the tenets of MI, SDT and SMART goal-setting (see Section 4.3). As well, the UI is easy to navigate and use, and the software has previously been designed for use for health purposes: as a light cognitive-behavioural therapy intervention (192), and as a health coach for heart failure (191). The Clevertar Virtual Human platform has an excellent level of data security: it does not require another platform (such as Facebook) for it to run, and all data entered into it is stored by Clevertar and is not sent to any other company.



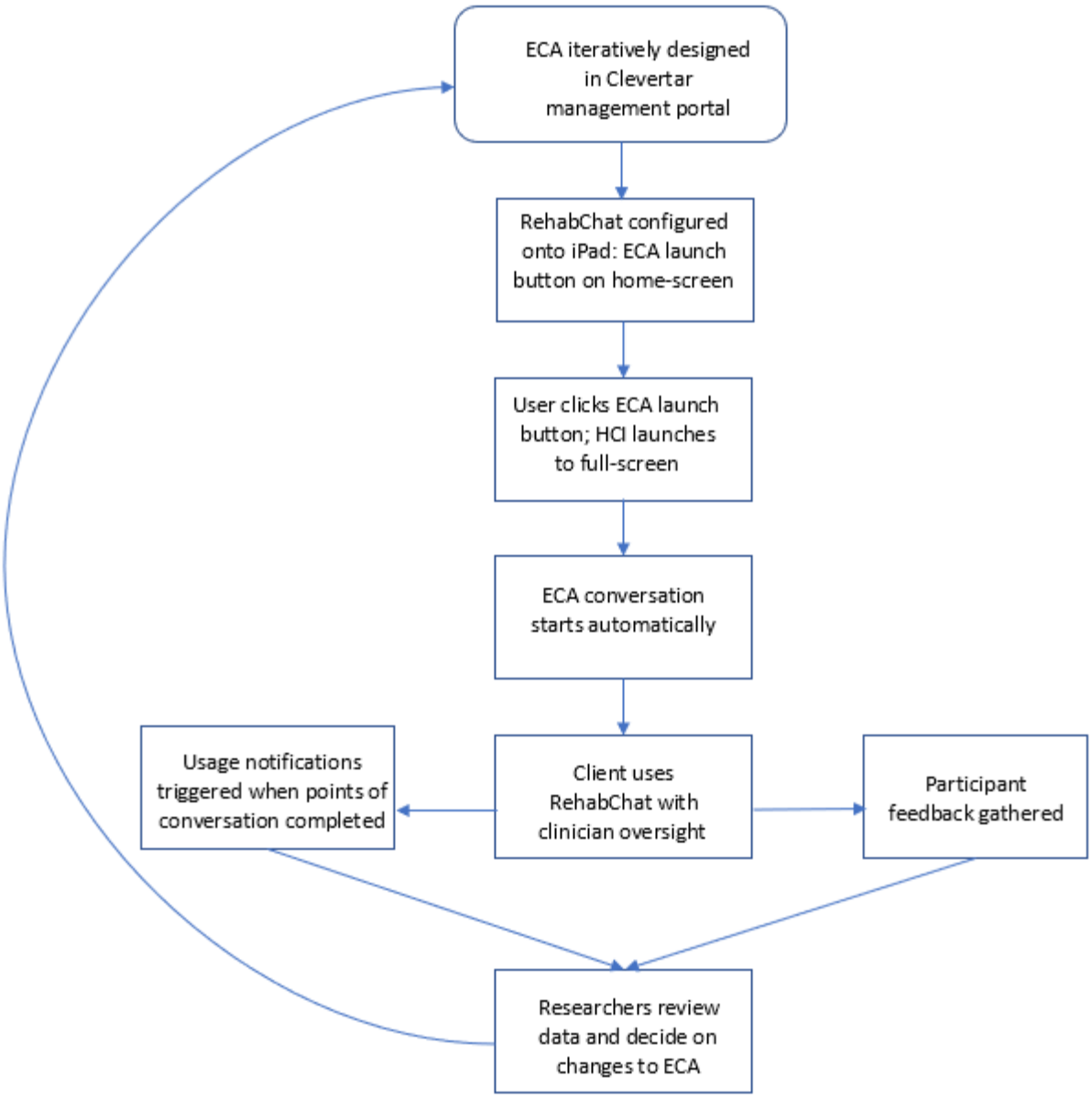
Legend: A = titles of sub-conversations; B = content of dialogues & response options; C = panel for editing dialogue content; D = section for choosing response type

Figure 8: ECA content management portal – showing content for alpha testing version

4.2 Making design changes to the ECA

4.2.1 Iteratively designing the conversation content and user interface

The content for RehabChat's conversation was developed iteratively throughout this PhD project in response to participant feedback at each stage of development. Each iteration was structured around goal-setting and pursuit, with dialogues styled to reflect MI and SDT. As well, the content was checked regarding SMART goal-setting components, and consideration given to the clinical needs of clients with TBI. Appendix VI shows how these aspects were integrated into the conversation content, specifically for alpha testing. These same aspects were reflected in the subsequent development iterations of RehabChat's conversation. After each stage of developing RehabChat, participants' feedback and ECA usage alert data gathered by the software was considered, and changes were made to the ECA conversation content and the UI (see Figure 8). These changes were saved to the software platform, and were remotely updated to the iPad by turning the iPad off then on again.



Legend: HCI = human-computer interface; ECA = embodied conversational agent

Figure 9: ECA designer inputs into ECA; user interactions with ECA; and user feedback

4.2.2 ECA content affected by software capabilities

Once the software was chosen, it was necessary to learn about its capabilities, and to match the flexibility and limitations of the software to the conversation content of the CA. The Clevertar software incorporates options for how the avatar looks and sounds, and a considerable array of possibilities for creating pre-determined conversations incorporating user input via confirmation clicks, multiple choice, and freeform text entry options. The ECA software allows the designer to input phrases and sentences that are spoken by the Avatar, as well as configuring the conversation to allow the user to choose click response options made up of words or conversation logic decisions such as continuing to a different section of the overall conversation. Additionally, the designer can create points at which the user may enter freeform text, and for these entries to

be saved as individual variables. These variables can then subsequently be inserted into later parts of the conversation content at relevant points.

4.2.3 Making design changes to the user interface

The design of the UI for RehabChat was determined by the software capabilities. These included options for colour of the UI background and the avatar's clothes, the accent for the avatar, and the positioning layout of the speech/text bubbles alongside the avatar. For design changes that were not possible from the prescribed choices available, modifications were made to the customised style sheet (CSS).

The ECA has been configured for use on an iPad. Two tile icons for each of the RehabChat modules – the training module and the rehabilitation module – were placed on the iPad home screen. The user was then able to locate a tile icon and click on it to launch the ECA.

4.3 Design and development considerations

The design of RehabChat was composed of three main components: the presentation of the UI, the content of the conversation dialogues, and the mode in which RehabChat was intended to be used in the clinic setting. These three aspects were designed with reference to key theoretical frameworks for the behavioural and technological aspects. This aligns with findings of a literature review exploring the considerations for building a user-centred CA (111) This review recommended that the key aspects of the CA design were based not only behavioural theory, but also centred around technological frameworks. Additionally for RehabChat, the unique clinical needs of clients were also essential to consider. All of these frameworks are described below.

There were several considerations for the design and development of the ECA's dialogue content and UI. These were: client needs; clinic requirements; motivation and health behaviour change (HBC); persuasive technology (PT); and frameworks for assessing RehabChat. These considerations are presented in Figure 10 below and discussed further in this chapter. They are also considered at relevant points throughout this thesis.

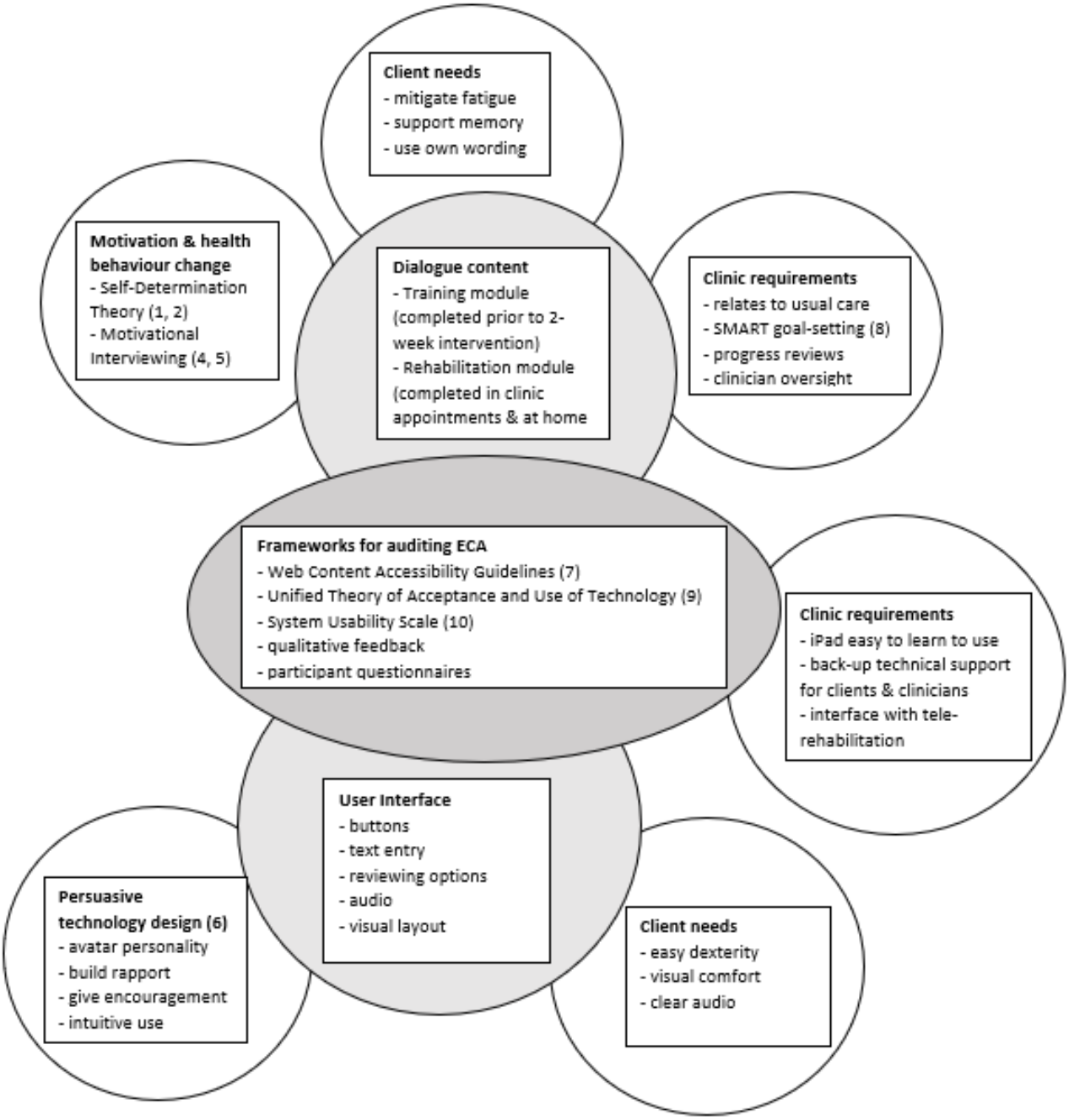


Figure 10: Design and development considerations

When designing a CA for rehabilitation, it is important to consider aspects that will contribute successfully to it achieving its defined purpose. These aspects are to ensure the purpose of the ECA meets a purpose that is meaningful and important to the end-users and to clearly define what the ECA is going to achieve (193). Additionally, it is necessary to pre-define what are the indicators to show that these ends are being achieved (193). The phases of developing the initial prototype ECA, alpha testing and beta testing, are aligned to the first stage of the CA evaluation proposed by Macedo et al 2019 (132) of evaluating technical performance, which is followed by the second and third stages of user experience (subjective and objective data regarding usability and acceptability), and health outcomes research (investigating intended health benefits of the CA) (132).

The design of RehabChat was underpinned by specific technological, behaviour change and clinical frameworks. Of note, there is no existing recommendation guideline for the design of HBC CAs. As such, the best available literature guidelines and clinical paradigms were utilised to guide each phase of in-house development. The technological frameworks used were the World Wide Web Content Accessibility Guidelines (WCAG) (20, 139, 140, 158) (see Section 1.9.2) and persuasive technology (PT) (see Sections 1.4.2 and 1.4.4). The behaviour change frameworks used were Self Determination Theory (SDT) and Motivational Interviewing (MI) (see Sections 1.3.1 and 1.3.2), and client-centred goal-setting using the SMART approach (Specific, Measurable, Achievable, Relevant, Time-limited) (17) (see Section 1.1.3). Finally, RehabChat was designed to accommodate specific clinical needs of clients with TBI such as cognitive fatigue, memory loss, reduced insight, and difficulty with executive reasoning including planning (see Section 1.1.2).

4.3.1 Clinical needs paradigm

The overarching purpose of this study is to intentionally develop an ECA which can integrate well to the clinical setting, relating to both the workflow of the clinic setting, and the clinical needs of client participants. To achieve this, RehabChat was designed with close consideration given to the main clinical paradigms of client-centred goal setting and pursuit, and the specific clinical needs of clients with TBI.

4.3.1.1 Client-centred goal-setting and goal-pursuit

Goal-setting, and its related approach of goal-pursuit, make up RehabChat's conversation structure which is designed to support recovery in adults with TBI. The SMART goal-setting paradigm (see Section 1.1.3) is integrated within the conversation content for RehabChat. Appendix VI shows how the Specific, Measurable and Achievable aspects are interwoven into the conversation dialogues. The Relevant and Time-bound aspects of SMART are addressed by firstly the goal relating to the client's broader rehabilitation priority (hence it is Relevant), and the main goal is set for a six-week timeframe, and followed by setting weekly sub-goals (thus addressing the

Time aspects). The types of goals that can be entered can relate to any part of the client's recovery, be at any level of complexity and detail, and can accord with goals currently being pursued in therapy. The goals are devised by the client and clinician discussing the client's priorities and needs, and as such are client-centred (see Section 1.1.3). The goal information entered into RehabChat must align with the clinical profession of the oversight clinician; for example, a physiotherapist can supervise strength or balance goals, and a speech pathologist can supervise language or swallowing goals.

Once the client identifies their main rehabilitation goal and a weekly sub-goal in RehabChat, they then progress to working with their clinician to defining home practice activities which will help them to achieve their goal. These practice activities are prescribed by the supervising clinician, and the client enters the details into RehabChat. RehabChat is then used by the client to support them when completing these activities independently between clinic appointments. RehabChat is also used as part of the process of reviewing the client's progress towards achieving each weekly goal, and their overall goal, at a subsequent appointment with the clinician. Following this review, the home programme details can be updated and entered into RehabChat thus enabling the client to pursue their goal.

There is precedent for focusing RehabChat's content on the rehabilitation concepts of a goal-setting, practice activities, and weekly reviews: these content areas have been previously integrated into a CA for anxiety management for stroke clients (156). In that project, the CA's intended mode of use was presented as complementary to usual care and not replacing of the human therapist input. RehabChat is similarly styled to be used alongside usual care.

A Cochrane quantitative review (33) of the effectiveness of using goal setting and goal pursuit strategies in adults with acquired disabilities found low quality studies, and heterogenous data. These authors highlight the need for a client to be actively involved in goal-setting, and that client self-efficacy should be supported (33). The authors also note that further research is needed to define which part/s of goal-setting work well in what contexts (33). For this RehabChat project, the client was involved in every stage of goal-setting and pursuit, and self-efficacy was supported as competency.

Specific dimensions for rehabilitation goal setting incorporate the components of Specific, Measurable, Achievable, Relevant, Time-limited (SMART) (17). RehabChat was intended to be pilot trialled in a clinic setting alongside usual care, and to require minimal time and concentration from both the client and the clinician. These purposes are achieved by matching the ECA sub-conversation dialogues to existing SMART goal-setting paradigms already used within the client-clinician alliance (see Appendix VI). As in usual practice, the client and clinician work together to determine specific prescribed exercises to support goal-attainment, to be practiced at home. These

exercises are entered into the ECA and then serve as the basis for subsequent ECA dialogues for times of home practice.

It is necessary to support the physiological process of neuroplasticity during rehabilitation. Neuroplasticity is the process by which a person continues to develop new brain connections enabling learning of new skills throughout the lifespan (194). Neuroplasticity following brain injury allows for recovery during rehabilitation. Importantly, neuroplasticity can be supported during rehabilitation by the client practising motivational tasks (29). RehabChat provides motivation-based conversation for the user to practise their home program tasks related to their motivational rehabilitation goal.

The design of RehabChat has been purposefully focused upon meeting the clinical needs of a distinct client group: adults with TBI. Conversational agents have been similarly designed to meet the specific needs of a client group including to provide memory support for memory loss (134), and care for clients with mental health needs (195).

4.3.1.2 Need for clinician oversight

The design of RehabChat has considered mitigating or avoiding known safety risks of using a CA. Some of the general risks of using CAs (see Sections 1.6 and 1.9), include frustration and stress. In RehabChat, the potential for these symptoms were mitigated by having a supervising therapist who understood these risks and who could watch for such symptoms. Additionally, other concurrent clinical symptoms such as vestibular issues, neck pain and headache, or visual strain, may also be exacerbated by using the ECA on an iPad. If needed, the client could have a break from using RehabChat or, if necessary, cease their participation in the RehabChat project at any time.

RehabChat is importantly situated within a recommended mode of intended use: RehabChat is not intended to be used without this surrounding construct of therapist supervision, integration into the clinic setting and application alongside usual rehabilitation care. This emphasis is to ensure that the client's well-being is adequately supported – as an ECA alone cannot do this (126) – and that the therapist can continue their medico-legal responsibility of providing supervisory oversight of whatever therapeutic input is being provided to their client. For RehabChat, it is intended that the clinician provides direct oversight for the client using RehabChat whilst inputting key data such as goals and practice activities.

Additionally, RehabChat prompts the client to contact the therapist with any concerns. It has been previously recommended that at junctures where the user is dissatisfied with or unsure about a response by a CA, it can be instigated that a therapist becomes then involved in the care and advice given to the user (126). This is essential for the current project, as RehabChat is a novel ECA which is not yet tested for full efficacy and risks.

4.3.1.3 Consider important clinical needs of clients

Designing an ECA for adults with TBI needs to consider the specific clinical needs of this cohort. These needs include challenges with concentration, decreased memory, low motivation, pain, tendency for frustration, and fatigue (see Section 1.1.2). These needs were addressed in the design of the ECA, and monitored during use of the ECA.

In the design of RehabChat, memory is supported through key content being reiterated throughout the conversation (such as the main and weekly goals, and symptoms to check for when doing practice activities). Fatigue is addressed through RehabChat teaching the client how to take a rest-break from using RehabChat and learning that when they come back to using it again, that they will be at the same point in the conversation, and later reminding them to take a rest break when needed. As well, each dialogue is short, and so does not require too much effort to focus on (see Table 9, Section 4.3.5.1 and Appendix VI)). Finally, low motivation is supported through the integration of MI and SDT (see Appendix VI), and by having weekly goals which enable the client to see progress being made toward achieving their larger overall goal.

4.3.2 Motivational Behaviour Change paradigms

Integration of a behaviour change theory influences the design of the conversation content, which affects the CA responses to user inputs, and also the overall usage of language in the CA programming. This is specifically achieved through ensuring that the CA content has an appropriate selection of words and phrases inbuilt which articulate concepts of health behaviour change, and that the CA is enabled to identify the user's change behaviour. As well, the CA should be programmed to respond to user input by providing outputs which match the stage of behaviour change in which the user is currently experiencing, and to follow a somewhat staged approach for supporting the user's progression through stages of change to reach an optimal level of success with personal health behaviour change.

It has been noted that design of a purposeful CA conversation – such as for health behaviour change – is pulled in two directions of being natural and open-ended, versus being purpose-directed and facilitatory of the outcome wanted by the user (122). For the conversation in RehabChat, this dichotomy was solved by designing it to firstly be demarked by rehabilitation goal-setting and goal-pursuit processes – in both its extent and its structure – and secondly that its dialogue content and phrasing be nuanced by MI (11) and SDT (52) (see Table 7 and Appendix VI).

4.3.2.1 Self-Determination Theory

Self-Determination Theory (SDT) is able to be adapted to suit a range of intervention approaches and contexts (57, 85) and has been specifically recommended as a theoretical base for developing

human-centred technologies (84) such as CAs. The ability of SDT to help clarify considerations of the broader social context (57) were relevant for the design of RehabChat. The broader social context of ambulatory care brain injury rehabilitation was considered expressly in relation to the role of the supervising clinician providing supportive, guiding input to the client. Additionally, the three tenets of SDT (52) – competency, autonomy, and connectedness – can be specifically integrated into the context of brain injury rehabilitation, and into RehabChat's design by: ensuring that the goals and practice activities are within the client's level of competency, supporting a client-centred approach to care planning, and ensuring the client has sufficient support resources and people around them during their recovery.

The main tenets of SDT are also represented in RehabChat's intended mode of use with clinician oversight in a range of ways. These include the client having regular reviews with their key therapist whilst using RehabChat (connectedness) and the therapist enabling the client to use their own wording when entering data into RehabChat (connectedness; autonomy supporting). As well, the CA content ensured the client had sufficient time to complete their practice activities (competency), and focused on asking the client for their personally meaningful goals (autonomy; competency) within the SMART goal-setting framework (see Table 7).

4.3.2.2 Motivational Interviewing

MI supports the individual to develop intrinsically meaningful goals and direction (1, 5, 57), and is supportive during setbacks in progress (11). Utilising MI to inform the dialogue content and phrasing was theoretically sound because MI is a conversation-based intervention with widely demonstrated efficacy for a range of health needs (196) including for a CA providing a brief MI counselling intervention for stress reduction (115) in which the CA responses were classed as either: 'Giving Information', 'Questions' (focusing questions and evoking questions), 'Reflections', and 'MI-Adherent Statements' (statements affirming client in change behaviour) (115). MI has also been combined with other behaviour change paradigms into a CA for health promotion counselling (129) by providing dialogues for goal-setting, trouble-shooting when progress is not as hoped, and praise for successes achieved (129). These examples are similar to RehabChat's conversations being reflective of both motivation and goal-setting, and by its conversation structure comprising: choosing a rehabilitation priority, developing a SMART goal, setting practice activities, practicing required tasks to achieve the goal, and reviewing progress towards achieving the goal.

Aspects of MI relevant to brain injury rehabilitation are those which align clearly to client-centred SMART goal setting. These aspects are initially supporting the client to engage in the conversation, then assisting them to focus on their personally identified need and helping them to think through how to address this need, and finally making plans to achieve meeting this need (5). These help to intensify motivational change in clients (69), and therefore can be integrated with goal-setting conversation content to support motivation for clients with TBI.

In MI, there are key categorisations of Change Talk (5) – in which the human-client's conversation content indicates impetus for and actuation of intended behaviour change – which can be usefully aligned to rehabilitation goal-setting and pursuit. This Change Talk is categorised into elements noted within acronym of DARN CAT (5): Desire, Ability, Reasons, Need, Commitment, Actuation, and Taking Steps. The DARNCAT elements have been incorporated into RehabChat's dialogues with particular focus on constructing questions that RehabChat would ask to help elicit user responses that aligned with the DARNCAT elements (see Table 7). Another key aspect of MI is the overarching premise of the 'spirit' of MI, which is based on Acceptance of which there are four contributors (absolute worth, autonomy, affirmation, and accurate empathy) (5) are reflected int the style of language used throughout RehabChat in both the longer more supportive conversation, as well as the shorter more directive conversation. This was incorporated globally as it was seen to be ethically sound and clinically relevant to produce an ECA that modelled these qualities (see Table 7).

It is recommended that for MI studies, that the fidelity of adherence by the therapist to the 'spirit' of MI should be audited at regular intervals (197). For this project, because MI was not included explicitly, but rather implicitly in nuancing the goal-setting conversation, MI auditing was not done. Instead RehabChat's goal-setting conversation content was reviewed regularly – during in-house testing (see Section 4.4), in the co-design workshops (see chapter 5), and also the feasibility pilot trial (see chapter 6).

The manner in which MI can be applied to a CA conversation content is by it providing an overall structure to the conversation which reflects the central processes of MI (evocative questions, elaboration request, reflection, acknowledge importance, summarize) (104). These factors were include in the RehabChat conversation. Integrating MI can also provide overarching category themes for the CA's coding of the user's comments including valence (change talk versus resistance), category (status-quo, change intention) and content (the actual focus of concern or user's sense of value on something) (104). When a CA ontology comprising MI and related HBC content was applied across two health behaviour change topics (physical exercise and, subsequently, healthy diet) it was found to have 98 percent re-usability (129). This aspect was highly relevant for RehabChat, in that the user could enter details for any type of rehabilitation goal, with this being made possible through the conversation structure being comprised of client-centred goal-setting nuanced with MI aspects.

Table 7: Motivational behaviour change and goal-setting paradigms informing RehabChat's conversation content

Paradigm	Support from supervising clinician and/or RehabChat researcher	RehabChat conversation example
Motivational Interviewing		
Desire	Actual choice to participate in the project and use RehabChat is aligned to the client's sense of 'Desire for change'	First part of the goal-setting conversation asks client to choose a general area of their life that they would like to improve int – a general domain. This allows them to choose to something that they desire to improve in.
Ability	Achieved through style of learning – offers the participant opportunity to practice as many times as they'd like prior to the assessment, and use the user guide as needed; participant is allowed to re-do the assessment if they aren't initially successful	Training module starts with topics likely familiar to all users (weather and transport) so builds trust, and helps client avoid becoming stressed.
Reasons	Clinician-client interactions in usual rehabilitation care enable discussion about reasons for the client's rehabilitation priorities.	ECA asks client to define what is the reason that they are motivated to achieve their main goal / that the goal is important for them to achieve
Need	Client is already participating in brain injury rehabilitation to address challenges following their TBI	A goal which client and clinician are currently working can be inputted into ECA
Commitment	Completion of the training and assessment module is an important step towards using RehabChat, and therefore also of participating in own rehab	Client commits to focussing on an overarching goal, and then actively working towards achieving each weekly goal by completing the prescribed practice activities.
Actuation	Clinician works with client to clarify goals, practice activities etc.	Client can take their time to think through each step of the ECA conversation; and develop own goals, and focus on weekly goals which feel achievable
Taking Steps	Clinician continues to provide usual rehabilitation care within a MDT setting; this inherently facilitates the client taking step within their rehabilitation journey.	Client identifies has enough time to complete the prescribed activity (In the longer conversation, chooses a support person or other resource)
Absolute worth	The ethos of brain injury rehabilitation is to provide client-centred care.	The focus of the conversation remains entirely on client throughout.
Accurate empathy	Clinician and researcher provide supportive assistance to client, and acknowledge difficulties experienced by client	Acknowledges if client has low confidence in achieving the goal; and asks client to consider how confidence could be improved

Paradigm	Support from supervising clinician and/or RehabChat researcher	RehabChat conversation example
Autonomy	The clinician supports the client to articulate a goal that is important to them in their own wording	Client types in responses to ECA using their wording; they also nominate their main goal along with input from clinician
Affirmation	Achieved through style of learning – JH provides supportive positive teaching input	ECA provides positive affirmations in the conversation
Self-Determination Theory		
Autonomy	Client chooses which topic to discuss first (weather or transport) Client can choose to take a rest break when they needed to.	Promoted by asking client's choices for main rehab priority area, and their actual goal, and motivation supports Client can choose to take a rest break when they needed to.
Competency	Supported through easy content, and time to practice, and can use user guide, and support provided by JH.	Supported through setting SMART goals (includes Achievable)
Connectedness	JH provides support for training session, and ongoing support during project	Client identifies a support person Clinician provides ongoing support for client using ECA
SMART goal setting		
Specific	The SMART aspects would be addressed as part of usual rehabilitation care	The general rehabilitation priority area is refined to a specific skill or activity
Measurable		The goal is defined in terms of how much of the skill or activity will be accomplished
Achievable		The ECA asks the client how confident they feel about the goal – and if low confidence then there is opportunity offered to modify the goal. The client tries completing the practice activities for the first time whilst still at their appointment with their clinician; if any issues, the details are modified until the client is able to complete the activities independently using RehabChat.
Relevant		The goals and exercises relate to the main rehabilitation priority area chosen by the client
Time-bound		Main goal is defined for a six-week period. Sub-goals are set for one-week intervals

4.3.3 Technological paradigms

4.3.3.1 Choice of embodied conversational agent software

The choice of using an ECA rather than CA for this project was based upon the persuasive technology (PT) aspects that an ECA can offer. Relational aspects of rapport and trust are more easily demonstrated by ECAs rather than CAs, due to the visual features, including non-verbal communication aspects, offered by the humanoid character (125). These benefits of an ECA may also result in less cognitive load for users which can then enhance adherence and satisfaction (125) (see Section 1.5.1).

An ECA was also chosen because it provided additional multi-sensory aspects – visual and auditory outputs – which can more adequately support the needs of clients with TBI relating to preferences for visual versus auditory content. The ECA provides spoken output, written text, and an engaging visual display of an animated humanoid character. It was thought that the avatar's gestures and facial expressions could help the client maintain their attention more easily on the UI, and so participate more effectively in the CA conversation. Additionally, the avatar's speech alongside the written text was thought to provide reinforcement for the conversation content, in contrast to just having written text.

The choice of the ECA software platform used in this project was based upon pragmatic considerations such as the software being low/no cost, and for there to be ongoing technical support, and important clinical considerations, such as able to design conversations which are relevant for TBI, and also that the software had been previously utilised for a clinical purpose. Additionally, the software needed to easily allow for iterative changes to the conversation content, so as to facilitate the process of making changes to RehabChat following each stage of its development. In regard to the usability of the software's UI, this needed to be straightforward to use, be able to have an MI-styled goal-setting conversation configured on it, have options for free-text entry (to capture the client's own wording), and be easy to teach client and clinician participants to use. For the data collected by the software, this needed to be managed in a confidential and safe manner according to Australian Standards, and that only intended users were able to see it. Additional considerations related to the potential of the software to be integrated with the clinic's technology framework which includes electronic case-notes and to send updates or alerts directly to the clinician. These considerations were developed with a view to the future development of RehabChat when it may be more fully integrated into the clinic setting. Accordingly, these extra considerations were not essential criteria to meet for this PhD project.

The Clevertar Virtual Human software was chosen for this project because it met all of the essential requirements for choosing a platform for this project. See Section 4.1.2 for a description of this software platform.

4.3.3.2 Language processing

It was necessary to consider the complexity of CA language capabilities employed in RehabChat. 'High-tech' language capabilities offer potentially comprehensive degrees of benefit to clients, but the increased time needed to train a CA in NLP capabilities would mean it would take longer to progress to the implementation phase of research enquiry. Simpler ECAs are [low-hanging fruit] which can be more easily assessed at the various stages of being developed, piloted, evaluated and finally implemented clinically (102) (see Section 1.5.2). A logical, layered conversation was developed for RehabChat without the use of Artificial Intelligence for Natural Language Processing (NLP).

In RehabChat, the conversation content was designed using constrained language. This choice saved considerable cost and time. As well, NLP Processing was beyond the scope of, and not ideal for, this project due to fact that it may produce comprehension and transcription errors when being used by clients with TBI. It was thought that the risk of producing errors outweighed the obvious benefit of reducing client effort in using the ECA (if voice to text could have been used, it would reduce or negate the need for typing responses). Instead, constrained language programming was used not only due to time and resource constraints, and also because it is able to avoid misunderstandings more easily, and it provides a reproducible, controlled content model (see Section 1.5.2) to use in the project. Within the constrained language model, a tree algorithm was used to create logic decision points responding to the user's input (111). The conversation structure and content were carefully designed for optimising client-user engagement and persistence in use, by simplifying what the user was required to enter when using the touchscreen interface, so as to help minimise or avoid fatigue.

4.3.3.3 Web Content Accessibility Guidelines

It was necessary to ensure that the design of RehabChat adhered to relevant best practice guidelines for digital technology design. To this end, website design guidelines were followed because no specific guidelines have been developed for ECA design, and because a website is a type of human-computer-interface (HCI) as are ECAs.

Choices for the presentation of RehabChat's UI, and for determining how the user interacts with RehabChat through the UI were informed by the world level recommendation

framework: the Web Content Accessibility Guidelines (WCAG) as presented in the Web Accessibility Initiative (WAI) (20). These accessibility guidelines were chosen because they seek to mitigate challenges that users with cognitive challenges may face when using a HCI (198). These guidelines include key domains of: Adaptable (information is presented in a way that is easy to understand); Enough Time (for users to read and use tool); Navigable (the tool is easy to navigate and has cues and helps to aid this process); Readable (text – based information can be reads and understood easily); Predictable (the tool behaves as anticipated); Input Assistance (the tool helps users enter data correctly and avoid mistakes) (20). All of the WCAG specifications were checked against the design of RehabChat, thus revealing that many WCAG aspects were already met in RehabChat due to the design of the Clevertar software itself; and other aspects were able to be met through how the conversation was structured, for example the option to review entered content and be able to change it if desired.

Other key points considered when designing RehabChat were the colour scheme and layout (to allow easy visual navigation of HCI), the timing and speed of the dialogues (to allow sufficient time for user to read, listen and/or respond to a question), audio aspects(the speed of any audio speech should enable ease of understanding by user), and ease of interactions (it should be easy to interact with the HCI in regard to dexterity and navigability) (158). The way that these factors and considerations were applied are outlined below.

4.3.4 Persuasive Technology

Persuasive Technology (PT) design principles are intended to support user engagement and persistence when using the technology device (see Section 1.4.2). It has been noted that PT is widely used in the design of digital technologies to improve user engagement generally (83) but this does not specifically consider the health-related needs of clients which are more nuanced compared to the needs of general consumers. Accordingly, for RehabChat specific behaviour change and clinical paradigms were considered (see Sections 4.3.1 and 4.3.2).

The interactive conversation between user and computer needs to be very carefully managed, just as in a conversation between human therapist and human client (117). Examples of these aspects are utilising empathy, ensuring clearly defined purposes for the interaction, and enabling the CA understand the users cognitive state (125).

There are relevant aspects of PT that relate specifically to the needs of clients with TBI (see Section 1.1.2) because they facilitate ease of use for clients. These aspects include creating pauses in the conversation and the conversation to feel familiar in nature, easy to use, and

friendly (see Table 8). These aspects can be achieved using practical PT approaches of anthropomorphic design and 'foot-in-the-door' and variance to support personalisation. These aspects and approaches are discussed below.

Table 8: Persuasive Technology aspects of conversation style

Persuasive aspect	Details for dialogues
Familiar	Use SMART goal setting; complete practice activities
Easy to use	Short dialogues; guiding cues; complete a sentence started by ECA
Friendly	Give encouragement e.g. 'well done'; introduces self and addresses user by their name; thanks user for inputting answers

4.3.4.1 Creating pauses in conversation

In human-to-human conversations, there are natural pauses, which allow for reflection and thinking. Creating natural pauses in a CA conversation is important (199, 200) for client-users with TBI. Conversation pauses were achieved by inserting a 'pause' command at specific junctions which ensured a small silence prior to the next dialogue being spoken. As well, the client is instructed by the ECA that they can rest at any time. And finally, the client can take as long as they need when answering a question in RehabChat, for example when selecting a reply to a question: the action of the client considering and then entering a typed response or clicking on a response choice invokes having a pause delay.

4.3.4.2 Conversation feels friendly, and familiar and easy to understand

It was felt that the user would interact with RehabChat more persistently if the conversation would feel simple and easy to participate in, and if it felt familiar and friendly. The friendly aspect was achieved through providing motivational comments, a friendly looking avatar and emphasizing autonomy and a sense of competency, which are tenets of SDT (see Section 1.2.1). As well, the avatar persona was styled as a virtual ECA coach (111).

There is a need to optimise the simplicity of the interface to decrease the cognitive load for the user, enable easier interactions, and ensure users spend minimal time just using the functionalities of the program (125) rather than focusing on the clinical content. The ECA was styled to be easy and pleasant to use through reducing the wordiness of the conversation itself, as well as minimising the number of required responses from the user. Additionally, clear instructions were provided in the training module and user guide so that the user would know what type of response was required. Also, the ECA conversation was made to feel familiar by utilizing content structure that mimicked the real-life setting. For

brain injury rehabilitation this meant using client-centred goal-setting content and structure (see Section 1.1.3).

4.3.4.3 Anthropomorphic aspects of conversation content

Anthropomorphic design features in a CA – such as the CA using the user's name and informally-styled dialogue to help establish rapport – are up to four times more important to promoting the perceived usefulness of a CA as compared to its functional aspects and content (201). Research has shown that personable CA interactions improve the user's impression of the CA being anthropomorphic, and therefore also have a closer affinity with the CA as a social entity (202). This study incorporated specific aspects into the design of the CA to promote the anthropomorphic essence: use a human name, use informal dialogue language, and start and end the conversation with hello and goodbye (202). In this study, participants used the anthropomorphically-designed CA, and a comparator CA in which the language was plain and machine-like – such as the conversation was commenced and concluded by start and quit, and the CA entity name was that of a computer product. The anthropomorphically-designed CA achieved higher ratings with the participants (202). As such, RehabChat was similarly designed with anthropomorphic features. In RehabChat, a personable, informal conversation style is used. The avatar and user each introduce themselves by name and the conversation opens with hello and concludes with salutations and goodbye. Additionally, content regularly includes praise, (e.g. 'That's great' 'well done') and empathy (e.g. 'it sounds like it's been difficult for you to…'), although these features are included more regularly in the longer, more supportive version of the conversation, and less so in the shorter, more directive conversation style.

4.3.4.4 Use foot-in-the-door approach for building engagement

The foot-in-the-door approach for HCI design incorporates the idea that the user is more likely to feel comfortable initially with a small amount of engagement and commitment, and that later interactions incorporate a higher level of buy-in and effort by the user (203). This approach has been inbuilt into RehabChat through the way the overall conversation is structured: from initially being simpler and more supported, to progressing to independently using RehabChat for doing a home program. It commences with greetings, and the user completes a simple training module in order to gain competency in interacting with the UI. From there the rehabilitation module asks questions regarding a main goal for rehabilitation, and then more granular details such as a weekly goal, and specific practise activities to complete. To this point, it was intended that the user would be supported by a therapist when initially using RehabChat, and then engage at a more advanced level of commitment

in using RehabChat independently at home to complete their practice exercises. Home practice using the ECA demands more engagement and autonomy from the client, and puts into reality the process of pursuing the rehabilitation goal that they have set.

4.3.4.5 Variance aspects of RehabChat to support personalisation

Use of personalization capabilities have been shown to improve the user's satisfaction with using a CA (81). Ideally, the client-user should be able to have choices regarding certain design options for the ECA interface. Such choices can include the visual style and type of voice of the humanoid character, and having the option to remove some ECA interface components such as audio output, or the visual avatar character. Choice-making helps to personalize the ECA to the user's needs and personal preferences, which in turn may help increase engagement and persistence in use of the ECA. These aspects for promoting personalization of the ECA were incorporated into the ECA for my project where feasible, for example providing choices of avatar style during the co-design workshops.

Personalisation was also represented in variance options. Specifically, RehabChat was enabled to offer a number of variance features for the avatar design and for the conversation style. The avatar options include two male and two female humanoids, with different ethnicity (109), and a more or less formal presentation. Two styles of conversation are offered in RehabChat: one that is longer, more supportive, and motivational; and another which is more succinct and directive. The longer style would suit users who require a step-wise, motivational approach to goal-setting and goal-pursuit, and who tolerate a moderate amount of HCI delivered language content. The shorter, more directive style would suit users who are familiar with the processes of goal-setting and goal-pursuit, and/or who require less motivational support, and who are unable to tolerate as much language input. The clinician helped the client's choice of which, in order to ensure best meet their clinical needs. Each style incorporates all four of the distinct phases of interaction as demonstrated in the flowchart below (see Figure 11). As well, both versions of the conversation share many of the same variables; with the longer version having additional variables related to the extra motivational support that this conversation offers.

4.3.5 Conversation construction

The overall RehabChat conversation structure was comprised of sub-conversations which were seamlessly linked together according to the timing and purposes of each of them (see Figure 7). Two versions of the conversation were developed to offer the user a choice. These were a longer more supportive conversation which provided more reiteration of main

points, and extra content about choosing a motivational support resource (either a support process such as using a whiteboard to track rehabilitation progress, or a support person to provide encouragement. The shorter, more directive conversation style provided more succinct cues and was more straight-forward in its delivery. Both styles of the conversation included the main content of goal-setting and pursuit (see Figure 11).

4.3.5.1 Dialogue design and use of variables

Each sub-conversation was comprised of specifically worded questions or statements which were spoken by the avatar, and also which would invite a response from the user (see Table 9). Options for types of responses included yes/no, multiple choice questions, a single confirmatory option to click, and freeform text entry. Free text entry fields were configured to have a maximum character limit, in order to ensure the entered text when captured as content to fill a pre-determined variable (see Figure 7 and Table 9) would fit into the overall structure of the ECA conversation. This approach has been used previously in a CA for alcohol abuse counselling (204). A dialogue could also be configured to progress with no response required from the user.

It was imperative that the ECA conversation dialogues would avoid exacerbating fatigue in the clients using it, and that memory and other cognitive needs were supported. These aspects were integrated through offering multiple choice options to reduce cognitive fatigue, and ensuring dialogue length was short. As well, dialogue content includes reiteration and interim summaries of items already discussed to support memory challenges.

The progression of the conversation after each dialogue is determined by configured logic decisions, for example relating to the user's response to a question. There can be single or multiple forward progression routes for any dialogue.

Table 9: Example series of conversation dialogues

Content	Components	Follow-on
"Your goal [user name] - next you will develop a goal for your rehab. **First, choose a rehab priority below that you'll focus on for the next 6 weeks.** **It needs to be one that your [therapist profession] can supervise.** **: Physical (e.g. strength, balance)** **: Language (e.g. speaking, reading)** **: Thinking (e.g. planning, problem-solving) …"**	A) Pre-set variables : in [square brackets] : auto-populate with freeform text entered by user in earlier dialogue : (in this example) are for user's name and supervising therapist's profession. B) Multiple choice options are provided.	: User selects one option. : Based on user's choice, ECA will jump to next dialogue : For this example, user chooses 'Physical' and is directed to next dialogue shown below.
"Please describe your Physical priority area in your own words. Complete the sentence below: **My Physical priority area for the next 6 weeks is ... (up to 10 words)"**	A) User is cued to enter freeform text (up to 10 words). : User enters text in text box with a placeholder statement of 'Describe physical rehab priority in own words' B) User clicks 'Send'.	: ECA saves the freeform text entered as a variable [rehab priority] : the user is directed to the next dialogue shown below.
"Why is your rehab priority of [rehab priority] important to you? **Please choose an option below.** **: Increased fitness** **: More independence** **: Manage fatigue** **: Be more connected** **: Something else"**	A) Variable of [rehab priority] populates with freeform text entered by user (see above) B) User selects one multiple-choice option	: If user selects 'Something else' they are directed to next dialogue for entering freeform text to populate variable of [priority's importance] : If user selects one of first 4 options, this wording is saved as variable [priority's importance]

112

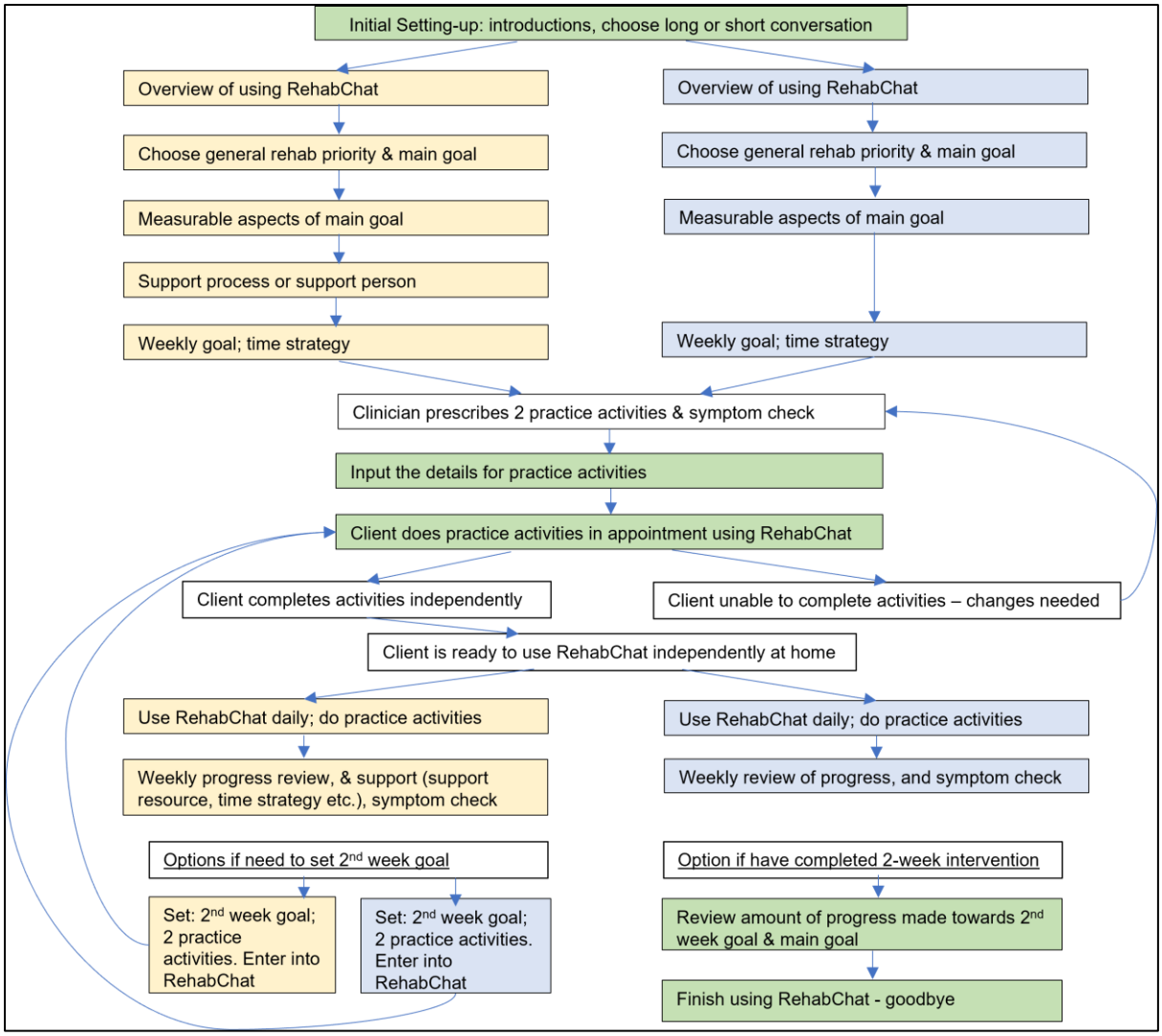
RehabChat incorporates key aspects of goal setting (40) and ensuring goals are SMART (17). It has been specifically designed for clinical rehabilitation, and to be minimally intrusive upon the usual rehabilitation approaches used in the clinics. RehabChat is used alongside usual care with therapist supervision whilst the client continues to receive usual multi-disciplinary rehabilitation care. The therapist provides direct supervision of the client using RehabChat during the appointments, and prescribes the home practice activities. Whenever new details for the practice activities are entered into RehabChat, this updated home program is trialed by the client during the appointment to ensure they can independently use RehabChat to complete the program, prior to continuing practice at home.

During independent use of RehabChat at home, RehabChat asks the client if they have any symptoms or issues whilst doing the home program, and how they managed this. RehabChat dialogues prompt the client to contact their therapist with any concerns, including if symptoms are difficult to manage.

At a pre-set weekly appointments with the therapist and client together, the weekly sub-goals are reviewed, and the client's practice exercises changed as needed. Engaging again with the therapist for this will bring support and a sense of checking in on the process of using the ECA – the client can ask any question, and if needed the client or clinician can contact the researcher with any queries. Ongoing use of RehabChat requires resilience and persistence in use. By having weekly RehabChat progress reviews with the clinician in the clinic, it was hoped that the client will receive a boosted sense of clinician support, and confidence to use the ECA because the home program details have been checked and if needed modified.

Details of the home program can be changed at this juncture, following the process outlined above. If any changes are made, then the new details are entered into RehabChat. As well, the client practices these new exercises using RehabChat in the clinic setting until they feel confident to do so independently. The client then continues with independent practice of the home program.

At completion of the trial, the client's progress towards achieving their overall rehabilitation goal could be reviewed using RehabChat with the therapist.



Legend for box shading: white = explanatory notes, no conversation content; green = sub-conversations used in both short and conversation styles; orange = long conversation style; blue = short conversation style

Figure 11: Flowchart of short and long conversations

4.3.5.2 Using content variables in conversation

The Clevertar platform can capture freeform text entered by the user, and save it ready for re-use in subsequent dialogues. In this way, the user's wording can be used in the conversation. The variables used in RehabChat related to the goal setting and pursuit topics that made up the conversation. The specific variables included: user's name, profession of supervising therapist, main goal, weekly goals, symptom to monitor for, strategy for managing symptom, and details for practice activities such as dose and frequency.

4.4 In-house testing

RehabChat underwent two rounds of in-house testing – alpha and beta testing – with professional and academic colleagues from the researcher's workplace, and not with

independently recruited participants. Colleagues involved in the in-house testing had an understanding, at least in overview, of the requirements of the intended clinical setting, and the nature of CAs. Colleagues were emailed a URL of RehabChat, a user guide explaining how to use RehabChat, and a form with the feedback questions. The colleague was asked to use RehabChat for 15-30 minutes. Feedback was then emailed back to the researcher. After each round of testing, feedback was analysed, and priorities for changes needing to be made to RehabChat were identified, and subsequently implemented. The changes made accorded with MI, SDT, clinical needs, WCAG and PT. Following the changes being made, and prior to the next round of testing, the researcher conducted checking of the prototype.

4.4.1 Alpha testing

Alpha testing checked for technical glitches, overall usability, and initial considerations of its potential ability to match the intended clinical setting's requirements. Participants (n=3) were senior academics working in the Flinders Digital Health Research Centre. The method used for alpha testing comprised the participant using an early simple version of RehabChat for approximately 20 minutes, and then providing written answers to the following five questions:

What went well?
What didn't go well?
What suggestions would you like to make for improving the ECA?
Any other comments?
Could you 'break' the ECA? If so how?

4.4.1.1 Feedback received in alpha testing

Results from alpha testing confirmed that the ECA software was easy to launch and use. The results also highlighted areas needing to be optimised including supporting client choice-making, allowing personalization of the ECA, and streamlining the conversation structure to minimize cognitive demand (see Table 10).

Table 10: Alpha testing feedback and design changes made in response

Feedback domain	Feedback received	Design response	Reason
Dialogue structure	More multiple-choice to decrease fatigue	More multiple-choice at key decision points	User is aware of expected input; lessens fatigue
Dialogue structure	Multiple choice more varied	Multiple choice options diversified	Supports detail in user's thinking, e.g. about their interest
Dialogue styles	Use simple language	Lower secondary school level	Promotes understanding
Personalization	Able to choose an avatar	Developed 2 avatar styles	Improves personalization
Personalization	An alternative conversation style	Two conversation styles: longer, supportive; shorter, directive	Client preference supported; & clinical need considered
Behavior change	Integrate specific aspects of behaviour change paradigms	Content includes choice-making, goal meaningfulness	Support user's motivation

4.4.1.2 Changes made to alpha prototype

Changes were made to address these feedback points. Table 10 provides an overview of alpha testing feedback and the design response changes made to the ECA. A key change amongst these was the inclusion of a shorter version of the conversation in addition to the longer more supportive version. Following completion of the changes to RehabChat in response to alpha testing feedback, RehabChat was checked for any errors, and to ensure the decision points were configured correctly, prior to it being used for beta testing. The updated ECA prototype was subsequently used for beta testing.

4.4.2 Beta testing

The purpose of beta testing was to test the working model of the ECA prototype and seek feedback on the overall concept and its conversation content relating to usability, perceivability and operability, and also its intended clinical application in brain injury rehabilitation. The beta feedback form was developed based upon software design and client-specific factors. The software factors were derived from the WCAG main principles of Perceivable, Operable, Understandable and Robust (205). Only the first three of these were applied; the Robust principle was not appraised due to RehabChat not yet being linked to other technologies. The beta feedback form was comprised of three main sections: Interacting with the technology of RehabChat; Using RehabChat for motivation, goal setting and goal achievement; Potential use of RehabChat alongside usual rehabilitation care. These sections were composed of 12 questions and a fourth section was included for any

other open comments. A separate user guide was developed describing: the intended clinical setting and end-users for RehabChat; the need for clinician oversight; an overview of the process of beta testing; instructions to launch and use RehabChat.

Potential participants invited for beta testing were Flinders University PhD candidates or academic staff affiliated with the Flinders Digital Health Research Centre, with experience in digital health technology and/or health and rehabilitation care. Participants were requested to choose to provide feedback based on the imagined perspective of either a clinician or that of a client. Eleven individuals ultimately participated.

4.4.2.1 Feedback received in beta testing

Feedback was gathered regarding not only any technical glitches, but opinions and suggestions regarding planned implementation in brain injury rehabilitation settings. Results from beta testing revealed that RehabChat functioned easily for users, and any ECA dialogue issues were the result of content configuration issues. Participant responses for beta testing were analysed using the Framework Analysis method (171). Framework Analysis was chosen because of its ability to enable a targeted and transparent review of data to achieve identifiable outcomes (171). This was relevant for this testing stage for RehabChat, as the intended outcomes of data analysis were to identify feedback which would help define how to design RehabChat. Application of the Framework Analysis approach included: making initial coding notes on the completed feedback forms; defining likely themes and categories to best fit the coded data; and organizing the data under the themes and categories. Changes to the thematic model were made iteratively during analysis to optimise clarity in how data was organized. Beta testing themes and main categories are presented below in Table 11.

The results for beta testing are presented alongside the design changes implemented for RehabChat in Table 12. The main areas of feedback were in regard to conversation style, the HCI, navigation and usability, user perspective, the need to provide training, clinical context and rehabilitation content. Feedback from beta testing included a number of recommendations for changes to RehabChat regarding its clinical application and feasibility. Specifically, these were in regard to enhancing specific aspects of goal setting, allowing for more choice-making during progress reviews, and providing visual feedback on progress being made.

Table 11: Beta testing feedback - main themes

Theme	Feedback referenced to participant (P) & line number (L)		
Acceptability & usability in clinic setting	Acceptability: non-intrusive (P4, L108); no personal information needed ((P1, L106)	Accessibility: easy to load & get started (P4, L109); only need 'a link' (P3, L99)	Integrate into clinic: 'very easily' (P3, L100); need clinician input (P1, L108); 'I think this could easily be used along side usual care as an extra support mechanism' (P11, L95)
User experience	Navigation: navigation seems quite intuitive (P11, L23); liked option to go back a few steps (P1, L24); forward backward ok but what if I want to jump a section? (P9, L39)	Typing responses: 'no issues' (P1, L21); user may need help; have more multiple-choice options (P4, L26); typing for me is easy, but I wonder about the BI population? (P9, L36)	HCI: clear, easy to read (P1, L16); easy to hear, good pace (P3, L16);
Motivation & behavior change	Make choices: 'to some extent, when you can enter text, but less so when clicking the response buttons' (P1, L99); to an extent – dependent on relationship with MDT (P8, L51)	Promote self-managing: yes, because user-focused (P3, L107); 'really think about yourself' (P7, L48)	Supports motivation: through goal setting (P2, L63); 'Provides support when needed, helps to set goals and review goals, keeping client motivated and on track.' (P10, L64)
Clinical relevance & use	Communicate with therapist: 'encouraging the user to follow-up with their therapist' (P1, L62); 'if the therapist could see the data entered that would be helpful' (P1, L70)	Support rehabilitation: 'Definitely, clear goals are the focus' (P4, L98); Enables client to review progress – revisit goals. (P10, L72)	Practice home tasks / exercises: 'looks like a good process' (P6, L77); 'need more breakdown of the tasks.' (P3, L74)
Ideas for future design changes	Goal setting: set measurable, specific goals (P5, L99); 'More guidance could be provided in development of goals' (P10, L113)	User interface: 'It would be enhanced with more audio, visual and interactive capabilities if possible.' (P3, L122)	Give feedback: 'More intervals than just baseline, halfway and after the program.' (P3, L60); may need to screen for suitability (P9, L111)
Browser & computer used; ECA performance	Browser: Chrome (9); Safari (1); Explorer (1)	Computer: laptop (5); desktop (6)	Performance: 'Good, no glitches or complications with the RehabChat itself.' (P3, L45)
Technical issues	Avatar speaks some punctuation e.g. says *dash* for - (P6, L133)	Some entered content not populating later dialogues (P6, L31)	Connections between dialogues at times not logical (P2, L174)

Table 12: Beta feedback: main themes; changes made to ECA

Main themes	Changes made to ECA
Clarity of conversation	
Avoid long chunks of text; reduce wordiness	Dialogues edited to reduce wordiness, but to still have same topic content
Provide explanations for necessary jargon terms; avoid unnecessary jargon	Jargon content has been minimised. For jargon terms included (e.g. goal, support person), very simple explanations provided
Include clearer instruction for when user is required to enter freeform text	Specific, simpler prompt cues for when user is to enter freeform text included
Tense of variables filled by freeform text entry by user	Corrections made to ensure tense for filled variables is correct when used across different sections of conversation
Logic issues (some dialogues linking incorrectly; some variables not pre-filling)	Corrections made to dialogue logic decisions and to management of variables to ensure dialogue flow is correct throughout conversation
User interface	
Option to choose own avatar	Three avatar styles developed in accordance to W3C guidelines: a default avatar (semi-formal female), and two other choices – a more formal female, and a semi-casual male
Option to use voice-recognition	Voice recognition is available on ECA platform but not implemented due to resource constraints regarding implementation of Natural Language Processing
Navigation and usability	**Changes made to ECA**
Able to navigate between sections; consider a home screen	Included a home-screen launch-conversation: in it, user has multiple-choice options for specific parts of conversation (e.g. goal-setting, practice home activities)
Able to review content when wanted (e.g. exercises, goal)	User can review home practice activities as desired between clinic-based appointments. In ECA conversation, rehab goal regularly reiterated
Able to stop, and return to ECA later	Client can pause or close ECA and re-open it later to resume from same point
Provide signposts of each conversation section just completed or to be done	At start of each conversation section, ECA explains the section At end of each section, ECA recaps on content completed, and states next section to be done
Have an exit point after each section	At end of each section, ECA states clearly when each section is finished, and option/s for next section
User perspective	
User's prior experience using technology impacts upon their experience using ECA	ECA accommodates varied experience levels through a training module; a user guide; and offering two conversation styles Oversight clinician will screen for eligibility
Role of clinician clearly stated - to help avoid unrealistic expectations	Clinician's role explained during recruitment, and participant's initial training. ECA refers to supervising clinician regularly. Clinician to provide clinical oversight, including ensuring goals and home exercises are appropriate.
Provide training	
Give prior explanation and training	A simple user guide developed for client and clinician users, which explains practical skills needed to use ECA. Additional instructions for clinicians also developed, which explains clinician role.

Main themes	Changes made to ECA
	Additional 'RehabChat Training' module developed, which comprises easy to understand, non-clinical content about weather and transport. The user firstly completes the training module (in which they practise using ECA), and secondly is assessed for competency in using ECA.
Allow opportunity to get used to using it	Training module can be practiced multiple times by the user prior to them being assessed. User guide is an ongoing resource about key skills for using ECA. Client will practice home exercises using ECA initially in clinic (rather than at home) with clinician to support.
Contextualise to clinic setting	
Clearly outline how ECA will be used alongside usual rehabilitation care	ECA is intended to be used alongside usual rehabilitation care. This will be explained during recruitment and initial training, and is included in the additional instructions for clinicians
Therapist to introduce ECA to client	Therapist will nominate which of their clients is eligible to participate in the project. Client learns to use RehabChat using Training module, with support of RehabChat staff-person. Then, client and clinician use the ECA in the clinic setting.
Home exercise to be prescribed by therapist	This will occur, and it will be explained to users during recruitment and initial training, and also included in the additional instructions for clinicians
Client remembering to do exercises	SMS messaging available with ECA software, but due to confidentiality requirements will not be implemented in project. How to support client to remember to do exercises for further discussion in workshops
Progress reviews (e.g. half-way, weekly, at completion of program)	ECA asks for details of a main rehab goal to be achieved by end of program, and a half-way goal to be completed by half-way through the program. ECA facilitates review of progress both at half-way through, and at end of, program. Frequency of reviews for further discussion in workshops
Goal-setting to include SMART* components	ECA asks distinct questions about SMART goal-setting components (17)
Increase motivational component	ECA not changed significantly as principles of SDT and MI already included (e.g. client chooses goal and identifies reason for foal being important for them; a support person identified)

Legend: ECA = embodied conversational agent; SMART = Specific, Measurable, Achievable, Relevant, Time-bound; SDT =Self-Determination Theory; MI = Motivational Interviewing

4.4.2.2 Changes made to beta prototype

Following beta testing, RehabChat was substantially modified in response to participant feedback (see Table 12). The conversation dialogues of RehabChat were modified to improve understanding and to refine goal-setting content. Broader strategic changes were also made. RehabChat was developed to incorporate a defined process for implementing it alongside usual care in the clinic setting, the user guide was considerably simplified (see Appendix VII compared to Appendix XII), including incorporating a training module, developing a training process for users to complete prior to intended clinical use, and clarifying the clinician's supervisory role. These changes are discussed in more detail below. It was this version of RehabChat, with its associated mode of intended use, that was presented for end-user consultation in the four rounds of the co-design workshops (see Chapter 5). Additionally, the beta testing feedback helped to clarify the

methodology for the subsequent co-design workshops (see Section 5.5), and the feasibility pilot trial (see Section 6.4).

Beta testing feedback directly informed how the conversation dialogues were to be constructed, and the specific focus areas of conversation content, to align with the needs of clients. Both the structure and style of the conversation dialogues were refined to include simple, plain English, explanations of key concepts, reiteration of what the client had entered – for example, their main rehabilitation goal, or details of the practice activities –, and more multiple-choice options. A specific change made to the conversation content was to ensure a more definitive approach to gathering SMART goal-setting information. As well, correction changes were made to the dialogues including improving cues for the user when required to enter freeform text responses, and correcting design errors which had impeded correct linking of inputted data for pre-set variables and or linking these with subsequent dialogues.

A substantial change made to RehabChat following beta testing was development of a separate ECA training module. This module contains two brief, simple conversations: a practice conversation; and an assessment conversation. The ECA training module was designed to be used to introduce the ECA to participants without focusing on the clinical goal-setting content. The topics discussed are about weather and transport. These simple topics were chosen so as to reduce the cognitive overhead of thinking through personal rehabilitation goals and needs. It was thought that by reducing cognitive effort, the user will more easily become familiar and confident using RehabChat.

Another key change made following beta testing was development of a distinct mode of intended use and implementation for RehabChat. The intended mode of use includes: clinician oversight, use alongside usual care, and align with established rehabilitation SMART goal-setting (17). The aspect of clinician oversight is supported through 1:1 clinician training and the development of additional clinician-specific instructions. The clinician's role is also enabled by providing a recording sheet for noting key content entered into RehabChat including goals and practice activities which are developed. For SMART goal-setting, the ECA asks distinct questions about the SMART (17) components of Specific, Measurable, Achievable. The Relevant component is reflected in that the client chooses the main goal, and the Time-bound component is reflected in the goal being something to achieve in a six-week period.

4.5 Discussion

Early testing of the ECA prototype RehabChat has examined its clinical relevance and potential usability, and also identified aspects requiring further development. The appropriateness of the conversation and dialogue structuring and the utility of the two style variants was confirmed by this process. A similar approach for developing a CA for use in stroke rehabilitation – specifically for

anxiety management – has been previously reported (156). In this study, many of the approaches used to develop the CA were similar to those used for developing RehabChat. For example, in their study, they used existing CA software, incorporated social engagement communication in the CA dialogues to establish rapport, and focused on reducing effort in client users by for example minimising the amount of click button responses required during the conversation (156). They also identified key topic components which needed to feature in the conversation, and tested the initial prototype in-house, following which technical issues were resolved (156). The final stage of testing of their CA was with colleagues (due to difficulty recruiting clients) and it focussed on technological ability and dialogue clarity of the CA. Feedback from this included the need to shorten the length of the dialogues, and to improve the natural feel of the conversation by including acknowledgement answers (156). Usability aspects in that study were appraised using the SUS, a structured questionnaire and also semi-structured interviews (156). Many of these research components were addressed in the RehabChat project, including: existing software used and developed to an initial prototype level; initial in-house alpha testing was conducted; and subsequent beta testing was completed with feedback being gathered from post-graduate students and academic participants through a comprehensive questionnaire covering aspects of usability, acceptability, and clinical relevance. The comprehensive approach used for the design and development of RehabChat provided the basis for further intended refinement and extension of it through the later co-design workshops and a pilot trial.

4.6 Conclusion

This chapter has presented the design and development processes and in-house testing implemented for achieving a stable model prototype of RehabChat ready for testing with clients and clinicians. In-house testing also provided the basis for defining the intended mode of use of RehabChat in the real-life setting. The next stages for developing the ECA prototype of firstly conducting a series of four co-design workshops with clients and clinicians of the collaborating brain injury rehabilitation clinics, and secondly, to conducting a feasibility and usability pilot trial at the same clinics are explained in Chapter 5 and Chapter 6.

5 Co-design workshops

> "It's the actual things of seeing goals and other points reiterated that helps memory … and the process of all the questions, that helps [me] to imagine who [I] could be" (Quote from a current client participant in the co-design workshops).

5.1 Overview

The overall aim of the co-design workshops was to further develop RehabChat through utilising feedback from the three cohorts: current clients with traumatic brain injury (TBI), discharged clients with TBI, and clinicians. Feedback from the four rounds of co-design meetings provided guidance for implementing updates and modifications to RehabChat. The version of RehabChat used in the workshops was that which was finalised following beta testing, and which included the actual ECA prototype, as well as its intended mode of use for it in the clinical setting (see Section 4.4.2). Participant feedback from the co-design workshops was analysed using a qualitative Framework Analysis approach (171, 206). Framework Analysis, although initially developed for social policy research, has also been used in qualitative research including applied health research (171, 206); and this RehabChat project is applied health research. The Framework Analysis approach is also useful for analysing data in which participants have discussed similar topics of data albeit sharing different perspectives on these topics (206). This was relevant for the current RehabChat study in that within each round of workshops, each cohort were asked the same topics of questions.

Data analysis focussed on extracting data relevant to deciding upon changes needed for RehabChat (both the ECA and its intended mode of use) such as in regard to participant clinical needs as they related to RehabChat, and any recommendations for changes to RehabChat that participants shared. These data provided the basis for making subsequent, targeted changes to RehabChat during and following the workshops, to develop a final refined prototype. For this refined prototype, an additional round of alpha testing was completed prior to the final stage of testing – the mixed methods feasibility pilot trial (see Chapter 6).

This chapter presents the rationale, methodology, and results of the co-design workshops conducted with clients and clinicians of two ambulatory care brain injury rehabilitation clinics of a specialist state-wide brain injury rehabilitation service situated in metropolitan settings. One of these clinics provides care for clients with moderate-severe acquired brain injury (ABI) including for clients with traumatic brain injury (TBI); the other clinic provides care for clients with mild TBI. The methodology for this project was developed with input from and consultation with the research coordinator for the brain injury rehabilitation services. The methodology carefully meets the needs of clients such as fatigue and difficulty concentrating, as similarly reported for co-designing with participants with learning disabilities (172). Unique approaches are needed for co-design when participants have specific needs regarding communication, such as occurs with adults with traumatic brain injury (TBI). Developing a successful novel digital health intervention should

incorporate in-depth co-design consultation with intended end-users (176) to obtain the unique perspectives of different groups of participants. Because RehabChat is intended to support engagement in rehabilitation and to be used by clients with oversight provided by a clinician, it is necessary that co-design should include both client and clinician participants.

5.2 Relevance of using co-design to further develop RehabChat

Co-design with intended end-users should be incorporated when developing a novel digital health intervention for self-management (176) or behaviour change (73). A recent review on the effectiveness of digital health platforms for self-management of non-communicable diseases, highlighted the necessity for iterative client-centred co-design of the digital health tool (207). Previously, co-design focus group consultations have been conducted for developing CAs to support clients with Parkinson Disease: for communication and speech needs (131), and for education and self-management needs (132). Co-design has previously been implemented for brain injury rehabilitation: with clients to develop solutions relating to employment (177) and self-management strategies (178), and with clinicians for developing telerehabilitation services (179). Similarly, end-user engagement is a central tenet of Living Laboratory (160) and has been aligned for specific use with designing technology tools (164) including for clients with TBI (162). Previous research has involved clinician experts in iterative consultation about the development of a messaging digital platform to support mental health (107).

5.3 Meeting the needs of client participants in how the co-design workshops were conducted

The specific needs of clients with TBI were addressed and met in how the co-design workshops were conducted. This was achieved through applying principles of precedent examples and recommendations reported in relevant literature, as discussed below, and through responsively adapting the delivery of the co-design meetings in response to client needs, such as reported fatigue, and levels of engagement, such as needing extra time to complete using a portion of the RehabChat conversation.

The literature provides a number of relevant principles and examples which were considered that relate to how to conduct the co-design workshops so as to accommodate participants' needs including cognitive fatigue and memory challenges. A range of co-design approaches previously used with participants with learning disabilities, are relevant also for participants with TBI. These approaches include: acknowledging and acting upon participant choices and feedback; empowering participants to perceive themselves as active influencers in the project; using cognitively similar approaches across different feedback sessions; and ensuring that materials delivered in sessions match participants' abilities (172).

5.4 Research aims and objectives

The aims and objectives for the co-design workshops are presented below. These refer to both of the rehabilitation clinic settings (for moderate-severe ABI/TBI and mild TBI) involved in this project, and to the plan for recruitment: of 5 clinicians and 10 clients (5 current clients and 5 discharged clients). The aims and objectives in overview endeavour to reflect the main purposes of this project – to understand the motivational needs of clients during rehabilitation, to collect feedback about and recommendations for RehabChat, and to ultimately develop a refined, stable model version of RehabChat to be used in the subsequent feasibility pilot trial. Aims 2 & 3 and Outcomes 2 & 3 were achieved in four iterative cycles through four workshops. Each of these aims aligns to the overarching research questions for this PhD (see Section 1.13), as indicated in bracketed notes for each aim below.

Aim 1: (Aligns with the main research question, and research sub-question 2)

Define the motivational support needs of individuals with traumatic brain injury during their rehabilitation, through workshop discussions with participants.

Outcome 1:

Report on the needs of clients for motivational support during their recovery following traumatic brain injury.

Aim 2: (Aligns with the main research question, and research sub-questions 1 and 2)

Through workshop discussions, explore how clinicians and individuals with traumatic brain injury would like an ECA intended to support the motivational needs of clients to be designed,.

Outcome 2:

Identify recommendations for the design of the ECA from clients with TBI and clinicians, through workshop discussions.

Aim 3: (Aligns with the main research question, and research sub-question 1)

Integrate the design recommendations made by clients with TBI and clinicians during the workshop discussions regarding the design of an ECA for supporting motivation in clients.

Outcome 3:

Achieve a refined, stable model ECA which is designed to support motivation for clients.

Aim 4: (Aligns with the main research question, and research sub-questions 2 and 3)

Through workshop discussion with clients with TBI and clinicians of the clinics, define the way in which the ECA could be used in clinical practice alongside usual care, and also in a subsequent feasibility pilot trial at the same clinics.

Outcome 4:

Report on the way in which the ECA will be used in a subsequent feasibility pilot trial at these same clinics.

5.5 Methodology for co-design workshops

The ECA version used for the co-design workshops was the refined prototype developed in response to beta testing feedback. This version incorporated a training module and a rehabilitation module (see Section 4.4.2).

5.5.1 Ethics details

Full ethics approval was obtained for these co-design workshops from the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) and the CALHN Governance Committee, project number 13007. See Appendix VIII for the ethics approval letters.

5.5.2 Population, Context, Concept

The Population, Context, and Concept (PCC) for this project were focussed specifically on the intended clinical setting and on the prototype of RehabChat developed following beta testing. The specific PCC details are presented below.

5.5.2.1 Population: Three cohorts

Three cohorts for the two intended clinic settings were chosen to participate in the workshops, to optimise the ability to gain different perspectives from each. The three cohorts were: previous clients discharged between one and three months ago; current or recently discharged (within the previous month) clients; and clinicians of any registered profession. Discharged clients were included to provide feedback based on their experience during their rehabilitation as well as contextualising their rehabilitation experience to the needs and priorities they have experienced following discharged. Current clients provided perspectives of their real-time experience in rehabilitation, with the benefit of this being an emerging an ongoing experience whilst the workshops were running and so would not require the effort of memory recall. For clients recently discharged in the prior month, their rehabilitation would still be a close enough experience to require less cognitive effort to recall. Finally, clinicians were included to draw upon their real-time, ongoing experience of supporting clients during rehabilitation, including considering aspects such as client motivation, and the use of digital technology for the care of their clients.

5.5.2.2 Inclusion criteria

Inclusion criteria were presented on promotional posters (see Appendix XI) and brochures, considered during the eligibility screening process conducted by clinicians, and discussed during the consent process.

Clients: Eligible client participants included clients who were currently receiving care or had been discharged within the three months prior to being screened. All client-participants needed to have sustained a TBI. They also needed to be able to use a hand-held tablet device for the ECA, in regard to hand dexterity, visual acuity and any other factors such as comfort in using technological devices. As well, they needed to have mental capacity to provide their own consent to participate in this project.

Clinicians: Eligible staff-participants were registered clinical professionals working at ether clinic. Any clinician of the clinics was eligible to participate, including staff who were a clinical professional but who were working in a role connected to provision of clinical care, but which did not include providing direct clinical care.

5.5.3 Context: clinical settings

The clinical settings for this project were two state-wide ambulatory care brain injury rehabilitation services located in metropolitan Adelaide. One of these services provided care for adults with mild TBI. The other service provided care for adults with moderate-severe ABI arising from varied aetiologies including clients with TBI. Both services provided multi-disciplinary care within outpatient, home-based and tele-rehabilitation contexts.

5.5.4 Concept: use RehabChat, provide feedback, and give recommendations

These co-design workshops provided a group setting for participants to use RehabChat, and to review RehabChat at subsequent workshops regarding changes made in response to previous feedback. The workshops also enabled feedback to be gathered from participants regarding their needs and experiences during rehabilitation, and their thoughts about RehabChat, and for the researcher to explain and demonstrate the iterative changes made to RehabChat between each workshop in response to feedback.

The workshops were conducted as a series of four rounds of meetings. The first three rounds of workshops were presented in separate meetings for each cohort. This was because of the inherent power difference between clients and clinicians, and the different perspectives of discharged and current clients. The final workshop was held with all participants together as a way to demonstrate equality between the participants, and opportunity for them to comment collectively on the

penultimate version of RehabChat. Below is a flowchart of how the four rounds of co-design workshops were conducted (see Figure 12).

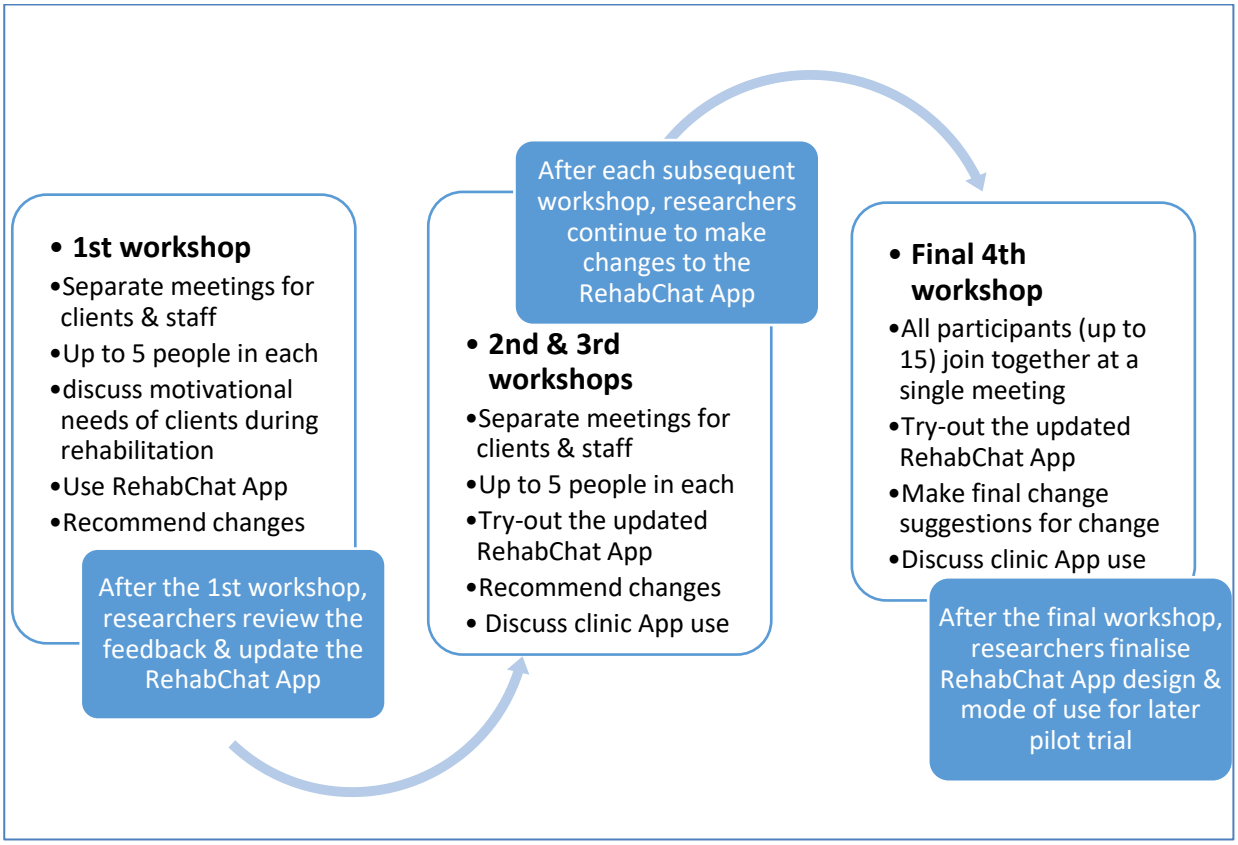


Figure 12: Flowchart showing how the four rounds of co-design workshops were conducted

5.5.5 Screening and recruitment

Prior to recruitment, an information talk was presented to clinicians of each clinic to explain an overview of the project, and the commitment required of participants. Promotional posters (see Appendix XI) were placed at both clinics. Interested clinicians expressed interest to the researcher (JH) who followed up regarding recruitment. Recruited clinicians screened potential clients for eligibility, and eligible clients were invited to consider participating in the project.

Each interested potential participants received an information and consent form and completed a formal consent process with the researcher. Consent was confirmed prior to commencing participation and reconfirmed via a telephone call prior to each meeting. All participants were free to withdraw from the study at any time. The data already obtained from the participant during their participation in workshop/s preceding their decision to withdraw would still be used in the project. This was because it would be impractical to identify the data and remove it due to the data being captured as an audio file of a group discussion.

5.5.5.1 Sample size

A sample of 15 participants (up to five clinicians; up to five discharged clients (discharged 1-3 months ago); and up to five current or recently discharged clients (within the previous month)) was targeted to take part in the study. These numbers are based upon recommendations for co-design usability projects from the Nielsen Norman Group (https://www.nngroup.com/articles/how-many-test-users (viewed 14-2-20)) that a sample size of 5 participants is sufficient for each end-user cohort. These recommendations were cited by the United States government technology development website usability.gov (www.usability.gov/how-to-and-tools/methods/recruiting-usability-test-participants.html (viewed 14-2-20)). Additionally, if at least one client was recruited from either service, then at least one clinician from the same service needed to also be recruited. Client participants were welcome to invite a family member, friend, or carer (carer) to attend with them. However, the carer would not participate in the workshop discussions.

5.5.5.2 Eligibility screening for client participants

A specific screening process was used for identifying eligible clients which met the requirements of confidentiality and the CONSORT guidelines regarding reporting of screening, recruitment and allocation processes (4). Recruited staff champions of the two clinics were responsible for screening potential client-participants for eligibility, with support from the service research coordinator. For screening and recruitment of client-participants, only clinic staff reviewed client records, and the researchers only reviewed demographic details of potential client-participants who expressed interest in participating.

Screening staff were instructed how to conduct the screening, and to record the process. The screening process was recorded onto an Excel (6) sheet to ensure all data required by the CONSORT statement (4) was obtained, including total number of clients considered, number eligible, and the number finally recruited. At completion of the project, this sheet was deidentified by clinic staff prior to sending it to the researcher. Contact made by the two clinics with eligible potential client participants was conducted via phone calls, text messaging and email. The wording of the scripts for these communications was pre-determined, and developed in consultation with the staff champions, research coordinator and clinic secretary. Screening staff were instructed regarding that discharged clients needed to have been discharged no longer than three months prior to the date on which the screening was conducted.

5.5.6 Participant commitment

Participants were invited to attend four 60-minute online (Zoom) video-conference meetings held approximately every 2-3 weeks over a two-month period (see Section 5.5.4). At the completion of the workshops, all participants were sincerely thanked for their participation, and invited to tell the researcher if they would like to be contacted regarding the subsequent feasibility pilot trial. As well,

each client participant was given a $25 gift card as a token of appreciation for participating in the project.

5.5.7 How co-design workshops conducted

Participants used RehabChat on an iPad during the co-design workshops. Only one type of tablet device – an iPad –was used during the workshops, rather than utilising an alternative android tablet as well. This was to ensure that all participants had the same experience of using the ECA on a hand-held device. The iPad was configured with two RehabChat click icons on the home screen – one for the training module and one for the rehabilitation module (see Figure 5 in Chapter 4). Each participant kept the iPad with them for the duration of the workshops. As well, participants who were discharged were provided with a second iPad upon which the tele-conferencing was done. (Participants who were clinicians or current clients would already have a computing device which they use for tele-conferencing). All participants, irrespective of their experience using an iPad or CA, were provided with 1:1 training prior and a RehabChat user guide to the workshops to ensure they learnt the simple steps of turning the iPad on/off and opening and closing RehabChat, as well as using Zoom.

The co-design workshops were conducted in ways to meet the clinical needs of clients, such as minimising fatigue and reducing cognitive effort. This was achieved through having a short break at half-time, by delivering the workshop content in a predictable manner, and using both visual cues (through PowerPoint) and spoken information by the researcher. Extra time and reiteration were provided for participants to think through each topic and what feedback they would like to give. As well, emphasis was given to providing sufficient time to use RehabChat in small chunks, and then to provide opportunity for the participants to provide feedback on just that chunk. Responsive help and trouble-shooting was provided by the researcher as needed for any participant.

5.5.7.1 Potential risks to participants and risk mitigation

During the workshops, known risks as discussed below, and also the potential for unknown risks, were mitigated by the researcher presenter monitoring for participant stress. The researcher was experienced in understanding the needs of clients with brain injury and in identifying distress.

Potential known risks to workshop participants included becoming upset or distressed by the discussion topics or questions, as can occur with any discussion-based research. If a participant became upset or distressed, they could take a rest break, and return to the workshop when ready. They could also discuss their needs with their clinician, ring Beyond Blue, or talk to the researchers who would assist them to receive any needed support but would not actually provide the support.

An additional known risk was that participants may become tired during the workshops. If so, they could take a rest break and recommence their participation when they felt able. Additionally, they could let the researcher know if they needed any support for this, and the researcher could facilitate this as required.

5.5.8 Content for Workshops

Each workshop included three main sections: researcher-led presentation of content, use of RehabChat on the iPad, and group discussion about RehabChat facilitated by the researcher. PowerPoint was used during the meetings to convey visual information, including showing details of changes made to RehabChat. Information was presented at a relaxed pace, to allow participants time to digest the ideas and generate and share points of feedback. Content for each of the workshops included an overview of the research process, presentation of the main topic for the workshop, and use of RehabChat. The RehabChat ECA was used on an iPad by each participant. Three avatar styles chosen from the available options in the Clevertar software were trialled in the workshops: a Eurasian, semi-formal lady with Australian accent; an Anglo-European, formal lady with English accent; and an Anglo-European, informal male with Australian accent.

The first workshop explored clients' experience of motivation and goal-setting during rehabilitation, and then introduced the ECA. Each of the following three rounds of workshops presented the updated ECA incorporating changes made in response to feedback in the prior workshop, as well as participants using further sections of RehabChat, and being able to provide their feedback comments. The second workshop focussed primarily on the user interface (UI), and the third workshop focused on how RehabChat would be integrated into the real-life clinical setting. The final fourth workshop covered both of these and other areas. Details for each workshop round are provided below.

5.5.8.1 Three main topics discussed in workshops

The three overarching topic areas discussed in the workshops were: client needs regarding motivation and their rehabilitation goals; content of the conversation dialogues presented by the ECA; and aspects of the ECA human-computer interface. These topics were explored iteratively across the four rounds of workshops, and are presented below.

1. **Motivation and rehabilitation goals** were discussed with specific attention given to: how does motivation impact upon rehabilitation?; what helps and/or hinders motivation?; how are goals set and achieved?; how does motivation link with goals?; what helps achieving goals?

2. **Specific ECA conversation dialogue factors** considered included how best to support motivation and goals; how long the sentences or question should be; and the style of wording.
3. **Specific UI factors** discussed were the visual display, avatar presentation, size of text, colour schemes, audio output (speed/prosody rate, accent).

5.5.8.2 Overview of semi-structured questions for workshops

A question guide for the workshops was developed which included the main principles of the WCAG (158) (see Section 4.3.3.3) and specific areas about the design of RehabChat and how it may incorporated into the clinical setting. See below for examples.

1. **Web Content Accessibility Guidelines (WCAG) principles** (158)
    a. **Perceivable:** Audio clear?; Text clear?; Level of wordiness; Detail & complexity of wording
    b. **Operable:** ease of launch, navigate, close; Using typing; Selecting a click button
    c. **Usable:** for clinic & home use; general how easy to use; how well will client use independently at home?; training needed?
    d. Robust: how will it perform being used in the real-life clinic setting?; how will it integrate alongside usual care?; how independent will the client be in using it?
2. **World Wide Web Consortium Web Accessibility Initiative (W3C WAI)** (158)
    a. Adaptable: Is information presented in a way that is easy to understand?
    b. Readable: Can text –based information can be read and understood easily?
    c. Predictable: Does the tool behave as anticipated?
    d. Input Assistance: Does the tool help users enter data correctly and avoid mistakes?
    e. Enough Time: For users to read and use tool
    f. Navigable: Is the tool easy to navigate and has cues and helps to aid this process?
3. **Clinical factors**
    a. **Clinician support**: how much; in what way; when to have support; what support from RehabChat staff is needed?
    b. **Conversation style:** styles: longer, more supportive; : shorter, more directive; Who chooses style? – preference, clinical need
    c. **Motivational support:** How to optimise, e.g. dialogue content
    d. **Integrate into clinical setting:** Focus upon the mode of implementation
4. **User interface**
    a. **ECA HCI options**: Selecting click buttons; Using multiple choice; Entering freeform text

b. **Avatar – 3 styles**: Eurasian, a bit relaxed, female; Anglo-European, formal, female; Anglo-European, informal, male; Consider visual aspects and tone of voice; Consider if it would be important for client/clinician to choose avatar

5.5.8.3 Iterative development of RehabChat in response to feedback

In preparation for the second, third and fourth workshops, the RehabChat ECA was updated prior to each round of workshops in response to feedback from the previous workshop. The updated version of the ECA could be remotely configured to each participant's iPad, and therefore utilised in the subsequent workshop. Presentation of these workshop rounds incorporated PowerPoint and spoken discussion by the researcher, and followed presentation structure below:

1. A succinct summary of the research project by the researcher in regard to the overall purpose, the point of progress in which the project was at (e.g. the third of four meetings), and that participants were free to contribute or not, and to take a rest when needed.
2. Provide a summary overview of the main points of feedback from the previous meeting. This summary reflected feedback from all cohorts
3. Describe how the feedback determined the type of changes for RehabChat, and which areas of feedback had either not yet been implemented, for example because needing further software refinement, or were not able to be implemented, for example if the software capabilities did not allow for it.
4. Explain the actual changes made to RehabChat.
5. Participants use RehabChat's rehabilitation module, and therefore experience the new changes integrated within it.
6. Participants share their feedback about RehabChat using an informal speak-aloud approach, as well as answering semi-structured question by the researcher.

The meeting closure included acknowledgement of the participants' input, and details for how the next meeting would be organised.

5.5.9 Data collection and management

The data collected in this project were demographic information of participants collected via a questionnaire, and audio content of workshop discussions gathered through digital audio recording.

Separate demographic questionnaires were implemented for client and clinician participants. For client participants, it asked details of their age, gender, vocation or occupation, and how long they had been a client at either clinic. For clinician participants, the questionnaire asked about age, gender, clinical profession, and how long they had worked in their profession in total, and also in

brain injury rehabilitation at any setting and also more specifically at either of the participating clinics in this project.

The audio recordings data was deidentified using version 3.1 of Audacity® recording and editing software (2), and then transcribed using Microsoft Transcribe software (12). Each transcription was checked for accuracy by reviewing it alongside listening to the deidentified recording, and making corrections as required. The corrected transcript was analysed thematically using a Framework Analysis approach (171). The transcription data was coded into themes and sub-themes using NVivo software (14). An audit check of the thematic analyses undertaken was completed by one of the PhD supervisors (BL). Following their feedback, the number of sub-themes was increased to better categorise and clarify the nature of the feedback data.

The coded data for the themes and sub-themes was organised onto separate tables for each workshop, with a separate column for each cohort in each table. This allowed for varied and multiple themes for each cohort to be identified for each workshop round. Following completion of the workshops, the data was iteratively reviewed and organised to enable these varied themes to be organised into themes that were common across all four workshop rounds (see Table 18). Finally, feedback which related directly to recommendations for changes needing to be made to RehabChat were pulled across into a separate table (see Table 19). Changes were made to the ECA platform in response to these recommendations (see Section 5.6.13).

Following the final workshop, clinicians contacted the researcher to provide additional feedback via email and also at a subsequent short meeting. This feedback was not included in formal data analysis, but instead used as general stakeholder consultation which helped inform planning for the user testing completed with clinician-participants during the start of the feasibility pilot trial.

5.5.10 Second alpha testing of ECA

Following completion of the workshops, data analysis, and changes being made to the ECA in response to feedback (see results presented at Section 5.6 below), a second round of alpha testing was completed for RehabChat. Similar to the first round of alpha testing completed during in-house development (see Section 4.4.1), the second alpha testing was completed to test for technical glitches and any apparent disjuncture in the flow of the conversation within and between dialogues. Second alpha testing was completed using the stable model ECA which was developed after the end of the workshops, as per the table of changes (see Sections 5.6.13 and 5.6.14). Two cycles of testing were required due to numerous changes being made to RehabChat after the first cycle. At the first testing cycle, the participant and researcher sat in the same room, and the participant used RehabChat on an iPad. The second cycle of testing was conducted via Zoom due to Covid-19 factors. During it, the participant used RehabChat on a personal computer (PC), and utilised screenshare as well as providing screenshots of technical problem areas, which assisted

later when the researcher was resolving the glitches. At both testing cycles, the researcher observed how the ECA was being used and took notes of any content disjuncture or technical glitches. Afterwards, the researcher condensed the findings into tabular format, and proceeded to resolve the issues where possible.

5.5.11 Preparing the refined prototype to be integrated into clinic setting

Following completion of the second alpha testing, the ECA was prepared ready for the subsequent feasibility pilot trial in which it was used alongside usual rehabilitation care. To achieve this, the researcher discussed the intended implementation of RehabChat for the feasibility pilot trial (see Chapter 6) with the clinics' Information Technology Administrator, who then facilitated a seamless integration of RehabChat into the clinic setting (see Section 5.6.15). Additionally, the researcher discussed with the relevant administrators about what were the needs for a specified case-note entry to be made by participating clinicians in the pilot trial (see Section 5.6.15).

5.5.12 Responsive technical checking and resolving of glitches

Software functionality was monitored prior to, during and following the workshops and as iterative design changes were made. Any glitches identified were resolved in-house and where needed with assistance from Clevertar.

5.6 Results

The co-design workshops were conducted from 30 March to 26 May 2021 at intervals of two to three weeks. All workshops were conducted using Zoom. Four clinicians were recruited (two from each clinic).

5.6.1 Screening and recruitment details

Overall, 88 clients were screened for eligibility, and nine clients were recruited to the study. Details of the results from screening and recruitment of all screened clients are presented in Table 13. Results specifically for each clinic are presented in Figure 13 and Figure 14. These results are discussed below with reference firstly to discharged and current clients, and secondly in regard to each clinic.

Results of screening of discharged and current clients showed that 25 discharged and 63 current clients were screened, and for the nine clients finally recruited five discharged clients and four current clients were finally recruited. Reasons for exclusion included: not meeting the inclusion criteria (36 clients: 13 discharged; 23 current); declined (eight clients: eight current; nil discharged), and stress (four clients: two discharged; two current). Attrition was one discharged and one current client.

Results of screening and recruitment based on clinic revealed that the number of clients screened for eligibility was 30 for the mild TBI clinic, and 58 for moderate-severe ABI clinic. The number of clients recruited to each study was five from the mild TBI, and four from the moderate-severe ABI clinic. It is important to remember that clients from the clinic for moderate-severe ABI were only considered if they had a TBI. Attrition was two clients from the mild TBI clinic, and no clients from the moderate-severe ABI clinic.

Table 13: Co-design workshops CONSORT details of screening and recruitment of client-participants: numbers for each stage

Clinic	Cohort	Clients screened	Clients excluded	Reasons				# clients recruited to study	Attrition	# clients completing Workshops
			Total	Not meeting inclusion criteria	Unable to follow-up	Declined	Other			
Mild TBI	Current clients	25	23	-	12	8	Psychosocial n=1 Stress n=2	2	1*	1
	Discharged clients	5	2	2	-	-	-	3	1*	2
Mod – severe ABI	Current clients	38	36	23	10	-	Overload/stress n=2 Communication difficulties n=1	2	0	2
	Discharged clients	20	18	11	7	-	-	2	0	2
Total numbers for each cohort	Current clients	63	59	23	19	8	6	4	1	3
	Discharged clients	25	20	13	7	-	-	5	1	4
Total numbers (%)	**Both cohorts combined**	**88**	**79**	**36**	**26**	**8**	**6**	**9 (10% of total)**	**2**	**7 (8% of total)**

Legend: # = number of; TBI = traumatic brain injury; ABI = acquired brain injury; * = withdrew after 1st workshop

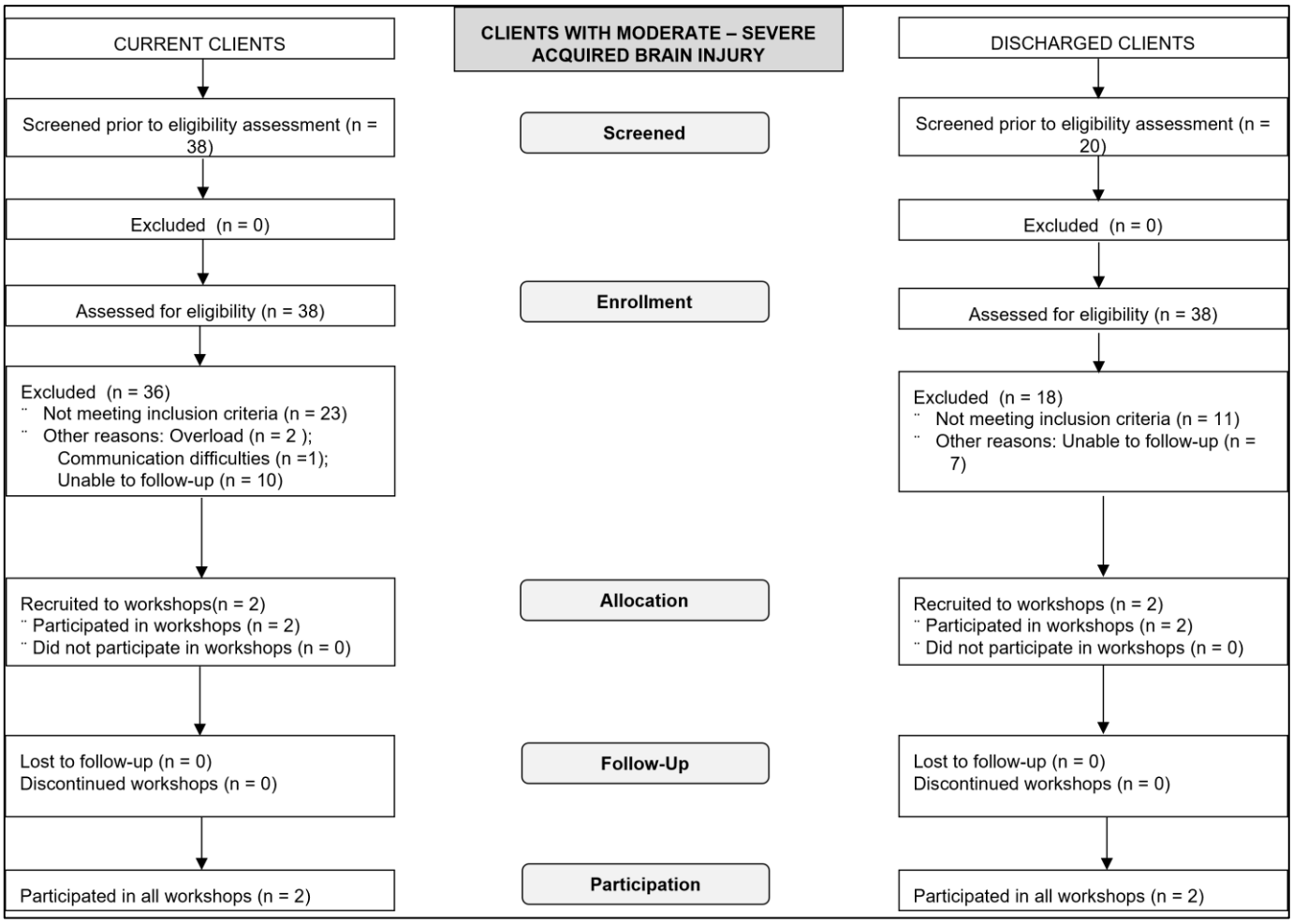


Figure 13: Co-design workshops CONSORT screening and recruitment details for clients with moderate - severe ABI

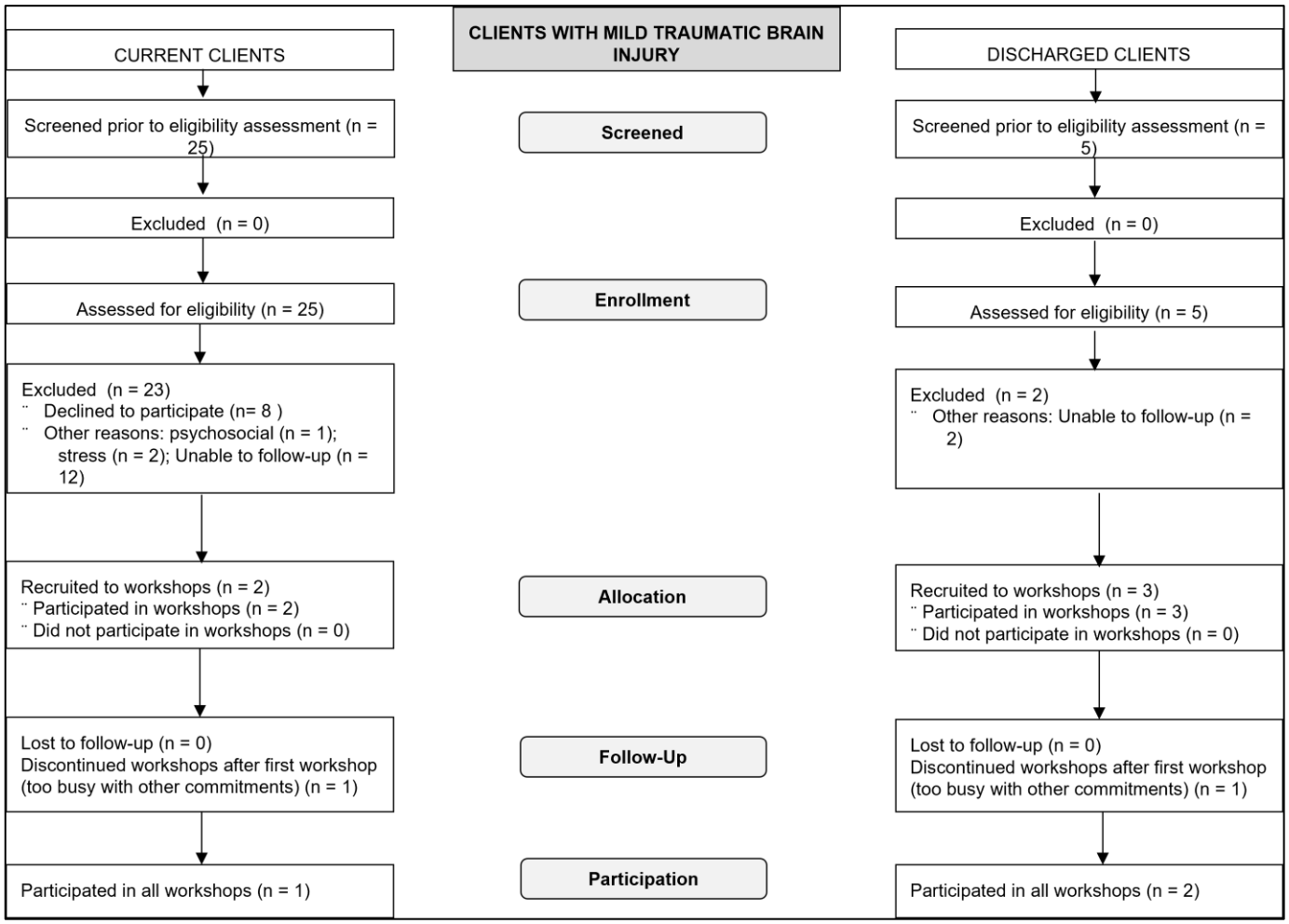


Figure 14: Co-design workshops CONSORT screening and recruitment details for clients with mild TBI

5.6.1 Demographic details

Clinicians recruited to the project (4 F, 0 M) included one occupational therapist, one physiotherapist, and two speech pathologists. The number of years they had practiced in their profession was the same as the length of time they had practiced in brain injury rehabilitation (mean = 14 (range 4, 23)) (see Table 14).

Discharged clients (1 F, 4 M) had varied timeframes since being discharged (mean = 22.6 weeks (range 12, 36) (see Table 15). Current clients (2 F, 2 M) had varied times for how long they had been receiving rehabilitation care (mean = 21.25 wks. (range 4, 30)) (see Table 16).

Table 14: Demographic data for clinicians in co-design workshops

	Clinic	Gender	Age bracket	Profession	Years practicing	Yrs working in brain injury rehab	Yrs at this clinic
1	Mod-severe ABI	Female	45-54	Speech Pathologist	27	20	20
2	Mod-severe ABI	Female	45-54	Physiotherapist	30	23	23
3	Mild TBI	Female	35-44	Speech Pathologist	4	4	8 months
4	Mild TBI	Female	25-34	Occupational Therapist	10	9	3
Mean; (Range)					17 (4, 30)	14 (4, 23)	11.5 (0.65, 23)

Legend: Mod-severe = moderate to severe; TBI = traumatic brain injury.

Table 15: Demographic data for discharged clients in co-design workshops

	Clinic	Gender	Age bracket	Vocation	Time attending clinic	How long ago discharged
1	Mod-severe ABI	Male	65-older	Retired	46 wks.	17 wks.
2	Mod-severe ABI	Male	35-44	Unemployed	Approx. 9 mo.†	approx. 6 mo.*
3	Mild TBI	Male	55-64	Avionics Technician	16 wks	12 wks.
4	Mild TBI	Female	45-54	Registered Nurse	3.5 mo.‡	5 mo.ɬ
5	Mild TBI	Male	35-44	ICT Officer	9 wks.	36 wks.
		3M, 2F			Mean=24.8 wks. (Range 9, 46)	Mean=22.6 wks. (Range 12, 36)

Legend: Mod-severe = moderate to severe; TBI = traumatic brain injury; wks = weeks; mo = months. Values approximated for purposes of calculating mean and range: * = 26 weeks; ɬ = 22 weeks; † = 39 weeks; ‡ = 14 weeks.

Table 16: Demographic data for current clients in co-design workshops

	Clinic	Gender	Age bracket	Vocation	Time attending clinic	How long ago discharged
1	Mod-severe ABI	Female	55-64	Unemployed	Approx. 6 months*	1 month
2	Mod-severe ABI	Male	35-44	Process Worker	4 weeks	N/A as current client
3	Mild TBI	Male	35-44	Building Maintenance	25 weeks	1 month
4	Mild TBI	Female	*m.d.*	*m.d.*	Approx. 7 months ɬ	N/A as current client
		2M, 2F			Mean=21.25 wks. (Range 4, 30)	

Legend: Mod-severe = moderate to severe; TBI = traumatic brain injury. Values approximated for purposes of calculating mean and range: * = 26 weeks; ɬ = 30 weeks; N/A = not applicable.

5.6.2 Participation and retention

Participation in the pre-workshop training and co-design workshops is presented in Table 17 below. All 13 participants completed pre-workshop training and the first workshop round. Eleven participants attended the second and fourth rounds, and 10 attended the second workshop round. Two client-participants (one per cohort) withdrew after the first workshop due to being too busy.

Table 17: Completion of pre-workshop training, and attendance at co-design workshops

Stage	Clinicians	Current clients	Discharged clients
Pre-workshop training: use iPad, ECA, Zoom	4	4	5
Workshop 1*	4	4	5
Workshop 2*	4	3†	4‡
Workshop 3*	3§	3	4
Workshop 4ɨ	4	3	4

Legend: * = separate meetings for each sub-cohort; ɨ = sub-cohorts all together; † = 1 current client withdrew following first workshop; ‡ = 1 discharged client withdrew following first workshop; § = 2 clinicians attended at main meeting, and 1 attended separately due to time constraints; 1 other clinician was unable to attend

5.6.3 Nine main themes of feedback across four rounds of workshops

Results of thematic analysis of the transcriptions for all workshop meetings revealed nine main themes, with five of these (#5-9) being represented in all workshop rounds (see Table 18). Four themes (#1-4) relating to motivation and participation in rehabilitation were present almost exclusively in the first workshop round. Three themes focussed on the client-clinician-ECA interactions: #5 Clinician input when client using RehabChat; #6 Goalsetting / pursuit conversation; and #7 Meet client needs in ECA. Finally, two themes related specifically to user experience: #8 Current aspects that improve user experience (UX); and #9 Suggestions to improve user experience (UX). Qualitative results for each main theme as well as sub-themes related to each main theme are presented below in Sections 5.6.4 to 5.6.12. The results are presented narratively, with relevant participant quotes highlighted in italics font. For the first three rounds of workshop meetings in which each cohort attended a separate meeting, the coding used for participants' quotes is CL = clinician, CC = current client, DC = discharged client, R1 = first round of workshop meetings, R2 = second round of meetings, and R3 = the third round. Presentation of feedback from the final fourth workshop meeting, in which the three cohorts were present together, is provided through summative comments on the perspectives and recommendations shared by participants at that meeting.

Table 18: Main themes across four rounds of co-design workshop

#	Theme	Workshop 1	Workshop 2	Workshop 3	Workshop 4
1	**Motivating factors**	√	√		
2	**Demotivating factors**	√			
3	**Enablers to participation in rehab**	√			
4	**Barriers to participation in rehab**	√			
5	**Clinician input when client using RehabChat**	√		√	√
6	**Goal setting and pursuit**	√	√	√	√
7	**Meet client needs in ECA**	√	√	√	√
8	**Current aspects that improve user experience (UX)**	√	√	√	√
9	**Suggestions to improve user experience (UX)**	√	√	√	√

5.6.3.1 #1 Motivating factors

Participants reported that support from caring people was an important motivator. Motivation was helped by '*having people that listened and let you heal the way that you knew you had to' (CC, R1).* These people could be family because '*family, they knew what I could do so they motivated me heaps every day' (DC, R1).* Similarly, having a goal to return to usual family roles was a key motivational factor – '*you know like getting your kids ready for school and concentrating on different things at home, even if it's cleaning up to try and make yourself know that you're not, you're not nothing because you're not at work' (CC, R1).* Goals if they are personally meaningful were reported as another motivating factor – '*Motivation is around finding something that's meaningful for the client, which may not be meaningful for us, but may be meaningful for them' (CL, R1)*, which links to the sense of forward thinking also being a motivating factor – '*Like enthusiasm, I guess but also hope for the future or something like that' (DC, R1).* The relationship between motivation and emotional recovery was also highlighted as being an interrelated journey – '*they're all interrelated. … For example, a meaningful goal, but you take the time and accept the whole emotional journey, so they're both interconnected' (DC, R2).*

Feedback on motivating factors reflected extrinsic and intrinsic factors. Extrinsic factors included having a pet – '*having a dog is a fantastic motivator because it makes you get off your ass and feed them because you want them to have fresh water, or you want them to*

eat' (CC, R1) - and exercising – '*I used a sport and exercise as my motivation' (DC, R1).* Intrinsic factors referred to having a positive mental outlook – '*it's more about the mental getting your head right and thinking positive things in your head' (DC, R1)* including to achieve a future goal – '*my big driver was my long-term motivation - all the way through really, and that was about deciding early on' (CC, R1).* Participants also commented specifically about self-motivation which was identified as coming '*from within - it does not come from outside people - happens within oneself' (DC, R2)* and continues even '*when you don't have family, you gotta do something, don't you?' (DC, R2).*

5.6.3.2 #2 Demotivating factors

Demotivating factors included personal factors such as: low self-esteem – *'…that can really get you down and make you feel like you know you're not good enough or whatever' (CC, R1);* anxiety *'…I don't I don't know where to go from here, and then that fades into that whole anxiety cycle' (CL, R1)*; and a tendency to not seek help – *'others who perceive help from others as a sign of weakness' (CL, R1).* Other factors can be due to external factors such as: a lack of support – '*I didn't have I suppose the right support around me' (CC, R1);* decreased control – '*my motivation - I just had none because I couldn't do anything and I lost a lot of control' (CC, R1)*, and being unable to do usual life roles – '*I could not do much about it for my family…, and that that made me a feel a bit sad' (CC, R1).*

5.6.3.3 #3 Enablers to participation in rehab

Enablers for rehabilitation participation included: having one's symptoms validated – '*validation from people in their lives to kind of sit in a space to grieve, to adjust, accept and then to motivate to recover is another significant factor' (CL, R1)*; having freedom to take time with rehabilitation – *'And it doesn't matter if you don't do it, because at the end of the day you will do it when you're ready' (CC, R1)*; and being able to adjust one's own expectations – '*We just have to accept our own expectations and maybe lower them, and build on them rather than kind of jump off' (CC, R1).*

5.6.3.4 #4 Barriers to participation in rehabilitation

Barriers to participating in rehabilitation comprised personal and external factors. Personal factors included: fatigue – *'I felt like 'cause of the brain injury I got really tired really quick so you only could do things for short bursts of time' (DC, R1)* – which could also precipitate feeling depressed – '*and tiring yourself and then you feel depressed' (CC, R1);* and difficulty connecting thoughts – '*just not quite connecting things like it should' (CC, R1).* External factors included: having stress in the family – *'family that's grieving over somebody not*

appearing to be the same' (CL, R1) ; and social norms around not seeking help – '*… there is that cultural you know that barrier where if I need rehab, it's because I'm weak' (CL, R1).*

5.6.3.5 #5 Clinician input when client using RehabChat

Participant perspectives regarding clinician support for the client using RehabChat highlighted the value of the therapist encouraging the client – '*I couldn't have done this, I don't think without the [rehabilitation] team, … that total encouragement all the time is amazing' (DC, R1);* and the need for the client to be valued as an expert in their own care – '*so it's their story their direction, their insight as well on to what their difficulties are, and their priorities' (CL, R1).*

Participant feedback included a focus on the clinician's support for the client when using RehabChat reflected required aspects of the real-life clinical setting. These aspects included: the ECA needed to match the clinician's usual care framework – *'…could be a good tool for the clinician as well. And I think it satisfies both requirements pretty well' (DC, R3),* including the client-clinician dyad needing to have pre-discussions on goal-setting prior to using the ECA – '*… the conversations that need to be done as a set up …. we might have already discussed some goals, but I might not have gone to the level of grading to then have a well-prepared conversation…' (CL, R3).* As well, it was identified that the clinician would need to oversee what the client entered into RehabChat to ensure it was achievable – a *goal 'that the client's stuck on, like they're really committed to it, it might not be realistic' (CL, R3),* but also allowing the client to have a sense of ownership over the data being entered – '*when they intervene at what stage or do they leave it - let the patient sort of carry on for a bit longer' (DC, R3).*

Feedback from the fourth workshop round reinforced the need for safety checking for when the client was setting their goal to ensure it was safe as the initial ideas from the client may need refining by the clinician. A similar focus on the importance of the client-clinician dyad working closely together was the observation that they should already be working on the client's rehabilitation goals.

5.6.3.6 #6 Goal setting and pursuit

Feedback on goal-setting and pursuit focused on setting small, achievable sub-goals – '*You're gonna get there again and you just need to look after yourself and small goals, small steps even if it's doing the dishes' (CC, R1),* which '*…might help them to work towards that aspirational goal or endpoint' (CL, R1)* which should be written from the client's perspective

and using the client's wording – '*…using their language or you know understanding their world … is important' (CL, R1).*

Feedback also referred to the priorities of helping the client to develop goal-setting skills that can be used post-rehabilitation – '*…so teaching them how to set their own goals as well to continue with their own rehab' (CL, R1)*; providing adaptive goal-setting frameworks which can be adaptive or restorative – '*…that goal will shift so rehab is certainly not a defined process. Sometimes it can end up more of an adjustment, sometimes it can be more about adaptation, sometimes it's more about restoration…' (CL, R1);* and having a system for measuring '*…progression towards that aspirational goal…' (CL, R1).*

Successful goal achievement was related to having more frequent progress reviews to support goal-pursuit – '*if the halfway goal seems huge still compared to the overall main goal, is there capacity to build in a first step' (CL, R3)* which allow for the client to '*…use what they like… to bring up their own methods of following their goals' (DC, R3)*; and over the whole process, that the clinician endeavours to avoid '*the risk of what becomes a therapist driven goal that the client has a lower sense of ownership on' (CL, R3).* Specific SMART (17) aspects of goal-setting were highlighted – '*Aah, SMART; and achievable chunks; specific, measurable, achievable, realistic, timely' (DC, R2)*, including regarding the ECA asking for achievable goal details – '*this is actually asking OK, well for you to do that, what else is achievable that will get to that end goal?' (CC, R3)*. Feedback for goal-setting in the fourth workshop similarly related to achievability, in that the client's effort toward pursuing a goal should match their ability and self-perceived sense of being able to achieve it.

5.6.3.7 #7 Meet client needs in ECA

Feedback for how to meet client needs in RehabChat related to offering options – specifically '*different versions of the App [which could be] a lot easier to use or a little bit harder to use depending on the person' (DC, R1).* Participants discussed the need for the ECA to allow for '*changes as [the client] progress from their initial injury through to their recovery and so it's constantly changing as the patient progresses and recovers' (DC, R2)*. The ECA dialogue style should mitigate the potential effort of remembering too much language content – as '*keeping all that [in] your working memory might be tricky' (CL, R2).* As well, it was emphasized that the ECA should accommodate varying client needs '… '*cause everyone's different, they need different things' (DC, R2)*, such as '*ataxia' (CL, R2)* or '*fatigue' (DC, R2).* Similar points of feedback included the requirement that the ECA should be able to accommodate varied client needs – '*you're aiming it to suit more people than to*

cover the all the different IQ so to speak' (DC, R3), including memory support through reiteration – '*really good just how she like you remembered your goals' (DC, R3*) –, and the need to support the client to initiate use of the ECA – '*it might just simply be that they don't remember that they need to use it' (CL, R3)*. Additionally, due to the inherent limitations of the avatar in being unable to utilise normal human-like voice intonations – '*it's a recognition of the package that you have to work with and the advances in Avatars at this point in time' (CL, R3)* – and that some clients rely on non-verbal communication to parse meaning – '*with some of our clients it's… something where they rely on that additional cueing' (CL, R3)* –, there is a need to carefully consider how to best use the available software features such as dialogue phrasing to facilitate understanding.

Feedback indicated the need for having options to either just read the ECA dialogues, or only listen to them – '*when I'm tired, I prefer people read it to me; or lethargic, and I prefer people to read. But when I'm on my A game, I like to actually use my brain and try and read it for myself' (CC, R3).* In the fourth workshop, participants also discussed that client fatigue should be considered when developing RehabChat, as well as the need to support the client to learn to use RehabChat because not all clients would be able to learn it easily. Similarly, training and ongoing support for clients using RehabChat was highlighted in the fourth workshop, with consideration that this could be provided by the researcher or perhaps also by the clinician.

5.6.3.8 #8 Current aspects that improve user experience

Participants identified an array of aspects that improved their experience of using RehabChat. They noted that RehabChat was simple – '*… very easy and very clear' (DC, R3)* to use – '*You can scroll it. Yeah, I thought it was awesome 'cause it was so simple' (CC, R1).* They also commented that the speech *'rate was OK' (CL, R3)*, and that overall it was *'… very relaxing and engaging' (CC, R3)* to use. Feedback also described that after some practice, it was easy to focus on the text rather than needing to watch the avatar – '*…I'm aware that she's talking to me because I can see her mouth moving out of my peripheral vision' (CL, R2).*

Participants identified some specific user interface options available in RehabChat which improved user experience (UX). These design options included being able to change an entered response *'…because you might want to change your approach, then go back. That works really well' (CL, R3)*, and the choices of avatar were *'… very visually easy to see'" (CL, R3)*. In the final workshop, participants also identified some helpful functionalities which included being able to freely start and stop a session, noting that the ECA re-opens at the

same place at which it was closed, and that the user can zoom the screen magnification on the iPad.

Finally, participants commented on unique impacts with using either the long or short style of conversation – the longer conversation *"… sort of promoted ideas and got your mind working … you start to imagine the person you could be, rather than the other Avatar [short conversation] would be saying – we're working with who you are now.' (CC, R3)*.

5.6.3.9 #9 Suggestions to improve user experience

Feedback for ways to improve UX related to the avatar design and audio, and interactive UI touch screen functionalities. Varied design recommendations were made, including: for the *'buttons [to be] bigger' (DC, R3);* that the UI should be made '*bigger on the screen' (DC, R1)*, and include a choice of keyboard style of either '*a QWERTY versus ABC keyboard' (CL, R1*). In regard to the avatar design, feedback suggested that the option '*to choose your own avatar' (DC, R1) was 'quite important' (CL, R3)*; and aspects of this include being able to choose the *'speed of her talking' (CL, R1),* and that optional avatar designs '*should be an androgenous character' (CC, R1)* or to '*just have [a] stick figure' (DC, R2).* It was also suggested that voice to text input by clients would help clients with *'…an acquired dysgraphia or [acquired] dyslexia… [and] brain injury vision difficulties' (CL, R1).* Feedback from the final fourth workshop for improving UX included that the font size should be increased, and the avatar's name to be non-gendered. It was highlighted that the UI should support the varied needs of clients regarding challenges with either reading or listening, by having the size of each half of the UI adjustable, with the general preference being that the avatar should be smaller and that there should be more room for the text areas.

In regard to the dialogue content and structure, it was thought that the ECA should reiterate the client's entered data during the conversation because it would then *"be more interactive" (DC, R3)*; and that the conversation dialogues should progress with less click options required, so as to avoid getting *'sick of -you wear your finger out' (CC, R2).*

Additional suggestions for improving UX included being able to choose how much space the avatar and the dialogue text bubbles take up on the UI, as some clients '*won't be able to follow the written, whereas other people will just rely on the written. …making more one dominant over the other would be good to be flexible' (CL, R2).* It was suggested that dialogue length should be short and also predictable, and that it is necessary to be '*… aware of sentence length and complexity of sentences …' (CL, R2)*, and avoid *'saying medical jargon, [because] they just switch off' (DC, R3).*

5.6.4 How change recommendations implemented

Feedback from all four workshop rounds incorporated suggestions of changes for RehabChat. This feedback was included explicitly in two of the main themes – to meet client needs, and to improve user experience – and implicitly in the other themes. The suggestions included ideas which helped to clarify the content of RehabChat, for example by applying the motivational factors and goal-setting aspects.

Recommendations of changes needing to be made to RehabChat were collated under two main domains. These were: #1 General planning of conversation structure and content (which comprised factors applying across the whole of RehabChat, such as dialogue structure, summarising content, and rest breaks); and #2 Specific topic content areas (which contained specific aspects such as motivational support, goal-setting and progress reviews) (see Table 19). All of the recommendations were able to be addressed either by updating the ECA content and design, changing the user guide or training mode, or by using a combination of these approaches. A narrative overview of the recommendations for these two domains is presented below, and Table 19 presents all points in tabular form.

Decisions for how to integrate changes were based upon being free or low cost, and the software's capabilities. Changes made within the software's existing template capabilities were achieved by utilising the content management portal (see Figure 8 and Figure 9). Changes to some of the ECA's template, such as increasing the font size and making buttons bigger, were achieved by reviewing the customised style sheet (CSS) in Scintilla based Text Editor (SciTE) (16) and then making alterations to the customised style sheet CSS (see Appendix XVIII).

5.6.4.1 #1 General planning of conversation structure and content

Change recommendations were identified for improving the overall structure and general content of RehabChat's conversation. Training of all skills required to use RehabChat were moved to the training module. Dialogue length was pruned to be shorter and more predictable. Content summaries were included at the opening and close of sub-conversation sections. Well-being prompts were more regularly interspersed in the conversation regarding taking a rest break whenever needed, and to discuss any concerns with the human clinician.

5.6.4.2 #2 Specific topic content areas

Recommendations for refining the topic content of RehabChat's conversation covered a variety of subjects. Motivation support included adding more encouragement and referencing

to hope. Goal-setting was refined to include weekly goals, as well as the main goal, and more detail explaining the steps of goal-setting. Home exercises were renamed as practice activities to reflect that these may be completed at places other than home, and flexibility regarding when the client could complete these activities was enabled through setting up of a reminder system.

5.6.4.3 #3 Recommendations for the user interface

Participant feedback highlighted recommendations for improving the UI. These related to the avatar style, increasing the size of font and click buttons, and the overall UI layout. Many of these changes were enabled through updating the CSS (see Appendix XIII). See Table 19 for details of these points, and Figure 15 for a visual presentation of the updated UI developed in response to this feedback.

Table 19: Change recommendations and how changes implemented

Conversation section / topic	Change recommendations	How recommendations addressed
#1 General planning of conversation structure and content		
Training module	Explain all UI capabilities and do all learning of skills in training module; don't do any in rehab module	Moved all set-up and training prompts from rehab module, into the training module
Ease of use	Promote that it should feel easy to use, and if needed ask for help from HCP or RehabChat staff person	Not specifically included in ECA content. Instead, mode of use includes people (clinician and researcher) who can support client's use: ECA content includes reminders to speak with clinician if any concerns, and have a rest if needed.
Dialogue structure	Predictable length of dialogues	Length of dialogues overall shortened and made to have a predictable length of up to 2-3 lines through modifying the content
	Reduce the amount of confirmatory clicking	The 'Continue' logic decision for dialogue progression (which enables the conversation to progress without the user needing to click or enter text) used more often. Confirmatory clicking still included where the user needs to initiate dialogue progression e.g. to indicate when has completed a practice activity
Choice making	Explain choice-making aspects in ECA, e.g. multiple choice options, being able to choose goals	Multiple choice options are introduced and practised in training module, and explanation is included in user guide (see Appendix XX). Goal-setting is covered in step-wise way in ECA content.
Summarising content	Introduction and summary at start and end of each sub-section.	This was included for each sub-section
	Reiterate main and weekly goals	Content is linked to goals – e.g. at start of section for completing practice activities
Rest breaks	Promote having rest breaks	Rest breaks explained in training module Reminders to take a rest break included occasionally in rehab module.
Client is active participant	Explain that client is active in choices, and in doing rehab activities	Included in 1:1 training, and clinician instructions.
Clinician oversight	Remind to discuss concerns with clinician at any time	Included in each sub-section for both long and short conversations
	Highlight that client and clinician already know each other	Included in 1:1 training session
	Highlight that clinician will encourage user	Included in opening section
#2 Specific topic content areas		
Motivational support	Add in more encouragement cues	General encouragement cues – e.g. well done, that's great, that will really help you achieve <main goal> etc. – in all clinical sub-sections
	Focus on hope	Included in section for setting a rehab priority by asking user to set a meaningful, important priority of an area of their rehab they would like to improve in.
	Motivational support resource (long conversation only) – offer choice for either a support person or a planning process (as not all clients have a support person)	This included

Conversation section / topic	Change recommendations	How recommendations addressed
	Explain that a motivational support can help with rehab and recovery	Included
	State focus is on the client's needs and hopes	Included in 1:1 training session
Goal-setting	Focus on increments of journey, e.g. goal for next week	ECA content explains overall steps for goal setting, and guides user through all steps. Main goal set represents aspirational priority area in SMART format One weekly incremental goal is set each week.
	Add in weekly goals & reviews	Included weekly goal setting, and weekly progress reviews.
	Prompt use to consider things they used to be able to do (e.g. life roles/activities) as basis for goal-setting	Included briefly near start of priority / goal-setting section
	Ensure wording focuses on personally meaningful, motivating	Motivation focused comments included, examples are: "You've said that this goal is important and motivating for you because you want to have <B: priority's importance>." "Why are you motivated about this?" (re rehab priority) "Measuring your progress can help with this, and help you stay motivated!"
	Use the word hope, incorporate the concept of hope	The word hope not used; instead the concept of hope was incorporated through the user choosing a meaningful rehab priority and setting meaningful goal
	The goal setting structure to include: aspirational goal, the 6-week goal, and the weekly goals.	This done with rehab priority (not an aspirational goal), 6-week goal and weekly goals.
	Ask user regarding their current level of ability for their rehab priority	This not done – as need to keep conversation streamed to the key purposes, and avoid the conversation being too long
	Change 'priority' to [aspirational] goal – i.e. the broad goal / ambition, hope, motivation	This not done – as needed simple wording to help user understanding - 'aspirational goal' as a phrase may not resonate with many/any clients
	For weekly goal: say it needs to be small, achievable and relevant to main goal	"Next, you'll set a small weekly goal for your 1st week. A small weekly goal is like a stepping-stone to reaching your main goal."
	For weekly goals, ensure these suit capabilities	Weekly review asks about progress including how well completed practice activities. This considers changes needed for goal for following week.
	Relate weekly goals to rehab priority or main goal	Linked to main goal: "A small weekly goal is like a stepping stone to reaching your main goal."
	Explain that [extrinsic] motivation is from supports from around you, and [intrinsic] from having something personally meaningful to aim towards.	This not done – because it would have added too much extra dialogue content.
Input HEP details	Acknowledge that client may not always feel up to doing rehab… but with encouragement reminder about main goal is more likely to be motivated	ECA conversation reiterates main goal, reminds can chat with clinician if any issues.

Conversation section / topic	Change recommendations	How recommendations addressed
	Update terminology for home exercise as practice activity.	Done. This was necessary because at times the prescribed activities are not completed at home.
Home practice	Have a flexible approach for when the user can complete their practice activities; relate this to how the client sets up the alarm / reminder system for using RehabChat	User is asked to choose a reminder system at start of section for entering details for practice activities; "Firstly, what Reminder System for your practice activities will you use? Write your Reminder System below." and then prompted to set it according to what is required for the practice activities.
Weekly reviews	- Give encouragement - give feedback	Encouragement cues included relating to acknowledging their progress and working towards overall meaningful goal
	Link progress review to achieving overall goal	Weekly reviews (rather than a half-way review at 3 weeks) explained as being steppingstones to achieving main goal
	Explain the benefit of progress review to identify the gains already achieved, and make new weekly goal	Included in Measurable part of goal-setting (in long conversation), with comment that measuring progress supports motivation. The short conversation does not have this level of detail – instead it asks for details, and the supervising clinician may need to help client with required SMART aspects.
	Explain the process for doing a progress review	Included for each weekly review. Also, at end of 2nd week, client offered option to review progress toward achieving their main goal, with a caveat that client has only done 2 weeks of their program. Positive affirmations provided at each of these points.
	Include extra review question about reminder system, e.g. if it is useful, or change it	This not done – as need to keep conversation streamlined.
#3 Recommendations for the user interface		
UI layout	Side-by-side display clearest to see (versus vertical overlap display)	Side-by-side display used
	Preferred sizing for two parts of UI: smaller area for avatar, and larger area for the text bubbles (rather than default 50-50 split)	One-third for avatar display, two-thirds for text bubbles content. Achieved through changes to the CSS
Avatar	Style of avatar clearest to see was Eurasian female avatar with long dark hair	Eurasian female avatar configured as default preference
	Accent clearest to listen to was the Australian accent	Australian accent used
	Preference for androgenous name	Avatar's name was 'Jo'
Size on screen	UI to be larger on iPad screen	RehabChat was configured onto the clinic iPad and filled the entire screen with no other visual presentation (e.g. the internet browser ribbon was not visible)
Buttons	Buttons need to be larger	Achieved through changes to the CSS
Font	Font needs to be larger	Achieved through changes to the CSS

Legend: HCP = Health Care Professional; HEP = Home Exercise Program; CSS = customised style sheet; UI = user interface

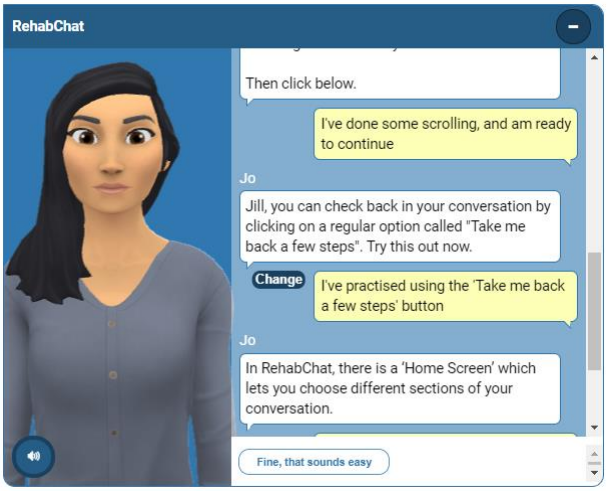
ECA used in co-design workshops	ECA updated following co-design workshops and second alpha testing, ready for user testing in feasiblity pilot trial
	
Design aspects : 50 – 50 layout : font smaller : buttons smaller : avatar name is smaller : RehabChat header is larger : British and Australian accents trialed; latter preferred	**Design aspects** : one-third for avatar – two-thirds for text display : larger font : larger size fir the mute and minimize buttons : avatar name is larger : RehabChat header is larger : Australian accent

Figure 15: User interface for, and changes made to user interface following, co-design workshops

5.6.5 Results of second alpha testing

The testing was conducted in two cycles, each lasting four hours. The testing participant was a computer science and engineering student from Flinders University with a previous degree in digital design.

The first cycle of second alpha testing was conducted in July 2021. Key findings were identifying a lot of small formatting mistakes, that the structure in some areas of how the conversation progressed was unclear, and that clarification of dialogue content was required in a number of areas. Below is a dot-point summary of the main issues identified, and how these were addressed.

- Incorrect logic links not connecting dialogues to the intended section; links were corrected
- It was possible to scroll back and change content in previous sub-conversation, resulting in the program crashing. To prevent the user crossing back into a prior sub-conversation section breaks saying ‘section completed – do not cross’ were inserted in the conversation at end of each sub-section.
- Decision point activation in response to the user entering a value on a visual analogue scale was not working – to resolve this, the numerical thresholds for activating specific decision point options were reset
- Some of the wording in the questions asked or statements said by the avatar were not clearly written – these were resolved with re-wording.

- The minimise button had been changed by Clevertar from ‘X’ to a ‘ – ‘. The dialogue references to this in the conversation were changed to ‘dash’.
- The closing statement at the end of each RehabChat module isn’t able to be configured to automatically close the UI – a dialogue prompt to close the UI was included with the closing statement.

5.6.5.1 Second cycle of second alpha testing

The second cycle of alpha testing was completed in August 2021. Results generally were about decision points, and links between sub-conversations. Below is a dot-point summary of the main issues identified, and how these were resolved.

- Sentence stems for cuing the client to enter freeform text content were not effective, as later use of clients’ entered content in subsequent dialogue/s is clunky – Sentence stems improved to better match the sentence structure used in later dialogues
- The click option ‘take me back few steps’ at times doesn’t go back to a useful point – changed to more suitable places
- Some repeated content – this issue was corrected
- Some logic decision points for conversation branching still linking incorrectly – subsequently were corrected.

5.6.6 Preparing RehabChat for integrated use in the clinics

Details of how RehabChat was to be integrated into the clinical setting in preparation for the subsequent feasibility pilot trial considered the hardware to be used, options for video-conferencing, and electronic case-note entries. RehabChat was loaded onto clinic iPads and utilised the Google Chrome browser. The clinics’ Information Technology Administrator managed the technical follow-up of clinic iPads, and assisted in resolving glitches with the how the ECA software worked on the iPads as these arose. Initial testing was done by the researcher to ensure that remote updates of the ECA could still initiated, and this was successful for the default ECA, but not for the option of enabling the user the option to choose their own avatar. Accordingly, this option was removed, and only the default avatar was provided for the feasibility pilot.

The option for video-conferencing was explored due to the possibility of Covid-19 restrictions precluding in-person review appointments between the client and clinician. The clinics used the Healthdirect video-conferencing platform (10) on both PCs and portable devices including iPads. Healthdirect allowed for screensharing from a PC but not from an iPad, which precluded it from being used with RehabChat which was loaded onto an iPad (as use of RehabChat on an iPad cannot be transferred across for use on another device). Accordingly, for any client-clinician appointment needing to be conducted remotely, RehabChat could not be screenshared.

A specific case-noting approach was developed for the feasibility pilot trial. The clinics utilised electronic case-notes. A summary script was developed which described the feasibility pilot trial and the participant's involvement. This was approved by clinic management for use by clinician participants during the feasibility pilot trial. This script was saved as a clickable acronym expansion in the electronic medical records software and made available for clinician participants to use.

5.7 Discussion

These four rounds of workshops provided the platform of iteratively reviewing RehabChat, considering and implementing design changes, and seeking follow-up feedback from the participants. Not only did this allow for successive refinement of RehabChat, but it also supported some of the specific clinical needs of the client such as needing time to think through their ideas and responses and to learn a new skill.

Using a video-conferencing format for the workshops did impose some challenges regarding that participants tended to talk mainly with the researcher rather than amongst each other, and that it was harder for the researcher to demonstrate and support learning of ECA skills when screen-sharing was not available. Nonetheless, the pre-workshop training sessions and ongoing support provided by the researcher appeared effective in helping participants to engage comfortably via Zoom (208) and in using the ECA during the workshops.

Sufficient numbers of participants were recruited for this study, with minimal attrition. However, it should be noted that only approximately 10 percent of the total number of screened clients were actually recruited. This factor related to many clients being ineligible to participate including for reasons outside of the explicit inclusion criteria, such as due to psychosocial stress. The need to screen a high number of clients and consider other domains for ineligibility should be considered in future research.

The meetings with single cohorts showed good cohesion evidenced in the high amount of feedback generated. As well, the first workshop round evidenced quite personal and candid reflection about motivating and demotivating factors affecting recovery, including the impact of input by support people. The final fourth workshop importantly enabled all participants to contribute feedback collaboratively, with important insights about integration of RehabChat into the clinic setting and the needs of clients when using RehabChat.

The later workshops which focussed on the more objective notion of the ECA, also contained open and honest appraisal of the tool and its intended aims, with candid constructive feedback provided. Many feedback comments related to the user interface, such as having bigger buttons, larger font, and a greater proportion of the screen dedicated to the text bubbles. These suggestions were linked to the priorities of improving ease of use and reducing the potential for fatigue – both of

which are highly important for clients with TBI. These outcomes indicate that a sense of trust was achieved during the meetings. Given this positive indication of participants being able to share their ideas comfortably, the feedback which ratified aspects of RehabChat could be hearkened.

It was very worthwhile having three cohorts represented, with the amount of feedback data for each being approximately equal. This helps to ensure that the unique perspectives of each cohort were 'heard'. However, it was outside the scope of this project to methodically categorise findings from each cohort separately and to then look for unique differences between them. Instead, the focus of this project was to ensure varied cohorts were included, and that their unique perspectives could be obtained through having separate meetings in first three rounds, whilst also allowing for a synthesized 'voice' in the final workshop.

Important clinical needs of clients were identified and were considered in the design of RehabChat. The need to minimise fatigue was addressed by improving how predictable the conversation felt, for example by having consistent dialogue length, and including reiterative summaries of the steps required in each section of the conversation presented at regular junctures. The affective challenges which may impact negatively on motivation were supported through including regular motivational cues and reminding the user of their motivating goal and why it was important to them. As well, reminders were interspersed in the conversation for the client to discuss any concerns with their clinician, in line with the ECA not assuming a therapeutic role but instead more of a coach role.

Throughout the process of deciding on the best approach to use for addressing a change recommendation, multiple factors needed to be considered. For example, a recommendation to reduce confirmation clicks and for the conversation instead to proceed more readily would actually then reduce the ability of the user to effectively control the pace of the conversation. In such circumstances, a mid-way approach was usually taken. The challenge of ECA software not being able to provide the level of non-verbal communication and cues normally provided in a human-to-human interaction was raised, but equally, potential solutions were posed, such as carefully choosing dialogue style and content which highlights important points, and including in the conversation content both affirmations and iterative coaching. This is an example of the benefit of using a semi-structured approach when interviewing end-user participants as it allows flexibility to follow-up any challenges or issues already raised and seek feedback on solutions for these.

5.7.1 Achievement of Study Aims

5.7.1.1 Aim 1: Clients' motivational support needs

This project defined the motivational support needs of individuals during their recovery following TBI particularly during their rehabilitation, through Zoom (208) workshop meeting discussions with

client and clinician participants. The main areas of need related to the value of support being provided by caring people, whether this be family or clinicians, and also acknowledgement that not all clients have a good support network close by, and so for them motivation must become more intrinsic to ensure ongoing rehabilitation success. In this sense the feedback added an extra dimension to the motivational paradigms being considered for this PhD project – those being Self-Determination Theory (SDT) (52, 53) and Motivational Interviewing (MI) (5, 11). Specifically, feedback from the co-design workshops added to the SDT model by highlighting the need for a support resource to be identified, rather than just a support person (connectedness aspect of SDT). Identifying a support resource could be seen as fitting in well to the MI focus of identifying personally appropriate supports and solutions to achieving one's goal.

Akin to motivational support needs was a related feedback theme regarding enablers to optimally participating in rehabilitation. This theme highlighted the need for emotional recovery and taking time for this to occur. Similarly, it was proposed that clients need to be able to adjust their own expectations of themselves. As a flipside to this, the negative equivalent themes of demotivating factors and Barriers to participation in rehabilitation included factors such as low-self-esteem, anxiety, fatigue, and depression. These affective factors suggest the need for psycho-emotional support to be highlighted during rehabilitation.

5.7.1.2 Aim 2: Participants' recommendations for design of a motivational ECA

Feedback from the co-design workshops enabled participants' recommendations for the design of a motivational ECA for brain injury rehabilitation to be identified. Data analysis of the qualitative feedback from all workshop rounds resulted in key recommendations for the overall structure of the ECA conversation, and of the topic content for the conversation, and recommended changes for the user interface (see Table 19 and Section 5.6.4). The structural recommendations related to dialogue length, reiteration and summarising of key content, and clarification of the client-clinician dyad relationship. The topic content refinement related to motivational support and goal setting, including to set smaller weekly goals which can be more readily updated to meet the client's changing needs and abilities.

5.7.1.3 Aim 3: Integrate design recommendations into ECA design

This project was able to integrate the design recommendations made by client and clinician participants during the workshop discussions, and to achieve a stable model ECA ready for use in the subsequent feasibility pilot trial.

Numerous change recommendations for RehabChat were able to be implemented by either updating the design of the ECA, refining the presentation of the user guide (see the refined version

of the user guide which was subsequently used in the feasibility pilot trial at Appendix XX), and/or adjusting the content of the training session. This blended approach to meeting the indications of the changes recommended was used to ensure the change was achieved whilst not resulting in a lot of extra content in the ECA conversation itself. It was also considered how and when to best convey the essence of the recommended change – for example, as carefully placed ECA content to ensure relevance, but perhaps at risk of being forgotten soon after as the conversation moved on; as part of the intended initial 1:1 training session where a more nuanced interaction could emphasize key points; or within the user guide which could be regularly reviewed by the user at any time. Ultimately a blended approach was used which enabled the benefits of each approach to be optimised in order to highlight key topic areas. The refined ECA was then further tested in the second alpha testing during which a number of technical and formatting glitches were identified and resolved. The result of this work was that a refined, stable model ECA which is designed to support motivation for clients with TBI was achieved.

5.7.1.4 Aim 4: Intended mode of use of ECA alongside usual rehabilitation care

An important part of the development of RehabChat was to clarify how it would be integrated for use alongside usual care. This was achieved through conducting the workshop discussions with clients and clinicians of the two clinics. The way in which the ECA could be used in clinical practice alongside usual care was defined to include having clinician oversight of the data that the client entered for goal setting, practice activities and reviews, and to use the goal-setting structure (SMART) already in place at the clinics. Practical aspects of integrating the ECA into clinical care were clarified though discussion with clinic administrative and management staff, and out of this RehabChat was successfully loaded onto clinic iPads. This practical integration model was used for the intended subsequent feasibility pilot trial at the same clinics.

5.8 Conclusion

This project demonstrates the usefulness of participatory co-design in developing a novel digital health tool in this case, a motivational conversational agent for ambulatory care brain injury rehabilitation. Feedback provided ratification of some points of the ECA's design, recommendations for changes, and a deeper understanding of the experience of motivation in rehabilitation. The ECA has been updated in response to feedback, and within constraints of what is possible with the software and practical to implement within the clinic settings. The ECA and its intended mode of use have thus been refined ready for the planned mixed methods feasibility pilot trial.

The co-design workshops appeared to be a suitable and supportive research model for ensuring participant engagement and comfort. This is important to note, given that this clinical cohort may at

times feel disempowered due to challenges arising from their TBI. Feedback data was not dominated by the clinician feedback but was broadly representative of all three cohorts. The participants' feedback comprehensively addressed more finite concerns such as the design of the UI, as well as more abstract considerations such as motivational support, appropriateness of the goal-setting framework, and the role of the supervising clinician.

6 Mixed methods feasibility pilot trial

> "I just found it helped me regulate what I was doing and made sure I was, yeah, doing it regularly." (Quote from client participant in feasibility pilot trial.)

6.1 Overview

This pilot trial assessed the feasibility, usability, and acceptability of an embodied conversational agent (ECA) called RehabChat within the ambulatory care brain injury rehabilitation clinics for clients with moderate-severe acquired brain injury (ABI). Some of the clients at these clinics have traumatic brain injury (TBI).

RehabChat – the ECA used in this project – was developed using Virtual Human software provided by Clevertar Pty Ltd (175) (Clevertar). RehabChat was initially developed in-house at the Flinders Digital Health Research Centre of Flinders University (see Chapter 4). RehabChat was also developed in the clinical setting through co-design workshops conducted with clients with TBI, and also clinicians (see Chapter 5). The stable model of RehabChat which was developed following the final fourth co-design workshop was utilised in this feasibility pilot trial.

This feasibility pilot trial enabled the refined RehabChat prototype to be tested in a real-life clinical setting regarding its feasibility, usability, and acceptability. Along with testing the CA itself, other factors were also tested for their feasibility such as participant training, researcher support for participants, outcome assessments, and repeated measures. Appraising both RehabChat itself as well as aspects related to its implementation was necessary to conduct in this study prior to any future larger pilot trial. This concurs with literature recommendation to conduct thorough contextual feasibility testing of a novel digital health intervention prior to clinical testing (88).

A six-week intervention using RehabChat – although the intended duration for RehabChat once it has been fully refined – was not appropriate to conduct for this study, because RehabChat was not yet a stable, refined model. Additionally, because RehabChat is a CA which has an intended mode of implementation closely embedded within rehabilitation care, it was necessary to conduct feasibility testing so as to appraise its design and implementation mode. A short intervention period of two weeks was thus chosen for this feasibility pilot trial (for more details see Section 6.4), so as to not infer it was a clinically meaningful duration, but still sufficient to allow participants to immerse in the experience of using RehabChat.

6.2 Background

Recovery following TBI is optimised through multi-disciplinary rehabilitation, when client-centred goals are identified and achieved (22, 32). Progress during rehabilitation and overall recovery can be impeded if motivation is low (13). Development of new therapies which address goal pursuit and

motivation is warranted. Conversational Agents (CAs) offer a responsive human-computer interface with which a client can converse (114). There is precedent for trialling a CA with participants with brain injury and disease including for speech training in people with PD (130) and dementia (131), and memory training for older adults (133, 134). As well, motivational approaches have been included into the design of ECAs, for example to promote physical activity and healthy diet (129).

When trialling a CA, it is necessary to assess both clinical outcomes such as physical activity and motivation, as well as non-clinical outcomes relating to the CA such as general user experience, safety, acceptability, and feasibility of the CA. These non-clinical aspects impact directly upon how much the end-user engages with the CA, and therefore how much they may benefit from the clinical content and purpose of the ECA (89). For this feasibility pilot trial, due to the short duration of the two-week intervention, clinical effectiveness was not being tested. However, relevant clinical measures that would likely be included in a larger later pilot trial were completed to test their feasibility and usability.

The use of an ECA could improve client motivation to achieve goals, provide an extension to usual rehabilitation, and enhance clinical functional outcomes. The clinical needs of clients with TBI could benefit from an iterative ECA dialogue platform through which motivational needs and goal setting could be supported and explored.

6.3 Aims and outcomes for RehabChat feasibility pilot trial

The research aims reflect that this is a feasibility pilot trial in which various user perspectives regarding the ECA, its intended mode of use, and aspects of the research process, are measured including acceptability and usability. Each aim aligns to the research questions for this PhD (see Section 1.12), as indicated in bracketed text for each aim below.

Aim 1: (Aligns to the sub-question 1)

Assess the functionality and performance of RehabChat and make any changes to RehabChat in response to feedback, prior to clients using RehabChat.

Outcome 1:

Conduct user testing of RehabChat with clinicians, in which the clinician uses RehabChat for approximately 30-60 minutes, and then provide feedback. Make changes to RehabChat in response to feedback and complete this prior to clients using RehabChat.

Aim 2: (Aligns with the main research question, and the sub-questions 1, 2 and 3)

Assess the usability and acceptability of using RehabChat alongside usual care in the ambulatory care brain injury rehabilitation setting.

Outcome 2:

Assess usability following completion of the two-week trial using RehabChat, by participants completing the System Usability Scale (SUS) (18) questionnaire, and a semi-structured 1:1 interview. Assess acceptability through the semi-structured 1:1 interview.

Aim 3: (Aligns with the main research question, and with sub-questions 1 and 2)

Appraise client motivation and wellbeing and monitor for any negative impact from using RehabChat.

Outcome 3:

Monitor these factors for client-participants quantitatively regularly during the trial, explore these factors through qualitative interviews after completion of the intervention.

Aim 4: (Aligns with sub-question 3)

Report on the feasibility of using RehabChat alongside usual care in the ambulatory care brain injury rehabilitation setting.

Outcome 4

Analyse the quantitative and qualitative results for this feasibility pilot trial and synthesize an overall result to describe feasibility: the feasibility of using RehabChat at the collaborating ambulatory care clinic services.

Aim 5: (Aligns with the main research question, and with sub-questions 1 and 3)

Identify aspects of RehabChat that need to be modified to improve the feasibility of using it alongside usual care in the ambulatory care brain injury rehabilitation setting.

Outcome 5:

Obtain direct feedback on recommendations for change from participants through the qualitative semi-structured 1:1 interviews.

6.4 Methodology

A mixed methods feasibility pilot trial was undertaken at two clinic sites of an ambulatory care rehabilitation services for adults with moderate-severe ABI. The version of RehabChat used for the

user testing was the refined prototype finalised following the co-design workshops and the second round of alpha testing for it (see Section 5.6.15.1).

As this was the first time RehabChat was to be tested in a clinical setting, a necessarily cautious approach was taken for the intervention duration (a short two-week intervention) due to RehabChat not yet being a proven effective intervention but instead still being in its nascent stages of development (see Section 6.1). Additionally, a careful approach was taken to monitoring client well-being, through screening for depression and anxiety on a twice-weekly basis (see Section 6.4.12.2.2). This was done due to the potential negative effects of using CAs which include known issues such as anxiety, and also unknown risks (see Section 1.6).

The main phases of the project were: user testing with recruited clinicians; making changes to RehabChat in response to user testing feedback; then using the updated ECA prototype for initial participant training and for the subsequent two-week intervention of using RehabChat alongside usual care with client-clinician dyads.

6.4.1 Ethics details

This project received full ethics approval by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) and the CALHN Governance Committee, project number 14079. See Appendix XIV for the ethics approval letters.

6.4.2 Rationale for a feasibility pilot trial

Specific reasons for choosing the feasibility pilot trial design align with guidelines for when feasibility testing should occur (209). These are when there is negligible evidence for testing the device (see Chapter 2 for scoping review findings of limited evidence available), the target population has unique needs which should be considered in the study design (clients with TBI have unique clinical needs (see Sections 1.1.2 – 1.1.4)), it is necessary to appraise acceptability for both the intended recipients and also the individuals delivering the intervention (clients with TBI and clinicians respectively), and it is needful to determine how best to deliver the intervention from a practicality perspective considering limited resources (for example staff time, access to technology, both of which may affect clinicians of the participating clinics in his study) (209). Additionally, a feasibility pilot trial can help to clarify the likely access to end-user participants including clinician assistance in recruiting clients, ease of completing assessments, any barriers to conducting the study and implementing the novel tool in the real-life setting (210); all of these factors are relevant to the current study. The importance of consulting with clinicians when developing a novel technology intervention for ABI has been previously highlighted, noting that without this, then subsequent uptake of the technology will be poorer (211). Similalry, clnicians are closely consulted in this study. Finally, the feasibility pilot design can help appraise the processes for obtaining

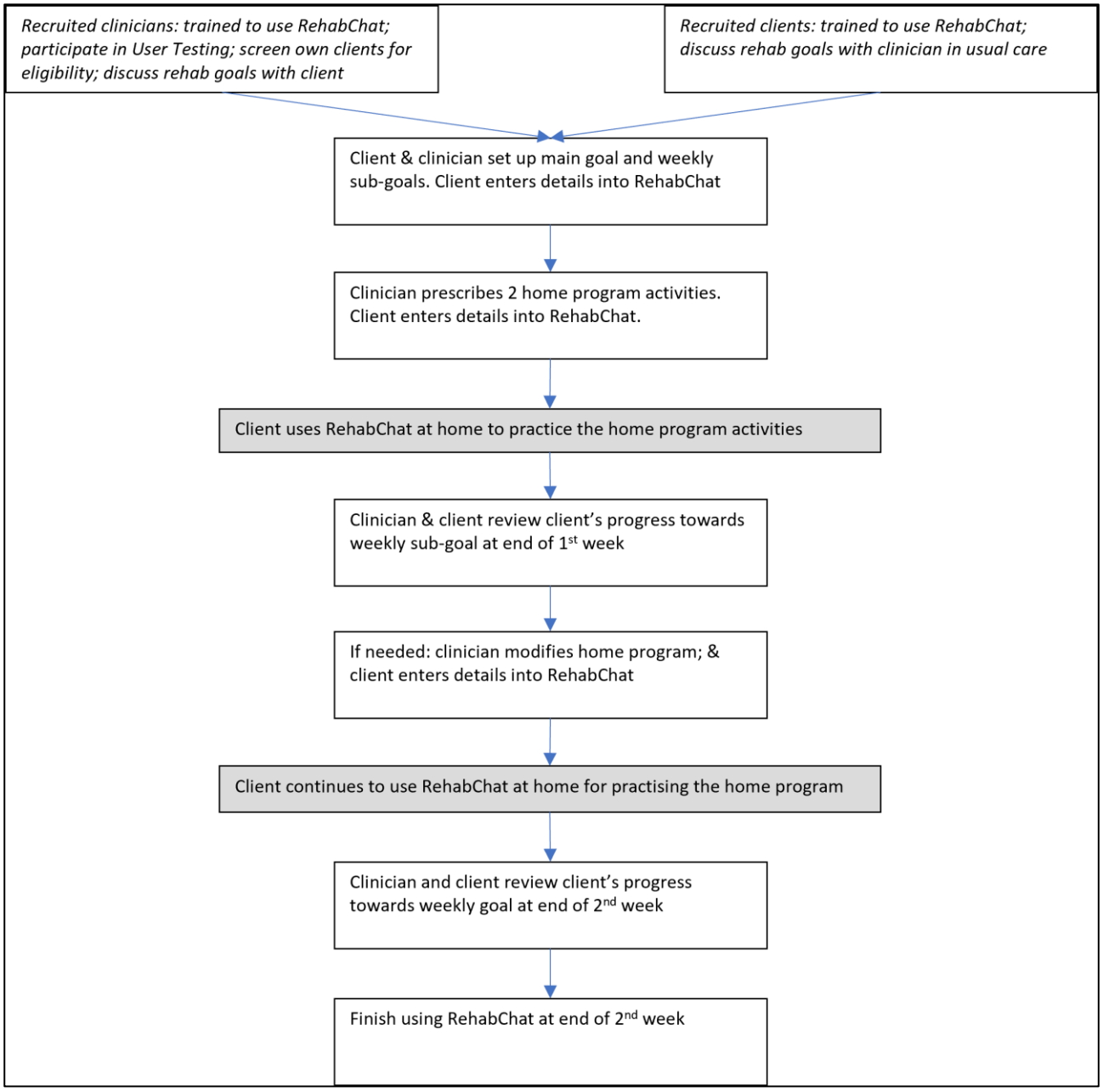
consent, for recruiting, and outcomes of retention and adherence to completing the intervention (212). Again, these are practical research considerations relevant for this study.

6.4.2.1 UTAUT framework for assessing usability and acceptability

The framework used for assessing usability and acceptability was the Unified Theory of Acceptance and Use of Technology (UTAUT) (19). The UTAUT components were integrated into the question guide for the semi-structured interviews. The UTAUT was chosen because it aligns with Living Laboratory (see Chapter 3) regarding the need to appraise the user's context. A clear focus upon the consumer's context was spearheaded by the UTAUT authors in 2012 (142). This was followed up by other authors similarly highlighting the need to appraise the use context in regard to social and other contextual factors influencing the choice to use a digital tool (213), such as perceived effort and social influence, and the impact of the real-life setting (214). Additionally, the UTAUT is able to be integrated alongside other behaviour change models for appraising intrinsic and extrinsic motivation, with intrinsic aspects relating to expectations of effort, and extrinsic relating to social determinants and facilitating conditions (141). The UTAUT was also chosen because it has previously been adapted for use in studies with a vulnerable population of older adults living in residential care regarding the use of interactive robot technology (215, 216). This demonstrates the relevance of the UTAUT for the current RehabChat project of testing a novel interactive technology (RehabChat) with a vulnerable population (adults with TBI).

6.4.3 Structure of pilot trial

The feasibility pilot trial was comprised of a two-week intervention in which the client-participant used RehabChat alongside usual rehabilitation care, with supervision provided by their clinician (See Figure 16 and Tables 20 and 21).



Legend: *text in italics* indicates activities completed just prior to two-week intervention; white text boxes = completed during intervention, in appointment time; grey shading = home based use

Figure 16: Using RehabChat alongside usual care

The pilot trial design was structured as a single case-series design using the A-B-A model. An A-B-A research design is intended to be used in a larger future pilot trial of RehabChat. For the current feasibility trial the A-B-A model was implemented to test its feasiblity. It included the following components:

- Clinical assessments: repeated measures conducted twice weekly for four weeks, from one-week prior through to one-week following the two-week intervention; and pre-post measures completed at the start and end of the two-week intervention.
- Training: to use RehabChat conducted prior to the intervention
- Two-week intervention: RehabChat used alongside usual rehabilitation care
- 1:1 interview and SUS: completed at the end of the intervention

The following two tables present the key activities in this pilot trial, for client-participants (Table 20), and for clinician-participants (Table 21).

Table 20: Outline of client-participant commitment

	Timeline of activities for client participants (in half-weekly intervals)					
	No participant activities	**Participant activities**				***No participant activities***
Main activities at each stage	***No activity prior to start of trial***	**Baseline assessment (1 week)**	**Training (1-3 days)**	**Intervention (2 weeks)**	**Follow-up assessment (1 week)**	***No research activity post trial***
Explanation of main activities being conducted at each stage	*Client receiving usual care (has had at least 3 clinic appointments with supervising clinician)*	Short assessments (phone discussion or online questionnaire) whilst client receiving usual rehabilitation care: **repeated measures** 5-10 minutes, **2x/week**: (e.g. Mon & Thurs, or Tues& Fri); **Pre-trial outcome questionnaires** completed at start of training)	Training conducted over 1-3 days **Twice weekly repeated measures:** 5-minute phone call twice per week during both training and intervention.	Intervention (total of 2 weeks): use RehabChat alongside usual rehabilitation care	Short assessments (phone discussion or online questionnaire) whilst client receiving usual rehabilitation care: **repeated measures** 5-10 minutes, **2x/week**: (e.g. M & Thurs, or Tues& Fri); **Post-trial outcome questionnaires** completed at end of intervention) **1:1 qualitative interview.**	*Trial completed. Clinic care: Client receiving usual care; or discharged during this time*

Table 21: Overview of clinician participant commitment

	Timeline of activities for clinician participants (in half-weekly intervals)					
	Participant activities					***No participant activities***
Main activities at each stage	**Usual care.** **Training for clinician**	**Baseline assessment** **(1 week)**	***Training for client*** ***(1-3 days)***	**Intervention** **(2 weeks)**	**Follow-up assessment** **(1 week)**	***No research activity after post-assessment***
Explanation of main activities being conducted at each stage	*Clinician provides usual care.* *(clinician has provided at least 3 clinic appointments for client)* Training for clinician:; then 1:1 User Testing	**Pre-trial outcome questionnaires** completed just prior to client commencing training	*Client receives training to use RehabChat*	Intervention (total of 2 weeks): clinician provides oversight of client using RehabChat alongside usual rehabilitation care	**Post-trial outcome questionnaires** completed just following 2-week intervention. **1:1 qualitative interview.**	*Trial completed.* *Clinician provides usual care; or the client may be discharged during this timeframe*

6.4.4 Recruitment

The feasibility pilot trial was promoted at the clinic settings by placing promotional posters (see Appendix XVII) in the clinic areas and providing short 10-15 minute monthly update talks at online team meetings. Recruitment was conducted with the intention to recruit client-clinician dyads. Clinicians were recruited first. Clinicians expressed interest to the researcher who followed up regarding recruitment. Recruited clinicians each screened their own clients for eligibility, and eligible clients were invited to participate.

The screening process was recorded onto an Excel (6) sheet to report all data required by the CONSORT extension for feasibility studies (4) regarding reporting of screening and recruitment activities. Each eligible client was contacted by their clinician to briefly explain the project and invite their consideration to be involved in it. There is precedent for clinician-participants identifying eligible potential client-participants in the literature: in a study investigating the use of serious gaming for cognitive training with ABI clients, the need to ascertain the client's abilities and challenges in order to identify their potential to interact with specific digital technology interfaces was highlighted (90).

Interested clients could contact the researcher who then followed up to explain the project and the informed consent process. If participating clinicians were unable to identify suitable / eligible clients to participate, then the clinician's training session went ahead, but no intervention period was undertaken. The semi-structured 1:1 interview was also still completed and this incorporated an initial mock client-clinician session using RehabChat (see Section 6.4.12.4).

All participants had a 1:1 discussion with the researcher about the project, and were provided with an information and consent form. Separate versions of the information and consent form were developed for clinicians (see Appendix XV) and clients, with the client version using simpler language (see Appendix XVI). Recruitment was confirmed when a signed consent form was returned. All participants were free to withdraw from the study at any time. Any data already obtained from the participant during their participation in the pilot trial would still be used in the project.

6.4.4.1 Inclusion and exclusion criteria

Any clinician providing direct clinical care was eligible to participate if they were willing to oversee clinical processes for which they are professionally trained (for example, a speech pathologist could oversee language and comprehension work, and a physiotherapist could oversee vestibular rehabilitation), and to continue their usual care for their clients whilst implementing RehabChat.

Client-participants were eligible to participate in the study if they: had a diagnosis of TBI of any severity; were able to use an iPad for the ECA; had mental capacity to provide their own consent to

participate in this project; and were receiving care from a clinician who was already recruited into the study for at least three appointments (to help ensure that the clinician had a good understanding of the client's needs).

6.4.4.2 Rationale for sample size

This feasibility pilot was purposed to provide a real-world initial testing of RehabChat in order to discover challenges to use, any safety issues and otherwise any barriers to implementation. The choice of sample size was guided by the need to evaluate the ECA for feasibility and usability. The Nielsen Norman Group (https://www.nngroup.com/articles/how-many-test-users (viewed 14-2-20)) recommends for co-design usability projects that a sample size of 5 is suitable when there is a single cohort of intended users, and that a sample size of 3-4 participants is sufficient for each specific end-user cohort. In this project, the proposed sample size for this feasibility was 3-5 for each cohort.

6.4.5 Participant commitment

Participant commitment was comprised of user training to achieve competency in using RehabChat independently, completing pre- and post-intervention outcome measures (questionnaires), and using RehabChat alongside usual rehabilitation care for two weeks. Additionally, clinician participants undertook eligibility screening of their client caseload; and client participants participated in twice weekly short phone calls with the researcher to complete well-being repeated measures for anxiety, depression and motivation. Each client participant was also given a $25 gift card at completion of their involvement as a token of appreciation for participating in the project.

6.4.6 Technology used

The RehabChat ECA was loaded onto iPads provided by the clinic. The clinicians were familiar with using these iPads. Client-participants used RehabChat on these iPads for their user training session, during the two-week intervention, and also at the three client-clinician-RehabChat appointment times (held approximately weekly during the two-week intervention). Each client-participant kept a clinic iPad for the duration of the pilot trial. Ongoing support for use of the iPads was provided by the researcher, including via phone and email contact. Clinicians used RehabChat on either their office personal computer (launched via an emailed URL link) or on the clinic iPad during their training and feedback sessions with the researcher.

Clinicians made a brief case-note entry of their client using RehabChat for each appointment that they incorporated RehabChat, by inputting a pre-developed text entry into the client's electronic medical record. Interactions between project participants and the researchers for this project

occurred face-to-face, over the phone, and/or via tele-conferencing. This enabled adherence to all required Covid-19 precautions, and increased access to study interactions.

6.4.6.1 Technical issues

Technical issues were managed promptly as they arose. Various technical issues arose during the early part of the pilot trial and were resolved in time to enable client participants to complete an uninterrupted two-week intervention. A similar approach has been reported for an adaptation and feasibility study for the development of a digital program for supporting diabetes management (217). In it, real-time adaptations of the tool were made during the feasibility study ready for a larger trial.

Types of technical issues encountered in the current project included: the software not performing adequately on certain clinic iPads (resolved by swapping the iPad), software functionality issues such as being unable to change a previously entered response using the 'change' click button, and having inconsistent launching of the training module. These issues were resolved by removing the change option, and removing the training module from the iPad after user training was completed. To compensate for removing the change option, ECA dialogue interactions were edited to enable the user to indicate if they needed to change an answer soon after entering key text; if so, the ECA would then redirect the user to enable this.

6.4.7 Presentation of RehabChat

The presentation of RehabChat on the iPad included an icon tile on the iPad home screen, which when clicked would launch RehabChat to fill the entire screen. RehabChat could subsequently be closed by clicking on an '-' in its top right corner, which would reduce it to a launch button. Clicking on the launch button would open RehabChat to full screen at the same point in the conversation at which it was closed. Similarly, if the iPad was turned off, when it was later turned back on and RehabChat was launched, the ECA conversation would resume at the same point at which it was previously used.

Two RehabChat ECA modules were utilised: a training module and, for the intervention, a rehabilitation module (see Section 4.4.2,). The training module contained opportunity for the user to learn the key skills required for using the rehabilitation module whilst participating in a simple conversation about weather and transport. These key skills included turning RehabChat on/off, entering freeform text responses, clicking on choice options, and scrolling to review content. A user guide was provided to the participant to use during the training session and later during the intervention. The user guide gave dot-point cues about how to do key skills for using RehabChat (see Appendix XX).

6.4.7.1 ECA conversation content

The RehabChat conversation was designed using constrained language content, meaning that all content was controlled, with no risk of unintended content. The conversation content is comprised of 7 parts which are:

1. Initial set-up of main rehabilitation goal, and weekly sub-goal
2. Two practice activities and motivational supports such as a reminder system
3. Entering in details of clinician-prescribed practice activities
4. Guidance for client to complete the practice activities at home
5. Review of client's progress after one week; entering in any clinician-prescribed updates or change to the practice activities
6. Client continues home practice
7. Final progress review completed at end of second week.

Each participant was offered the choice of using either a short-style conversation or a long-style conversation. Both options comprised the main tenets of goal-setting, prescribing practice activities, symptom management and weekly progress reviews. The longer conversation also included more reiterative explanation of content and options for choosing a motivational support such as a support person (see Figure 11). The differences between the two conversation styles were explained during the recruitment process and also in the training session. Advice was provided to the clinician that if they felt that the client may not tolerate a lot of language-based interaction, then they should choose the shorter conversation.

6.4.8 User testing with clinicians

User testing was conducted with clinician participants prior to any client using RehabChat. The purpose of user testing is to identify glitches in the product being developed, and it can be completed whilst developing a novel device rather than just at completion of design. This differs to usability testing which instead focuses on how easy it is to use the device as intended (https://digital.gov/2014/10/06/user-acceptance-testing-versus-usability-testing-whats-the-dif/ viewed 12-2-22).

In the current project, the main considerations when deciding how to conduct user testing included the following:

- Not all of RehabChat could be used during a one-off session, as it is intended to be used over multiple sessions within rehabilitation context
- The participants would need to understand the conceptual design of RehabChat including its intended mode of use in the rehabilitation clinic setting involving a client-clinician dyad
- The participants would need to be able to cope well if any software glitches occurred (researcher support would be available to solve the glitches at the time)

- User testing and follow-up changes made to RehabChat needed to be conducted prior to client-participants using RehabChat
- Essential to ensure that clinicians were confident in the design of RehabChat including it being easy to learn to use for their clients, as they would be overseeing its use during the pilot trial.

In line with the above considerations, it was decided that recruited clinicians would participate in user testing at the end of their training session in which they would have learnt to use RehabChat and also about their role as a supervising clinician. The focus of user testing was to identify bugs or glitches in the software and seek feedback on any potential issues that may occur with implementing RehabChat in the clinical environment with clients with TBI. User testing, including making subsequent changes to RehabChat in response to feedback received, was completed prior to any client using RehabChat.

User testing was done with the first three clinicians recruited, during each of their 1:1 training sessions. During the user testing the clinician used RehabChat on a PC or iPad, and could offer general feedback during and/or after use, and also respond to semi-structured questions by the researcher. The questions asked during user testing followed a question guide (see Appendix XIX). Questions covered areas of initial impressions and feedback, and how well, both the RehabChat ECA and also the user guide were able to meet client needs and recommendations for improving this. As well, clinicians were asked for feedback about using RehabChat alongside usual care, and any recommendations for improving its integration into the clinic setting. Feedback data was collected by the interviewing researcher as hand-written notes. One clinician also provided additional emailed feedback due to lack of time during their training session.

Feedback data collected during user testing was collated into general themes and then prioritised to identify the changes that were needing to be made to the ECA prototype. Modifications were then made to RehabChat in response to user testing feedback prior to client-participants using it in their training and during the subsequent two-week intervention. The results for user testing are presented at Section 6.5.2.

6.4.9 Single case design with an A-B-A research model

A ‘within-subjects’ single case design (SCD) (218) research model was chosen for this feasibility pilot trial because it accommodates low sample sizes by analysing the results for each subject separately using within subject analysis (219). The sample size for a SCD trial can be one, but is usually up to eight (220). Generalisability of SCD results is not intended, as there would need to be other SCD studies to ratify the results more broadly (221). This is not a limitation for the current project where the intent was to appraise the feasibility of using RehabChat in a specific brain injury

rehabilitation setting. The SCD approach has been particularly recommended for assessing novel digital health interventions (222), neurological client cohorts (223) and special education (220).

This SCD study utilised an A-B-A design (223, 224). This included two 'A' observation phases prior to and immediately following a central 'B' intervention phase. For the current project, 'A' was limited to one week to minimise client burden; and 'B' was limited to two weeks to ensure that the intervention did not impact overly upon usual care nor inadvertently convey that the tool could provide effective care; but it was still long enough to enable participants sufficient experience using RehabChat and to provide feedback. During both the A and B phases, repeated measures data (see Section 6.4.12.2.2) were collected on a twice-weekly basis. Results were compared between A and B phases. Because the current study's quantitative measures utilised ordinal data, the results could not be analysed for significant effect.

6.4.10 Participant training, and ongoing support for participants

A specific approach was adopted for conducting participant training which met clients' clinical needs. People with TBI can experience unique learning needs including the need to have regular rest breaks, take longer time to complete a task, and have written notes provided of the topic (https://www.brainline.org/article/accommodations-guide-students-brain-injury (viewed 18-1-22)). Additionally, this cohort benefits from having the task demonstrated to them with examples used to illustrate concepts, and subsequent repeated practice of the task done in a consistent manner (http://www.projectidealonline.org/v/traumatic-brain-injury/ (viewed 18-1-22)). All of these factors were integrated into the training approach for participants learning to use RehabChat.

In the current project, a supportive approach was taken for participant training: the RehabChat training module was completed by the participant; the participant could practice using RehabChat prior to being assessed for competency, and the training process could occur in an unhurried manner over 1-3 sessions. Prior research has similarly reported the use of supportive pre-training for clients with ABI using tele-health technology in which the training occurred over three training session (225). All participants received the same training for learning to use RehabChat. Each training session was conducted 1:1 with the researcher and lasted approximately 30-60 minutes.. In the training module, the user practices essential skills of launching and closing RehabChat, selecting a multiple-choice option, and entering freeform text. The user can refer to their user guide (see Appendix XX) as needed. During the first part of the training session, the researcher provided supportive instruction and cues, and the participant practiced using RehabChat until they felt ready to be assessed for competency. A user could request a repeat training session if required. During the second part, the participant used the ECA independently without supportive cues, so as to demonstrate that they were able to execute the key skills for using RehabChat. If the researcher assessed the participant as successful with this, they were deemed ready to commence using RehabChat in the clinical context.

Client training session were conducted in-person using an iPad. Clinician training sessions were conducted either in-person using the iPad, or via tele-conferencing which required them to use RehabChat on their personal computer (PC) with screensharing. In the clinician training sessions, additional content was included about their role of providing clinical oversight, and of screening their own clients for eligibility.

6.4.11 Two-week intervention

The RehabChat intervention commenced after both the client and clinician were assessed as being competent in using RehabChat, and the baseline assessments (see Section 6.4.12.2.1) were completed.

RehabChat was used alongside usual rehabilitation care for two weeks. Two-weeks is shorter than the intended six- week duration intended for RehabChat once its design and mode of implementation are stable, but sufficient for allowing participants sufficient time to experience using all of the functional aspects of RehabChat (see Section 6.1). There is precedent for conducting a two-week intervention alongside usual care. A two-week intervention period has been previously utilised in research investigating use of a wellbeing CA used in mental health care (226); for a mHealth intervention for monitoring mood following TBI (227); and for use of tablet-based visual feedback for improving exercise adherence after stroke, administered for two weeks within a four-week home exercise program (174). There is also precedent in the literature for using novel technology devices alongside usual rehabilitation care. A study investigated the use of mHealth tools alongside usual care for supporting exercise therapy interventions; in this study, feedback was gathered from both client and clinician participants (228, 229). Similarly, both clients and clinicians participated in this feasibility pilot trial.

6.4.11.1 Structure of intervention

Below is an overview of how the two-week intervention was structured. (Refer also to table A and table B above).

Day 1: in appointment time:

1. Clinician provides clinical oversight for client's use of RehabChat
2. Client enters details of rehabilitation goals (main goal and weekly goal)
3. Clinician prescribes two practice activities along with a symptom to monitor for and details how to manage the symptom if it occurs (collectively described as the home exercise program (HEP)
4. HEP details are entered into RehabChat
5. Client practises the HEP using RehabChat during the appointment

6. HEP details are updated in RehabChat as required to facilitate independent practice by client
7. When finalised, client is ready to use RehabChat independently at home to complete their HEP.

Client uses RehabChat at home

1. Client uses RehabChat daily for practicing the HEP
2. RehabChat provides details of practice activities and symptom to monitor for
3. Client completes the practice activities
4. Client reviews if any symptom, and manages accordingly.

After one week: in appointment time

1. Client and clinician review progress for achieving the weekly goal and enter a new weekly goal and two practice activities for second week
2. Client practises the HEP using RehabChat
3. HEP details are updated in RehabChat as required to facilitate independent practice by client
4. When finalised, client is ready to use RehabChat independently at home to complete their HEP.

At the end of two weeks: in appointment time

1. Client and clinician review progress for achieving the weekly goal and reviews the main goal.
2. The intervention is completed.

6.4.11.2 Participant safety and wellbeing

The safety and wellbeing of participants incorporating risk management was a key focus of this study. See Table 22 and Table 23 for details of approaches for this for clients and clinicians respectively. Clients' wellbeing and safety was ensured through three means. Firstly, the clinician provided attentive supervision and monitoring of the client throughout the intervention. This approach of having clinician oversight has been previously reported in a study in which a personal coach CA was used in a private allied health setting to augment therapist work (230). Secondly, the researcher conducted twice-weekly phone calls to the client to complete the repeated measures which included Likert scale questions for anxiety and depression (see Appendix XVIII). If a score indicated moderate or more significant symptoms, and/or the client otherwise indicated distress, the researcher asked the client if they would like additional support organised for them and could organise this as required by referring to the clinic's therapist/s. Conducting twice weekly

phone calls during a study have previously been reported in a study investigating the use of a CBT online agent for mental health support: this two-arm trial offered either twice-weekly or daily check-in by a clinician (135). Thirdly, all participants were informed that the ECA did not provide clinical care, and that all concerns should be discussed directly with their clinician.

The wellbeing of clinicians was assured through providing thorough initial training about their supervisory role for the client using RehabChat, the potential clinical issues that may arise, and how to undertake the screening process. Additionally, clinicians could balance their other work commitments with participation in this project by choosing when to undertake eligibility screening, and whether they would participate in the project without supervising a client and instead just provide feedback based on a mock client-clinician practice session.

Table 22: Risk management – for client participants

Safety or wellbeing concern	Mitigating the issue	Managing the issue if it arises
Struggling to understand what is expected of user	Conduct preliminary education and training session prior to start of trial; emphasize the nature of how RehabChat is used, and what to expect from it. Clinician is trained in RehabChat and can support client on ongoing basis.	Clinician and/or researcher to provide ad-hoc education and/or reassurance (can do so during any appointment time)
Frustration	Conduct preliminary training on how RehabChat is used, and what to expect from it. Clinician is trained to monitor client wellbeing and can support client on ongoing basis.	Clinician to monitor for any symptoms; and suggest appropriate clinical management to resolve problems; client can take a rest break when needed
Cognitive fatigue or overload	User guide and RehabChat ECA explain that client can take a rest at any time. Clinician can remind client of this. Clinician is trained to monitor client wellbeing and can support client on ongoing basis.	
Physical symptoms, e.g. muscle strain (hand, neck) or eye strain	Ensure each stage of using RehabChat is time-limited to approximately 5-15 minutes. Clinician is trained to monitor client wellbeing and can support client on ongoing basis.	

Table 23: Risk management – for clinician participants

Safety or wellbeing concern	Mitigating the issue	Managing the issue if it arises
Feeling overloaded in work role due to using RehabChat	Develop methodology in consultation with SABRIS Research Coordinator to ensure it is a fair and reasonable workload for clinician participants. Methodology is intended to be minimally invasive upon usual rehabilitation care at both clinics. Ensure clinician understands what is required in project participation.	Clinician can talk to site contact person, and/or JH to resolve this issue.
Concerned about client wellbeing	Explain potential client wellbeing issues and ways to mitigate/manage these prior to start of trial, during education session.	

Worried about data security	Conduct preliminary education and training session prior to start of trial; emphasize the nature of how RehabChat is used, and what to expect from it. Explain data security.	Clinician can contact JH who will reiterate data security measures.

6.4.12 Assessment

In this mixed methods project, both quantitative and qualitative data was collected. It has previously recommended that both types of data be collected and analysed in usability studies (231).

6.4.12.1 Feasibility, usability, and acceptability testing

The focus of this project was to assess the feasibility, usability, and acceptability of implementing RehabChat in two clinic sites of an ambulatory care brain injury rehabilitation service. Usability testing of a CA requires a unique approach because of its key difference to other software applications of comprising a conversational interface, which in itself may make it more usable (232). Each of the mixed methods approaches used in this project have a precedent in the peer-reviewed literature, and these are presented below.

This RehabChat study focused on testing the feasibility of using the ECA in the two clinics, and also of conducting the research processes. Similarly, previous feasibility testing has focussed on assessing pragmatic aspects such as the recruitment strategy, and administration of the outcome measurements (233). Acceptability assessment can be conducted through qualitative interviews (234). It can look specifically at perspectives on barriers and facilitators related to implementing the device, user engagement, any technical issues relating to the clinical context and its technological setup (229). Acceptability appraisal of both client and clinician participant (233) experiences of using the device in the context of the study (233) can focus on their perceptions of the device's strengths and weaknesses, ideas for future developments, and secondly align feedback to participants' experience and attitudes toward technology (228). In the current project, feasibility, usability, and acceptability were appraised using a mixed methods approach comprising semi-structured qualitative interviews and a quantitative questionnaire (System Usability Scale (SUS) (18)) (see Section 6.4.12.3). Previous research has reported that user experience of a well-being CA was appraised qualitatively (226). Additionally, the SUS has been recommended for quantitatively appraising usability and acceptability aspects of a CA for dementia care CA (155) and used in a feasibility and usability study for cognitive telerehabilitation for clients with severe TBI (225).

The qualitative interview questions for this feasibility pilot trial were structured using the UTAUT (see Section 6.4.2.1) and focused on usability, acceptability, and clients' clinical needs and

wellbeing (see appendices XXI and XXII for the separate interview guides for client and clinician participants).

6.4.12.2 Quantitative measures

The quantitative measures used in this study encompassed the domains of client motivation, anxiety and depression and therapy engagement. Interestingly, in a randomised feasibility pilot trial assessing an intervention for low mood for clients with ABI, the outcomes included self-report of anxiety, depression, motivation and therapy participation (235), which are similar to the measures used in the current study.

6.4.12.2.1 Pre-post clinical outcome measures

Four quantitative pre-post clinical outcome measures were used in this pilot. These have all been validated for brain injury rehabilitation, and all incorporate Likert scale questions. Clinicians supervising a client using RehabChat completed the questionnaires. Clinicians with no client were not required to complete the clinical questionnaires. These measures were:

1. **Client self-report**
    a. Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q) (236): 31 questions for factors relating to extrinsic factors affecting motivation: Lack of Denial, Interest in Rehabilitation, Lack of Anger, Reliance on Professional help (236); suitable for inpatient and day rehabilitation (236).
    b. BMQ- S (Brain Injury Rehabilitation Trust Motivation Questionnaire-Self) (237): 34 questions for intrinsic factors affecting motivation.
2. **Clinician report**
    a. BMQ-R (Brain Injury Rehabilitation Trust Motivation Questionnaire-Relative) (237): 34 questions for intrinsic factors affecting client's motivation. This version, although being a 'relative' report, is used by clinicians in research reports (3).
    b. RTES (Rehabilitation Therapy engagement Scale) (15): 15 questions of how well the client engages in rehabilitation.

Of note, prior literature recommends the use of the MOT-Q and BMQ in research for moderate-severe brain injury (238), and that both the MOT-Q (which appraises intrinsic motivation) and the (BMQ-S) (which appraises extrinsic motivation) (3) are recommended to be used together (3).

6.4.12.2.2 Repeated measures

Twice weekly researcher-developed Likert scale measures about anxiety, depression, motivation, and energy levels (see Appendix XVIII) were completed during the A-B-A phases. Similarly, in a previous feasibility pilot study investigating an mHealth tool for mood monitoring following TBI, participants completed twice weekly Likert scale questions regarding satisfaction (227).

The repeated measures were conducted via a brief phone call to the participant. The measures included weekly administration of the Hospital Anxiety and Depression Scale (HADS) (8, 9), and twice weekly administration of four researcher-developed questions for Anxiety, Depression, Motivation and Energy (ADME).These measures were implemented to monitor for any potential negative impact that using RehabChat may have on client-participant anxiety or depression, due to the known risks of using CAs including exacerbation of anxiety or stress (see Section 1.6). Additionally, screening for motivation and energy levels was done as an informal proxy indicator for stress or other unknown negative factors impacting on the client's wellbeing, given that previous research has noted that there are unknown risks associated with CA use (see Section 1.6).

The repeated measures are explained below.

- The HADS is comprised of 14 Likert Scale questions (0-3 scale), measuring anxiety (seven questions) and depression (seven questions) (239), and can be administered at intervals of at least one week (240). Cut-off scores for symptom severity are 8-10 for mild, 11-14 for moderate, and 15 or more for severe (241). The HADS questions were asked in the order presented on the scale. The HADS has been previously recommended for use with clients with severe brain injury (238).
- The four ADME questions (see Appendix XVIII) incorporated a 0-10 Likert scale, and were designed to be brief and simple to complete, so as not to fatigue the client-participants. The ADME questions were asked in random order (randomised by pulling numbers 1-4 out of an envelope and applying these to the questions on the form).

6.4.12.3 System Usability Scale as a post-measure

The System Usability Scale (SUS) (18) was completed by each participant following completion of the two-week intervention. The SUS has 10 Likert scale questions. It has been used in studies reporting on digital health interventions for brain injury, disease and stroke including: a feasibility pilot trial appraising additional visual feedback for upper limb stroke rehabilitation adherence (174); a user testing study of a memory support ECA for dementia care (155); and a feasibility and usability study for cognitive rehabilitation for clients with severe TBI (225).

6.4.12.4 Semi-structured qualitative interviews

Following completion of the two-week intervention, each participant participated in a 1:1 semi-structured interview. The interviews were conducted by Judith Hocking via Zoom (208) or phone and lasted 25-60 minutes. The semi-structured interviews were conducted using a question guide comprising questions based on feasibility, usability, and acceptability to meet the aims and objectives of the pilot trial. The questions for the semi-structured interviews were developed using recognised theoretical frameworks. These frameworks were the UTAUT for technology acceptance and usability (19), and the WCAG for aspects of Perceivability, Operability, Understandable,

Robustness (20). See Appendix XXI for a copy of the question guide for clinician-participants, and Appendix XXII for a copy of the guide for client-participants.

There is precedent for conducting qualitative interviews in research for digital health technologies, including for stroke patients. For example, interviews were conducted with client and clinician participants following trial of a novel digital health tool alongside usual rehabilitation care for knee surgery patients (228); and for appraisal of wearable accelerometers with a linked Web platform provided as part of an exercise referral scheme (229). Both studies included an emphasis on appraising acceptability, barriers to implementation into the clinical setting, and the client's engagement with the tool itself (228, 229) which align with the UTAUT-related purposes for the interviews in this feaiblity piot trial. Qualitative interviews have also previously been recommended to augment quantitative results for a digital health feasibility study for stroke rehabilitation which had a small sample size (174), which again aligns to this RehabChat study. For these reasons, qualitative interviews were included in this project.

For clinician-participants for whom no clients could be recruited, the qualitative interview session incorporated a mock client-clinician session to use RehabChat. This session lasted approximately 30-minutes and enabled the clinician-participant to gain some experience in using RehabChat. In this mock session, the clinician-participant used RehabChat as a mock client, and the researcher played the part of a mock-clinician providing support for the client. In a previous study investigating the feasibility of a digital motivational interviewing tool incorporating serious gaming (242), the participants similarly used the tool for 30 to 60 minutes before then providing feedback (242).

All semi-structured interviews were conducted via Zoom (208) and were recorded digitally. If there was a failure of the digital recording process, the researcher completed a detailed written summary of the interview, and the participant reviewed this for accuracy and made corrections or points of clarification as required.

6.4.13 Data Management

As this is a mixed methods study, both quantitative and qualitative data were collected, compared, and narratively discussed. All project data, (including completed questionnaires, audio recordings, transcriptions, ECA usage data, and iterative design changes to the ECA) was saved onto the Flinders University Cloud 'R' research drive in the form of audio files, word.doc files, and Xcel spreadsheets. Password protection was used. All hard copy data (including written notes taken during the interviews) is stored in a locked filing cabinet at the Flinders Digital Health Research Centre (FDHRC). Additionally, all data entered into the ECA by participants was stored by the software company Clevertar (see Section 4.1.2).

The qualitative audio data collected in this study from the 1:1 interviews was de-identified using version 3.1 of Audacity® recording and editing software (2). The de-identified audio recording was then transcribed using Microsoft Transcribe (12) and finally entered into NVivo software (14) for analysis and coding of the transcriptions. Thematic analysis using the Framework Analysis approach (171) was undertaken of the transcribed data. Framework Analysis is appropriate for qualitative analysis in which pre-defined purposes or directions of analysis are sought (171. This was relevant for the current RehabChat study which was purposed for identifying and interpreting feedback to further refine the design of RehabChat and its intended mode of implementation. Thus, during data analysis, emphasis was given to extracting data relevant to the further improvement of RehabChat.

6.5 Results

6.5.1 Demographic details

Recruitment was conducted as a rolling programme from July to December 2021. Four clinicians (4F) were recruited representing varied professions: Speech Pathologist (SP) (n=2), Occupational Therapist (OT) (n=1) and Education Tutor (ET) (n=1). The years working in brain injury rehabilitation and the years working at the current clinic were the same: a mean of 20.25 years, with a range of 9-30 years. Comfort in using a CA was scored on a scale from 0 – 4 (4 indicating high comfort) as 3 (n=3), or as 0 (n=1).

Details were collected regarding screening and recruitment of client participants according to CONSORT requirements for this data (see Figure 18). Clinicians screened a total of 23 clients, of which 21 were excluded. Reasons for exclusion were being ineligible (n=10); eligible but declining to participate (n=6); and other reasons such as psychosocial stress (n=5).

Demographic data for participants is presented in Table 24 for clinician participants and Table 25 for client participants. For the two clients recruited (1M, 1F), they received the full intervention. Both recruited clients reported good comfort in using a CAs (Visual Analogue Scale (VAS) of 0-4, with clients scoring 3 and 4) despite minimal prior use of CAs, but varied comfort in using technology in rehabilitation (VAS scores of 1 and 4).

Each client-participant had their own supervising clinician. The two remaining clinicians were unable to identify any eligible clients. These clinicians were instead able to provide feedback about RehabChat during a mock client-clinician-RehabChat session with the researcher (see Section 6.4.12.4). Each of these three sub-cohorts comprised two participants, and one participant from each had participated in the co-design workshops (see Tables 24 and 25).

All four dyad participants as well as one of the clinicians with no clients completed the training module and achieved competency in a single training session. The other clinician with no client declined to complete the training module as they felt comfortable using RehabChat following their earlier participation in the co-design workshops.

Both dyad pairs of participants completed the full two-week intervention. They all chose to use the shorter conversation style. All four dyad participants completed the clinical quantitative assessments. All participants participated in qualitative interviews and completed the SUS.

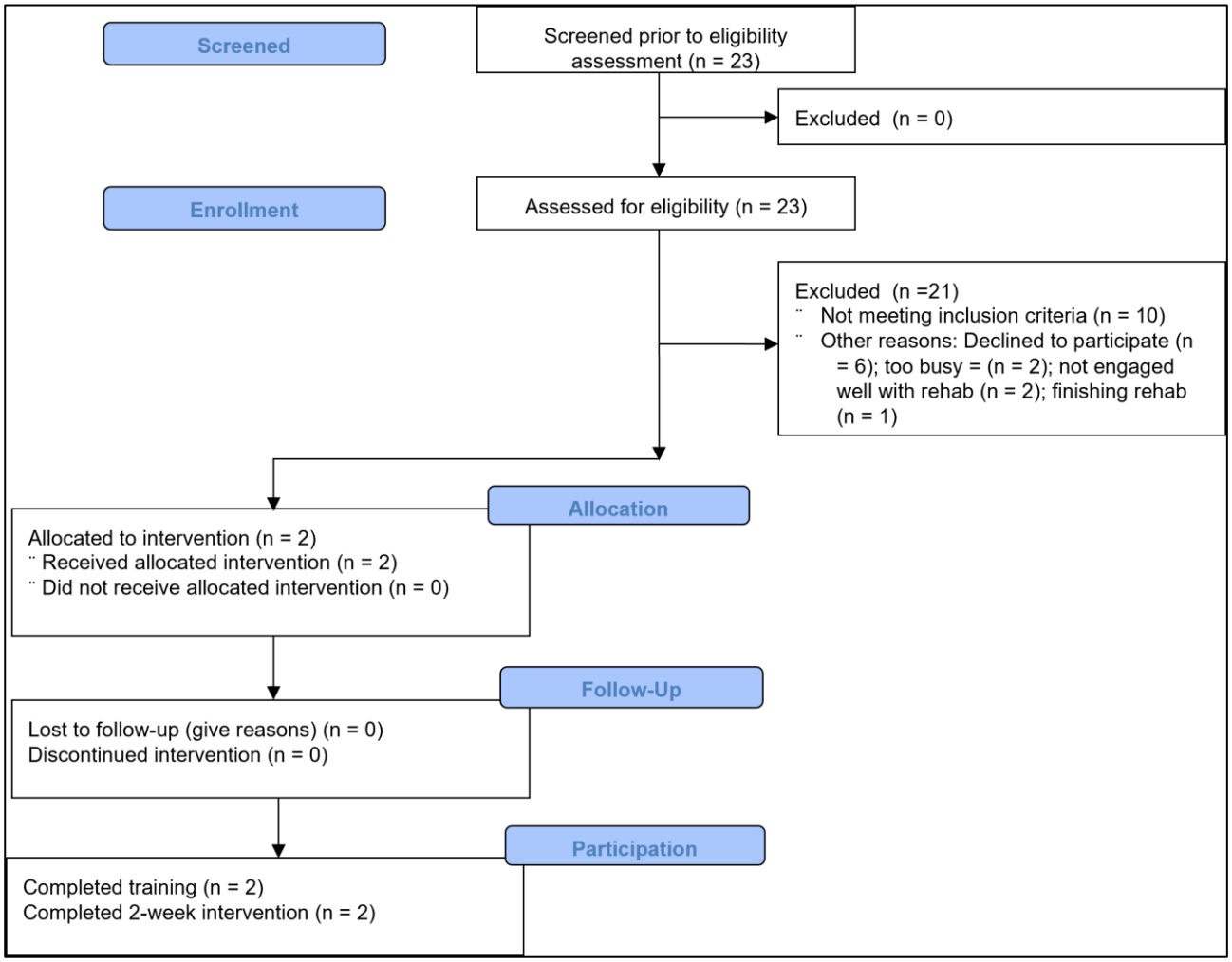


Figure 17: Feasibility pilot trial CONSORT details for screening and recruitment

Table 24: Demographic data for clinicians in feasibility pilot trial

Participant	Age bracket	Gender	Profession	Yrs in profession	Yrs in brain injury rehab	Yrs at current clinic	Comfort using tech in rehab (0 – 4)	# of times used CA	Comfort using CA (0 – 4)	Participated in workshops*
Clinician (with client)	65-older	Female	Education Tutor	22	22	22 (in mod-severe ABI clinic)	2	Never	0	No
Clinician (with client)	45-54	Female	Speech Pathologist	28	20	20 (in mod-severe ABI clinic)	3	1-3	3	Yes
Clinician (no client)	45-54	Female	Speech Pathologist	33	30	30 (in mod-severe ABI clinic)	3	10 or more	3	No
Clinician (no client)	25-34	Female	Occupational Therapist	10	9	total 9 (7 in mod-severe ABI; 3.5 in mTBI)	3	Never	3	Yes
Mean (M); (Range)				23.25 (10, 33)	20.25 (9, 30)	M = 20.25 (R 9, 30)				

Legend: mod-severe = moderate to severe; ABI = acquired brain injury; mTBI = mild traumatic brain injury; # = number; CA = conversational agent; * = co-design workshops

Table 25: Demographic data for clients in feasibility pilot trial

Participant	Age	Gender	vocation / occupation	How long ago TBI occurred	How long attend clinic	Comfort using technology in rehab (0 – 4)	# of times used CA	Comfort using CA (0 – 4)	Participated in co-design workshops
Client A	45-54	Female	Home Duties	22wks.	20 mo.ǂ	1	4-6 times	4	Yes
Client B	25-34	Male	Unemployed	6 wks.	16wk	4	1-3 times	3	No
Mean; (Range)				14 wks. (10, 30)	M = 51 wks. (4, 20)				

Legend: ABI = acquired brain injury; mTBI = mild traumatic brain injury; # = number; CA = conversational agent; * = co-design workshops; ǂ = approximated to 86 weeks for mean and range calculation)

6.5.2 User testing with clinicians

User testing was conducted with 3 recruited clinicians (2 speech pathologists, 1 education tutor) during each of their individual training sessions. The main themes of feedback requiring follow-up changes to RehabChat were Change content, Reviewing entered content, Wordiness, Phrasing for cues, and Single choice confirmation click options (see Table 26). User testing was not conducted for the fourth clinician because they were recruited later on when at least one client participant had already commenced using RehabChat; and thus no further changes would be made to RehabChat and therefore the user testing was not indicated.

Table 26: User testing: feedback and changes made

Main theme	Feedback received	Changes made to RehabChat
Change content	Close of conversation experience needs to acknowledge user input and finalisation of conversation more fully Final closing screen needs clear instruction to close Chrome Don't use assessment and assessor [in training module] -relace with practice, coach - Single choice confirmation click options- need more variety not just 'that sounds good'- each one should be specific to context just discussed, and not just a general comment like 'thanks' - outline the steps to be taken in conversation not just say at end of a section what the next step will be, because the client is not aware of it coming up	Closing comments more clearly acknowledge user's input, and a goodbye. Closing screen instructs to close Chrome Wording changed to 'practice' and RehabChat 'staff-person' Confirmation single choice options varied in wording, and included more specific content related to context of conversation Steps to be taken in a section of conversation were stated earlier
Reviewing entered content	Don't use 'take me back a few steps' as it is clunky because it goes back to an unexpected section and you're not ready for where it takes you Instead, use scrolling = client-directed	'take me back option' removed Scrolling emphasized
Wordiness	Have less wordiness Too much detail in some dialogues (3-4 lines in some whereas others had 2-3)	Dialogues limited to maximum of 2-3 lines each
Phrasing for cues	Lead in cuing for user to complete a sentence need to be more open ended e.g. not 'because it' but 'because' - make placeholder cue more explicit	Lead-in cues made simpler, shorter, and placeholder cues included brief explanatory content

6.5.3 Technology issues encountered

Types of technical issues encountered in the current project included the software not performing adequately on certain clinic iPads (resolved by swapping the iPad), with software function issues including unable to the change function of changing a previously entered response, unable to reliably upload a different avatar style, and having inconsistent launching of the training module (resolved by removing the change option, only offering one avatar, and removing the Training module from the iPad after training was completed). To compensate for removing the change option, ECA dialogue interactions were edited to enable the user to indicate if they needed to change an answer, following which the ECA would redirect the conversation to a point where this was possible. Technical issues were resolved to enable each client to complete a two-week intervention without interruption.

6.5.4 Version of ECA used for two-week intervention

The final stable ECA prototype of RehabChat was utilised in the two-week intervention. This version of the prototype incorporated the many changes made in response to feedback recommendations from all stages of user consultation (alpha and beta testing, co-design workshops, second alpha testing, and user testing), and technological adjustments for resolving glitches and ensuring successful integration into the clinic setting as preparation for the feasibility pilot trial. This final prototype is outlined visually in Appendix XXIII as a series of screenshots each showing aspects of the conversation content with some brief explanatory notes which highlight key factors displayed in the screenshot for the UI or the conversation structure and content.

The final prototype design of RehabChat is also described below (see Section 6.5.8) according to the reporting criteria recommended in the scoping review (see Section 2.7.1) and based on the data extraction instrument used in the scoping review (see Appendix II).

6.5.5 SUS scores

The results for SUS scores for dyad participants (two clients and two clinicians) are presented in Table 6 below. Three results indicate that RehabChat has very good usability; and one score was just below the average threshold, which was possibly due to the client initially experiencing technical issues with RehabChat prior to then having a smooth two-week intervention period.

Table 27: System Usability Scale scores

Participant	Attended prior co-design workshops	SUS score	Interpret SUS score*
Client	Yes	67.5	just below the av score of 68; this client initially experienced multiple technical issues (due to software upgrade and iPad issues); these issues were resolved, and the client could then progress to complete an uninterrupted two-week period using RehabChat
Client	No	82.5	yes has good usability; this client experienced negligible technical issues
Clinician	Yes	75	yes is usable
Clinician	No	80	very usable

Legend: * = Score results are considered against the average SUS score of 68 (see Measuring Usability with the System Usability Scale (SUS) Jeff Sauro, PhD, February 3, 2011 (viewed on https://measuringu.com/sus/ accessed 8-1-22)).

6.5.6 Quantitative results

Quantitative results were collected for the repeated measures (incorporating once weekly HADS scores and twice weekly screening scores for anxiety, depression, motivation and energy (ADME)) completed during the 'A-B-A' phases, and for the pre-post measures completed at the start and end of the 'B' intervention phase

The clients completed the repeated measures via twice-weekly phone calls with the researcher. The clients completed their pre-measures independently at their training session, and their post measures they chose to complete via a phone call with the researcher. Clinicians completed the pre-post measures independently.

6.5.6.1 Repeated measures

Client A's repeated measures results are presented in Figures 18 and 19, and in Table 27. For Client A's ADME Likert-scale measures, ratings for both Anxiety and Depression ratings showed an overall gradual reduction, with scores in each category varying by 4-6 points. The rating scores for both Motivation and Energy varied during the trial and the ratings for each of them did not align to the other.

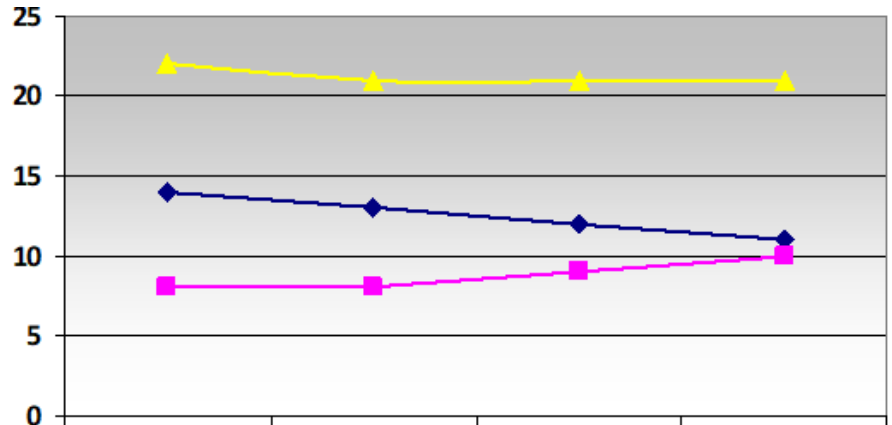
Client B's repeated measures results are presented in Figures 20 and 21, and in Table 28. Each of Client B's ADME scores remained stable during the trial with only minimal variation for each (varied by 2-3 points). Client B's HADS scores showed a slight improvement over the trial, primarily attributable to reduction in the HADS depression score component.

6.5.6.2 Pre-post measures

The quantitative results for the pre-post measures for both clients are presented in Table 29 below.

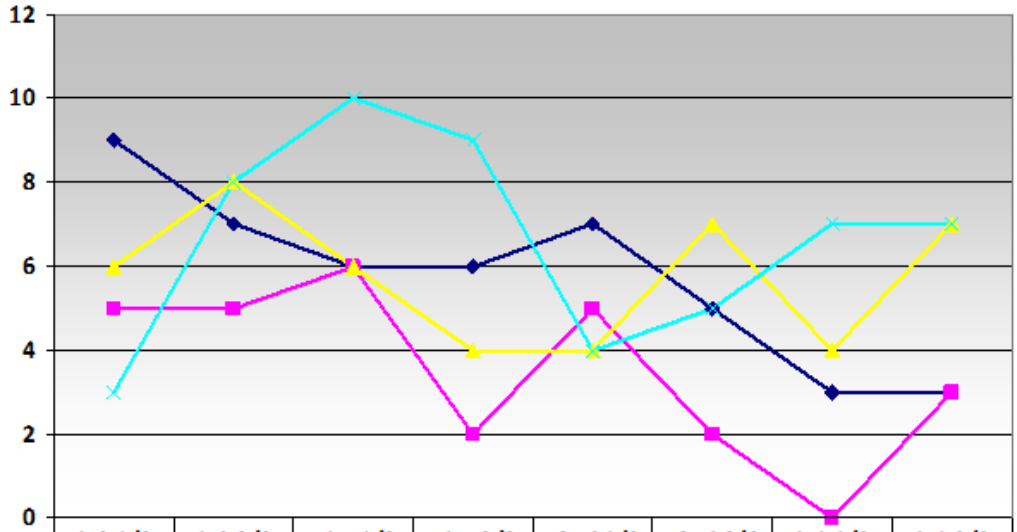
The pre-post measures for Client A remained generally stable for all four outcome measures. The scores for both the BMQ-S and BMQ-R increased slightly between pre and post time points, which indicated a small amount of deterioration in motivation. Comparing the BMQ-R clinician report and BMQ-S client report scores for client A showed that the clinician scored the client has having higher motivation than what the client self-reported with a difference in scores of up to 25 points. As well, the baseline BMQ-S for this client was incomplete, which may skew the comparative result. The MOT-Q and RTES results only differed by 1 point from pre to post intervention. The MOT-Q appraising intrinsic motivation (3) score of 42 indicates good motivation, from a possible range of scores of -62 to +62 (13). The clinician's score of Client A's therapy engagement in the RTES was stable at pre = 39 and post = 38, out of a possible total score of 45 (15).

The pre-post results for client B showed consistency in pre-post measures for the BMQ-S and MOT-Q. The clinician reported scores for BMQ-R and RTES showed some indication of improvement. Comparing the BMQ scores for self-report (BMQ-S) to clinician report (BMQ-R) reveals fairly close affinity with 10-11 points difference in scores. Client B's self-report score in the MOT-Q score for intrinsic motivation indicated reasonable motivation pre = 32, post = 31), and similarly the clinician report for therapy engagement in the RTES indicated reasonable engagement (pre = 24)) and improved somewhat at the end of the intervention (post = 32).



	A:0	B1st	B2nd	A:1
HADS – Anxiety	14	13	12	11
HADS – Depression	8	8	9	10
HADS – total	22	21	21	21

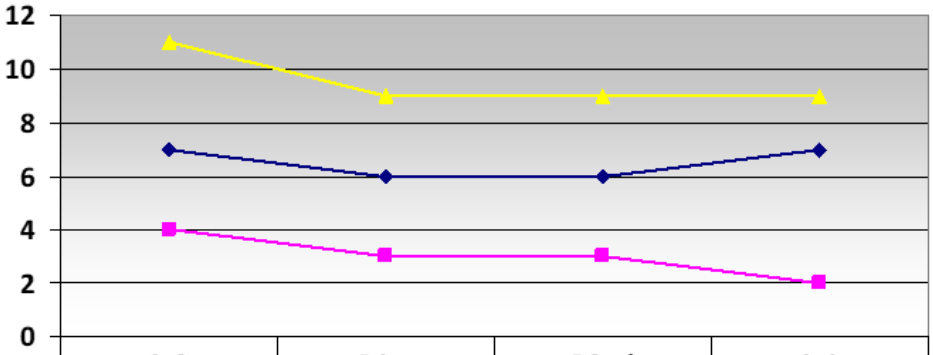
Figure 18: Client A Hospital Anxiety and Depression Scale scores
Legend: A:0 = pre A phase; B1st = B phase 1st week; B2nd = B phase 2nd week; A:1 = post A phase; 1/2 = first measure for that week; 2/2 = second measure for that week



	A:0 1/2	A:0 2/2	B1st 1/2	B1st 2/2	B2nd 1/2	B2nd 2/2	A:1 1/2	A:1 2/2
Anxiety	9	7	6	6	7	5	3	3
Depression	5	5	6	2	5	2	0	3
Motivation	6	8	6	4	4	7	4	7
Energy	3	8	10	9	4	5	7	7

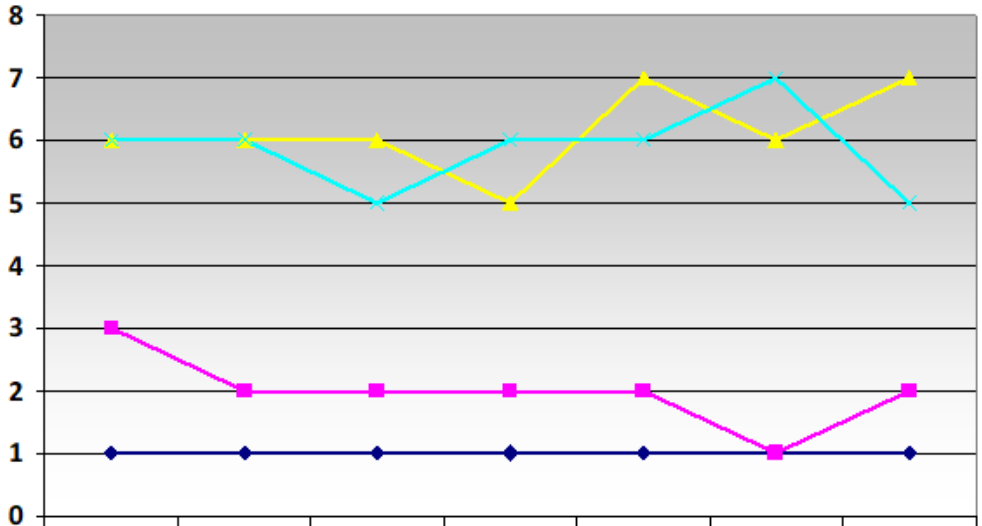
Figure 19: Client A scores for Anxiety, Depression, Motivation, Energy researcher-developed questions)

Legend: A:0 = pre A phase; B1st = B phase 1st week; B2nd = B phase 2nd week; A:1 = post A phase



	A:0	B1st	B2nd	A:1
HADS – Anxiety	7	6	6	7
HADS - Depression	4	3	3	2
HADS – total	11	9	9	9

Figure 20: Client B Hospital Anxiety and Depression Scale scores
Legend: A:0 = pre A phase; B1st = B phase 1st week; B2nd = B phase 2nd week; A:1 = post A phase



	A:0 1/2	A:0 1/2	B1st 1/2	B1st 2/2	B2nd 1/2	B2nd 2/2	A:1 2/2
Anxiety	1	1	1	1	1	1	1
Depression	3	2	2	2	2	1	2
Motivation	6	6	6	5	7	6	7
Energy	6	6	5	6	6	7	5

Figure 21: Client B scores for Anxiety, Depression, Motivation, Energy researcher-developed questions)
(N.B no results for A:11/2 because client not available)
Legend: A:0 = pre A phase; B1st = B phase 1st week; B2nd = B phase 2nd week; A:1 = post A phase; 1/2 = first measure for that week; 2/2 = second measure for that week

Table 28: Client A repeated measures – 4 researcher-developed questions & Hospital Anxiety and Depression Scale

A or B phase	Anxiety	Depression	Motivation	Energy	HADS – Anxiety	HADS – Depression	HADS – total
First A phase	9	5	6	3			
First A phase	7	5	8	8	14	8	22
B phase – 1st week	6	6	6	10			
B phase – 1st week	6	2	4	9	13	8	21
B phase – 2nd week	7	5	4	4			
B phase – 2nd week	5	2	7	5	12	9	21
Second A phase	3	0	4	7			
Second A phase	3	3	7	7	11	10	21

Table 29: Client B repeated measures – 4 researcher-developed questions & Hospital Anxiety and Depression Scale

A or B phase	Anxiety	Depression	Motivation	Energy	HADS – Anxiety	HADS - Depression	HADS – total
First A phase	1	3	6	6	7	4	11
First A phase	1	2	6	6			
B phase – 1st week	1	2	6	5	6	3	9
B phase – 1st week	1	2	5	6			
B phase – 2nd week	1	2	7	6	6	3	9
B phase – 2nd week	1	1	6	7			
Second A phase	*	*	*	*			
Second A phase	1	2	7	5	7	2	9

Legend: * = client not available

Table 30: Pre-post measures

Measure	BMQ-S		BMQ-R		MOT-Q						RTES	
Client		Total score		Total score		Four sub-scales*				Total score		Total score
						IR	LA	LD	RP			
A	pre	81 *(had 5 missing responses)*	pre	58	pre	6	11	14	12	43	pre	39
	post	89	post	64	post	2	14	17	9	42	post	38
	change; implication	*+ 8; minimal deterioration*	change	+ 6 (minimal deterioration)	change	-4	+3	+3	-3	-1 (equivocal)	change	-1 (equivocal)
B	pre	80	pre	91	pre	6	10	12	4	32	pre	24
	post	78	post	68	post	8	9	9	5	31	post	32
	change; implication	- 2; negligible improvement	change	- 23; small trend for improvement	change	+2	-1	-3	+1	-1; equivocal	change	+8; some improvement

Legend:
Italics font = unable to obtain definitive score due to missing five responses in baseline MOT-Q
MOT-Q = Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (236): items rated on 5-point scale -2 (strongly disagree) to +2 (strongly agree), 0 being undecided; score range -62 to 62; higher scores suggest higher motivation (13)
* = MOT-Q four subscales: IR = Interest in rehabilitation, LA = Lack of anger, LD = Lack of denial; RP = Reliance on professional help (13)
BMQ-S = Brain Injury Rehabilitation Trust Motivation Questionnaire-Self: score range 34 to 136, higher scores suggest more challenges (244) (237)
BMQ-R = Brain Injury Rehabilitation Trust Motivation Questionnaire-Relative: score range 34 to 136, higher scores suggest more challenges (244) (237)
RTES = Rehabilitation Therapy engagement Scale (15): items rated 0 to 3; score range 0 to 45; lower scores indicate lower engagement (245)

6.5.7 Qualitative results

Feedback from the semi-structured interviews covered a comprehensive array of topics pertinent to feasibility testing: things that are already going well; issues that need addressing, and recommendations to improve RehabChat further. Qualitative data from the interviews was categorized into six main themes and 28 sub-themes as outlined in Table 30 below. The main themes were ‘What went well’, ‘Motivation and engagement’, ‘Barriers and concerns’, ‘Use in clinical setting’, ‘Usual Care Considerations’, and ‘Recommendations’. The sub-themes for each of main themes are presented below, with participant quotes highlighted in italics font.

Table 31: Themes and sub-themes for interview feedback

Theme	**Sub-themes**											
1. What went well	Usability	Understandable	Alongside usual care									
2. Motivation and engagement	Goal pursuit	Reinforcement	Planning ability	Supported motivation	Positive personal experience	Internal motivation						
3. Barriers and concerns	Potential risks	Potentially stressful	Barriers to use	Clinical needs								
4. Use in clinical setting	Amount of use	Technical issues	Three-way interactions									
5. Usual care considerations	Covid-19	Transition to independence	Focus on goal pursuit									
6. Recomm-endations	Reminder to use	Integrating into clinic routines	Support cognitive framework	Support auditory processing needs	Content clarity regarding user interactions	Flexible approach to using RehabChat	Clinician role	Client's wording for goals	Use pattern	User interface changes	Use with decreased clinician input	Technical support

6.5.7.1 Theme 1 – What went well

For the theme of What went well, for three sub-themes were identified which were: Usability, Understandable, and Alongside usual care.

Usability: Participant feedback indicated that RehabChat was highly usable, being easy to use – *'I found it pretty straightforward, pretty easy' (C); 'It was very easy for me' (CWC)* – and not requiring much effort – *'I didn't feel that there was a lot of effort needed' (C)* – which related to being able to use the clinic iPads –*'that probably helped that there was a familiarity with the iPads in themselves' (CWC)* –, and the pace of the conversation was appropriate – *'it's not slow, but it's accommodating' (CWC).* Particular areas that worked well were being able to pause use when needed – *'I could pause it if I needed to, and being able to turn it off … I have really good control over it' (C)* – and that *'the instructions were very clear in terms of setup' (CWC).*

Understandable: Feedback indicated that RehabChat was very understandable, both in regard to the audio-visual presentation with the avatar's diction being clear, and the dialogued text bubbles being spaced appropriately – *'I thought the spacing you know of the writing was good. You know how it was like little clouds all the time and they had spaces' (CWC).* It was felt that the visual display suited the needs of clients with visual challenges in that each dialogue text bubble was quite short, the user interface had low contrast, and the avatar was quite still when speaking versus showing gesturing whilst awaiting a client response – *'he found that quite clear, he was able to type in with no problems yeah so I guess that was a good test of someone with visual issues' (CWC)*. Additionally, the actual content of the conversations was easy to follow, having an adequate level of complexity and sufficient cues included to guide the user through the conversation –*' I didn't have any issues understanding the language' (C)* –, with a client reporting 8/10 score for ease of use.

Alongside usual care: Participants reported that the way in which RehabChat was used alongside usual care was well organised – *'I think the way it was organised was very well done' (C)*. Clinician feedback included that it was easy to support their client's use of RehabChat, with minimal need to provide technical support, and the main area of their input for the client was in clarifying rehabilitation goals and related content – *'I didn't really need to support a lot. … You know I needed to help him with idea generation in terms of goal setting but otherwise, no, I think that's all fine' (CWC).* This paralleled with client feedback stating that a goal which was currently being considered in their appointments could also be easily included in RehabChat – *'Planning the [the goal] has been something we were talking about, so it was good to incorporate that and have something else to work with' (C).* A benefit of using RehabChat of being able to offer more frequent check-ins with the client was noted – *'So I think more and more if there are opportunities for people to have check-ins and making sure that they're on target with their goals I think it's great' (C).* It

was also found that RehabChat provided the client with regular cues (for staying focused on their goals) similar to input provided by a therapist – *'Obviously, I don't think it diminishes the need for therapists to still check in, but I think it is a good tool that allows people to stay on track or encourages them to stay on track with their goals' (CWC).*

6.5.7.2 Theme 2 – Motivation and engagement

The theme of Motivation and engagement contained sub-themes of Goal-pursuit, Reinforcement, Planning ability, Supported motivation, Positive personal experience, and Internal motivation.

Goal pursuit: The ability of RehabChat was able to assist with goal pursuit by helping clients plan how they completed their practice activities – *'It would it kept me on schedule, made me get up early, made me think about my fitness and you know really made me focus on my mental health' (C); 'she could see you know the steps, what she had to be ready for' (CWC)* - and helping ensure regular practice – *'I think it's a good tool for you know, sustainable practice' (CWC)*. It was felt that the SMART structure was appropriate – '*a simple, clear framework, which incorporates the SMART framework, and which meets the standardised requirements of what should be done' (CNC).* – and that details for goal setting were able to be inputted at the start of the conversation – '*I think anything else that you know could be added, could have been added from the start' (C).*

Reinforcement: RehabChat's ability to reinforce and support goal-pursuit was related to being motivated – '*having something just to reinforce and motivate me to keep working on things' (C)*; '*It's yeah, just really good to have something reinforcing' (C)*. RehabChat's ability to reinforce information was related to an appropriate use of the client's name during the conversation – '*Using the client's name could help with increasing the client's level of focus and attentiveness to what is then being said. It's good that that the user's name is placed at start of a section in which the avatar re-states a summary of what the user has entered' (CNC).* Reinforcement was effective when it linked to the client's goal – '*Even when I couldn't do it, you know, reminded me that I really did want to do it' (C); 'I have no one here to remind me of it so I really rely on it, it really reminds me that I am working towards a bigger goal' (C).*

Planning ability: It was noted that RehabChat supported the client's planning ability through prompting the client to review their key symptom – *'it's reminding me what I should be looking for … about different activities but for my activity would be so easy just to go out there and just slog it out, but it made me more aware' (C);* and that by doing so the client could check if they needed to have a break from doing their practice activity – *'have come to the conclusion that I don't have to go I don't have to make myself sick to make myself do it, I can take a day or two off' (C).* RehabChat's ability to prompt the client to complete their specific activities was also noted to improve vigilance in the client – *'I think have just using the RehabChat made him more accountable to the goal that he set' (CWC).* Clinician feedback also identified RehabChat's ability

to provide support and structure for executive function that would then help with planning – *'might be more of an executive function sort of support for the people I would see in terms of [getting a] specific plan and having a way of getting alarms or follow up kind of structure so it's a structure to intended behavior' (CNC)*.

Supported motivation: In regard to RehabChat's ability to support motivation, client feedback stated it achieved this well – '*She's been my motivation to good health, Yeah, definitely yeah, I felt more motivated with things' (C).* Clinicians expanded this to explain that RehabChat helped to support engagement in rehabilitation by allowing the client to see progress being made which in turn increased motivation – '*So I think that was really positive tool and I think once you start to see some progress, like, even if it's just an initial prompt to get going with that, once you can see that you [are] actually able to achieve an outcome felt motivating in itself, I suppose' (CWC).* Similarly, clinician feedback also noted that some clients may prefer a computer-based conversation in comparison to just with a human therapist – '*for some people they are more likely to be interested and engaged in a little computer thingy then they will the conversation that they'll have with the clinician' (CNC)* – which could increase access to therapeutic input and engagement in rehabilitation. It was also thought that RehabChat supported both motivation and accountability together to help decrease reliance on clinician input – '*I think they're very intertwined, I guess motivation and accountability, but I think you know it did give him an internal drive, whereas before I guess I was sort of pushing the issue and encouraging him' (CWC).*

Positive personal experience: Some positive personal experiences arising from participating in the feasibility pilot trial and using the ECA were a sense of personal connection felt by the client to the avatar, including a sense of grief when the pilot trial finished – '*I will miss her because I don't wake up with her anymore now. … Well, we usually wake up at the same time, have a morning chat. I'm sure if I had the coffee machine [we] would have done it together' (C).* Having a sense of trust and being able to be honest with the avatar was also identified – '*I would struggle to tell my family that my therapy is not working for me. They wouldn't believe you know, for a start. But yeah, you would struggle to take hope away from them; so at least I can take hope away from Jo, and she doesn't mind' (C).* Clinician feedback similarly noted that personal connection was facilitated by the avatar using the client's name regularly during the conversation – '*Liked that the user's name is used regularly in the conversation – to help it more feel more personalised, feel as though the avatar understands me / what I've said' (CNC).* Additionally, RehabChat was seen as comprising a supportive conversation experience which was akin to a personal trainer– '*I guess the whole thing is that you see that this is actually a buddy' (CWC); 'It's sort of like a personal trainer yes but, you know, not shouting with me, and I'm still controlling it' (CWC).* There was also a sense of personal accomplishment from having participated in the research itself – '*I feel good about what I've experienced and how I've had input, and it gives you self confidence that you can still do*

things, you can have input' (C); 'she you know really liked it through the Uni side of it; so, she knew that it would be ethical and things like that. So, she trusted it' (CWC).

Internal motivation: A focus on Internal motivation was described by client participants, relating to self-responsibility for improving in rehabilitation – '*So you've gotta have it. You've gotta have it in you' (C)* – particularly in the context of living alone – *I' don't have anyone here to regulate me or motivate me, or to give me the drive to get better 'cause you know, if you have a family you want to get better for them' (C).* There was also a focus on being self-motivated within the supportive rehabilitation context – '*I've got a great team around me. And at the end of the day, I'm the one who's responsible, for how much better' (C).*

6.5.7.3 Theme 3 – Barriers and concerns

The sub-themes identified for describing the theme of 'Barriers and concerns' were Potential risks, Potentially stressful, Barriers to use, and Clinical needs.

Potential risks: Participants identified a number of potential risks which they thought could occur for clients using RehabChat. These included a risk for breach of confidentiality regarding details of the set rehabilitation goals containing information that could identify the client; for this risk it was suggested that the clinician's input would help ensure that the entered content assured confidentiality for the client – '*I suppose something could sort of cross into that, but having worked with the therapist to start out, I don't think it'd be a problem' (C).* Another risk was that a client's sense of feeling overwhelmed could increase due to the new experience of using RehabChat and that this concern meant that a client at risk of experiencing this was not considered for the feasibility pilot trial – '*yes, he would have gotten overwhelmed by having, he was already overwhelmed, and so I was initially thinking having something nice and concrete might just help anchor him, but I think he also had just, this overwhelmed-ness, yeah, and the stress of you know, grief and change and work sort of stuff, as well as just attentional stuff (CNC)*. Similarly, wellbeing was seen to be at risk for client-users if the client had diminished self-insight, as their ability to reflect on their symptom/s could be impaired, which could effectively allow them to over-exert themselves when completing their practice activities or otherwise place themselves at risk of negative clinical issues. Additionally, this risk could be exacerbated if the client had a strong drive to achieve their goal – '*I guess that's the only caveat I guess is that sometimes that self-awareness can be very poor. […] early on, I think until you build some insight' (CWC); ' 'cause I think clients can get caught up in things and forget to rest and then overdo it and then it's counterproductive' (CWC).* A contributor to this risk was the actual design of RehabChat to motivate the client towards regular practice to achieve their goal – '*I just know that some personality types and … if clients are not self-aware early on [as] in they have a fairly 'A' type personality where you know they need to*

achieve that goal at all costs, whether or not you know, because the chat is telling them to, I just wonder if they would push through and maybe could risk themselves' (CWC).

Potentially stressful: RehabChat was seen to be potentially stress-inducing, not so much due to the software's user interface, but due to if an unrealistic goal was entered into it for which the client felt unable to achieve but also pressured to try to do. Another factor causing mild stress were the technical difficulties encountered which participants said were manageable – '*was very mildly frustrating but I'm used to technical issues, and things like that' (C)*; '*We had some, I wouldn't call it stress[ful], we were laughing most of the time when we had the technology not actually working, but we stuck to it. So you know she … didn't throw up her hands and say enough's enough. She went through with that; and I wouldn't call it actually stress – you know we always had a smile on our face' (CWC).*

Barriers to use: Multiple barriers were identified which could impede use of RehabChat. These included having a research structure that imposed numerous requirements –' *I think if it wasn't done within a research format where you have to go - we're gonna do this form, and now you have to understand what this is and then we're gonna…' (CNC*). Other barriers were also identified concerning the client's experience: of the client already having other technology tools to manage at home – '*but when you've got lots of other things on your table, … and extra thing might be … challenging' (CWC)* –; or having financial limitations – '*she's on fixed income. You just don't leave things on' (CWC)*; with either of these barriers resulting in not keeping RehabChat turned on. Finally, if the client was experiencing unexpected life challenges, these could also potentially interrupt ECA use: '*there were a lot of external factors that occurred in those two weeks around family, accommodation, all sorts of things that I thought would distract or deter him, probably from working on what we'd agreed to work on' (CWC).*

Clinical needs: A range of clinical needs which affected the use of RehabChat and/or participation in rehabilitation were identified in the interviews. These needs included decreased memory – ''*cause that's the biggest thing with my mind is that I can't remember' (C)* –, and forgetting rehabilitation goals – '*people forget, I guess, what goals they have set sometimes' (CWC); 'they're likely to have prospective memory difficulties, attentional stuff, they'll forget what they want to do' (CNC)* –; low mood – '*you do get down' (C)* –; fatigue; and '*auditory processing issues… If someone is needing more time to process auditory information' (CWC*).

6.5.7.4 Theme 4 – Use in clinical setting

The theme of 'Use in clinical setting' categorises feedback referring to the experience and practical details of using RehabChat alongside usual rehabilitation care. The sub-themes for this were Amount of use, Technical issues, and Three-way interactions.

Amount of use: Participants reported that RehabChat was used either every second day, or the user '*missed two out of the five days' (CWC).* Use could be influenced by a client not feeling like using RehabChat at times, within a context of otherwise being very happy to use it – '*that one day I was like, no I don't want to talk you … so I'll talk to you later' (C).* Related to this feedback was the observation that – '*seven days is too long .. to stick at a physical program' (CWC)* daily.

Technical issues: Participants described the impact of technical issues whilst using RehabChat alongside usual care, including the need to find simple solutions to resolve the issues, or to re-schedule follow-up review appointments as required – *'had to look at … my timetable and [be] flexible … to manage it' (CWC)*.

Three-way interactions: Feedback also articulated the importance of the three-way interaction between the client-clinician dyad and RehabChat for clarifying goals and following up details for weekly reviews – '*it was sitting and thinking about how can I make it better and then [name of therapist] discussing my symptoms with me and then refining what I was doing' (C)* –; with emphasis on the clinician playing a supportive role – '*I was the second one in it. … I was waiting for her to do the goals and things like that and just, you know, supported her to do that goal and maybe edit it, little bit' (CWC)*. Further to this, the clinician was seen as integral to introducing RehabChat to the client with a focus on its helping qualities – '*I would probably introduce her as she's a lovely girl but she doesn't have a lot of you know vitality about her. Don't worry about that, she really, you know wants to give you cuing' (CNC)* – with this quality seen as an important adjunct to usual care – '*I think sometimes having another thing that just adds to a focus point to help people have that conversation' (CNC); 'it may provide a structure of just keeping everybody on track a little bit' (CNC).*

6.5.7.5 Theme 5 – Usual care considerations

The theme of 'Usual care considerations' incorporates factors of usual rehabilitation care which could impact upon the use of RehabChat. The subthemes for it were Covid-19, Transition to independence, and Focus on goal pursuit.

Covid-19: Clinician feedback indicated that with Covid-19 restrictions and the increase in tele-rehabilitation, clinicians were '*not able [to do] … as much face to face work with clients … still accessing the clients through telehealth' (CWC)*, and this had resulted in less reiteration for the client about the focus of their rehabilitation – '*perhaps not having as many people around to help facilitate that' (CWC)*.

Transition to independence: Clinicians described that during rehabilitation, clients are supported in the transition from the rehabilitation environment to independence. This is achieved through planned therapy breaks during which a client has opportunity to self-direct their care, and following it their ability to do so is reviewed with the clinical team – '*we do offer people sometimes a rehab*

break which means maybe two weeks, maybe in the middle of their program, that we might set them up to see how they go at being independent in and carrying things over just to test it' (CWC). The therapy break is a time to help the client to become their own '*self coach … what we wanna do is gradually reduce the amount of cuing or prompting that we're having to do, to encourage them to take that on themselves' (CWC).*

Focus on goal pursuit: It was noted that goal-pursuit in and of itself requires effort and focus by clients – '*any you know targeting any goal takes energy' (CWC)*. Clinician feedback described approaches for improving client focus on goal pursuit included using the client's name during clinical interactions, and helping the client to learn and adopt a self-evaluation framework to enable them to think clearly about their rehabilitation and progress including planning for the next step of their recovery – '*how did I go, what would I do differently next time?' (CNC).*

6.5.7.6 Theme 6 – Recommendations

Multiple recommendations for improving RehabChat and its intended mode of use were collated under the theme of 'Recommendations'. Twelve sub-themes identified for this were: Reminder to use, Integrating into clinic routines, Support cognitive framework, Support auditory processing needs, Content clarity regarding user interactions, Use pattern, Flexible approach to using RehabChat, Clinician role, Client's wording for goals, User interface changes, Use with decreased clinician input, and Technical support.

Reminder to use: Both client and clinician feedback included comment on the need for a reminder system to prompt the client when to use RehabChat. Client feedback indicated this was needed due to forgetting to use RehabChat – '*I did wonder whether or not they shouldn't have some sort of remind ability to turn on and use 'cause I did, I reckon I chooffed off three times without turning it on' (C)*. However, there was also reticence for an alarm-type reminder system because that could be stress-inducing, and/or also reduce the client's sense of independence in choosing whether or not to use RehabChat – '*if you had a reminder that would then take independence away from you because she'd be relying on to even to remind you to do it and that's probably not a good idea. You've got to have some independence still, still got to be a choice, hasn't it?' (C).* A potential solution to this dichotomy, as suggested by a clinician, was to use whatever is the client's current preferred reminder system – *'people will be having their own external memory and organizational aids' (CNC)* – such as an online calendar system.

Integrating into clinic work processes: Clinician feedback highlighted it would be useful to regularly integrate RehabChat into usual work processes including staff '*orientation, written manuals [and] case / conference discussion' (CNC)* to help ensure that RehabChat '*remains present in the minds of the treating team' (CNC).* Similarly, it was recommended that team discussion could facilitate developing and maintaining '*a shared understanding of an agreed*

common approach to using RehabChat' (CNC) in clinical care. Additionally, clinician participants recommended that an additional style of goal setting should be added into RehabChat. This style should be based upon planning '*more subjective type goals' (CWC)* which could relate to cognitive training for aspirations including for communication skills, such as relating '*more to people; or did it give me confidence to talk to people, or something like that' (CWC)*, rather than being a SMART-styled goal.

Support cognitive framework: Dyad clinicians spoke about the benefit of RehabChat providing a supportive cognitive framework for clients to help address challenges of '*executive dysfunction. … [which] can also be described by the client and / or interpreted by the clinical team as 'low motivation' (CNC).* This supportive framework could appropriate '*metacognitive strategies into a functional context' (CNC).* Results of the client being cognitively supported in this way would include the client being able '*to monitor for their own fatigue or overload or anything like that, because … [there] could be a tendency for people to [otherwise] push through' (CWC); 'RehabChat is a really good tool for just prompting those thoughts and to get, keep someone on track with that evaluation cycle' (CWC).*

Support auditory processing needs: Clinician participants identified potential solutions for how RehabChat could possibly support a client with auditory process needs. These solutions included the clinician working alongside the client and RehabChat to '*assist the client directly over multiple sessions' (CNC)*, the content of RehabChat to '*provide examples … reword sentences sometimes, … [or provide] repetition' (CWC),* and the design of RehabChat to have *'text bubble of what avatar is saying … in-sync as she says it' (CNC)* rather than appearing after as occurs currently.

Content clarity regarding user interactions: Suggestions were made regarding additional content to be developed regarding the skills and knowledge needed by the user when interacting with RehabChat. The recommended extra information to be included: in case of a technical issue, to try turning RehabChat off then on again to resolve it – '*just turn it off and on again, and see if that works. So just a reminder to do something like that' (C)* – ; provide examples regarding how to write a free-text response, so as to improve smoothness in later dialogues which incorporate this entered text – *'things could have a bit more explanation in terms of the wording that needs to be used' (C)* –; and clarifying transition points of the conversation. For example, the transition of completing input for the two practice activities, and then being ready to commence performing the activities needed some '*definition, I guess, of where our discussion ended. The part where he was to go home and start it, and he, confused about where he, was he in the right place' (CWC).* As well, it was recommended, that brief explanation be given in the conversation about the single-choice click options that these should be clicked when the user has understood what the avatar has said, and that when the option was clicked, it causes the conversation to progress to the next step; and that through this, the user could control the pace of the conversation. A suggested cuing

idea for this was – '*can you click the box below if you understand and you're ready for me to keep going? Because then it's about helping people understand that they can control her pace' (CNC).* Finally, it was suggested that the structure of the dialogues and the style of the conversation should be somewhat predictable so as to support clients becoming independent in using RehabChat – '*I'm assuming that maybe down the track they could, you know, develop an ability to learn to use it themselves if there's predictability, I guess in some of the questions … being asked or, you know, the information provided, but I think maybe initially that [is] supported' (CWC).*

Use pattern: Feedback related to optimising client use of RehabChat, focused on RehabChat offering the practice activities to be completed on five out of seven days each week, as the current model of – '*seven days is an unnatural timeframe anyway' (CWC)* – and if a client was under-using RehabChat, then a trusted clinician should follow this up to find out why, for example because *'it's not actually working … [or] they're not really enjoying it' (CWC)*.

Flexible approach to using RehabChat: Clinician feedback included ideas for improving flexibility in the ways in which RehabChat could be used in the clinical setting. These included being able to use RehabChat for as long or short as relevant – '*We try stuff in rehab and if it looks bad it quickly gets side swiped' (CWC)* –; and to initiate use of RehabChat in a more immediate response to the apparent need for it being emerging in a client's care – '*You know, where these things that just emerge in a conversation, you want to be able to move with that traction' (CWC)*. For example, a clinician may make the decision to initiate using RehabChat during a particular appointment, and then commence using it a bit later in the same appointment – *'if I had it as a tool just next to me like I said, do you want try this?, it could work it might not' (CNC)*. As well, it was recommended that RehabChat be a tool which, when a clinician went on leave, that it could be handed over like any other clinical intervention – '*to another clinician to oversee the use of it whilst the primary clinician was on leave' (CWC)*.

Clinician role: It was felt that the weekly review appointments with the clinician and client using RehabChat should be conducted in-person if possible '*to make sure you know that they're using the iPad correctly' (CWC)*, but in fact could (and were in this project) conducted via tele-conferencing if required. It was also recommended that it would be the clinician's responsibility to monitor for the client's acceptance with and comfort whilst using RehabChat – *'because a tool that can be well set up to start with, … can over time become less easy to use, because of changes in one's life situation, or a crisis occurs' (CWC).*

Client's wording for goals: Feedback indicated that the client's own words should be used for wording for the goals – '*I think especially if people's goals can be the words that they've got you don't try to didn't make them change that too much' (CNC);' 'cause if it ends up being like watered down, they'll lose their sense of that fits my personal values and then they'll lose their motivation*

for it, I'm making a goal for the sake of it' (CNC). As well, there was a recommendation for the client to be able to enter in their goal using a greater number of words to allow them to express the meaningfulness of it for them; but then for the purposes of the ECA using this goal as a variable later in the conversation dialogues, the client would also be required to enter in a shortened version of their goal and for this the ECA to ask something like – '*Later on, when we're recapping how you're going, is there a short way I can talk about it?' (CNC)*.

User interface changes:

It was recommended that the RehabChat user interface needed to have '*more space to write more text in the free-text fields, because as at times there was not enough space' (CWC)*. Recommendations for improving scrolling included for the avatar to read again the dialogue at the point to where the user had scrolled; and to visually highlight key points of the conversation content so that, when scrolling, these would be easier to find, because currently '*the text bubble content is all in same font, and so the key points do not visually stand out' (CWC).*

Use with decreased clinician input: RehabChat was recommended for use during times of decreased clinician input, such as when the client is transitioning to independence '*from a formal rehab program into the person developing their own skills' (CWC)*; particularly as it helps to reduce the required input from clinicians – '*It's a good interim step, I guess, between a real person and … the avatar prompting you, which I guess is a good step down from us and reliance on us, so I see it as a good transitional tool' (CWC*). Client feedback also included that they could '*definitely see' (C)* RehabChat being a tool that could be used on discharge.

Technical support: As well, it was recommended that a research staff person be available by phone to help during a client-clinician-RehabChat appointment if/as needed– '*just phone support would be enough I think' (CWC)*. As well, it was recommended that iPads with RehabChat loaded onto them, should be more freely available for clinicians to use at any time: to have – '*a few around the place that are easily grabbabl'e (CNC)* – so as to expediate being able to respond at any time to a client's need – '*because a conversation, you might not have it on your agenda at all' (CNC).*

6.5.8 Formal description of RehabChat

A formal description of RehabChat reported according to recommendations from the Scoping Review (see Section 2.7.1 and Appendix II) is provided below. It describes the final design of RehabChat developed following user testing and the resolution of technical issues encountered in the feasibility pilot trial, as well as summary details of the type of testing conducted for it. The fourth section of the reporting criteria concerned with Natural Language Processing (NLP) is not used because RehabChat does not employ NLP. Another Living Laboratory project for the design of

stroke rehabilitation facilities (182, 183) similarly used a systematic review (243) to help inform the approach for their project.

The RehabChat ECA is simple – it used constrained language, input via text and click buttons, a directed conversation with iterative review and repeated content for practicing exercise. Nonetheless feedback from project participants has confirmed initially that it meets clinical needs both for the clients, and also for the clinical setting.

6.5.8.1 Evidence source details

Country: Australia

Context: Two state-wide two ambulatory care brain injury rehabilitation services, and clients' homes

Participants: Clinicians from two ambulatory care brain injury rehabilitation services providing care for adults with TBI

Recruitment process: Clinicians were invited to participate through project promotion activities; clinicians screened potential clients for eligibility; eligible clients were invited to consider participating in project. De-identified CONSORT data collected for screening and recruitment process. Researcher contacted regarding interested participants. Formal information and consent form provided to interested participants (see Appendices XV and XVI), and formal consent process completed for recruitment. Full ethics approval obtained from health service ethics committee.
Research methodology: Prototype description and development. Co-design of ECA using Living Laboratory approach.

Type of research activity reported: In-house prototype development, alpha and beta testing, co-design workshops, mixed methods feasibility pilot study

6.5.8.2 Research design and health rationale

Type of intervention – Rehabilitation purpose for ECA: Support client -centred goal-setting and pursuit, using a motivational approach

Type of intervention – Mode of use: Two ECA modules developed: training module; and rehabilitation module. Initial user training using a training module (content based on travel and transport) to learn the required skills for using RehabChat – user must achieve being an independent user prior to using ECA in clinical setting. Rehabilitation module used alongside usual care, with clinician oversight.

Content of conversation: Client-centred goal-setting (using the SMART approach) and pursuit, prescribed practice activities, weekly progress reviews. Conversation nuanced with elements from Motivational Interviewing (MI) and Self-Determination Theory (SDT).

Content development: Base on recognised approach of client-centred goal setting (using SMART approach). Conversation content iteratively refined in consultation with client and clinician participants

Outcomes measured: In alpha and beta testing: - researcher-developed questionnaires. In co-design workshops: semi-structured group interviews. In feasibility pilot trial: Likert scale outcomes – Pre-Post measures - MOT-Q, BMQ-S, BMQ-R, RTES; Repeated measures – HADS and four researcher-developed screening questions; Post measures – SUS, and semi-structured 1:1 interviews

Results: Of pilot trial: very good usability; easy to understand; able to be integrated alongside usual care; multiple recommendations for further refinement of RehabChat to improve its breath of application

Safety: No adverse events overall. Safety feedback identified in feasibility pilot trial: potential risks -confidentiality breach; client feeling overwhelmed; client over-working in their rehabilitation; potentially stressful - increased client stress if the rehab goal set was too difficult to achieve; mild frustration when (resolvable) technical issues occurred

Use barriers: Identified in feasibility pilot trial: barriers to use - the research structure imposed numerous requirements, client already having other technology tools to manage, client has financial limitations, client experiences unexpected life stressors; clinical needs - decreased memory and may forget to use ECA, fatigue, feeling overwhelmed

Use facilitators: Identified in feasibility pilot trial: ECA has very good usability; ECA is easy to understand; mode of use alongside usual care is well-organised, requires minimal technical support by supervising clinician, integrates well into usual care because it can incorporate a goal already being considered in rehabilitation care, and it provides cues for client which are similar in style to clinician’s cues

6.5.8.3 Technology description

Task-orientated: Yes

Hardware: iPad used by clients; iPad or PC used by clinicians

Software: Clevertar Virtual Human software platform; Google Chrome web browser

Dialogue management: Finite

Dialogue initiative: Mixed: system asks for required information; - user input determines the direction of the conversation e.g., which section is used (enter details for practice activities, progress review etc.)
Input modality: Text; click button responses

Output modality: Speech, text, visuals: embodied humanoid character, text bubbles

Appearance: User interface (UI) has two sections divided longitudinally: LHS (one-third of UI) displays the animated avatar: female, long dark hair; speaks with Australian accent; RHS (two-thirds of UI) displays text boxes of conversation dialogues; in lower fifth of section, has section for freeform text entry. Upper right corner has minimise button. Lower left corner has mute button.

6.6 Discussion

This mixed methods feasibility pilot trial successfully implemented a two-week trial of a novel ECA alongside ambulatory care brain injury rehabilitation in a real-life clinical setting. This is the first time that an ECA has been trialled in this context. Client goals and practice activities could be adequately inputted to RehabChat, enabling the client to complete their required practice activities between appointment-based reviews with their supervising clinician. The ECA performed well on the iPad, with participants reporting RehabChat had very good usability as evidenced by the SUS scores. Feedback also indicated that the model for using RehabChat alongside usual care and with clinical supervision worked well. Despite the short two-week duration of the trial – noting that RehabChat is intended to eventually be used for six weeks in order to achieve clinical benefit – the results of this feasibility study provide a solid basis for pursuing future research for refining the design of RehabChat and its intended mode of use.

Recruitment although small (n=6, comprising 3 sub-cohorts: 2 clients, 2 dyad clinicians, and 2 clinicians with no client) showed good representation of varied clinicians' professions (SP, OT and ET), and an equal proportion of participants who had participated in the earlier co-design workshops (n=1 for each sub-cohort). This diversity importantly added to the heterogeneity of perspectives.

Assessment completion rates were excellent, with all quantitative assessments and qualitative interviews completed. Breadth of perspective was gained through interviewing both the primary end-users (clients) and secondary end-users (clinicians). This enabled collection of considerable qualitative content which gave some indication of RehabChat's usability, and has informed ideation for the next stages of development for RehabChat.

The choice to use the short conversation style by all participants could be due to factors identified in a comparable study investigating a web-based MI intervention for supporting physical activity (246). In that study participants showed decreased engagement in clicking through the whole of a web-based MI session; the authors discussed that this could have been because the MI-style was seen as too lengthy (246). Similarly, participants in this project may not have wanted to use the longer conversation due to concern that it could cause fatigue.

The number of recruited participants was lower than was planned, despite recruitment being conducted over a six-month period. Challenges with recruitment were possibly due to a few reasons. These included firstly that anticipated involvement from another clinic (for mild TBI clients), which participated in the earlier co-design workshops, was unable to occur due to service restructuring. As well, the participating clinic settings underwent a major service accreditation review during the pilot trial which impacted on clinician's' time and availability. In regard to the low number of clients recruited, and the relatively high proportion of screened clients that were

identified as ineligible, it was notable that some clients were excluded due to reasons apart from the formal inclusion-exclusion criteria, such as due to having other stressors occurring for them. This is an important consideration for brain injury rehabilitation research. Previous research has reported challenges with recruiting clients with brain injury: including for with TBI (247) including mild TBI (248), and also for stroke (249). Notably, sample sizes for studies conducting initial testing of a conversational robot for dementia had only three participants (250), and CAs used for brain injury, disease or stroke had sample sizes ranging from 1 – 33 participants (see Section 2.5.2). In contrast, a sufficient number of clinician participants were recruited (n=4) as per the advice of the Nielsen-Norman group for the recommended sample size of a sub-cohort being 3-4 (see Section 6.4.4.2).

This study demonstrated the benefit of testing in the real life setting of obtaining candid insights on safety, tolerance, exclusion criteria, clinician role, and stress factors. But it is because of these negative impact factors, that having a small sample size was so important – i.e. a larger sample size may have increased the likelihood of even a mild adverse event. Two areas of feedback regarding Barriers to using RehabChat and Recommendations for further development of RehabChat were somewhat complementary, with the latter providing solutions to some of the former. It is anticipated that unaddressed barriers could however be addressed with further end-user consultation in future research.

Addressing technical issues in the early part of the trial and making subsequent changes to RehabChat (being unable to directly change a previously entered response, having a single design for the avatar, and not leaving the Training module in place on the iPad), did not result in negative feedback from participants about these changes. Future research for RehabChat will require thorough and repeated rounds of alpha testing following each stage of development and close collaboration with the software company to resolve issues promptly. It has been previously reported that technological issues and difficulty integrating the technology into the clinical setting were barriers to use identified by client and staff participants for a feasibility and acceptability RCT for use of a web portal to support exercise care (229). Accordingly, future research for RehabChat should continue to provide prompt follow-up for any technological issues experienced. As well, the research design should build in strategies to manage participant involvement in the project if a technical issue arises during the trial, such as having access to back-up iPads, the software being able to behave for a particular client across devices (for the current project this was not possible); and providing pre-emptive education about these strategies.

6.6.1 Discussion of qualitative findings

The qualitative feedback from the three cohorts from the feasibility pilot trial represented the varied and nuanced clinical needs of clients at the brain injury rehabilitation service, and also indicated

how to integrate these needs into the design of RehabChat and its intended mode of use. Regarding the latter, feedback considered how clinician oversight should be provided, and the need for clinical team discussions for determining agreed approaches for using RehabChat in the clinic. These points of feedback provide the basis for a potentially successful translational approach in future development.

Participant feedback specifically about the ECA provided some clear indications that RehabChat's UI was easy to use, its actual conversation content was pitched at the right level of complexity and duration, and that it matched usual care well. These findings concur with the results of the co-design workshops (see Chapter 5) and user testing (see Section 6.5.2). These findings also align with design recommendations for behaviour change CAs , that it should prioritise appraising user experience in regard to usability and also users' preferences of content and conversational style (111).

Interestingly, all participants chose the shorter conversation and were satisfied with this option. One feedback point recommended that the conversation should include prompting the client to nominate a support person. This topic is in fact included in the longer conversation and can be easily transferred to the shorter one. Given that all participants chose the shorter conversation, it is likely that future research will only employ a modified, improved version of the shorter conversation.

Some feedback reported concerns about future use of RehabChat in regard to client wellbeing (risk of overwhelm in clients with increased stress) and confidentiality (potential for the content entered into RehabChat to inadvertently reveal confidential data). These valid concerns require further consideration and discussion with future research participants. However, for the current project, these concerns were managed through having attentive clinician oversight by the supervising therapist. Future use of RehabChat in a larger trial will require that clinical oversight is provided in a consistent manner by all clinicians, irrespective of their experience or area of specialty. A potential solution for enabling this was included in feedback for Recommendations – and suggests that the broader clinical team would need to discuss RehabChat use and purposes in team meeting settings. This indicates the importance of considering the broader clinical service context for implementing RehabChat.

The overall feedback demonstrates the evolving ethos of RehabChat being a purpose-designed ECA for brain injury rehabilitation and having a specific intended mode of use developed for it. The stepwise approach taken though alpha and beta testing and then the co-design workshops and second alpha testing were indeed successful in developing a relevant prototype ECA embedded within an acceptable and clinically appropriate mode of use. Feedback from the pilot trial indicated

that the mode of use developed was appropriate as is, but that from hereon it could be developed further to optimise integration and sustained usage in the clinical setting of RehabChat.

Feedback also included recommending that a more a flexible approach be applied for how often RehabChat was used each week. It was suggested that it could be for just five days per week. Additionally, feedback also included the suggestion that a clinician could instigate using RehabChat at any time during a client's care. Participants also highlighted that there could be a need for the clinician to provide extra face-to-face support for a client using RehabChat, in order to support specific client needs. This extra clinician-provided support could include helping the client develop improved self-evaluation skills if they had decreased self-perception of their own needs; coaching the client in the style and usage of RehabChat particularly if the client had auditory processing difficulties or relied more heavily on lip-reading; and providing any required support for clients with limited experience in using technology devices. Additionally, the clinician should regularly check with the client if they had difficulties using RehabChat, as their comfort and confidence in using it could decrease if other life stressors increased. As well, at any juncture in which the client was experiencing stress from using RehabChat, the clinician needed to have flexibility to immediately cease use of it with their client. This approach would reflect usual care in which therapy interventions are introduced at times which match the current and emerging needs of the client.

Importance was placed upon using the client's own wording for the goals and if needed, to allow a client to enter in a long-worded answer, which could then be truncated by the client. Related to this was the suggestion that the user interface should allow for longer text entry, to accommodate clients who benefit from clearly explaining their goals prior to developing a shorter version. Two recommendations were made regarding the scrolling function: firstly, for the avatar to read aloud any prior dialogue that the user indicated they needed to hear again; and secondly that key data in the conversation such as goals or practice activities be visually highlighted to enable easier spotting when scrolling through. The current software did not allow for these functionalities.

Feedback included suggestions for additional ways that RehabChat could be used. These included providing support for clients who were receiving reduced contact with their clinician such as during a therapy break. RehabChat was seen to be a potentially useful tool for promoting weaning from clinician-directed care and for promoting self-management as a basis for ongoing self-directed recovery following discharge. This idea was complementary to another suggestion of RehabChat facilitating choice of a support person who would facilitate self-evaluation styled thinking, and thus extending the client's support apart for clinician input. Feedback also indicated that RehabChat could be used for other cohorts due to its transferable relevance of supporting goal-setting and pursuit. Similarly, it was thought that including additional content in RehabChat which enabled setting of cognitive goals and/or practice of a self-evaluation framework would be beneficial to

helping a wider range of client needs. Finally, the broader context of the clinic team environment was also considered. In regard to the need for a common understanding of how to optimally integrate RehabChat into care, it was identified that this be discussed amongst and adopted by the team's clinicians.

6.6.2 Consideration of the single case design research model

Using the SCD research model suited this feasibility pilot trial due to the challenges in recruitment for this cohort, and as such it is anticipated to be used in any subsequent trial of RehabChat. It has been reported that SCD can be used for effectiveness trials with sample sizes of three or less (251). For the current feasibility pilot trial, the SCD research model using the withdrawal/reversal design of A-B-A (219) was used. Moving from one phase to the next in a SCD can be based on the steady state strategy so as to minimise 'noise' and be able to better determine change in the outcome of interest (252). However, it has been previously noted that steady state can be difficult to achieve in rehabilitation population and therefore it has been recommended that use of the SCD in rehabilitation studies does not needs to achieve a stable state in the baseline 'A' phase due to this inherent variability (251). For the purposes of the current feasibility pilot trial, the A-B-A repeated measures testing was implemented as a way to monitor client wellbeing, to test the feasibility of conducting repeated measures, and to minimise the burden for client participants. These aspirations were achieved, as indicated by participant feedback stating that the manner in which the project was conducted was suitable, that sufficient support was provided, and that using RehabChat did not increase stress. This provides a basis for future research development of RehabChat to include longer duration A phases, for thoroughly appraising variability in the recruited participants, both between each participant, and possibly also within the results for each participant in respect that a steady state may not be reached in the initial A phase of testing.

The SCD model incorporates the ability to assess for mean and standard deviation (SD) of repeated measures data across the 'A' and 'B' phases if the repeated measures utilise continuous outcome data (223). This has been done in research with small sample sizes of n=10 for appraising the feasibility of using visual feedback in stroke rehabilitation (174), and of n=12 for appraising the effectiveness of novel strengthening exercises in TBI rehabilitation (253), and for n=5 childhood TBI research (254). In the current project, ordinal data repeated measures were used and so could not be assessed for mean and SD. These ordinal measures were chosen because they focused on screening for negative effects on wellbeing – such as anxiety and depression – that may have occurred for the clients during the trial. Additionally, the measures were able to map variably at baseline, and were non-burdensome for the client to complete. These factors relating to meeting client needs were prioritised for safety and wellbeing reasons, and also because in this feasibility study the intervention duration was not deemed long enough to produce a meaningful clinical effect. As such, there was not a need to prioritise assessing the mean and SD

of results. Future research for RehabChat should however seek to utilise continuous data repeated measures which similarly meet important clinical needs, and which would enable summary statistical analysis of significance between the A-B-A phases.

6.6.3 Addressing the project's aims

The five research aims for this project were all addressed. Below is a summary of how each aim was addressed.

Aim 1: Assess functionality and performance, and make necessary changes to ECA

This was achieved well by conducting user testing with three clinician participants, from which with a number of very salient feedback points were received. Indeed this phase of testing resulted in small but important changes to the whole of RehabChat's presentation – in particular, shortening the dialogue length and placing some content as placeholder text content directly above the text box where the client would type their response. This decreased the amount of listening and eye-tracking required by the client, and focused their attention more specifically upon what they would write in the text box.

Aim 2: Assess usability and acceptability

The qualitative interview results were used to appraise the usability and acceptability in the clinic setting. All participants indicated their acceptance of RehabChat for clinical use, and also that it was easy to use RehabChat including, for clinicians, providing supervision of a client using it. This feedback was particularly evident in the considerable number of factors identified by participants as functioning well, and also in the way in which suggested recommendations matched to some of the identified barriers and concerns. Additionally, the SUS scores quantitatively indicated RehabChat's usability. Three of the scores indicated above average usability, and one client's score indicated slightly below average usability. This latter score may have been influenced by this client experiencing multiple technical setbacks with RehabChat prior to subsequently experiencing a smooth-running two-week period using RehabChat. In summary, RehabChat in its current state was appraised as being usable and acceptable for use in the clinic setting.

Aim 3: Appraise client motivation and wellbeing and monitor for any negative impact from using RehabChat

It should be noted that quantitative measures were conducted to test their feasibility and acceptability, and they were not expected to reveal significant results due to the short nature of the intervention (see Section 6.4.1.1).

Client motivation was measured using mixed methods: quantitatively with pre-post measures; and qualitatively through the 1:1 interviews. Client qualitative feedback indicated that RehabChat supported motivation, and that well-being was improved somewhat with using RehabChat due to RehabChat reinforced a structure for completing prescribed tasks designed for achieving their goals. Additional aspects related to well-being included that RehabChat offered a sense of personal connection and company, allowed the client to provide candid answers, and enabled the client to make well-thought through decisions (along with consultation with their clinician).

Client motivation, wellbeing and depression and anxiety were quantitively assessed. Scores for these showed quite consistent results (no significance testing conducted) for pre-post measures, and for the repeated measures, both for the client with scores indicating higher overall negative affect, and for the other client with minimal negative effect. Due to the short duration of this study, these quantitative results do not definitely prove that RehabChat does not have either a positive or negative impact on the client. However, because they showed reasonably consistent results, and the qualitative feedback indicated that the use of RehabChat was positive for all participants, it can be suggested that there are no negative sequelae precluding further development and trial of RehabChat in the clinical setting. No adverse events occurred during the study, and so similarly it appears safe to pursue further research for RehabChat.

Participants described that motivation was well supported by RehabChat. Clients reported that using RehabChat helped them to remain more focussed on their goals and practice activities, and to have improved wellbeing. Clinicians gave perspectives about RehabChat being able to support goal pursuit for the client by providing a cognitive framework, thus allowing for improved focus on and achievement of goals; and that this in turn could help the client to feel more motivated.

The participants indicated that they coped with the disruption of mildly frustrating technical difficulties and were not stressed by them. However, this feedback was in the context of a short pilot trial of two weeks, and both clients had prior technical knowledge either generally, or of RehabChat. For a new client participant with no technical knowledge nor prior experience of using RehabChat, and/or in a future longer trial, technical issues could be a cause of stress and would need to be adequately monitored for and managed.

An identified barrier to use was if the client experienced any unexpected life stressors which may cause them to de-prioritise RehabChat due to having more pressing issues. A way to mitigate this risk for disengagement was indirectly recommended in participant feedback: that staff should regularly check in with the client using RehabChat to ensure that the way it was set-up remained suitable for them.

Aim 4: Feasibility of using RehabChat in clinic setting

The feasibility of using RehabChat in the clinic context was able to be determined by appraising both the qualitative feedback and quantitative results. Numerous points of qualitative feedback indicated that RehabChat was, and would be, feasible to use in the clinic setting. These included that the software was easy to use and was easily integrated alongside usual care. Using RehabChat on the familiar clinic iPads was found to facilitate usability of RehabChat. It also ensured that the usual back-up technical support was available for the users. Other points of feasibility were in regard to matching usual rehabilitation care well, for example in regard to seamlessly conveying current rehabilitation goals into the RehabChat conversation. The recommendation to diversify the style of goal-setting available on RehabChat to include options for faster turnover of step-wise goals for cognitive and psycho-social purposes, such as social skills, would be possible and appropriate to integrate within the conversation capabilities of RehabChat. This additional goal-setting structure should focus on the client achieving distinct steps or tasks, rather than a weekly program of repeated practice activities. Nonetheless, clinicians indicated that cognitive goal-setting was still possible during the two-week intervention with the available SMART-styled goal-setting and goal-pursuit format

Feedback also indicted that RehabChat's feasibility could extend to supporting situations where there is decreased in-person clinician contact with the client, including during therapy breaks, during times of increased Covid-related restrictions, or even to support the discharge process.. This indicates a potential need for a tool such as RehabChat for supporting rehabilitation care and supporting the client's transition to independence with self-evaluation skills. Importantly too, no safety issues were experienced, albeit a few suggestions for how to prevent safety issues were expressed (see Section 6.6). Finally, regarding the recommendations for improving RehabChat, these all appear to all be feasible to achieve, albeit requiring further consultation with clients and clinicians and the software company Clevertar.

The quantitative results concurred with the qualitative findings, in that high SUS scores, and minimal variability in repeated measures data indicated very good usability and no indication of increased stress from using RehabChat, respectively. As well, the results for the pre-post measures were overall equivocal. Again, this indicates that participant wellbeing did not deteriorate during the intervention. Additionally, it was not expected that these scores would improve, as the two-week intervention was much shorter than the intended six-week duration of use intended for RehabChat in a full trial.

In regard to practical aspects of feasibility, RehabChat was able to be integrated into some of the current technological frameworks used by the rehabilitation settings: the ECA was uploaded for use on clinic iPads, and design updates were able to be remotely configured to it. As well, a simplified electronic case note entry was prepared for the clinician participants to include in the client's electronic medical record.

Aim 5: Identify areas of RehabChat requiring modification to improve feasibility

Numerous recommendations for areas of RehabChat requiring modification to improve its feasibility were identified from the feedback from the semi-structured 1:1 interviews. Recommendations for improvements related to the intended mode of use of RehabChat, as well as to barriers to, or concerns about, using RehabChat in the clinic context. Key recommendations included needing to further clarify the clinician's role regarding their need to monitor how easy RehabChat was for the client to use, to ensure confidentiality and achievable-ness of content entered into RehabChat, and, within a professional team context, to clarify optimal ways of integrating RehabChat within usual clinical care. Key factors needing to be changed in RehabChat's content included explaining that a user should click on a choice response only when they had understood what RehabChat was conveying, as clicking the response would automate progression of the conversation. Also, brief prompts are required for solving technical issues if they arose, by turning RehabChat off then on again. As well, examples illustrating how clients should structure their free text answers, so as to optimise how smoothly this content is used in subsequent dialogues, should be provided.

A further recommendation related to the mode of implementation of RehabChat alongside usual care. It was suggested that the client-clinician dyad would be able to commence the ECA conversation at any point, to best match the client's needs as they present in a clinic appointment. This, as well as the recommendation to have increased access to iPads in the clinic setting, would directly increase the ability of clinicians to use RehabChat in a responsive manner rather than needing to adhere to a pre-determined structure of a more traditional research trial. Such a responsive model for clinical integration would potentially enable more dyad pairs to participate, particularly with clients who may have increased risk of stress or feeling overwhelmed. Nonetheless, the two-week structure employed in the current study was well tolerated, and indeed participants expressed that they would have been happy to continue using RehabChat if given the opportunity.

Participant feedback regarding support provided for the participants included recommendations that the researcher should be available to provide backup phone support during client-clinician-RehabChat appointment times, and that there should be freedom for the client to cease using RehabChat early if their needs necessitated this. Both of these recommendations were already integrated into the feasibility pilot trial and were explained during the recruitment process and reiterated in the early parts of the trial. As such, this feedback could suggest that the overarching premise for this study having a two-week trial of RehabChat dominated the perceptions of participants. Accordingly, it could be worthwhile in future research to explicitly state that any amount of time using RehabChat up to a meaningful maximum total time of six weeks was permitted, and that the researcher could be booked in as a back-up phone support particularly for

the first client-clinician-RehabChat appointment, rather than offering these as spoken but unwritten options.

6.7 Conclusion

This is the first time an ECA feasibility pilot trial has been conducted to consider the needs and perspectives of both clients with TBI and clinicians. It is this broad perspective that has enabled a thorough appraisal of usability and feasibility of RehabChat being used alongside usual ambulatory rehabilitation care, clearly identifying both the aspects that are already functioning well, and factors that need further development.

This study well situates the planning for RehabChat to have further refinement and improvement, through providing broad indications for aspects of RehabChat needing development, opportunities for expanded options for who it can be implemented, and clearly identifying which aspects of RehabChat are currently performing well. Difficulties with recruitment can be managed by utilising a SCD with continuous data repeated measures. Close attention to safety, confidentiality and ongoing client comfort whilst using RehabChat is essential during any further research developments, as these factors are necessary to clinical acceptability and for promoting uptake.

Future research should include iterative co-design with clients and clinicians, along with close collaboration with the software developer, to ensure that software's capabilities are utilised optimally. Given the positive feedback received during this study, there appears to be potential that RehabChat, with further development, could effectively augment usual rehabilitation care for adults with TBI.

7 Overall discussion, future directions, and final conclusion

This PhD has successfully developed a motivational embodied conversational agent (ECA) to support goal-setting and pursuit for brain injury rehabilitation, highlighting this PhD's original, and meaningful contribution to knowledge.

This chapter will provide an overview of the main achievements of this PhD project, and proposed approaches for future research development of RehabChat. The aims and objectives for this PhD will be addressed, and final conclusions will be presented.

7.1 Overview

To start, this PhD defined traumatic brain injury (TBI), and the particular needs of clients with TBI. The needs identified were physical challenges, memory difficulties, cognitive disabilities, and low motivation. A particular focus on motivation, and how it impacts upon a client's rehabilitation was described.

The physiological basis of recovery following TBI was presented – this being neurogenesis. The process of neurogenesis refers to the ability of the brain to form new neuronal connections throughout the lifespan. It is this ability of the brain to change in response to experiences and training that enables recovery to occur following TBI. Brain injury rehabilitation as the model for optimising recovery was presented. Key aspects of it were highlighted: it being provided by a multidisciplinary team environment; that the client is the central focus of care planning and delivery; and that usual rehabilitation care is a time-limited service.

For rehabilitation, the gold standard approach of client-centred goal-setting using the SMART (17) framework was highlighted. To achieve outcomes in rehabilitation, a client needs to perform consistently with completing prescribed practice activities which relate directly to their rehabilitation goals. To enhance success, clients should feel motivated and engaged with the therapy process and the goals which have been set. Motivational support during rehabilitation for these clients is important to help optimize engagement in therapy.

The conundrum of brain injury rehabilitation being time-limited despite ongoing recovery being possible was discussed. It was also identified as an opportunity for which the development of novel therapies and approaches to care was warranted. It was emphasised that any novel therapy approach developed would need to align with client-centred goal-setting and pursuit, be able to integrate successfully into usual care practices.

Conversational agent (CA) technology was identified as a potential tool to use for creating a novel approach for supporting brain injury rehabilitation for adults with TBI. Conversational agent

technology provides conversation-based human-computer interactions. Often the CA can be configured onto a portable device such as an iPad. By default, this means that the CA is highly accessible and non-fatigable. It is these aspects that were identified as potentially providing a means for leveraging usual rehabilitation care. It was also hypothesized that by thus leveraging care, there would be benefit for clients with TBI through receiving more therapeutic input, which in turn may enable better rehabilitation outcomes.

Positive motivational behaviour change paradigms relevant to both brain injury rehabilitation and CA development were presented. These were specifically Self-Determination Theory (SDT) and Motivational Interviewing (MI). Both paradigms were explained in regard to how they could be applied to brain injury rehabilitation. The concordance between the theoretical paradigms in this project provided a cohesive base for the development of the CA.

From there, the research aims and objectives for this project were determined; these will be directly addressed later this chapter (see Section 7.3). Following on from the research aims, this PhD project progressed through distinct phases of ideation and development of the CA, and identification of relevant theoretical approaches to use for its development. As well, the overarching methodology for this PhD was chosen, which was the Living Laboratory methodology (Living Lab). Living Lab provided a comprehensive framework approach which included five main tenets: engaging end-users; using multiple methodologies; undertaking authentic co-creation; consulting with multiple stakeholders; and testing in the real-life setting. All of these tenets were incorporated into this PhD and helped ensure its success.

The conversational content for RehabChat was carefully considered so as to align with usual rehabilitation care, and to include client centred goal setting incorporating the SMART framework. Additionally, the focus was on providing motivational support for clients whilst they pursued their rehabilitation goals, which was achieved by nuancing the ECA conversation with SDT and MI principles.

The phases for the development of the CA – called RehabChat – included early prototype design and in-house testing, co-design workshops, and a final feasibility pilot trial in the real-life clinic setting. Additionally, a scoping review investigating the use of CA technology in rehabilitation for brain injury, disease and stroke was undertaken to better inform how to approach developing and testing the novel tool for this PhD. Results of the scoping review revealed that research in this area is at an early stage. Most included papers reported description of the prototype and early user testing. In particular, the review found that there was an apparent lack of detail reported regarding clinical validation of the conversational content, appraisal of barriers and facilitators, and of safety aspects regarding utilizing the CA with a clinical cohort. Additionally, there was inconsistency in how each CA prototype was described in the papers. All of these factors were discussed in the

scoping review chapter (Chapter 3), and a model for standardised reporting of CAs was proposed. This reporting model was subsequently used for describing the final version of RehabChat developed for the two-week intervention in the feasibility pilot trial (see Section 6.5.4).

In-house development and testing of RehabChat incorporated the design of an initial prototype embodied conversational agent (ECA), followed by alpha and beta testing. It was decided that having a human-like avatar in the CA would improve client engagement with the tool which in turn would support engagement with the content of the conversation in the CA. The ECA software used was the Virtual Human platform by Clevertar Pty Ltd (175) (Clevertar).

The initial ECA prototype was designed to include a basic goal-setting conversation. This was tested in-house using an alpha testing approach, which focused on identifying technical glitches and gathering initial feedback on general usability. Feedback from alpha testing identified several technical issues in the ECA that were subsequently resolved. Beta testing of the ECA was then conducted, in which a larger sample of in-house participants were recruited and who provided feedback on RehabChat regarding user experience, usability, and conversation content, with consideration of the intended use setting of brain injury rehabilitation. Feedback for beta testing was comprehensive and provided the basis for clarifying the rehabilitation goal setting content for the ECA, developing a separate ECA training module, and clarifying the role of the supervising clinician for the client using the ECA. Through this process, Rehab Chat was developed to be more than just an ECA; to also incorporate a mode of intended use within the intended multi-disciplinary rehabilitation context. It is this version of RehabChat that was implemented for the co-design workshops.

The co-design workshops were styled specifically to meet the clinical needs of client participants. Consideration of these needs meant that each participant received pre-workshop training in how to use RehabChat and Zoom (208). As well, during the four workshop rounds, participants were given enough time to practice using RehabChat, to think through their responses, and to provide feedback. All feedback was treated equally from the three cohorts – discharged clients, current clients, and clinician participants. Given the inherent power differences between clients and clinicians, as well as different perspectives between the three cohorts, separate meetings were held for individual cohorts for the first three rounds of workshops. In the final fourth workshop, all participants were together to enable a synthesized approach for gathering feedback. Participant feedback from all workshop meetings included many design recommendations for changes needing to be made to RehabChat. All of the change recommendations were addressed: important updates were made to the design of the user interface, the content of the conversation and the mode of implementation of RehabChat in the clinical setting. The final stable model of RehabChat arising from the workshops was subsequently tested in a second round of alpha testing. This later

stage of testing identified numerous technical glitches, all of which were addressed. This refined version of RehabChat was used in the feasibility pilot trial.

The feasibility pilot trial enabled RehabChat to firstly be user tested by three clinicians. Feedback from this helped to define how the ECA dialogues were to be further pruned, and the need to have extra reiteration of conversation content so as to help the client-user follow the conversation flow more easily. These changes were completed prior to clients using RehabChat for the planned two-week intervention. All participants in the pilot trial received initial 1:1 training using RehabChat to ensure that when the two-week intervention commenced that there would not be interruptions due to participant inexperience or their lack of ability to use the tool. Two clinician-client dyads were recruited as well as two clinicians for whom no clients could be recruited. Quantitative results for the pilot trial indicated that client well-being did not deteriorate during the trial, and that the usability of RehabChat was very good. Qualitative feedback indicated that RehabChat matched the usual rehabilitation care setting well, due to it incorporating known goal-setting frameworks, and that it was easy to use. Numerous suggestions for areas of RehabChat needing further development were also expressed by the participants. These included reference to RehabChat's ability to support clients with auditory processing difficulties, and the need to ensure it did not contribute to a client feeling cognitively overwhelmed. Some safety concerns were identified concerning participant stress, and a small risk of confidentiality breach, with solutions also identified for both issues: of refining the conversation content, and clarifying the clinician's role in supervising the client's use of RehabChat, respectively. Feedback was also received regarding potential future uses of RehabChat. These included that it could be used alongside usual care, as modelled during the pilot trial, and also for other phases of the client's rehabilitation journey during which there was minimal or no clinician support. Such times included when the client had a structured therapy break during which they would not have their usual contact with their clinicians. For such times, it was felt that RehabChat could facilitate ongoing cognitive framing support for clients to continue their goal pursuit practice activities whilst having reduced clinician input. Another time suggested for when RehabChat could be used was on discharge. Once again, the perceived benefit of using RehabChat for this phase of the client's journey was around supporting the client's ability to focus on set goals and goal pursuit activities. This benefit of using RehabChat also aligned with the clinicians' priority to not only help a client rehabilitate specific aspects of their clinical needs but also to help the client learn how to set goals and pursue them, as this was a skill that could become part of their lives following finishing their structured rehabilitation clinic care.

7.2 Findings about motivation from co-design workshops and feasibility pilot trial compared

Findings about motivation identified from the co-design workshop and from the feasibility pilot trial focused on related but separate areas, based on feedback from both client and clinician participants.

For the co-design workshops, the focus was on the client's lived experience of motivation during rehabilitation. Feedback for this focused on what helped or hindered motivation during rehabilitation, and related aspects of finding meaningful activities to do when usual roles (e.g. providing for family, work) and opportunities (e.g. driving) were taken away at least for a while. The importance of client-centred goal-setting for facilitating achievement of meaningful rehabilitation goals was discussed, and the overall positive impact of having a supportive family, and consistent support from therapist input, was highlighted. The discussion also briefly explored intrinsic aspects of motivation, with this being seen as arising from within a client even when there was negligible external social support, and as aligning to the priorities of the client such as family connectedness, and choosing rehabilitation goals which were both achievable, and realistic.

In contrast, in the feasibility pilot trial feedback on motivation focused the client's experience of motivation whilst using RehabChat alongside usual care. Aspects for this related to being more motivated generally in rehabilitation, and that this was facilitated through being able to see step-wise progress being made towards achieving a goal. As well, closely aligned areas of feedback concerned factors which supported therapy engagement: having a structure provided by RehabChat for planning the steps to achieving a motivating and meaningful rehabilitation goal, the benefits of RehabChat reinforcing what needed to be accomplished for achieving this. Some mention was made about intrinsic motivation and being self-responsible for achieving one's rehabilitation goals, whilst also receiving external support from the therapy team. Finally, participating in the project as well as using the ECA itself were both seen as positive experiences, which would have helped enable any motivating influences from RehabChat to be experienced optimally.

Feedback from both the co-design workshops and the feasibility pilot trial demonstrated the workability of combining MI and SDT into a goal-setting and goal-pursuit framework which sensitively meets the clinical needs of clients. Feedback from the workshop meetings referred to motivation and how it was intertwined with rehabilitation goal-setting. This contrasted to the pilot trial feedback which focused on the client's experience of being more motivated when using RehabChat, that this was closely associated with RehabChat providing a cognitive support framework and cues to complete the practice activities, and with RehabChat helping the client to remain focused on their meaningful rehabilitation goal. These results indicate the need to consider motivation in future research development for RehabChat.

7.3 Meeting project aim, questions, and objectives

7.3.1 Research Aim

This PhD project achieved its overall aim of co-designing a motivational ECA to support adult clients with TBI during brain injury rehabilitation. This achievement is discussed in relation to the project's research questions and objectives below.

7.3.2 Research Questions

This project was able to answer all of its research questions, as outlined below.

7.3.2.1 Main research question

Main question: How can an Embodied Conversational Agent be used to support motivation and goal-setting in brain injury rehabilitation?

The main research question regarding how the ECA could be used within usual rehabilitation care was addressed through this project's comprehensive and iterative consultation with end-users. Aspects of the intended mode of use for the ECA which were ratified during the pilot trial included utilising clinic iPads, having pre-use training in how to use RehabChat, clinical oversight during the intervention provided by a clinician who is well informed about the client's needs, and weekly reviews of progress. Likely future developments for how RehabChat could be used in rehabilitation care, are to offer greater flexibility for which sections of RehabChat can be used and for how long, and to incorporate an additional goal-setting framework to better support cognitive training.

7.3.2.2 Research sub-question

Each of the research sub-questions was able to be addressed through the sequential co-design phases conducted in this PhD project.

Sub-question 1: What optimal ECA design can be developed using co-design in a real-life rehabilitation setting?

The optimal design of RehabChat was finalised following user testing at the start of the plot trial, and represented a culmination changes made in response to feedback received during all of the phases of development for RehabChat. Key aspects of the design were in regard to its user interface (UI) and avatar presentation. The UI featured visual aspects of larger font size, bigger click buttons, and greater area given to the rolling conversation text boxes than to the avatar. The UI's functionality included the conversation recommencing at the same place following a period of non-use or after closing the program and re-opening it, and the user was able to scroll to review prior conversation content. The avatar presentation was a Eurasian female design, with an Australian accent, as these were the clearest to see and hear for the participants.

Sub-question 2: What are the key elements to be considered when developing a motivational ECA for brain injury rehabilitation?

The key elements considered when designing RehabChat were determined not only through iterative consultation with end-users, but also through conducting an overarching background literature search, and the more structured scoping review. Collectively, these sources of information identified two motivational behaviour change paradigms – SDT and MI – to be used to nuance the goal-setting content, and two main domains of considerations to be addressed when developing the ECA and ratifying an intended mode of use. The ECA's development needed to consider the specific clinical needs of clients with TBI such as memory challenges and fatigue, and provide a step-wise generic goal-setting framework which could be used for setting and pursuing any type of goal suited to the varied needs of clients with TBI. The domain of considering the intended mode of use included: clarifying the clinician's role in supervising the client, to utilise goal-setting content that matched that which was already used in the clinic, and to emphasize the limitations of the ECA's purpose, including that the client should discuss any concerns with their clinician.

Sub-question 3: What is the feasibility of using a motivational Embodied Conversational Agent in brain injury rehabilitation?

The final phase of testing of RehabChat enabled the feasibility of using RehabChat in the real-life setting to be appraised. Feedback indicated that RehabChat was feasible to implement: it was easy to use; usual goal-setting paradigms were incorporated; and clients found it to be motivating.

7.3.3 Research objectives

The research objectives for this project were met in full, and are discussed below.

7.3.3.1 Main research objective

Main objective: To design and pilot trial an ECA to support motivation in brain injury rehabilitation.

This main objective was thoroughly met: the overall content of the PhD demonstrates how a motivational ECA was developed in-house, iteratively reviewed during co-design workshops with end-users, and then implemented as a feasibility pilot trial in the real-life setting.

7.3.3.2 Research sub-objectives 1 - 6

Sub-objective 1: Identify the reported literature for the use of conversational agents in brain injury, disease, and stroke rehabilitation via a Scoping Review

A full scoping review was completed which investigated the use of CAs in brain injury, disease and stroke (see Chapter 2). This review's findings described a limited field of research which is currently in its early stages.

Sub-objective 2: Choose an appropriate ECA software platform for which ongoing technical support is provided.

The Virtual Human software platform by Clevertar was chosen because it met all of the requirements for this project (see Sections 4.1.2 and 4.2.2). Additionally, both the software and provision of ongoing technical support for the use of it were provided *pro bono* by Clevertar.

Sub-objective 3: Develop an initial ECA prototype in-house.

The initial prototype of RehabChat was developed in-house and used for alpha testing (see Chapter 4). It included a simple goal-setting conversation (see Table 9, Section 4.4.1, and Appendix VI).

Sub-objective 4: Test and iteratively refine the initial ECA prototype through alpha testing and beta testing.

The initial ECA prototype underwent in-house alpha testing and beta testing (see Section 4.4). Feedback from these rounds of testing resulted in meaningful changes being made to the ECA and also to developing a model for its intended mode of use in the clinical setting.

Sub-objective 5: Conduct co-design workshops with clients and clinicians of the collaborating brain injury rehabilitation services, to develop the prototype ECA to a stable model ECA design.

Four rounds of co-design workshops were conducted with clinicians and clients from these rehabilitation services. Numerous changes were made to RehabChat in response to the comprehensive feedback from these workshops. The stable model ECA design was determined following completion of the workshops, and was used for the feasibility pilot trial.

Sub-objective 6: Complete a feasibility and usability pilot trial of the stable model ECA at the collaborating brain injury rehabilitation services.

A mixed methods feasibility pilot trial which investigated RehabChat's feasibility, usability and acceptability was conducted at two clinic sites of the brain injury rehabilitation service for clients with moderate-severe acquired brain injury (ABI). The other rehabilitation service for clients with mild TBI was unable to participate due to a major service restructure. Findings from the feasibility pilot trial ratified many aspects of RehabChat's design as being currently satisfactory, and also included a number of suggestions for changes to be made to it to further increase its clinical relevance and applicability for a grater array of clinical needs.

7.4 Limitations of this research

This PhD has presented the design and development of a novel CA for supporting motivation in clients participating brain injury rehabilitation. It is important to note that the context for this research was for ambulatory care brain injury rehabilitation, and the participant cohort of adults with TBI was limited to clients who could use an iPad and provide their own consent to participate in the study. These factors mean that the results from the present research cannot be generalised to other brain injury rehabilitation clinical settings such as inpatient settings, or to other clinical cohorts with TBI, such as clients with TBI who are unable provide their own consent or who have difficulty in using an iPad due to visual, hearing or dexterity challenges.

The difficulties experienced with recruitment for the feasibility pilot trial, which resulted in a small number of client participants recruited, meant also that generalisability of the feasibility results for this research is not yet possible. Nonetheless, a substantial amount of feedback data was obtained for the feasibility pilot trial from the four clinicians and two clients, and no adverse events were experienced during testing. As such, there is a base for ongoing research to further develop RehabChat.

The immediate next step of research should focus on ratifying both a stable model of RehabChat itself, and a feasible and acceptable model for implementing RehabChat in the real-life clinical setting, through conducting a pilot trial with recruitment of a larger sample size. This step is considered below. Following this step, subsequent research could then investigate the comparative clinical effectiveness of using RehabChat alongside rehabilitation care compared to usual care alone.

7.5 Considerations for future developments of RehabChat, with reference to relevant literature

Future research development of RehabChat could include not only a longer duration of clinical testing in the rehabilitation setting, but also further consultation with clinicians and even clinical managers regarding how to integrate the concept of RehabChat more broadly into the clinical setting. This latter factor was identified in the pilot trial qualitative feedback, and suggested that whilst RehabChat was being used eventually as a clinical tool, that it could be discussed as a regular item at team meetings to ensure a common approach was taken for how it was used by various clinicians. This could help resolve any concerns about impact on workflow, clinical outcomes, and time management. A similar approach could be used for reviewing and iteratively co-designing the workflow for RehabChat, in a subsequent study. This would enable thorough appraisal regarding how best to RehabChat into the clinic setting more broadly, as the current work

in this PhD focused primarily on participants' experiences and perspectives regarding the mode of use by a client-clinician dyad.

An exciting aspect of feedback from the feasibility pilot trial considered how to increase the accessibility and acceptability of using RehabChat as part of a research project by better accommodating the fluctuating needs of clients with TBI. Suggestions for achieving this included having the option to not have to do the practice activities daily, to ensure enough iPads are available for easy use, and for the clinicians to choose when RehabChat would be used by their client. The clinician's decision to use RehabChat may occur with minimal notice, for example, during a clinical appointment when a certain aspect of rehabilitation goal setting emerges in the client-clinician conversation, the clinician may decide that RehabChat could support this part of the rehabilitation journey. At that point the clinician could introduce RehabChat to the client and also provide initial training input for the client to learn to use RehabChat, based on that the clinician would have received prior train-the-trainer instruction. To enable such a responsive research design, the informed consent process would need to be completed earlier on, and include a provision that RehabChat could be used at an appropriate juncture if/as appropriate.

A further idea for optimising responsiveness to client needs was for the client-clinician dyad to be able to use any or all aspects of RehabChat's conversation: to use just the goal-setting part, the practice activities sections, and/or the progress review components. Being able to use RehabChat on a flexible basis and for varying amounts of times, could help to accommodate the clients' fluctuating needs and achieve the purpose of RehabChat – to provide additional goal-setting and pursuit support alongside usual rehabilitation care. From a research perspective, this would demand a high degree of flexibility in how data was collected, managed, and assessed. Additionally, mixed method study results would need to be compared with data for ECA usage (duration, frequency, sections of conversation used).

This PhD study identified some aspects of acceptability appraisal, for example regarding participants' perspectives on the overall reach design for the feasibility pilot trial (which was favourably received with some recommendations for change). There is precedent for testing acceptability of a novel digital health intervention being used alongside usual care by a client-clinician dyad. This has been done previously to assess their acceptability of a website tool for tailoring exercise progression and providing information for physiotherapy clients recovering from knee surgery (228). In this study, feedback highlighted contextual issues which impacted on its delivery, and how to best integrate the technology in the clinical service (228). Existing frameworks for appraising acceptability of digital technology tools such as the Website Content Accessibility Guidelines (WCAG) (20) and the Unified Theory of Acceptance and Use of Technology (UTAUT) (142) support review of context relevant factors. The WCAG includes aspects related directly how well does the tool integrate into the use setting; and the UTAUT has precedent for being adapted

for specific use purposes, such as social assistive technologies for older adults (215). Both of these frameworks were used in this PhD and could be again used in a subsequent clinical trial to map robustness, acceptability and usability matched specifically to the use setting.

It is important to thoroughly test any type of novel therapeutic tool regarding its feasibility, effectiveness, and safety including over extended follow-up periods. A previous research protocol for a therapeutic CA incorporated planning for intensive longitudinal follow-up (124).This is particularly relevant for testing of a digital health intervention such as a CA for rehabilitation, because the impact of the use of health behaviour change (HBC) CAs is unknown and requires ongoing multi-disciplinary planning, monitoring and development (73). As well, multiple stakeholders are involved in appraising the impact of such a tool, these being the client, their family member, clinicians, and managerial staff. Future research for longitudinal testing of RehabChat incorporating a longer intervention period of six weeks, followed by extended follow-up assessment for up to 12 months should be considered.

This PhD project has contained a clear focus on client-centred goal-setting, and this should be considered further in future developments of RehabChat. Interestingly, clinician feedback recommended incorporating providing an extra goal-setting structure in RehabChat which would more adequately support cognitive rehabilitation goal-setting for which distinct tasks can be prescribed rather than practice activities which need to be completed regularly. A specific focus on refining the goal-setting approaches used in RehabChat could be included in future co-design workshops. Previous research has focused on the development of a goal setting framework for stroke rehabilitation by using iterative co-design with multi-disciplinary clinicians (255). This study reported that the co-designed framework integrated well with usual care (255). Prior research has investigated goal setting in brain injury rehabilitation, looking particularly at occupational therapists' decision making for how they approach goal setting with their clients (256). Qualitative results revealed that key influences on their decision-making were their own perceptions of the client's ability to participate in goal setting, and managerial support and structures. As well, because of these influencing factors, the therapist could vary between delivering client-centred goal centred or a more clinician lead, discharge-focused goal setting approach (256). Similarly, research investigating the barriers and facilitators for goal setting in stroke rehabilitation identified that facilitators included the therapist using a supportive approach and having sufficient time, and barriers were the therapist having inadequate skills and having insufficient time to engage in goal-setting (40). This paper emphasizes the need to meet the specific communication needs of clients (40). Both of these studies highlight multiple factors influencing how goal setting practices are integrated into usual care. Future research for RehabChat should appraise the goal-setting frameworks used in RehabChat and investigate the barriers and facilitators for using RehabChat as a goal-setting tool in the clinical setting.

Future research for RehabChat should incorporate gathering and analysing feedback from a range of stakeholders apart from the clients and clinicians. The client's family or carer should be consulted. Precedent from the literature for this is from a user testing study for a novel CA for a client with severe TBI, in which the authors highlight the need for considering the spouse's view of the ECA in regard to acceptability (120). Similarly for a broader scoping review of goal setting theories and approaches for paediatric rehabilitation for motor disabilities, it identified that the dominant theme was family centred care (257). This aligns with this PhD's research in that a similarly complex clinical setting of multi-disciplinary rehabilitation with a focus on the client and their family was the context for the research. Future research of RehabChat should include a structured approach for considering the perspectives of the client's family member. As well, given that broader contextual factors impact upon uptake and integration of novel work practices – such as managerial support, staff skill levels and having sufficient time – it would be advantageous to again involve multiple stakeholders – including clinic management, Information Technology staff, clinicians, and clients – in future research for RehabChat.

Future research for RehabChat should continue to apply motivational behaviour change paradigms. In a recent 2020 scoping review (258) investigating use of technology to support goal setting in rehabilitation for adult clients with any diagnosis revealed that these technologies incorporated progress reviews and some utilised behaviour change theories, including SDT (258). Nine of the 16 technologies included incorporated goal-setting that was completed by the client, whereas the other technologies provided automated goal setting and goal-priority decision making. The technologies incorporated progress reviews, and some technologies incorporated positive behavior change theories including SDT (258). This review illustrates that client-centred goal setting which incorporates positive behaviour change paradigms can be integrated into the development of digital technology tools for rehabilitation. Interestingly, SDT was recommended for goal-setting approaches for rehabilitation in a much earlier commentary from 2004 (259).

In future research for RehabChat SDT should be integrated into the design of the ECA and its intended mode of use, as well as applied to the research methodology itself. A 2018 commentary recommended SDT specifically for brain injury rehabilitation (39). The tenets of SDT have also been reflected in the results of a recent 2021 study (260) of 179 clients with mild TBI regarding their symptoms and experience of basic human psychological needs as defined in SDT (260). The study found that participants' sense of autonomy, connectedness and competency all decreased whilst symptoms of anxiety and depression increased following injury. The study emphasized the need to address these areas of challenge in therapy (260). These factors were addressed in this PhD project: during the pilot trial, repeated measures were obtained for anxiety and depression, and the three SDT tenets were integrated into both the ECA conversation content and the approach to training of participants.

In the feasibility pilot trial, the choice to use the short conversation style by all participants indicated that there was possible concern about the longer conversation potentially causing increased fatigue. Additionally, participant feedback identified aspects of motivational support which would be useful in RehabChat: interestingly, aspects regarding having a motivational support resource such as a support person were included in the longer conversation style developed after beta testing and the co-design workshops. Based on these findings, future research development for RehabChat will consider offering only one version of the conversation, which is the shorter style, but which includes the additional motivational content from the longer conversation of identifying a support resource or person.

The lack of established best practice guidelines for the development of health CAs indicates the need to use relevant other respected design frameworks such as the WCAG (20) and the UTAUT (141). However, recent literature illustrates early efforts to standardise development guidelines. A 2022 article outlines five best practices for CA design based on the author's prior review of successful and unsuccessful CAs (261). The five practices are: understand the needs of intended end-users; goals for development to be realistic (for example, by keeping a clear focus for the CA's purpose); the CA to address a specific purpose; choose a software platform that matches the purposes and requirements for the CA's intended use; and prioritise optimising CA usability (261). Interestingly, all of these practices were incorporated into this PhD project for developing RehabChat. These five practices should continue to be used in future research development of RehabChat.

Other research concerning development of the effective integration of SDT into CA design recommends key factors for consideration by CA developers. Recent research by Yang et al (2021) (262) investigated what helps or hinders the development of a CA which integrates SDT's tenets of competence, autonomy, and relatedness, through conducting participant interviews with CA users experienced in using general use chatbots such as Google Assistant and Cortana (262). This research was based on prior recommendations for the use of SDT when developing human-centred digital technologies by Peters et al 2018 (84). Key findings were that 10 guidelines were developed (262). These 10 guidelines were grouped into four categories. In the first category regarding initial interactions, the CA needed to provide an overview of its capabilities to help the user develop an appropriate understanding of what to expect from the CA. The second category regarding ongoing interactions focused on the need for the user to interact easily with the CA, which can be optimised by the flow of conversation, and the CA language being brief and clear. The third category was concerned with when the CA was wrong and highlighted that the CA could acknowledge when it was wrong or otherwise could not complete a task, including updating the client on the system's current status regarding functionality. The final category focused on factors relating to using the CA over time: that the CA should learn about the user from prior interactions, which would help to improve the tailoring of services from the CA. As well, customisation of

commands and responses should be facilitated, including allowing the user to have an increasing sense of being able to impact and control the conversation. Additionally, options for the user to view, interact with and manage data obtained in the conversations should be offered. It is important to note that these recommendations were developed from feedback from participants who had experience interacting with general use CAs, and they were not participants with a particular clinical need. As well, some of the guidelines clearly relate to natural language processing (NLP) CAs, for example regarding making mistakes or being unable to complete a task. However, the essence of the guidelines can be applied to a constrained language CA, such as RehabChat: for example, ensuring very clear expectations for the user of what the CA's purpose is, enabling the user to influence the focus of the conversation, and allowing the user to interact with their entered data. These factors were applied to the development of RehabChat during this PhD project and should continue to be considered in future research.

7.6 Priorities for next stages of testing for RehabChat

There is considerable scope for the future research and development of RehabChat to include broad innovative inquiry regarding whether RehabChat could be delivered without an avatar, and to compare this to the current ECA style; investigating the speech and language patterns and preferences of clients with TBI; and development of an appropriate NLP framework to parse spoken user input. These research foci are larger scale developments. In contrast, the immediate next steps of development for RehabChat are defined below: these are essentially 'low-hanging' fruit which reflect directly the feedback received from the feasibility pilot trial and are necessary to pursue prior to larger scale investigations.

The priorities for the next stages of development for RehabChat are to extend feasibility testing through implementing a longer intervention with a greater number of participants, with a focus on addressing the needs of clients and of the clinical setting within the content of the ECA and also the design of the research. This research should also identify key translation factors for facilitating more sustainable integration of RehabChat into the clinical setting. There is precedent in the literature for appraising a novel HBC digital health intervention by initial feasibility testing followed by clinical testing. Use of a methodological approach to integrating a positive behaviour change paradigm into a motivational digital technology tool prior to subsequent testing has been reported in the literature. A novel web-based physical activity App was developed to incorporate SDT and MI in the App's content for promoting physical activity which included an ability of the App to tailor the physical activity interventions (263). This App was developed through in-house prototype development followed by user testing and interviews, prior to a subsequent RCT by the same research team reported elsewhere (246). This is similar to this PhD project in that SDT and MI were incorporated, and that in-house testing and user testing were conducted. It also concurs with

the proposed next stages of testing for RehabChat to firstly ratify the design of RehabChat and its intended mode of implementation, and then to progress to a clinical effectiveness study.

The design for this future testing will take ideas identified from the feasibility pilot trial, and framework it by using the Living Laboratory approach. An outline of what this future testing could look like is presented below as a proposed model. It incorporates an initial phase of co-design workshops, during and following which the aims objectives and planning for a subsequent pilot implementation trial, as well as refinements for the ECA, would be completed. Future testing of RehabChat should also prioritise usability testing and utilise the best available tools for this: a recent 2022 study describes the development and piloting of a novel usability measure for appraising usability in CAs (264); this tool could be suitable for use.

For the proposed future research priorities for developing RehabChat as outlined below, the parameters of Participants, Context, Concept (PCC) would be used to define the subsequent proposed co-design workshops and pilot implementation trial. The PCC details for each of these are mapped out below.

7.6.1 Proposed co-design workshops to review the refined ECA prototype and proposed mode of use for subsequent piloting in the clinical setting

Participants: Clients aged 18 years and older, with traumatic brain injury (TBI) of any severity, who are able to provide their own consent, and can use an iPad. Clinicians who provide ambulatory care rehabilitation for adult clients with TBI. Four or five participants from each cohort to be recruited. If a client is recruited from a distinct service, then at least one clinician also has to be recruited from that same service.

Context: Ambulatory care brain injury rehabilitation services for adults with TBI; these can be public health services or not-for-profit rehabilitation services. Extending recruitment beyond the public health services will improve the transferability of RehabChat to different settings, and also facilitate recruitment.

Concept – design of RehabChat and its proposed mode of use presented at co-design workshops: Three rounds of workshops will be held – two with separate meetings for each cohort, and a final third meeting where all participants are together. At the meetings, the proposed model for the subsequent pilot trial will be presented, as will the updated version of the RehabChat ECA (see Section 7.5.2). Iterative changes to the ECA and its intended mode of use will be completed between each meeting and following completion of all workshops. The final stable model will be tested in-house prior to being used in the subsequent pilot trial.

7.6.2 Proposed pilot trial to test the refined ECA and intended mode of use in the clinical setting

Participants: Clients aged 18 years and older, with traumatic brain injury (TBI) of any severity, who are able to provide their own consent, and can use an iPad. Clinicians who provide rehabilitation care for adult clients with TBI. and the supervising clinician must have worked with the client for at least three appointment times prior to the client being considered for eligibility. A clinician needs to be recruited as the supervising clinician for each client recruited; any clinician can have more than one client whom they are supervising in the project. Each client must have only one supervising clinician; although this role can be handed over to another clinician during periods of staff leave.

Context: Ambulatory care brain injury rehabilitation services for adults with TBI; these can be public health services or not-for profit rehabilitation services. Extending recruitment beyond public health services will facilitate recruitment.

Concept – use RehabChat as an intervention alongside usual care: The client-clinician dyad use RehabChat alongside usual ambulatory care brain injury rehabilitation. Usual care comprising multi-disciplinary therapies and any required therapy breaks continues. The clinician decides with the client whether to use RehabChat during usual care periods, and/or during a therapy break. Use of RehabChat is ceased by the time of discharge of client from rehabilitation care: RehabChat will not be used post-discharge because of the inherent lack of clinician supervision for that. RehabChat will be used for up to six weeks. One version of the ECA conversation will be provided, which will be the shorter styled current version, incorporating additional content for identifying a motivational support resource or person. The ECA conversation will also comprise two options for the main domains of goal-setting, practice activities and progress reviews. The first of these conversation options will be the current version of goal-setting used in RehabChat which comprises SMART goal-setting, two practice activities, and weekly progress reviews. The second conversation option will support cognitive training of aspirational goals, for which non-daily practice tasks can be prescribed, and progress reviews can be conducted as required.

7.7 Final conclusion

In conclusion, RehabChat has evolved in response to feedback, both as an embodied conversational agent – for which the user interface design and conversation content was aligned to client needs – and as an intervention package incorporating the ECA as well as its intended mode of use alongside usual brain injury rehabilitation care in ambulatory care settings. Living Laboratory provided a comprehensive framework for conducting the PhD project – in which multiple stakeholders and a complex clinical setting were involved. It also ensured that through consultation

with end-users occurred, and in a way that was sensitive to the needs of client-participants and the requirements of the clinical setting.

End-user feedback has suggested that further testing and development of RehabChat could enable it to be used more broadly than its current mode of implementation alongside usual care, and that future research should incorporate responsive models of implementation that more closely integrate to the style of brain injury rehabilitation care – which is itself supportive, flexible. and nuanced.

This project has illustrated that the judicious use of theoretical paradigms and end-user feedback has enabled a feasible prototype ECA to be developed for supporting motivation in clients with TBI. The degree to which integration into the clinic context was considered has helped premise this work for future research of RehabChat regarding its use in brain injury rehabilitation; but perhaps to also be considered more broadly for other conditions within the banner of brain injury, disease or stroke, for which motivational support for goal achievement is required. RehabChat in this project illustrates the use of a CA in a novel setting and for a novel purpose, and goes beyond the level of reporting included in related literate of CAs for similar cohorts, in that it uniquely defines the ECA in very specific terms regarding its design and purpose, as well as presenting the multiple aspects considered in its design including requirements for its use in the real-life setting. Further research for RehabChat could secure it as being a reliable and effective adjunct tool which is easily integrated into rehabilitation care for adults with TBI.

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9 Appendices

Appendix I: Scoping review – Database search strategy

Below are the database search strategies used in this scoping review. All searches were limited to English, human and adult.

MEDLINE (Ovid)

#	Searches
1	(("Text based" or "text-based" or virtual or relational or intelligent or synchronous or asynchronous or user-computer or "user computer" or human-computer or "human computer" or "computer assisted") adj2 (assistant or human or agent* or coach or chat* or person or people or interface or therap*)).ti,ab,kw.
2	(Chatbot* or avatar*).tw,kw.
3	((Conversational or "embodied conversational" or artificial or "natural language") adj1 (agent or intelligence or processing)).tw,kw.
4	(Dialogue systems or Artificial Conversational Entity or Dialogue systems).tw,kw.
5	("automated question answering system" or "3D human" or "AI agent" or "believable agent" or "conversive agent" or "cyber individual" or "desktop mate" or "digital animated avatar" or "electronic virtual interactive entity" or "language bot" or "lifelike animated character" or "natural language system" or "online chat agent" or "language bot" or "lifelike animated character" or "natural language system" or "online chat agent" or "relational agent" or "smart virtual assistant" or "synthetix agent" or "teachable agent" or avatar or bot or buddy or character or chatbot or chatterbot or chatterbox or ECA or intellitar or IVA or IVR or smartbot or VDA or ((anthropomorphic or automated or embodied or intelligent or pedagogic or talk* or virtual) adj3 (advisor or agent or assistant or coach or consultant or expert or head or human or interface or machine or person or persona or people or representative or robot or specialist or teacher or tutor)) or ((animated or artificial or asynchronous or automated or chat or computerized or computerised or conversation* or dialog* or intelligent or interact* or relational or synchronous or "text based" or "text-based" or virtual) adj3 (agent or assistant or attendant or chat* or coach or computer or entity or human* or interface or person or people or person or program or response or robot or system or "talking head"))).tw,kf.
6	1 or 2 or 3 or 4 or 5
7	exp brain injuries/ or exp brain diseases/
8	("acquired brain injury" or "ABI" or "traumatic brain injury" or "TBI").tw,kw.
9	((brain or cerebr*) adj4 (injur* or hypoxi* or damage* or trauma* or neoplasm* or lesion* or tumor* or tumour* or cancer* or infection*)).tw.
10	(MTBI or "mild traumatic brain injury" or TBI or "traumatic brain injury" or "ABI" or "acquired brain injury" or "brain injury" or concuss* or "post concuss*" or "post-concuss*" or PCS).tw,kf.

11	((brain* or cerebr* or cerebell$ or intracerebral or intracran* or parenchymal or intraparenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or putaminal or putamen or posterior fossa or hemispher* or subarachnoid) adj5 (h?emorrhag* or h?ematoma* or bleed*)).tw.
12	((brain or cerebr* or cerebell* or vertebrobasil* or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or middle cerebr* or mca* or anterior circulation or basilar artery or vertebral artery) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus* or hypoxi*)).tw.
13	(stroke* or "post stroke" or poststroke or "post-stroke" or apoplex* or "cerebral vasc*" or cerebrovasc* or cva or SAH).tw.
14	7 or 8 or 9 or 10 or 11 or 12 or 13
15	exp Dementia/
16	(dementia or alzheimer* or "mild cognitive impairment" or "cognitive impairment" or neurodegen* or parkinson*).tw,kw.
17	15 or 16
18	14 or 17
19	6 and 18
20	exp animals/ not humans/
21	(animal* or canine* or dog* or feline* or hamster* or lamb* or mice or monkey* or mouse or murine or pig* or porcine or primate* or rabbit* or rat* or rodent* or sheep).tw,kf.
22	20 or 21
23	19 not 22
24	(child* or adol* or teen* or infan* or toddler or school-age*).mp.
25	23 not 24
26	limit 25 to (english language and humans and ("adolescent (13 to 18 years)" or "young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)"))

Google scholar (first 300)

(“virtual coach” OR chatbot OR avatar OR “conversational agent” OR “natural language agent” OR “virtual assistant” OR “virtual human”) AND (“brain injury” OR concussion OR stroke OR dementia OR “cognitive impairment”)

Scopus

(((*TITLE-ABS-KEY* (((*"Text based"* OR *"text-based"* OR *virtual* OR *relational* OR *intelligent* OR *synchronous* OR *asynchronous* OR *user*

-computer OR *"user computer"* OR *human-computer* OR *"human computer"* OR *"computer assisted"*) W/2 (*assistant* OR *human* OR *agent** OR *coach* OR *chat** OR *person* OR *people* OR *interface* OR *therap**))) OR *TITLE-ABS-KEY* ((*chatbot** OR *avatar**)) OR *TITLE-ABS-KEY* (((*conversational* OR *"embodied conversational"* OR *artificial* OR *"natural language"*) W/1 (*agent* OR *intelligence* OR *processing*))) AND *TITLE-ABS-KEY* ((*"Artificial Conversational Entity"* OR *"Dialogue system"* OR *"automated question answering system"* OR *"3D human"* OR *"AI agent"* OR *"believable agent"* OR *"conversive agent"* OR *"cyber individual"* OR *"desktop mate"* OR *"digital animated avatar"* OR *"electronic virtual interactive entity"* OR *"language bot"* OR *"lifelike animated character"* OR *"natural language system"* OR *"online chat agent"* OR *"relational agent"* OR *"smart virtual assistant"* OR *"synthetix agent"* OR *"teachable agent"* OR *avatar* OR *bot* OR *buddy* OR *character* OR *chatbot* OR *chatterbot* OR *chatterbox* OR *eca* OR *intellitar* OR *iva* OR *ivr* OR *smartbot* OR *vda*)) OR *TITLE-ABS-KEY* (((*anthropomorphic* OR *automated* OR *embodied* OR *intelligent* OR *pedagogic* OR *talk** OR *virtual*) W/3 (*advisor* OR *agent* OR *assistant* OR *coach* OR *consultant* OR *expert* OR *head* OR *human* OR *interface* OR *machine* OR *person* OR *persona* OR *people* OR *representative* OR *robot* OR *specialist* OR *teacher* OR *tutor*))) OR *TITLE-ABS-KEY* (((*animated* OR *artificial* OR *asynchronous* OR *automated* OR *chat* OR *computerized* OR *computerised* OR *conversation** OR *dialog** OR *intelligent* OR *interact** OR *relational* OR *synchronous* OR *"text based"* OR *"text-based"* OR *virtual*) W/3 (*agent* OR *assistant* OR *attendant* OR *chat** OR *coach* OR *computer* OR *entity* OR *human** OR *interface* OR *person* OR *people* OR *person* OR *program* OR *response* OR *robot* OR *system* OR *"talking head"*))))) AND (((*TITLE-ABS-KEY* ((*"acquired brain injury"* OR *"ABI"* OR *"traumatic brain injury"* OR *"TBI"*) OR ((*brain* OR *cerebr**) W/4 (*injur** OR *hypoxi** OR *damage** OR *trauma** OR *neoplasm** OR *lesion** OR *tumor** OR *tumour** OR *cancer** OR *infection**))) OR *TITLE-ABS-KEY* ((*mtbi* OR *"mild traumatic brain injury"* OR *tbi* OR *"traumatic brain injury"* OR *"ABI"* OR *"acquired brain injury"* OR *"brain injury"* OR *concuss** OR *"post concussion"* OR *post-concussion* OR *pcs*)))) OR ((*TITLE-ABS-KEY* (((*brain** OR *cerebr** OR *cerebell** OR *intracerebral* OR *intracran** OR *parenchymal* OR *intraparenchymal* OR *intraventricular* OR *infratentorial* OR *supratentorial* OR *"basal gangli*"* OR *putaminal* OR *putamen* OR *"posterior fossa"* OR *hemispher** OR *subarachnoid*) W/5 (*hemorrhag** OR *haemorrhag** OR *hematoma** OR *haematoma** OR *bleed**))) OR *TITLE-ABS-KEY* (((*brain* OR *cerebr** OR *cerebell** OR *vertebrobasil** OR *hemispher** OR *intracran** OR *intracerebral* OR *infratentorial* OR *supratentorial* OR *"middle cerebr*"* OR *mca** OR *"anterior circulation"* OR *"basilar artery"* OR *"vertebral artery"*) W/5 (*ischemi** OR *ischaemi** OR *infarct** OR *thrombo** OR *emboli** OR *occlus** O

R *hypoxi**))) OR *TITLE-ABS-KEY* ((*stroke** OR *"post stroke"* OR *poststroke* OR *"post-stroke"* OR *apoplex** OR *"cerebral vasc*"* OR *cerebrovasc** OR *cva* OR *sah*)) OR *TITLE-ABS-KEY* ((*dementia* OR *alzheimer** OR *"mild cognitive impairment"* OR *"cognitive impairment"* OR *neurodegen** OR *parkinson**)))))) AND NOT ((*TITLE-ABS-KEY* ((*animal** OR *canine** OR *dog** OR *feline** OR *hamster** OR *lamb** OR *mice* OR *monkey** OR *mouse* OR *murine* OR *pig** OR *porcine* OR *primate** OR *rabbit** OR *rat** OR *rodent** OR *sheep*)) OR *TITLE-ABS-KEY* ((*child** OR *adol** OR *teen** OR *infan** OR *toddler* OR *school-age**)))) AND (*LIMIT-TO* (*SUBJAREA* , *"COMP"*) OR *LIMIT-TO* (*SUBJAREA* , *"ENGI"*) OR *LIMIT-TO* (*SUBJAREA* , *"MEDI"*) OR *LIMIT-TO* (*SUBJAREA* , *"NEUR"*) OR *LIMIT-TO* (*SUBJAREA* , *"HEAL"*) OR *LIMIT-TO* (*SUBJAREA* , *"PSYC"*) OR *LIMIT-TO* (*SUBJAREA* , *"NURS"*) OR *LIMIT-TO* (*SUBJAREA* , *"DECI"*) OR *LIMIT-TO* (*SUBJAREA* , *"MULT"*)) AND (*LIMIT-TO* (*PUBSTAGE* , *"final"*) OR *LIMIT-TO* (*PUBSTAGE* , *"aip"*)) AND (*LIMIT-TO* (*DOCTYPE* , *"cp"*) OR *LIMIT-TO* (*DOCTYPE* , *"ar"*) OR *LIMIT-TO* (*DOCTYPE* , *"cr"*) OR *LIMIT-TO* (*DOCTYPE* , *"re"*) OR *LIMIT-TO* (*DOCTYPE* , *"ch"*)) AND (*LIMIT-TO* (*LANGUAGE* , *"English"*))

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asynchronous OR automated OR chat OR computerized OR computerised OR conversation* OR dialog* OR intelligent OR interact* OR relational OR synchronous OR "text based" OR "text-based" OR virtual) NEAR/3 (agent OR assistant OR attendant OR chat* OR coach OR computer OR entity OR human* OR interface OR person OR people OR person OR program OR response OR robot OR system OR "talking head"))) AND (((brain OR cerebr*) NEAR/4 (injur* OR hypoxi* OR damage* OR trauma* OR neoplasm* OR lesion* OR tumor* OR tumour* OR cancer* OR infection*)) OR (MTBI OR "mild traumatic brain injury" OR TBI OR "traumatic brain injury" OR "ABI" OR "acquired brain injury" OR "brain injury" OR concuss* OR "post concuss*" OR "post-concuss*" OR PCS) OR ((brain* OR cerebr* OR cerebell* OR intracerebral OR intracran* OR parenchymal OR intraparenchymal OR intraventricular OR infratentorial OR supratentorial OR “basal gangli*” OR putaminal OR putamen OR “posterior fossa” OR hemispher* OR subarachnoid) NEAR/5 (haemorrhag* OR hemorrhag OR haematoma* OR hematoma* OR bleed*)) OR ((brain OR cerebr* OR cerebell* OR vertebrobasil* OR hemispher* OR intracran* OR intracerebral OR infratentorial OR supratentorial OR “middle cerebr*” OR mca* OR “anterior circulation” OR “basilar artery” OR “vertebral artery”) NEAR/5 (ischaemi* OR ischemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR hypoxi*)) OR (stroke* OR "post stroke" OR poststroke OR "post-stroke" OR apoplex* OR "cerebral vasc*" OR cerebrovasc* OR cva OR SAH) OR (dementia OR alzheimer* OR "mild cognitive impairment" OR "cognitive impairment" OR neurodegen* OR parkinson*))) NOT ((animal* OR canine* OR dog* OR feline* OR hamster* OR lamb* OR mice OR monkey* OR mouse OR murine OR pig* OR porcine OR primate* OR rabbit* OR rat* OR rodent* OR sheep) OR (child* or adol* or teen* or infan* or toddler or school-age*)

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OR
(Chatbot* OR avatar*)
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OR

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) AND (
("acquired brain injury" OR "ABI" OR "traumatic brain injury" OR "TBI")
OR
((brain OR cerebr*) NEAR/4 (injur* OR hypoxi* OR damage* OR trauma* OR neoplasm* OR lesion* OR tumor* OR tumour* OR cancer* OR infection*))
OR
(MTBI OR "mild traumatic brain injury" OR TBI OR "traumatic brain injury" OR "ABI" OR "acquired brain injury" OR "brain injury" OR concuss* OR "post concuss*" OR "post-concuss*" OR PCS)
OR
((brain* OR cerebr* OR cerebell* OR intracerebral OR intracran* OR parenchymal OR intraparenchymal OR intraventricular OR infratentorial OR supratentorial OR “basal ganglia” OR “basal ganglion” OR putaminal OR putamen OR posterior fossa OR hemispher* OR subarachnoid) AND (hemorrhag* OR haemorrhag* OR hematoma* OR haematoma* OR bleed*))
OR
((brain OR cerebr* OR cerebell* OR vertebrobasil* OR hemispher* OR intracran* OR intracerebral OR infratentorial OR supratentorial OR “middle cerebr*” OR mca* OR “anterior circulation” OR “basilar artery” OR “vertebral artery”) NEAR/3 (ischaemi* OR ischemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR hypoxi*))
OR
(stroke* OR "post stroke" OR poststroke OR "post-stroke" OR apoplex* OR "cerebral vasc*" OR cerebrovasc* OR cva OR SAH)
OR
(dementia OR alzheimer* OR "mild cognitive impairment" OR "cognitive impairment" OR neurodegen* OR parkinson*)))
NOT
(animal* OR canine* OR dog* OR feline* OR hamster* OR lamb* OR mice OR monkey* OR mouse OR murine OR pig* OR porcine OR primate* OR rabbit* OR rat* OR rodent* OR sheep OR child* or adol* or teen* or infan* or toddler or school-age*))

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OR

(Chatbot* OR avatar*)

OR

((Conversational OR "embodied conversational" OR artificial OR "natural language") AND (agent OR intelligence OR processing))

OR

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OR
((anthropomorphic OR automated OR embodied OR intelligent OR pedagogic OR talk* OR virtual) AND (advisor OR agent OR assistant OR coach OR consultant OR expert OR head OR human OR interface OR machine OR person OR persona OR people OR representative OR robot OR specialist OR teacher OR tutor))
OR
((animated OR artificial OR asynchronous OR automated OR chat OR computerized OR computerised OR conversation* OR dialog* OR intelligent OR interact* OR relational OR synchronous OR "text based" OR "text-based" OR virtual) AND (agent OR assistant OR attendant OR chat* OR coach OR computer OR entity OR human* OR interface OR person OR people OR person OR program OR response OR robot OR system OR "talking head")))
AND
(((brain OR cerebr*) AND (injur* OR hypoxi* OR damage* OR trauma* OR neoplasm* OR lesion* OR tumor* OR tumour* OR cancer* OR infection*))
OR
(MTBI OR "mild traumatic brain injury" OR TBI OR "traumatic brain injury" OR "ABI" OR "acquired brain injury" OR "brain injury" OR concuss* OR "post concuss*" OR "post-concuss*" OR PCS OR stroke* OR "post stroke" OR poststroke OR "post-stroke" OR apoplex* OR "cerebral vasc*" OR cerebrovasc* OR cva OR SAH OR dementia OR alzheimer* OR "mild cognitive impairment" OR "cognitive impairment" OR neurodegen* OR parkinson*)
OR
((brain* OR cerebr* OR cerebell* OR intracerebral OR intracran* OR parenchymal OR intraparenchymal OR intraventricular OR infratentorial OR supratentorial OR “basal ganglia” OR putaminal OR putamen OR “posterior fossa” OR hemispher* OR subarachnoid) AND (hemorrhag* OR haemorrhag* OR hematoma* OR haematoma* OR bleed*))
OR
((brain OR cerebr* OR cerebell* OR vertebrobasil* OR hemispher* OR intracran* OR intracerebral OR infratentorial OR supratentorial OR middle cerebr* OR mca* OR “anterior circulation” OR “basilar artery” OR “vertebral artery”) AND (ischemi* OR ischaemi* OR infarct* OR thrombo* OR emboli* OR occlus* OR hypoxi*))))

NOT

(animal* OR canine* OR dog* OR feline* OR hamster* OR lamb* OR mice OR monkey* OR mouse OR murine OR pig* OR porcine OR primate* OR rabbit* OR rat* OR rodent* OR sheep OR child* or adol* or teen* or infan* or toddler or school-age*))

Appendix II: Scoping review – Data extraction instrument

Sections in italics are based directly on Laranjo et al (100) recommendations for reporting on chatbots; * indicates a category based on Macedo et al (132).

Topic	Data
1. Evidence source details and characteristics	
Citation	
Country	
Context (health domain; setting): intended, actual*	
Participants: intended, actual*	
Recruitment process	
Research methodology	
Type of research activity reported	
2. Research design & health rationale	
Type of intervention: **Clinical rehab purpose of CA***	
Type of intervention: **Mode of use**	
Content of conversation	
Content development	
Outcomes measured	
Results	
Safety	
Use barriers	
Use facilitators	
3. Technology description	
Task-oriented: yes / no *Yes: designed to gather essential data* *No: Not focussed; instead provides conversation experience*	
Type of technology: ***Hardware***	
Type of technology: ***Software***	
Dialogue management: *Finite-state: pre-determined steps* *Frame-based: need to complete a template; unconstrained language* *Agent-based: system intelligent behavior; builds a conversation*	

Topic	Data
Dialogue initiative: *User: conversation led by user* *System: conversation led by system* *Mixed: led by user &/or system*	
Input modality *Text, speech*	
Output modality *Text, speech, visual*	
Appearance	
4. NLP related areas	
Dialogue success rate (%)	
Automatic speech recognition: word, sentence *Word accuracy / error rate / insertion rate / substitution rate* *Sentence accuracy*	
Natural language understanding *# of times user requests repetition of reply provided by CA* *# of times CA does not answer* *User response time* *Rate of out-of-vocabulary words*	
Dialogue management *% values for:* *- words correctly understood, not covered or partially covered;* *- sentences correctly analyzed;* *- words outside the dictionary;* *- sentences whose final semantic representation is the same as the reference;* *- correct frame units, considering the actual frame units; frame-level accuracy; frame-level coverage*	
Natural language generation *% values for:* *- correct responses;* *- half-answers;* *- times the system works trying to solve a problem;* *- times the user acts trying to solve a problem*	
Speech synthesis *Intelligibility and naturalness*	

Appendix III: Scoping review – Excluded studies with reasons

#	Citation
	Not reporting on a CA
1	Abbasi J. Augmented reality takes Parkinson disease dance therapy out of the classroom. JAMA - Journal of the American Medical Association. 2017;317(4):346-8.
2	Abdi J, Al-Hindawi A, Ng T, Vizcaychipi MP. Scoping review on the use of socially assistive robot technology in elderly care. BMJ Open. 2018;8:e018815.
3	Abdollahi H, Mollahosseini A, Lane JT, Mahoor MH. A pilot study on using an intelligent life-like robot as a companion for elderly individuals with dementia and depression. 2017; Piscataway: The Institute of Electrical and Electronics Engineers, Inc. (IEEE); 2017. p. 541-6.
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8	Beck CA, Beran DB, Biglan KM, Boyd CM, Dorsey ER, Schmidt PN, et al. National randomized controlled trial of virtual house calls for Parkinson disease. Neurology. 2017;89(11):1152-61.
9	Begum M, Huq R, Wang R, Mihailidis A. Collaboration of an assistive robot and older adults with dementia. Gerontechnology. 2015;13(4):405-19.
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13	Cameirão MS, Smailagic A, Miao G, Siewiorek DP. Coaching or gaming? Implications of strategy choice for home based stroke rehabilitation. Journal of neuroengineering and rehabilitation. 2016;13(1):1-15.
14	Chan J, Nejat G, Chen J. Designing intelligent socially assistive robots as effective tools in cognitive interventions. International Journal of Humanoid Robotics. 2011;8(1):103-26.

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15	Coninx K, De Weyer T, Lemmens R, Luyten K, editors. ReHappy - The house elf that serves your rehabilitation exercises. Conference on Human Factors in Computing Systems - Proceedings; 2016. p. 2192-2199
16	Cooney M, Orand A, Larsson H, Pihl J, Aksoy EE. Exercising with an "Iron Man": Design for a Robot Exercise Coach for Persons with Dementia*. 2020; Piscataway: The Institute of Electrical and Electronics Engineers, Inc. (IEEE); 2020. p. 899-905.
17	De Oliveira Assis L, Tirado MGA, De Melo Pertence AE, Pereira LSM, Mancini MC. Evaluation of cognitive technologies in geriatric rehabilitation: A case study pilot project. Occupational Therapy International. 2010;17(2):53-63.
18	Des Roches CA, Kiran S. Technology-based rehabilitation to improve communication after acquired brain injury. Frontiers in Neuroscience. 2017;11(JUL).
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26	Ibarra Zannatha JM, Tamayo AJM, Sánchez TDG, Delgado JEL, Cheu LER, Arévalo WAS. Development of a system based on 3D vision, interactive virtual environments, ergonometric signals and a humanoid for stroke rehabilitation. Computer Methods and Programs in Biomedicine. 2013;112(2):239-49.
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33	Kintsakis AM, Reppou SE, Karagiannis GT, Mitkas PA. Robot-assisted cognitive exercise in mild cognitive impairment patients: The RAPP approach. Nov 2015; Piscataway: The Institute of Electrical and Electronics Engineers, Inc. (IEEE); 2015. p. 1-4.
34	König A, Malhotra A, Francis LE, Hoey J, editors. Defining affective Identities in elderly Nursing Home residents for the design of an emotionally intelligent cognitive assistant. PervasiveHealth: Pervasive Computing Technologies for Healthcare; 2016. p. 206-210.
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111	Yasuda K, Fuketa M, Morita K, Aoe J, Kuwahara N. Videophone conversation of two individuals with dementia using an anime agent system. Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)2016. p. 317-26.
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114	Biallas M, Birrer E, Bolliger D, Rumsch A, Kistler R, Klapproth A. Living safely and actively in and around the home: Four applied examples from avatars and ambient cubes to active walkers. Safe at Home with Assistive Technology2017. p. 5-30.
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117	Ceccaldi E, Damiano R, Battaglino C, Galetto V, Zettin M. An Emotional Agent for Moral Impairment Rehabilitation in TBI Patients. Frontiers in Psychology. 2020;11. Article 1102.
118	Cruz-Sandoval D, Favela J. Incorporating Conversational Strategies in a Social Robot to Interact with People with Dementia. Dementia and geriatric cognitive disorders. 2019;47(3):140-8.
119	de Jong M, Bolliger D, Stara V, Heerink M, von Döllen V, Evers V, editors. Users requirements in the design of a virtual agent for patients with dementia and their caregivers. ACM International Conference Proceeding Series; 2018.p. 136-141.
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129	Wolters MK, Kelly F, Kilgour J. Designing a spoken dialogue interface to an intelligent cognitive assistant for people with dementia. Health Informatics Journal. 2016;22(4):854-66.
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131	Yaghoubzadeh R, Kramer M, Pitsch K, Kopp S. Virtual agents as daily assistants for elderly or cognitively impaired people: Studies on acceptance and interaction feasibility. Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)2013. p. 79-91.
	Different cohort
132	Liu W-D, Chuang K-Y, Chen K-Y. The Design and Implementation of a Chatbot's Character for Elderly Care. 2018; Piscataway: The Institute of Electrical and Electronics Engineers, Inc. (IEEE); 2018. p. 1-5.
133	Nadarzynski T, Miles O, Cowie A, Ridge D. Acceptability of artificial intelligence (AI)-led chatbot services in healthcare: A mixed-methods study. Digital health. 2019;5:2055207619871808.
134	Suppipat S, Cheng WM, Wang SM. Contextual Design of Intergenerational Innovative Service for Aging in Place. Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)2020. p. 531-44.

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136	Wilks Y, Jasiewicz J, editors. CALONIS: An artificial Companion for the care of cognitively impaired patients. AISB 2014 - 50th Annual Convention of the AISB; 2014.
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137	Nakatani S, Saiki S, Nakamura M, editors. Integrating 3d facial model with person-centered care support system for people with dementia. International Conference on Intelligent Human Systems Integration; Springer. 2018: p. 216-222. *Content essentially repeated in paper already included in this review:* Nakatani S, Saiki S, Nakamura M, Yasuda K, editors. Generating personalized virtual agent in speech dialogue system for people with dementia. International Conference on Digital Human Modeling and Applications in Health, Safety, Ergonomics and Risk Management; 2018: Springer. p. 326-337.
138	Sakai Y, Nonaka Y, Yasuda K, Nakano YI, editors. Listener agent for elderly people with dementia. HRI'12 - Proceedings of the 7th Annual ACM/IEEE International Conference on Human-Robot Interaction; 2012.p. 199-200. *Content essentially repeated in paper already included in this review:* Huang HH, Matsushita H, Kawagoe K, Sakai Y, Nonaka Y, Nakano Y, et al. Toward a memory assistant companion for the individuals with mild memory impairment. Proceedings of the 11th IEEE International Conference on Cognitive Informatics and Cognitive Computing, ICCI*CC 2012. 2012:295-299. DOI: 10.1109/ICCI-CC.2012.6311164

Appendix IV: Scoping review – Reference list checking of included studies

The following table presents the results of reference list checking of the included primary research studies and reviews. The eleven included primary studies are presented first, followed by the details for the two included reviews being included at the end of the table.

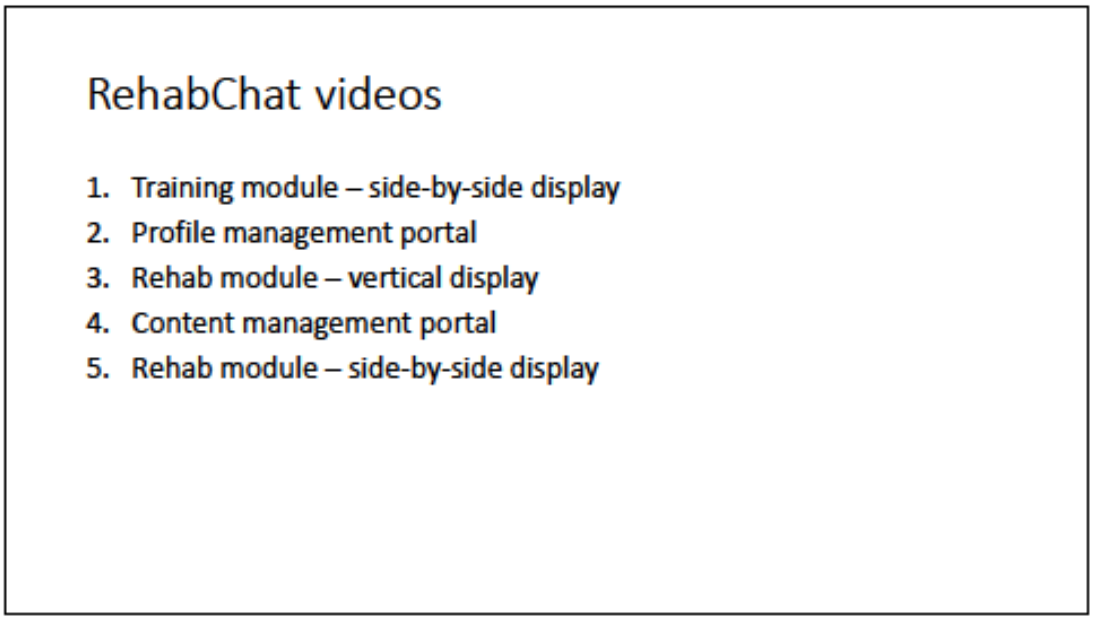
Included studies	#	**Citations identified from reference list checking (n=22)**	**Excluded, with reasons (n=18)**
Huang et al 2012 (149)	1	G. Sieber and B. Krenn, “Towards an episodic memory for companion dialogue,” in Intelligent Virtual Agents (IVA 2010), 2010, pp. 322–328.	Not a CA
	2	M. Y. Lim, R. Aylett, W. C. Ho, S. Enz, and P. Vargas1, “A socially aware memory for companion agents,” in 9th International Conference on Intelligent Virtual Agents (IVA 2009), 2009, pp. 20–26.	Not a CA
Ireland et al 2016 (131)	3	Ireland et al.. 2015	Previously considered in review
Ireland et al 2015 (130)	-	None	-
Leo et al 2019 (155)	4	D’Onofrio, G., Sancarlo, D., Seripa, D., Ricciardi, F., Giuliani, F., Panza, F., et al. (2016). Non-pharmacological approaches in the treatment of Dementia. In D. V. Moretti (Ed.), Update on dementia (pp. 477–449). Rijeka, Croati: InTech.	Not a CA
	5	Douglas, S., James, I., & Ballard, C. (2004). Non-pharmacological interventions in dementia. Advances in psychiatric treatment, 10(3), 171–177.	Not a CA
Lohse 2019 (156)	6	Ho Yan Yvonne Chun, Richard Newman, William N. Whiteley, Martin Dennis, Gillian E. Mead, and Alan J. Carson. A systematic review of anxiety interventions in stroke and acquired brain injury: Efficacy and trial design. Journal of Psychosomatic Research, 104(November 2017):65–75, 2018.	Not a CA
	7	Allison Ellington, Richard Adams, Marga White, and Paul Diamond. Behavioral intention to use a virtual instrumental activities of daily living system among people with stroke. American Journal of Occupational Therapy, 69(3):p1–p8, 2015.	Not a CA
	8	Caitlin Brandenburg, LindaWorrall, David Copland, and AmyD Rodriguez. Barriers and facilitators to using the CommFitTM smart phone app to measure talk time for people with aphasia. Aphasiology, 31(8):901–927, 2017.	Not a CA
	9	Lesli E Skolarus, John D Piette, Paul N Pfeiffer, Linda SWilliams, Jason Mackey, Rebecca Hughes, and Lewis B Morgenstern. Interactive Voice Response-An Innovative Approach to Post-Stroke Depression Self-Management Support. Translational stroke research, 8(1):77–82, 2 2017.	Not a CA
	10	Didi Surian, Liliana Laranjo, Rabia Bashir, Enrico Coiera, AdamG Dunn, Blanca Gallego, Annie Y S Lau, Farah Magrabi, Ahmet Baki Kocaballi, Huong Ly Tong, and Jessica Chen. Conversational agents	Different cohort

Included studies	#	**Citations identified from reference list checking (n=22)**	**Excluded, with reasons (n=18)**
		in healthcare: a systematic review. Journal ofthe American Medical Informatics Association, 25(9):1248–1258, 2018.	
Macedo et al 2019 (132)	11	Linares-del Rey M, Vela-Desojo L, Cano-de la Cuerda R. Mobile phone applications in Parkinson's disease: a systematic review. Neurol (English Ed 2019;34:38–54. doi:10.1016/J.NRLENG.2018.12.002.	Not a CA
	12	Laranjo L, Dunn AG, Tong HL, Kocaballi AB, Chen J, Bashir R, et al. Conversational agents in healthcare: a systematic review. J Am Med Informatics Assoc 2018;25:1248–58. doi:10.1093/jamia/ocy072	Different cohort
	13	Montenegro JLZ, da Costa CA, da Rosa Righi R. Survey of conversational agents in health. Expert Syst Appl 2019;129:56–67. doi:10.1016/J.ESWA.2019.03.054. Completed reference list checking for this review; one citation identified for review: Shaked NA. Avatars and virtual agents - relationship interfaces for the elderly. Healthc Technol Lett. 2017;4(3):83-7.	Different cohort
	14	Pereira C, Macedo P, Madeira RN. Mobile Integrated Assistance to Empower People Coping with Parkinson's Disease. Proc. 17th Int. ACM SIGACCESS Conf. Comput. Access. - ASSETS '15, New York, New York, USA: ACM Press; 2015, p. 409–10. doi:10.1145/2700648.2811394.	Not a CA
	15	Madeira RN, Pereira CM, Clipei S, Macedo P. ONParkinson – Innovative mHealth to Support the Triad: Patient, Carer and Health Professional. Pervasive Comput. Paradig. Ment. Heal., Springer, Cham; 2018, p. 10–8. doi:10.1007/978-3-319-74935-8_2.	Not a CA
Nakatani et al 2018 (153)	16	Tokunaga, S., Tamamizu, K., Saiki, S., Nakamura, M., Yasuda, K.: VirtualCareGiver: personalized smart elderly care. Int. J. Softw. Innov. (IJSI) 5(1), 30–43 (2016)	Not a rehabilitative focus
Nakatani et al 2019 (152)	-	Tokunaga et al 2016 a/a	*(repeat of a/a)*
Saito et al 2015 (150)	17	L.P. Vardoulakis, L. Ring, B. Barry, C.L. Sidner and T. Bickmore. 2012 *Designing Relational Agents as Long Term Social Companions for Older Adults:* Intelligent Virtual Agents conference IVA).	Not a rehabilitative focus
Sakakibara et al 2017 (154)	-	Tokunaga et al 2016 a/a	*(repeat of a/a)*
Wilks et al 2015 (120)	18	Wilks, Y., Catizone, R., Worgan, S., Dingli, A., Moore, R., Field, D., Cheng, W.: A prototype for a conversational companion for reminiscing about images. Comput. Speech Lang. 25(2), 140–157 (2011)	Different cohort
INCLUDED REVIEW: Riboni FV, Comazzi B, Bercovitz K, Castelnuovo G, Molinari E, Pagnini F. Technologically-enhanced psychological interventions	19	Botella C, Etchemendy E, Castilla D, Baños RM, García-Palacios A, Quero S, et al. An e-Health System for the Elderly (Butler Project): A Pilot Study on Acceptance and Satisfaction. Cyberpsychol Behav. 2009;12(3):255-62.	Not a 2-way conversation *- after ref list check, the Riboni et al (2020) review was excluded*

Included studies	#	**Citations identified from reference list checking (n=22)**	**Excluded, with reasons (n=18)**
for older adults: a scoping review. Bmc Geriatrics. 2020;20(1).			
INCLUDED REVIEW: Schachner T, Keller R, Wangenheim FV. Artificial intelligence-based conversational agents for chronic conditions: Systematic literature review. Journal of Medical Internet Research. 2020;22(9).	20	Griol D, Molina JM. An ambient assisted living mobile application for helping people with alzheimer. Communications in Computer and Information Science. 2015. p. 3-14.	Previously considered in review
	21	Ireland D, et al 2016. a/a	Previously considered in review *- after reference list checking, the Schachner et al (2020) review was excluded)*

Appendix V: Design and development processes – Images of RehabChat

Below are copies of the six slides of a PowerPoint presentation included in original thesis; live link to videos in this PowerPoint have been disabled.



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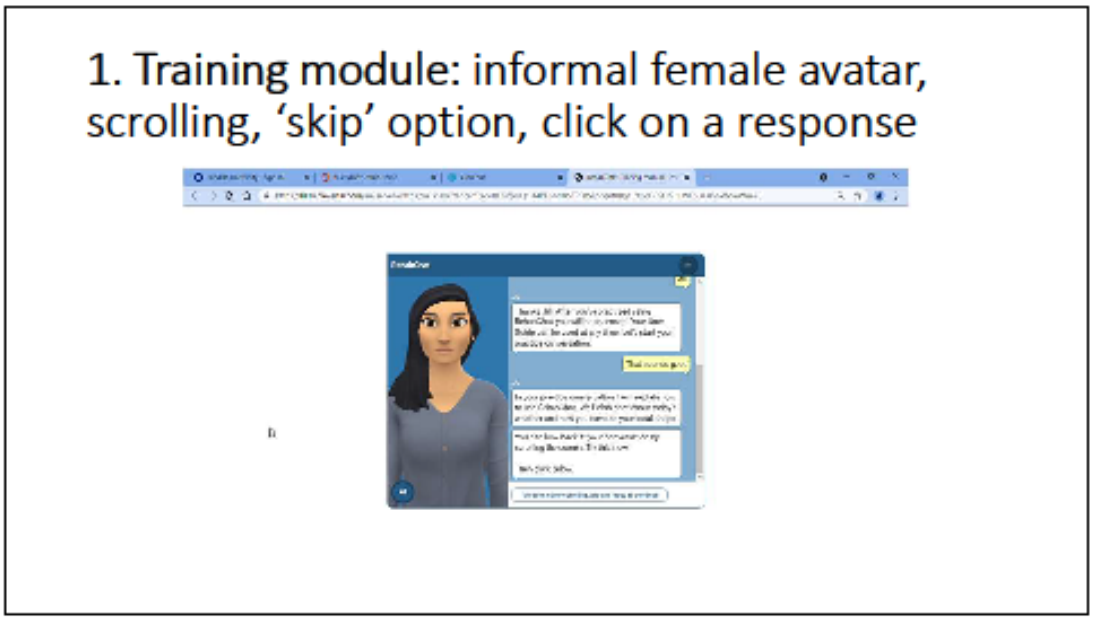
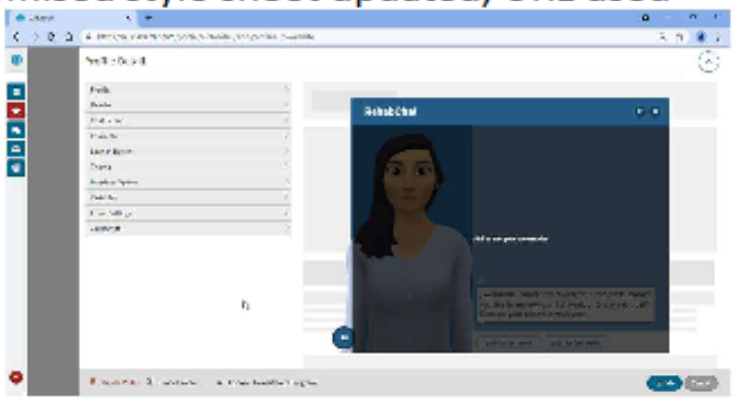


2

2. **Profile management portal:** choose UI functionality, avatar design, UI colour & size, customised style sheet updated, URL used



3

3. **Vertical display:** formal lady avatar; role of therapist emphasized; demonstrates take me back

4

4. Content management portal: sub-conversations, dialogue content, logic decision points connecting dialogues, shows simple continuation option & multiple choice question

5

5. Side-by-side display: informal male avatar; introductions; set a motivational rehab priority

6

Appendix VI: Design and development processes – Dialogue development

The following tables depicts conversation dialogues from the initial ECA prototype used for alpha testing. The table demonstrates how MI, SDT, SMART and clinical needs are incorporated into the dialogue content. This table depicts the early parts of the ECA conversation, specifically the Introduction and Goal setting parts.

Key:

ECA = Embodied Conversational Agent

MI = Motivational Interviewing, with key aspects of: rolling with resistance; define motivational goal; plan change; persist despite setbacks; monitor progress

SDT = Self-Determination Theory tenets of: Autonomy; Connectedness; Competence

SMART = goal setting pneumonic Specific, Measurable, Attainable, Relevant, Time-bound

TBI = Traumatic Brain Injury, and key clinical issues of: concentration; fatigue; pain; dizziness

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
#1 Hi! Thank you for visiting. Click "OK" when you are ready to begin your conversation with RehabChat.				SDT - Autonomy	TBI – cognitively prepared for conversation
	Clicks "OK" (single/only choice to make)			SDT - Autonomy	TBI – time to think before proceeding
#2: Hi I'm Jo, your virtual rehab coach. I'm here to help you in your rehabilitation. Your rehab therapist will also be with you to help out at any time too. It's great to talk about your rehab with you. What is your name? Please write your first name or nick name.				MI – supportive approach SDT Connected	TBI – simple androgenous name, easy to remember
	Enters first/nick name as free text = variable [client name]. This used			SDT – Connectedness	

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
	throughout conversation.				
#3: Hi [client name]. Today it'd be great if we could talk about what you'd like out of your rehabilitation. How does that sound?				MI - focusing SDT - autonomy	SMART - prepare for goal setting TBI – guiding cues to focus attention
	Click "OK" (single/only choice to make)			MI – focusing SDT – Autonomy	TBI - Pausing and confirming at each stage of conversation to enable cognitively can keep up
#4: Have you thought about a goal that is important to you in your rehab?				MI – personal motivation SDT - autonomy	SMART – focus on a single goal TBI – 1 goal is simpler
	Yes	Click "No" **Go to #6**		MI – acknowledging readiness SDT – Autonomy	TBI - Pausing and confirming at each stage of conversation to enable cognitively can keep up
#5: That's great [client name]. How can you describe your rehab goal? Please write a few words to complete the sentence: "My goal is to be able to..."				MI – reinforce positive steps in client's thinking & decision-making SDT - Autonomy	SMART – focusses upon Specific aspect TBI – support learning through positive reinforcement, and errorless learning principles (used throughout)
	Free text to enter main goal = variable [main goal] used during rest of conversation. **Go to #20**			MI – change talk SDT – Autonomy, competence	SMART – goal-setting commenced TBI – using client's own words helps to keep client engaged in process
From No response for #4 a/a: **#6:** That's OK. Instead of thinking of a goal, sometimes it's easier to think of something that feels hard to do, or that you're struggling with. From there, you can look at developing a goal. So [client name], can you think of something that is hard for you to do at present?				MI – rolling with resistance, empathy, non-judgmental, building trust, SDT - Autonomy	SMART – approaching Specific aspect from different angle TBI – utilizing alternative phrase & words to describe & enable goal setting. This is needed because not all clients will know what goal setting means, &/or they may not see it as meaningful.
	Choose "Yes"	Choose "No" **Go to #14**		MI – allowing for & rolling with resistance	TBI – simple decisions to make along the way enable the client to pause &

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
				SDT – Autonomy for choice-making	reflect on the process, & on what they're thinking. This stepwise approach to thinking could help the client remain focused, engaged, and help avoid frustration & fatigue.
#7: OK. OK. Tell me something that's hard for you to do at the moment. Complete this sentence: "At the moment it's hard for me to..."				MI - focusing SDT - Autonomy	SMART – approaching Specific aspect from different angle TBI – the reiterative style of the ECA could help avoid cognitive fatigue & could build trust in the client that the ECA will track what they are wanting and have already chosen.
	Free text = variable [hard to do]			MI – identify barriers SDT - Autonomy	SMART- starts to prepare linking in with Meaningful aspect TBI – allows client to focus upon their current experience, rather than trying to project a future hope and make a goal. This option is important to provide for the clients, because they may have difficulties with planning for future times, and in visualising possibilities.
#8: So, at the moment you find it's hard to [hard to do]. That must be difficult. Rehabilitation can help you with this. How would you like to focus on it in your rehabilitation? You are welcome to describe what you would like to focus on. Please don't use 'I' or 'you'. Please complete the sentence: "I would like to focus just on ... (up to 7-10 words)". Placeholder = your focus in rehab				MI – empathy, build trust. SDT	SMART – progressing with Specific aspect TBI – acknowledging & focusing upon where the client is at currently- thinking about the current situation can be easier for people with brain injury than trying to envisage the future.
	Free text = variable [focus for rehab]			MI – desire for change SDT – Autonomy	SMART – progressing with Specific aspect TBI – time to think things through
	Free text = variable [focus for rehab]				

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
#9: So you're interested in focusing on [focus for rehab]?				MI – supports client-centred choice-making SDT	SMART – confirming Specific details TBI – checking the decision made, allowing client to review the decision
	Click "Yes"			MI – focusing; reinforcing decision made	
#10: That's a great step. Tell me, why is it important for you to focus on [focus for rehab]? You are welcome to describe why this focus for your rehabilitation is important to you. Please don't use 'I' or 'you'. Please complete the sentence "My focus for rehab of [focus for rehab] is important to me because it…(up to 7-10 words)". Placeholder = "reason my focus of rehab is important"				MI – reiterating helps to improve trust & rapport. Focusing in on meaningfulness [motivating factor] will support ongoing engagement and help overcome barriers in the future. SDT - Autonomy	SMART – focuses on Meaningful aspect TBI – using alternative words apart from goal setting & motivation allows client to explore the process using cognitive processes in alternative ways
	Free text = variable [why focus is important]			SDT – Autonomy; allowing client to identify key information	SMART – this strengthens the Meaningful aspect TBI – supporting the client to explore their chosen area of rehab focus, to identify why it is actually important for them. These are two separate but related cognitive efforts.
#11: I see. That sounds really important - you're wanting to focus on [focus for rehab] which is important to you because [why focus is important].				MI – building trust through accurately reiterating the important think that the client has said	
	Click "Yes"			MI – reinforcing decisions made	TBI – pause and reflect moment
#12: What do you think of the idea of your rehabilitation focusing on [focus for rehab]? Would you like this?				MI – focusing; supportive approach SDT – autonomy; reinforcing that the client is able to	

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
				choose the direction of their rehab	
	Choose "Yes"	Choose "No" **Go to #14**		MI – strengthens commitment; and alternatively allows disengagement – roll with resistance SDT - Autonomy	TBI – pause and reflect moment, to allow client to keep up with process of conversation
#13: That's great. The first step [client name], is to turn your idea for what you want to change into something you want to do, something you want to achieve. This then becomes your goal. goal is something that you're aiming for, something you are wanting to change. What goal could help you achieve changing [focus for rehab]? You are welcome to describe this goal for what you want to change. Please don't use "I" or "you", Please complete the sentence: " I want to be able to... (up to 7-10 words)". Placeholder = "write you goal for what you want to do or achieve"				MI – supporting client's early change thinking – i.e. the steps before actual goal setting SDT – connectedness with ECA through using client name. Also, autonomy, in that the client is learning they can impact the focus of their rehab.	SMART – focuses on Meaningful aspect TBI – allows the client to think about their rehab needs in an alternative way
	Free text = variable [main goal]. **Go to #20**			MI SDT – Autonomy, competence. Li k with intrinsic motivation	SMART – clarifies the Specific aspect TBI – can focus clearly upon goal-setting process from the beginning of conversation, if they are ready to do so.
(From No response at #6 a/a, & from #12 a/a) **#14:** That's OK. I wonder [client name], when you started your rehab, did you have in mind something that you hoped you'd get out of it?				MI– using different wording to help client try to connect MI with what is intrinsically motivating	
	Choose "Yes"	Choose "No" **Go to #18**		SDT - Autonomy	TBI – still providing opportunity for client to not go down the path of intrinsic motivation, as their brain recovery may not yet allow for this.
#15: Okay. Can you tell me what you've hoped to get out your rehabilitation? You are welcome to				MI – ongoing rapport building by following where the client	

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
describe this hope for your rehab. Please don't use "I" or "you". Please complete the sentence: " I've hoped that in my rehab I'd be able to... (up to 7-10 words)". Placeholder = "what I hope for in rehab"				wishes to go with their responses	
	Free text = variable [rehab hope];			MI – using client's own words, not para-phrasing	TBI – asking this question promotes in the client time to reflect upon the deepr intrinsic motivators. Linking to this motivation will help recovery
#16: [client name], your hope to be able to [rehab hope] sounds really important to you. Is that right?					SMART – appraising Meaningful aspect
	Choose "Yes"	Choose "No" **Go to #18**		MI – clarifying, focusing; ensuring clear understanding of client's needs	
#17: It sounds like you're ready to try working towards that hope. Your rehabilitation can focus on helping you work towards achieving what you've hoped for. The first step is to set a goal for achieving what you've hoped for in your rehab. Would you like to try setting this goal?					TBI – using variety of approaches to focus on intrinsic motivation i.e. the word hope; ad also to link in with hope which has some early research supporting this aspect for recovery
	Click "Yes" Jump back to #5	Choose "No" **Go to #18**			TBI – regularly allow simple choice making to reinforce client's sense of engagement in process of the ECA conversation
(From No response at #14, #16 & #17 a/a) **#18:** It seems it has been difficult for you to see your way forward in rehab.				MI – empathy, rapport, roll with resistance	TBI – not demanding too much from the person before they are ready; stage of recovery from brain injury may not yet allow planning and goal setting
	Yes it has			MI – facing challenges	
#19: It would be great for you to spend some more time talking with your therapy team to explore what rehab can do for you. Once you've had some time to think about your rehabilitation goals, please link in with this program again!				MI – supportive approach, but clarifying and focusing where the person is actually at currently	

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
	Click "OK" Jump to #37			MI – self-acknowledgement of current personal situation SDT – connectedness: still stating can ref=join this program	
(from #13 above) **#20:** Let's talk about your goal of being able to [main goal]. How confident are you that you can achieve your goal of [main goal]? Please give it a score of a number out of 10, where 10 out of 10 means extremely confident, and 0 out of 10 means not at all confident.					SMART – appraise Achievable aspect
	Score between 0-10 (If <= 4 indicates not confident)	Score between 0-10 (If >=5 indicates confident) **Go to #23**		MI – honest appraisal of situation SDT – competence	SMART – appraise Achievable aspect
#21: Why are you not feeling confident? Please write the main reason that causes you to struggle with feeling confident. You are welcome to describe this reason. Please don't use 'I' or 'you' in your answer. Please complete the phrase "The reason I'm not that confident I can achieve my goal of [rehab goal] is because of … (up to 7-10words)". Placeholder = "reason I'm not that confident"				MI – empathy; identify barriers; roll with resistance SDT - Autonomy	
	Free text = variable [reason not confident]			MI – identify barriers, roll with resistance	
#22: Would you like to focus on improving your confidence by working on the reason for your low confidence which is [reason for low confidence]?				SDT – Autonomy, competency	SMART – ensuring Meaningful aspect TBI – using alternative ways to help the client think through goal setting

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
	Choose "Yes" Jump back to #10	Choose "No" Jump back to #18		SDT - Autonomy	
(From Confident at #20 a/a) **#23:** That's great to hear you are feeling confident. Being confident will help in your rehabilitation. Your confidence can benefit from having someone who can support you in achieving your goal. Who is someone who can help you achieve this goal? This support person can be anyone, except not your health care professionals or RehabChat. Please write your support person's first name or nick name.				MI – reinforcing overcoming of ambivalence, & making proactive steps forward	SMART TBI – using variety of words i.e. not just motivation; galvanizing & supporting confidence; confidence is essential for improved learning
	Free text = variable [support person] **Go to #24**			SDT – connectedness, autonomy	
#24: How can [support person] help you?				MI – focusing; identifying resources SDT – Autonomy, competency	SMART – reinforce Achievable aspect
	Chose "encouragement" **Go to #25**			MI – making achievable plans; rolling with resistance; overcome apathy SDT – autonomy, competency	SMART - Achievable TBI – encouraging reflection on what of support is most helpful to match needs & preferences
	Choose "reminders" **Go to #26**			MI – making achievable plans; rolling with resistance; overcome apathy SDT – autonomy, competency	
	Choose "do the exercises and activities with me" **Go to #27**			MI – making achievable plans; rolling with resistance; overcome apathy	

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
				SDT – autonomy, competency	
	Choose "not sure" **Go to #28**			MI – making achievable plans; rolling with resistance; overcome apathy SDT – autonomy, competency	
#25 It would be great if [support person] could encourage you. Would you like to talk to [support person] about this, or do you want your therapist to include this in your home program?			**#27** It would be great if [support person] could do your rehabilitation program with you. Would you like to talk to [support person] about this, or do you want your therapist to include this in your home program?	MI – roll with resistance; empathy	SMART – ensure Specific & Meaningful aspects are clear
#26 It would be great if [support person] could give you reminders for your rehabilitation home program. Would you like to talk to [support person] about this, or do you want your therapist to include this in your home program?			**#28** That's OK that you're unsure. Perhaps you could focus instead upon what will help you be motivated to achieve your goal. After that you could decide if [support person] could help with your motivation. How		

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
			does that sound?		
For #25-28 above, the response options are all the same as here…	Choose "I will talk to [support person]"	Choose "I want my therapist to include it in my home program"		MI – stepwise forward planning for change SDT – Autonomy, connectedness	TBI – single -step decision making to avoid mental fatigue; option for having it written as a prompt reminder on home program
#29 That sounds great. Their support will be really helpful for your rehab.			#30 That's fine. This can be included in your home program for you.	MI – positive reinforcement of personally-set decisions	SMART – making specific details for goal TBI – person chooses if they will benefit from doing it themselves or by having the prompt included in their home program
	Yes, I agree	Great		SDT - Autonomy	TBI – step-wise confirmation of ideas
#31 Thanks for chatting about your rehabilitation! You have set a very important goal of being able to [main goal]. You have also identified that [support person] can support you in your rehabilitation program. Next we will talk a little about motivation during your rehabilitation.				MI – confirming the plans made	TBI – orientation for stages of conversation
	Sure			MI – reinforce plans made	TBI – confirming each step to ensure keeping clear on each step
#32 What will help you feel motivated to achieve your rehab goal of [main goal]? You are welcome to describe this below. Please don't use the words "I" or "you". Please complete the following sentence - "The thing that will help me feel motivated to achieve my rehab goal is ... (up to 7-10 words)".				MI – strengthening talk SDT – Autonomy, motivation factors	SMART - achievable TBI – step-wise approach to planning
	Free text = variable [motivating factor]			SDT – Autonomy, motivation factors	TBI – specific personal need regarding motivational support
#33 Thank you for describing what will help motivate you [motivating factor] to achieve your rehab goal. How can [support person] help you with this? Please				MI – planning for resources to help ensure success	SMART - Achievable TBI – choosing specific ways that are tailored to preferences and needs

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
describe this by completing the sentence: "[support person] can help me be motivated to achieve my rehab goal by ... (up to 7-10 words)".				SDT – connectedness, autonomy	
	Free text [motivational support]			MI – planning for success SDT- Autonomy, Connectedness	TBI – identifying type of motivational support needs
#34 That would be great if [support person] could support your motivation by [motivational support]. Would you like to talk to [support person] about this, or do you want your therapist to include this in your home program?				MI – planning to make progress with supports, identifying resources SDT – connected; & motivational aspects	SMART - achievable TBI – need for motivational support
	I will talk to [support person]	I want my therapist to include it in my home program		MI – choosing ways to progress forward SDT- autonomy	SMART- get support for goal means it'll be more achievable TBI – stepwise decision making
#35 That sounds great.			#36 Sure. this can be included in your home program. That sounds great. Go to #37.	MI – reinforce planning SDT - connectedness	TBI – confirming each step decided
#37 We've almost reached the end of our chat – thank you very much for your time! After this conversation, I will next catch up with you during your practice times. Before we finish, did you want to ask any other questions about your rehabilitation goals?				MI – rapport, reinforcement, exploring barriers SDT - autonomy	TBI – allowing sufficient time to think through each phase before progressing to next phase
	Choose "Yes"	Choose "No" **Go to #45**		SDT- autonomy	TBI – each point of decision making is not rushed
#38 Ok that's great. Please write your question below? You are welcome to ask about anything to do with your rehabilitation goals.				MI – explore barriers SDT- autonomy	SMART – ensuring achievable & relevant

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
	Free text = variable [rehab question]			MI – considering the way forward SDT - autonomy	
#39 Thanks for writing down your question about your rehab goal setting. For this question – [rehab question] – could your health care professional or your support person [support person] help you with it?				MI – affirmation, roll with resistance SDT – connectedness, autonomy	
	Yes my health care professional can help **Go to #40**			MI – support to overcome barriers SDT – connected, autonomy	TBI – simple problem solving supported
	Yes, [support person] can help **Go to #41**			MI – support to overcome barriers SDT – connected, autonomy	SMART – reinforcing planning to solve queries in a way that is Achievable
	No, neither could help **Go to #42**			MI – identify negatives, roll with resistance SDT - Autonomy	
(From above) #40 That's great. The therapist helping today can follow this up with you.				MI – confirming the plan SDT – connectedness	TBI – reinforce planning made
	Thanks Go to #45			MI – positive agreement	TBI – step-wise confirmations as progress through conversation
(From above) #41 That's great. Did you want to talk to [support person], or would you like your therapist to include it in your home program?				MI – planning the way forward SDT - autonomy	SMART – supports the set goals & achievable aspect TBI – choices that suit
	I will talk to [support person] **Go to #43**	I would like my therapist to include it in my home program **Go to #44**		SDT – Autonomy; choice-making	SMART – clarifying information to include on the home program to support Achievability

ECA dialogue iteration	Client-user's response to dialogue iteration	Alternative user response options to dialogue iteration	ECA dialogue iteration following alternative user response	MI & SDT	SMART goal setting & TBI clinical needs
(From above) #42 OK. It would be great if you could have some help to answer your question. It may be worth talking about this question with your rehab therapist, when you're ready to do so.				MI – reinforcing positively the client's decision	TBI – progress at rate of change that is comfortable for client
	Thanks **Go to #45**				TBI – a pause & reflect moment; validating their choices and process they've participated to
#43 That sounds great. It would be good for you to talk with [support person] about your question.				MI – reinforcing planning SDT - connectedness	TBI – ensuring clear understanding of process
	Yes it will be good to get the help **Go to #45**			MI – reinforcing planning, highlighting the need to not only identify supports u to seek and receive the support and help SDT - connectedness	
#44 That will be fine. Your therapist will include this in your home program.				MI – reinforcing planning SDT - connectedness	
	Thanks – that'd be great **Go to #45**			MI – positive reinforcement of planning of the plans they've made	
(From #37, #40 & #43 a/a) **#45** That's fine. All the best with doing your rehab program! I will catch up with you during your practice times. Bye for now!				MI – positive reinforcement; acceptance	TBI – orientating to each phase of conversation
	Thanks!				SMART – complete the goal setting process TBI

Legend: ECA = Embodied Conversational Agent; MI = Motivational Interviewing, with key aspects of: rolling with resistance; define motivational goal; plan change; persist despite setbacks; monitor progress; SDT = Self-Determination Theory tenets of: Autonomy; Connectedness; Competence; SMART = goal setting pneumonic Specific, Measurable, Attainable, Relevant, Time-bound; TBI = Traumatic Brain Injury, and key clinical issues of: concentration; fatigue; pain; dizziness.

Appendix VII: Design and development processes – Beta testing user guide

Flinders UNIVERSITY | Flinders Digital Health Research Centre

RehabChat: Motivational Chatbot for Brain Injury Rehabilitation – *User guide*

1 Overview of RehabChat

RehabChat is a chatbot App designed to motivate adults with mild traumatic brain injury during their rehabilitation. It is being **developed as part of Judith Hocking's PhD within the Flinders Digital Health Research Centre. RehabChat is** the first time a chatbot has been developed to support motivation in adults with brain injury. So far it has undergone Alpha Testing, which focused on improving technical aspects and general usability. RehabChat is intended to be pilot trialed at the Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS) based at the Repatriation General Hospital. It is envisaged RehabChat will be used on iPads or tablet devices, alongside usual rehabilitation care, and with clinician oversight.

1.1 The way RehabChat is used

The main purposes intended for using RehabChat are to provide the client-user with a motivational conversation which focuses upon their rehabilitation priority, and to clarify this priority as a real goal which will be addressed in during their rehabilitation. **RehabChat supports the client's motivation and persistence to do their prescribed** exercises. **The clinician carries clinical responsibility for the client's care.**

There are some criteria which must be met prior to a client being able to use RehabChat

- The client must already be receiving rehabilitation care at EMMBIRS
- One of their therapists must **commit to providing clinical oversight of the client's use of RehabChat**
    - This therapist needs to have received training by a RehabChat researcher to understand how RehabChat works
    - This therapist will provide clinical oversight which includes
        - **Monitoring the client's well**-being when using RehabChat
        - Ensuring that any required information is provided for using RehabChat, for example completing details for home program activities; and if needed communicate with a RehabChat researcher about any problems which arise.

1.2 What is included in the RehabChat conversation?

A RehabChat conversation comprises the following main parts

- Define the main priority and why it is motivating for the client
- Turn the priority into a rehabilitation goal
- (then the client and clinician work together in the clinic to devise a home program)
- Enter details of the home program into Rehabchat
- RehabChat supports home practice of the program
- **RehabChat enables review of the client's progress overall**

1.3 Limitations of RehabChat

RehabChat does not provide clinical advice nor does it resolve clinical challenges. RehabChat must be used with clinician oversight.

2 RehabChat Beta Testing

Beta testing of RehabChat is focused upon the its clinical relevance and acceptability; with attention given to the perspectives of clinicians and clients. Participants will practice using the RehabChat prototype, and provide written feedback using the provided feedback form. All feedback will be treated anonymously and considered equally. Beta Testing recommendations will be integrated within the design of RehabChat wherever possible. Ethics Committee approval is not required for Beta Testing.

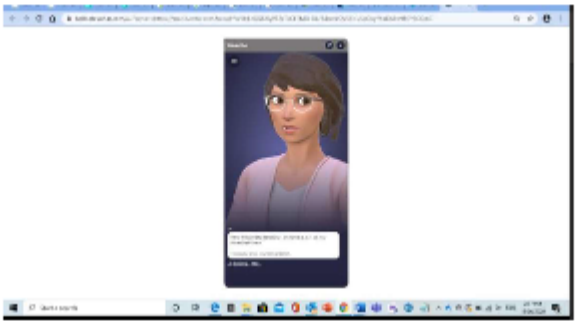
3 Your involvement in RehabChat Beta Testing

You have been invited to participate in Beta Testing because you are a Flinders University researcher or PhD candidate with an interest in brain injury clinical research utilising digital technology. If you participate, you will practice using RehabChat for 20-30 minutes, and think about your perspectives regarding clinical relevance and acceptability. You will then write you perspectives and recommendations onto the Feedback form supplied and email this form back to Judith Hocking (######). You will need access to a computer or tablet device, and a web browser (not Internet Explorer). You should not share RehabChat with other people or sites.

4 How to use RehabChat

1. You will receive an email from ######
    a. This email will include the e-link for the prototype chatbot, and the Feedback Form
2. Open the email on the laptop or desktop computer that you intend to use for trialling the chatbot
3. Click on the e-link for the prototype chatbot
4. The chatbot will open in a window on your computer's web browser
5. When the chatbot opens on your screen, it will look like this:

6. Click on the chatbot icon.
7. The chatbot will open on your screen and look like this:



    a. If you cannot see all of the humanoid figure, try decreasing the magnification of your screen by zooming down so that you can see all of the humanoid character.

8. Follow the prompts of the chatbot to commence your conversation.
9. Stopping your conversation, and recommencing it
    a. When using RehabChat you can stop your conversation at any point and recommence it again later
        i. To recommence at the same point in the conversation

        Firstly, you need to stop the RehabChat conversation by clicking on the 'X' in the top right corner of the RehabChat interface. Alternatively, you can close your internet browser window.

        To recommence your conversation, you just need to re-open RehabChat using the URL already sent to you.

    a. To restart the conversation from the beginning

    If you would like to restart your conversation from the beginning, you need to click n the circular arrow **'refresh' button in the top right of the RehabChat interface. Please note that clicking on the refresh button** will clear RehabChat of all of your previous entries, and so it is not recommended unless really needed.

10. Answer all of the questions in the conversation.
11. Complete the chatbot conversation.
12. Make notes of your feedback directly onto the Feedback Form. Return your completed feedback form to ######

Thank you for your involvement!

Appendix VIII: Co-design workshops – Ethics approval

Below are copies of the approval letters from the Central Adelaide Local Health Network CALHN Human Research Ethics Committee (HREC) for Ethics approval and site-specific governance approval.

Government of South Australia
Health
Central Adelaide Local Health Network

Central Adelaide Local Health Network
Human Research Ethics Committee

North Terrace
Adelaide, SA, 5000

RAH Tel 08 7117 2229
TQEH/BHI Tel 08 8222 6841

Health.CALHNResearchEthics@sa.gov.au
www.health.sa.gov.au

ABN: 96 269 526 412

Approval Date: 20 July 2020

Prof Anthony Maeder
Flinders Digital Health Research Centre
COLLEGE OF NURSING AND HEALTH SCIENCES

Dear Prof Anthony Maeder

CALHN Reference Number: 13700

Project Title: The Development of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation

Human Research Ethics Committee APPROVAL

Thank you for submitting the above project for ethical and scientific review. The application was first considered by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) at its meeting held on 04 April 2020

The CALHN HREC has reviewed all responses, and I am pleased to advise that the application has been granted full ethics approval. The project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* updated 2018.

The documents reviewed and approved include:

Document	Version	Date
HREA Application - AU/1/224B318	-	30 March 2020
Cover Letter	-	-
Protocol	2	-
Participant Information Sheet/Consent Form - Client	3	02 July 2020
Participant Information Sheet/Consent Form - Clinician	3	02 July 2020
Phone process obtaining initial consent/re-negotiating consent	-	-
Demographic Questionnaire for clients	-	-
Demographic Questionnaire for clinicians	-	-
Guide for conducting co-creation workshops	-	-
Promotional brochure	-	-
Promotional poster	-	-
Supporting Documents: ▪ Investigator CV – Anthony Maeder ▪ Investigator CV – Belinda Lange ▪ Investigator CV – Maggie Killington ▪ Investigator CV – David Powers ▪ Investigator CV - Lua Perimal-Lewis ▪ Investigator CV – Judith Hocking		
Response to request for further information - email	-	27 April 2020
Response to request for further information - email	-	20 July 2020

Sites covered by this approval:

Site	State	Investigator
South Australian Brain Injury Rehabilitation Services (SABIRS), Early Management of Mild Brain Injury Rehabilitation Services (EMMBIRS).	SA	CPI: Prof Anthony Maeder
South Australian Brain Injury Rehabilitation Services (SABIRS), Early Management of Mild Brain Injury Rehabilitation Services (EMMBIRS).	SA	PI: Dr Maggie Killington

CALHN HREC approval is valid for 5 years from: **20 July 2020 to 20 July 2025**

13007 Maeder - Approval Letter

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the project must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. The CALHN HREC is certified by the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review. The CALHN HREC is the reviewing HREC for the purpose of this ethics approval. Any project sites that are not listed on this letter are not covered by this ethics approval. Any project sites that wish to be added must contact the CPI, who must formally request the additional sites to be added by CALHN HREC.
3. Researchers must notify the CALHN HREC of any events which might warrant review of the approval or which warrant new information being presented to research participants, 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) premature termination of the project.
4. All all clinical trials approved by the CALHN HREC must comply with the NHMRC Guidance on *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016)*. https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018.
5. The CALHN HREC must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.
6. Confidentiality of the research participants must be maintained at all times as required by law.
7. Adequate record keeping is important and must be maintained in accordance with Good Clinical Practice, NHMRC and state and national guidelines. If the project involves signed consent, researchers must retain the completed Consent Forms which relate to this project and a list of all those participating in the project to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years from completion of the project.
8. Approval is valid for **5 years** from the date of this letter after which an extension must be applied for.
9. **Annual Progress Reports must be submitted to the CALHN HREC, every 12 months on the anniversary of the above approval date**. The Coordinating Principal Investigator for all multi-site projects or the Principal Investigator for single site projects must provide reports 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 HREC approval. Continuation of ethical approval is contingent on submission of this report, due within 30 days of the approval anniversary. Failure to comply may result in suspension of the project.
10. **A Final Report must be submitted to the CALHN HREC on completion of the project and for all site closures.** The Coordinating Principal Investigator for all multi-site projects or the Principal Investigator for single site projects must provide a final report of the outcome for completed research projects and for all site closures. A copy of any published material must also be provided with the report, or following when available.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the CALHN Governance Office: ***Health.CALHNResearchGovernance@sa.gov.au***

The CALHN HREC is constituted in accordance with the NHMRC's *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates.

Should you have any queries about the CALHN HREC's consideration of your project, please contact the CALHN HREC Support Officer on 08 7117 2229, or Health.CALHNResearchEthics@sa.gov.au.

The CALHN HREC wishes you every success in your research.

Yours sincerely,

Ian Tindall
Chair, Human Research Ethics Committee
Central Adelaide Local Health Network

Government of South Australia | Health
Central Adelaide Local Health Network

Central Adelaide Local Health Network
Research Office
Level 3, Roma Mitchell House
North Terrace, Adelaide SA
Australia 5000

T : 08 7117 2209
T : 08 8222 6841
E : Health.CALHNResearchGovernance@sa.gov.au
E : Health.CALHNClinicalTrials@sa.gov.au

31 July 2020

Prof Anthony Maeder
Flinders Digital Health Research Centre
COLLEGE OF NURSING AND HEALTH SCIENCES

Dear Prof Maeder,

CALHN Reference Number: 13007

Project Title: The Development of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation

RE: Governance Review

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to commence at the South Australian Brain Injury Rehabilitation Services, SA.

Authorisation is valid from **31 July 2020 to 31 July 2022**. Proposed extensions beyond this term must be submitted as an amendment to the CALHN Research Office.

The following conditions apply to the authorisation of this research project. These are additional to those conditions imposed by the Human Research Ethics Committee (HREC) that granted ethical approval to this project:

1. Authorisation is limited to the site/s identified in this letter only.
2. Project authorisation is granted for the term specified above.
3. The study must be conducted in accordance with the conditions of ethical approval provided by the lead HREC, SA Health policies, and in conjunction with the standards outlined in the *National Statement on Ethical Conduct in Human Research* (2007) and the *Australian Code for the Responsible Conduct of Research (2007).*
4. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the HREC for review, are copied via email to the CALHN Research Office;
5. Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted via email to the CALHN Research Office;
6. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
7. Proposed amendments to the research protocol or conduct of the research which may affect both the ongoing ethical acceptability of the project and the site acceptability of the project are to be submitted to the CALHN Research Office after a HREC decision is made.
8. A copy of this letter should also be maintained on file by the Coordinating Principal Investigator as evidence of project authorisation.
9. Notification of completion of the study at this site is to be provided to the CALHN Research Office.

You are reminded that continuation of governance approval is contingent on submission of the Annual Progress Report to the reviewing HREC, a copy of which must be submitted to the CALHN Research Office along with acknowledgement of the report by the reviewing HREC. Failure to comply may result in suspension of the project.

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.

We wish you every success in your research project.

Yours sincerely

Bernadette Swart
Manager, CALHN Research Office
Ph: 7117 2209
Email: Health.CALHNResearchGovernance@sa.gov.au

Appendix IX: Co-design workshops – Information & consent form for clinicians

Flinders University | Flinders Digital Health Research Centre

Participant Information Sheet/Consent Form for Clinicians

Health/Social Science Research - *Adult providing own consent*

Early Management of Mild Brain Injury Rehabilitation Service, RGH, Daw Park

Title	The Development of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Developing a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	13007
Project Sponsor	Professor Anthony Maeder
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Hocking
Associate Investigator(s)	Dr Lua Perimal-Lewis, Prof David Powers, A/Prof Belinda Lange
Location	Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS), and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project called **Developing a motivational RehabChat App for Brain Injury Rehabilitation**. You are able to participate because you are a clinician who is currently working at EMMBIRS or BIRCH South.

This Participant Information and Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or co-worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project

- **Consent to be involved in the research described**
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The aims of this project are to learn about the needs of EMMBIRS or BIRCH South clients regarding their rehabilitation goals and recovery, and to develop a motivational RehabChat App which supports these needs.

- The RehabChat App is computer-based and can have simple conversations with a person. It can be designed to support motivation and recovery for EMMBIRS or BIRCH South clients. Motivation is important for brain injury rehabilitation. A motivational RehabChat App could help improve recovery after brain injury. This is the first time that a motivational Chat App has been developed for brain injury rehabilitation.

Using a hand-held device

How the RehabChat App may look

The project researcher Judith Hocking will speak with current and discharged clients of EMMBIRS or BIRCH South, and with clinicians from EMMBIRS or BIRCH South, about brain injury rehabilitation goals, motivation and recovery, and how to design the RehabChat App. Four workshops will be held at EMMBIRS and/or BIRCH South for these discussions. A second project researcher, Lua Perimal-Lewis, may also be involved in these discussions.

The results of this research will be used by Judith Hocking to obtain a Doctor of Philosophy degree. This research has been initiated by, and will be conducted by, Judith Hocking and the Flinders Digital Health Research Centre, Flinders University (FDHRC).

3 What does participation in this research involve?

If you are interested in taking part in this research, you will be asked to read and sign a consent form before any part of the study is completed.

Four rounds of co-creation workshops will be conducted either face-to-face or using tele-conferencing. Face-to-face workshop meetings will take place in a private meeting room at the Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS) or Brain Injury Rehabilitation Community and Home, South, (BIRCH South), Daw Park SA. Tele-conferencing workshop meetings will require you to use a mobile device or computer.

Each workshop meeting will last one hour, and be held about monthly. You will be required to attend and participate in four workshop meetings.

Details of the four workshops:

- All participants will have equal opportunity to speak.

- You will be invited to discuss recovery following brain injury, rehabilitation goals, and motivation.

- You will be able to try out the RehabChat App and provide feedback about its design.

- For the first three workshops, you will meet with up to 4 other clinicians. Separate meetings will be held for current and recently discharged (within the past month) clients, and for prior clients discharged in the previous 1-3 months.

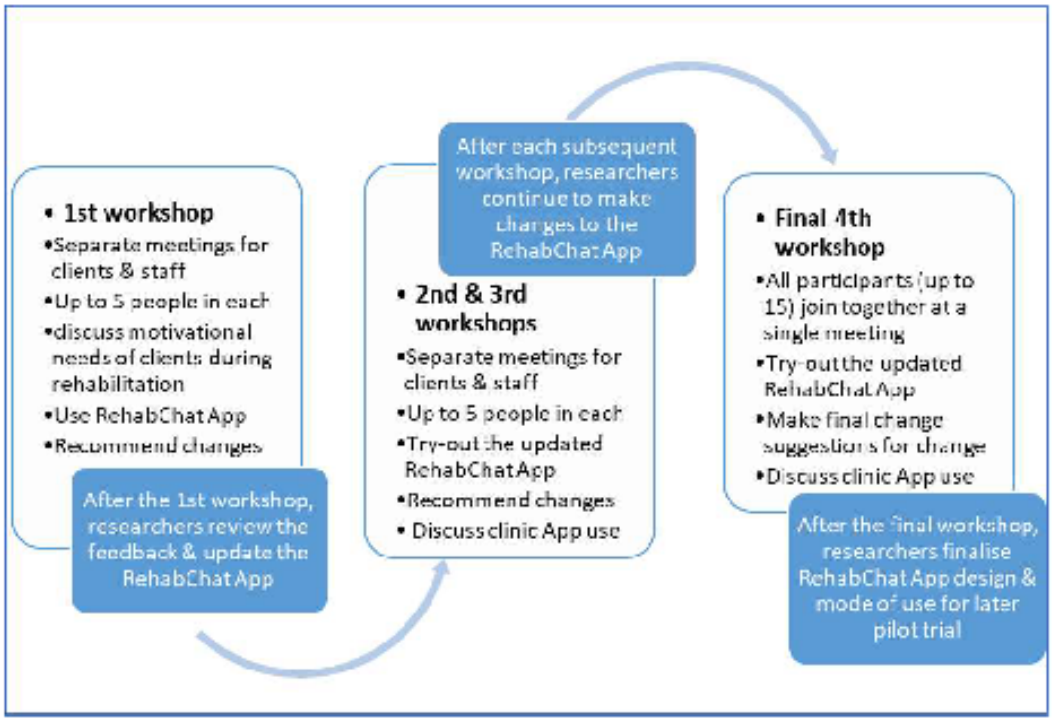
- One final workshop will be held with all client participants, and also with up to 5 clinicians from EMMBIRS and BIRCH South, meeting together.

- After each workshop, the researchers will update the design of the RehabChat App according to what the participants have recommended.

- Light refreshments will be provided (tea, coffee and biscuits) at each workshop.

- **See the '***Flow-chart of how the workshops* **will be run'** below.

Flow-chart of how the workshops will be run:



This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoid jumping to conclusions. We will audio record the workshops so that participant feedback can be accurately collected and analysed. Results from the project may be included in publications or presentations. No identifying information of the participants will be shared outside of the project, nor in any report or other write-up or presentation of the project.

Following completion of the study, you will not have any follow-up from the research team. There are no costs associated with participating in this research project. You will receive a $25 Coles-Myer gift card at the final workshop.

4 Other relevant information about the research project

Up to 15 participants will be taking part in this project at EMMBIRS and/or BIRCH South: up to 5 current clients, up to 5 discharged clients, and up to 5 clinicians.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your clinical care at EMMBIRS or BIRCH South, or your relationship with staff at EMMBIRS or BIRCH South, or your relationship with the researchers.

6 What are the possible benefits of taking part?

There are no direct benefits to you from your participation in this research; however, your participation will contribute to developing a motivational RehabChat App for use by people with a brain injury.

7 What are the possible risks and disadvantages of taking part?

During the workshops you may become tired. If so, you can take a rest break. You may feel that some of the questions we ask during the workshops are distressing; if so, you may take a rest break and return when you feel comfortable. Please let the facilitators know if you need to take a rest during the workshop or leave early. If you do not wish to answer a question, you may remain quiet. If need, you may like to **contact 'Beyond Blue' telephone counselling on Free call 1800 010 630. The research team will not** provide any counselling.

While the researchers do not expect these risks to be present during the study, if this happens to you during the research project you may take a rest break or discontinue your participation in the workshop. Your safety is important to us. You can tell us if you are worried or feel uncomfortable about anything during the project.

Confidentiality

The research team will keep data and information confidential and secure. Whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of **Consent' form; t**his will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional information from you. Information already collected will be retained to ensure that the results of the research project can be analysed properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as research member/s becoming ill. As well, the researchers may recommend that you cease your involvement in the workshops if this is in your best interests.

10 What happens when the research project ends?

At the end of this study, we can provide you with a summary report of the research so that you can be aware of the outcomes. Individual results will not be available. If you are interested in receiving a summary of the study findings, please discuss with the researcher. We will also ask you if you wish to be

contacted for participation in a future pilot trial of the RehabChat App at EMMBIRS and BIRCH South. The research team will otherwise not make any contact with you after the project ends.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The personal information collected in this project is individually identifiable, and will include: your name, contact details, age, gender, and occupation/vocation details. During this project, your medical / health records will not be reviewed at all. In the workshops, participants will be instructed to only use their first name or nickname, and to not share personal information.

Audio recordings will be taken of the workshop discussions. The audio data will be transcribed into text. Any names will then be deleted from the transcribed text. This ensures that no individual can be identified from the transcribed text. Due to the nature of this project, it will not be possible for you to review the specific data of your contributions. This is because the audio recordings made during the workshops will **include all participants' input.**

Information and data obtained during this project will be stored securely and confidentially on the Flinders University Cloud drive under password control. Any paper records will be filed in a locked filing cabinet at the Flinders Digital Health Research Centre. Only the research team will have access to the data. All records and data from this project will be deleted or destroyed after five years from the completion of the project or from the date of publication of this research.

During the workshops, you will be able to use the RehabChat App. The software company – Clevertar - **stores the data of the RehabChat App being used. Clevertar's privacy statement can be found at** https://www.clevertar.com/privacy-policy/ **. Clevertar**'s terms of use can be found at https://www.clevertar.com/wp-content/uploads/2018/10/Clevertar-App-User-Terms-October-2018.pdf .

It is anticipated that results of this project will be published and/or presented in a variety of forums, and may inform future research. Confidentiality will be assured by not including any identifying information about you in published reports or presentations about this research project, or in future research which uses information and results from this project.

Any information obtained for the purpose of this research project and for the future research described that can identify you will be treated as confidential and securely stored.

12 Complaints and compensation

If you suffer any distress or psychological stress as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support. You are welcome to discuss your needs by contacting your treating health professional, or Beyond Blue (ph. 1300 224 636). This research is covered by Flinders University Indemnity Insurance.

13 Who is organising and funding the research?

The FDHRC is organising this research. No funding is being received for this project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). You or your family will not benefit financially from participating in this research project even if, for example, knowledge gained from the project proves to be of commercial value to Flinders University, or leads to discoveries that are of commercial value to Flinders University, the researchers or their institutions.

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The Central Adelaide Clinical Human Research Ethics Committee has reviewed and approved this project.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on (08) 8201 2226.

Research contact person

Name	Judith Hocking
Position	Lead Researcher, PhD Candidate, FDHRC
Telephone	######
Email	######

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	######
Position	Research Coordinator, SABIRS including EMMBIRS and BIRCH South
Telephone	######
Email	######

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	CALHN Human Ethics Committee
HREC Executive Officer	Chair, ######
Telephone	######
Email	######

Local HREC Office contact

Name	######
Position	Manager CALHN Research Office
Telephone	######
Email	######

Flinders Digital Health Research Centre

Consent Form - *Adult providing own consent*

Title	The Development of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Developing a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	13007
Project Sponsor	Professor Anthony Maeder
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Hocking
Associate Investigator(s)	Dr Lua Perimal-Lewis, Prof David Powers, A/Prof Belinda Lange
Location	Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS), and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project. ¶ understand that audio recordings will be taken of each meeting group and that the recording will be transcribed to text and de-identified'.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Appendix X: Co-design workshops – Information & consent form for clients

Flinders Digital Health Research Centre

Participant Information Sheet/Consent Form for Clients

Health/Social Science Research - *Adult providing own consent*

Early Management of Mild Brain Injury Rehabilitation Service, RGH, Daw Park

Title	The Development of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Developing a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	13007
Project Sponsor	Professor Anthony Maeder
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Hocking
Associate Investigator(s)	Dr Lua Perimal-Lewis, Prof David Powers, A/Prof Belinda Lange
Location	Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS), and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project called **Developing a motivational RehabChat App for Brain Injury Rehabilitation**. You are able to participate because you are aged 18 years or older, and you are a current client of EMMBIRS or BIRCH South, or you have received care from EMMBIRS or BIRCH South within the last three months.

This Participant Information and Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or co-worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- **Understand what you have read**

- Consent to take part in the research project
- **Consent to be involved in the research described**
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

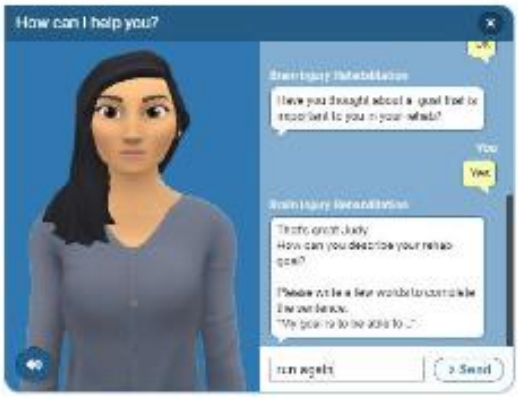
2 What is the purpose of this research?

The aims of this project are to investigate whether we can improve the experience for EMMBIRS and BIRCH South clients when you set your rehabilitation goals, and potentially enhance your motivation and recovery, by developing a motivational RehabChat App.

- The RehabChat App is computer-based and can have simple conversations with a person. It can be designed to support motivation and recovery for EMMBIRS and BIRCH South clients. Motivation is important for brain injury rehabilitation. A motivational RehabChat App could help improve recovery after brain injury. This is the first time that a motivational Chat App has been developed for brain injury rehabilitation.

Using a hand-held device

How the RehabChat App may look



The project researcher Judith Hocking will speak with current and discharged clients of EMMBIRS and BIRCH South, and with clinicians from EMMBIRS and BIRCH South, about brain injury rehabilitation goals, motivation and recovery, and how to design the RehabChat App. Four workshops will be held at EMMBIRS and/or BIRCH South for these discussions. A second project researcher, Lua Perimal-Lewis, may also be involved in these discussions.

The results of this research will be used by Judith Hocking to obtain a Doctor of Philosophy degree. This research has been initiated by, and will be conducted by, Judith Hocking and the Flinders Digital Health Research Centre, Flinders University (FDHRC).

3 What does participation in this research involve?

If you are interested in taking part in this research, you will be asked to read and sign a consent form before any part of the study is completed.

Four rounds of co-creation workshops will be conducted either face-to-face or using tele-conferencing. Face-to-face workshop meetings will take place in a private meeting room at the Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS) or Brain Injury Rehabilitation Community and Home, South, (BIRCH South), Daw Park SA. Tele-conferencing workshops will require you to use a mobile device or computer. You are welcome to invite a family member, friend or carer to be with you during the workshops if you would like, however that person would not participate in the workshops.

Each workshop meeting will last one hour, and be held about monthly. You will be required to attend and participate in four workshop meetings.

Details of the four workshops:

- All participants will have equal opportunity to speak.

- You will be invited to discuss recovery following brain injury, rehabilitation goals, and motivation.

- You will be able to try out the RehabChat App and provide feedback about its design.

- For the first three workshops, you will meet with up to 4 other clients. Separate meetings will be held for current and recently discharged (within the past month) clients, and for prior clients discharged in the previous 1-3 months.

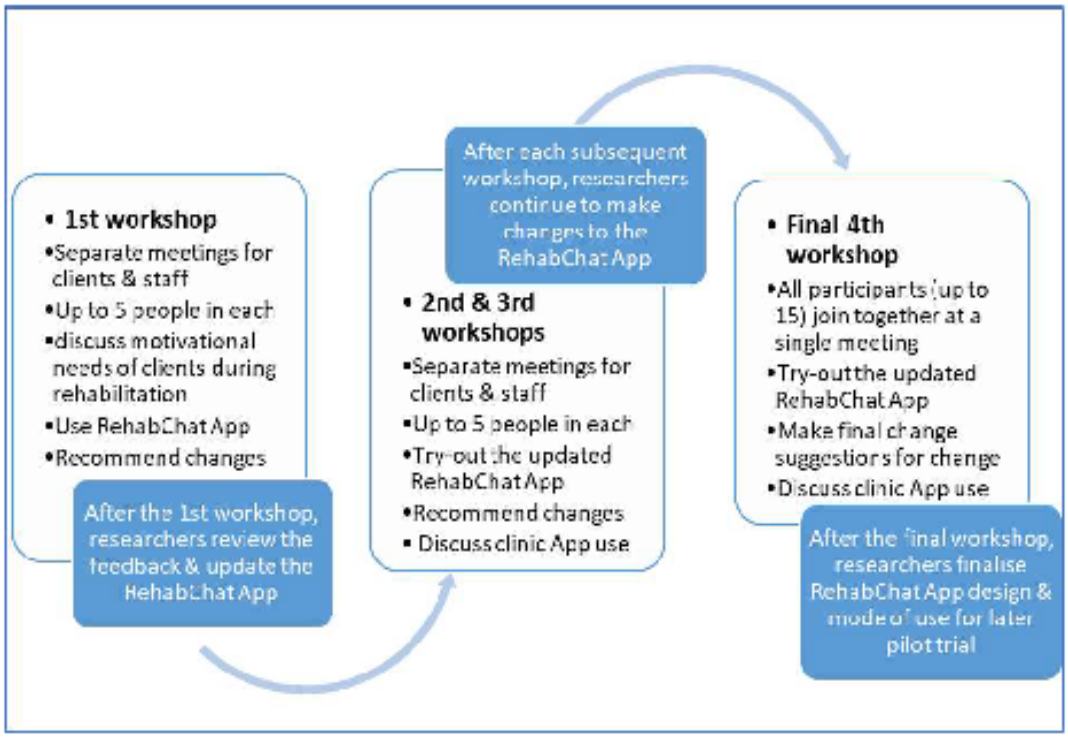
- One final workshop will be held with all client participants, and also with up to 5 clinicians from EMMBIRS and BIRCH South, meeting together.

- After each workshop, the researchers will update the design of the RehabChat App according to what the participants have recommended.

- Light refreshments will be provided (tea, coffee and biscuits) at each workshop.

- **See the '***Flow-chart of how the workshops* **will be run'** below.

Flow-chart of how the workshops will be run:



This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoid jumping to conclusions. We will audio record the workshops so that participant feedback can be accurately collected and analysed. Results from the project may be included in publications or presentations. No identifying information of the participants will be shared outside of the project, nor in any report or other write-up or presentation of the project.

Following completion of the study, you will not have any follow-up from the research team. There are no costs associated with participating in this research project. You will receive a $25 Coles-Myer gift card at the final workshop.

4 Other relevant information about the research project

Up to 15 participants will be taking part in this project at EMMBIRS and/or BIRCH South: up to 5 current clients, up to 5 discharged clients, and up to 5 clinicians.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your clinical care at EMMBIRS or BIRCH South, or your relationship with staff at EMMBIRS or BIRCH South, or your relationship with the researchers.

6 What are the possible benefits of taking part?

There are no direct benefits to you from your participation in this research; however, your participation will contribute to developing a motivational RehabChat App for use by people with a brain injury.

7 What are the possible risks and disadvantages of taking part?

During the workshops you may become tired. If so, you can take a rest break. You may feel that some of the questions we ask during the workshops are distressing; if so, you may take a rest break and return when you feel comfortable. Please let the facilitators know if you need to take a rest during the workshop or leave early. If you do not wish to answer a question, you may remain quiet. If need, you may like to **contact 'Beyond Blue' telephone counselling on** Free call 1800 010 630. The research team will not provide any counselling.

While the researchers do not expect these risks to be present during the study, if this happens to you during the research project you may take a rest break or discontinue your participation in the workshop. Your safety is important to us. You can tell us if you are worried or feel uncomfortable about anything during the project.

Confidentiality

The research team will keep data and information confidential and secure. Whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw, you will be asked to complete and sign a **'Withdrawal of Consent' form; t**his will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional information from you. Information already collected will be retained to ensure that the results of the research project can be analysed properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as research member/s becoming ill. As well, the researchers may recommend that you cease your involvement in the workshops if this is in your best interests.

10 What happens when the research project ends?

At the end of this study, we can provide you with a summary report of the research so that you can be aware of the outcomes. Individual results will not be available. If you are interested in receiving a summary of the study findings, please discuss with the researcher. We will also ask you if you wish to be

contacted for participation in a future pilot trial of the RehabChat App at EMMBIRS and BIRCH South. The research team will otherwise not make any contact with you after the project ends.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The personal information collected in this project is individually identifiable, and will include: your name, contact details, age, gender, and occupation/vocation details. During this project, your medical / health records will not be reviewed at all. In the workshops, participants will be instructed to only use their first name or nickname, and to not share personal information.

Audio recordings will be taken of the workshop discussions. The audio data will be transcribed into text. Any names will then be deleted from the transcribed text. This ensures that no individual can be identified from the transcribed text. Due to the nature of this project, it will not be possible for you to review the specific data of your contributions. This is because the audio recordings made during the workshops will **include all participants' input.**

Information and data obtained during this project will be stored securely and confidentially on the Flinders University Cloud drive under password control. Any paper records will be filed in a locked filing cabinet at the Flinders Digital Health Research Centre. Only the research team will have access to the data. All records and data from this project will be deleted or destroyed after five years from the completion of the project or from the date of publication of this research.

During the workshops, you will be able to use the RehabChat App. The software company – Clevertar - **stores the data of the RehabChat App being used. Clevertar's privacy statement can be found at** https://www.clevertar.com/privacy-policy/ **. Clevertar**'s terms of use can be found at https://www.clevertar.com/wp-content/uploads/2018/10/Clevertar-App-User-Terms-October-2018.pdf .

It is anticipated that results of this project will be published and/or presented in a variety of forums, and may inform future research. Confidentiality will be assured by not including any identifying information about you in published reports or presentations about this research project, or in future research which uses information and results from this project.

Any information obtained for the purpose of this research project and for the future research described that can identify you will be treated as confidential and securely stored.

12 Complaints and compensation

If you suffer any distress or psychological stress as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support. You are welcome to discuss your needs by contacting your treating health professional, or Beyond Blue (ph. 1300 224 636). This research is covered by Flinders University Indemnity Insurance.

13 Who is organising and funding the research?

The FDHRC is organising this research. No funding is being received for this project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). You or your family will not benefit financially from participating in this research project even if, for example, knowledge gained from the project proves to be of commercial value to Flinders University, or leads to discoveries that are of commercial value to Flinders University, the researchers or their institutions.

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The Central Adelaide Clinical Human Research Ethics Committee has reviewed and approved this project.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on (08) 8201 2226.

Research contact person

Name	Judith Hocking
Position	Lead Researcher, PhD Candidate, FDHRC
Telephone	######
Email	######

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	######
Position	Research Coordinator, SABIRS including EMMBIRS and BIRCH South
Telephone	######
Email	######

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	CALHN Human Ethics Committee
HREC Executive Officer	Chair, ######
Telephone	######
Email	######

Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact

Name	######
Position	Manager CALHN Research Office
Telephone	######
Email	######

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Consent Form - *Adult providing own consent*

Title	The Development of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Developing a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	13007
Project Sponsor	Professor Anthony Maeder
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Hocking
Associate Investigator(s)	Dr Lua Perimal-Lewis, Prof David Powers, A/Prof Belinda Lange
Location	Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS), and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project. I understand that audio recordings will be taken of each meeting group and that the recording will be transcribed to text and de-identified.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Flinders Digital Health Research Centre

Form for Withdrawal of Participation - *Adult providing own consent*

Title	The Development of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Developing a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	13007
Project Sponsor	Professor Anthony Maeder
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Hocking
Associate Investigator(s)	Dr Lua Perimal-Lewis, Prof David Powers, A/Prof Belinda Lange
Location	Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS), and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA.

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or EMMBIRS or BIRCH South.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Appendix XI: Co-design workshops – Promotional poster

Promotional poster. Version 2. 27/8/20

Would you like to help create a RehabChat App?

Would you like to share your thoughts about rehabilitation goals & recovery after brain injury?

We want to hear your thoughts about motivation & rehabilitation.

Using a hand-held device	How the RehabChat App may look
	

- **Are you a client at EMMBIRS or BIRCH South?**
- **Have you been a client at EMMBIRS or BIRCH South within the last 3 months?**
- **Or do you work as a clinician at EMMBIRS or BIRCH South?**
- **Are you English-speaking? Are you aged 18 years or older?**

Please contact Judith Hocking: (08) 8201 2226; Judith.hocking@flinders.edu.au

- Clients with traumatic brain injury, and clinicians of the Early Management of Mild Brain Injury Rehabilitation Service (EMMBIRS) and BIRCH South (Brain Injury Rehabilitation Community and Home, South) are invited to help design the RehabChat App for brain injury rehabilitation.
- Participants will attend four, one-hour focus group meetings held monthly.
- Client-participants will receive a $25 Coles-Myer gift card to acknowledge their efforts.
- Client-participants must be able to use a hand-held tablet device, and be able to provide their own consent.

Project title: The Development of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation. This research is being conducted by researchers from Flinders University and SABIRS (South Australian Brain Injury Rehabilitation Service). This research has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. Ethics approval number 13007.

Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######	Rehab Chat App Judith Hocking Ph. ######

Appendix XII: Co-design workshops – User guide

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RehabChat: User guide

Setting up iPad

1. Unpack iPad from the box.
2. Place cover onto iPad – ensure all edges and corners are securely in place.
3. Keep iPad well charged using the charger and cord provided.
4. To return the iPad at end of Workshops, pack it safely, and post
   a. Take the cover off the iPad
   b. pack the iPad, charger and cord into the iPad box,
   c. place the packed iPad box and iPad cover into the reply-paid return packaging. Ensure the correct address is clearly showing:

      Judith Hocking
      Flinders Digital Health Research Centre, CNHS, Flinders University
      ######
      ######
      ####

   d. Ensure your sender address is clearly written too.
   e. put it in the post (drop into the Post Office) as soon as practical
   f. email Judith to say you have posted it and the date you posted it.

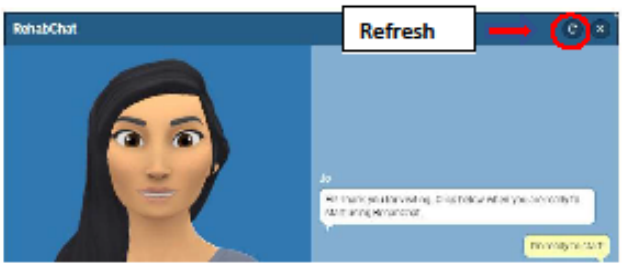
How to use RehabChat

1. Turn on the iPad (switch on top right corner)
2. Enter the 6 digit passcode _____.
3. Click on the icon for RehabChat (found on the home-screen)
   - For the training module click on [RehabChat Training] ; you may only see **'RehabChat Trial'**
   - For the rehabilitation conversation click on [RehabChat]
4. RehabChat will open in a window on iPad, and it will look like this:

5. Click on this RehabChat launch button.

6. RehabChat will then launch on your screen, and it will look like this:

7. At the start of each Workshop, click on the Refresh (circular arrow) button



- *Only use the refresh button at other times if asked* by the Workshop facilitator, as using it deletes prior conversations you have had

8. How to stop your RehabChat conversation, and start it again later
   - Stop your conversation by closing your internet screen, or by **clicking on the 'X'** Restart button in the top right corner

   - When you start your RehabChat conversation again, you will be at the same point; to start your conversation again, follow steps 1 – 6

9. Follow the prompts of RehabChat to have your conversation.

Contact Judith Hocking with questions: ######; Ph ######

Thank you for using RehabChat!

Appendix XIII: Co-design workshops – Changes to customised style sheet

Factor	CSS item	Default value	Changed to
Font size	font-size: .9em	.9em	1.4em
Single response button size	clevertar-chat button.ky-response-btn	3px 10px:	6px 20px:
Name of avatar	clevertar-chat .ky-bubble-block .ky-name	12px	18px
Height of box for free-text entry	clevertar-chat .ky-response form .ky-date-picker-panel input, clevertar-chat .ky-response form input[type=number], clevertar-chat .ky-response form input[type=text]	30px	45px
Increase margins around text entry box	clevertar-chat .ky-text-submit	Bottom = 10px Padding = 10px	Bottom = 20px Padding = 20px
Make ‘change’ button bigger	clevertar-chat .ky-bubble-block.ky-user .ky-actions	8px	16px
Header title	clevertar-chat .ky-header	1.1em	1.4em
Header buttons overall button size: shut-down ‘-‘ button	clevertar-chat .ky-header button.ky-close.icn-dash	Height = 24px Width = 24px	Height = 44px Width = 44px
Header button internal “-“ size	clevertar-chat .ky-header button.ky-close.icn-dash span.icn-dash-txt	24px	44px
Size of left side of UI (done 16-6)	clevertar-chat .ky-wrapper .ky-content .ky-character-wrapper	Width = 150% Left = -50%	Width = 150% Left = -57%
Increase button size for multiple choice options	clevertar-chat button.ky-response-btn	Padding = 3px 10px	Padding = 5px 10px
Space between each multiple choice option	clevertar-chat .ky-response .ky-single-answer button	Margin = 1px 5px 5px	Margin = 5px 10px 10px
Increase size of send button: overall size of circle	clevertar-chat .ky-response .ky-btn-send	Width = 30px Height = 30px	Width = 45px Height = 45px
Increase size of send button: size of arrow	clevertar-chat .ky-response .ky-btn-send i	Size = 16px	Size = 24px
Increase size of mute button: overall size	clevertar-chat .ky-mute button	Border = 1px Padding = 10px	Border = 8px Padding = 10px
Increase font-size of text box prompt cues	clevertar-chat .ky-text-submit label	Font-size = .7rem	Font-size = 1.05rem

Legend: CSS = customised style sheet; em= element size (proportional to the section font size); px = pixel; UI = user interface

Appendix XIV: Feasibility pilot trial – Ethics approval

Below are the approval letters from the Central Adelaide Local Health Network CALHN Human Research Ethics Committee (HREC) for Ethics approval and site-specific governance approval.

Government of South Australia

Health
Central Adelaide
Local Health Network

Central Adelaide Local Health Network
Human Research Ethics Committee

North Terrace
Adelaide, SA, 5000

RAH Tel 08 7117 2229
TQEH/BHI Tel 08 8222 6841

Health.CALHNResearchEthics@sa.gov.au
www.health.sa.gov.au

ABN: 96 269 526 412

Approval Date: 03 February 2021

Prof Anthony Maeder
Flinders Digital Health Research Centre
FLINDERS UNIVERSITY

Dear Prof Maeder

CALHN Reference Number:

Project Title: Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation.

Human Research Ethics Committee APPROVAL

Thank you for submitting the above project for ethical and scientific review. The application was first considered by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) at its meeting held on 17 December 2020. The CALHN HREC is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates (the National Statement).

The CALHN HREC has reviewed all responses, and I am pleased to advise that the project meets the requirements of the National Statement application and has been granted full ethics approval.

The documents reviewed and approved include:

Document	Version	Date
HREA Application - JH03484	-	23 November 2020
Health/Medical Research Project Application Form	-	23 November 2020
Protocol	1	23 November 2020
Participant Information Sheet/Consent Form - client participants	2	21 January 2021
Participant Information Sheet/Consent Form - clinician participants	2	21 January 2021
Demographic Questionnaire for clients	1	23 November 2020
Demographic Questionnaire for clinician	1	23 November 2020
Question guide for 1-1 qualitative interviews	1	23 November 2020
Data Collection Tool - Screening	1	23 November 2020
Step-by-step screening instructions for staff.	1	23 November 2020
User guide for Clients and Clinicians	1	23 November 2020
Clinician instructions for RehabChat	1	23 November 2020
Check list for assessing participant is capable of using RehabChat	1	23 November 2020
Phone script for repeated and pre-post measures	1	23 November 2020
Phone scripts for initial contact, & for obtaining consen	1	23 November 2020
Promotional brochure	1	23 November 2020
Promotional poster	1	23 November 2020
Supporting Documents: • Investigator CV - Anthony Maeder • Investigator CV - Belinda Lange • Investigator CV - Maggie Killington • Investigator CV - David Powers • Investigator CV - Lua Perimal-Lewis • Investigator CV - Judith Hocking		
Response to request for further information – email	-	03 February 2021

Sites covered by this approval:

Site	State	Investigator
Repatriation General Hospital,	SA	PI: Dr Maggie Killington

CALHN HREC approval is valid for 5 years from: **03 February 2021 to 03 February 2026**

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the project must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. The CALHN HREC is certified by the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review. The CALHN HREC is the reviewing HREC for the purpose of this ethics approval. Any project sites that are not listed on this letter are not covered by this ethics approval. Any project sites that wish to be added must contact the Coordinating Principal Investigator (CPI), who must formally request the additional sites to be added by CALHN HREC.
3. Researchers must notify the CALHN HREC of any events which might warrant review of the approval or which warrant new information being presented to research participants, 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) premature termination of the project.
4. All clinical trials approved by the CALHN HREC must comply with the NHMRC Guidance on *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016)*.
5. The CALHN HREC must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at any approved sites.
6. Confidentiality of the research participants must be maintained at all times as required by law.
7. Adequate record keeping is important and must be maintained in accordance with Good Clinical Practice, NHMRC and state and national guidelines. If the project involves signed consent, researchers must retain the completed Consent Forms which relate to this project and a list of all those participating in the project to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years from completion of the project.
8. Approval is valid for **5 years** from the date of this letter after which an extension must be applied for.
9. **Annual Progress Reports must be submitted to the CALHN HREC, every 12 months on the anniversary of the above approval date**. In accordance with the National Statement, it is the researchers' responsibility to provide reports of the progress of approved research projects at least annually, and related to the degree of risk to participants, to the reviewing Human Research Ethics Committee (HREC). This report must be completed by the Coordinating Principal Investigator (CPI) for all multi-site projects or the Principal Investigator (PI) for single site projects for all research projects approved under the CALHN HREC. The report is due on the anniversary of HREC approval. Continuation of ethical approval and local governance authorisation is contingent on submission of this report, due within 2 weeks of the approval anniversary. Failure to comply may result in suspension of the project
10. **A Final Report must be submitted to the CALHN HREC on completion of the project and for all site closures.** In accordance with the National Statement, it is the researchers' responsibility to provide a final report of the outcome for completed research projects and for all site closures to the reviewing Human Research Ethics Committee (HREC). This report must be completed by the Coordinating Principal Investigator (CPI) for all multi-site research projects or the Principal Investigator (PI) for single site research projects approved under the CALHN HREC.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

For any queries, please contact the CALHN Governance Office:
Health.CALHNResearchGovernance@sa.gov.au

Should you have any queries about the CALHN HREC's consideration of your project, please contact the CALHN HREC Support Officer on 08 7117 2229, or Health.CALHNResearchEthics@sa.gov.au.

The CALHN HREC wishes you every success in your research.

Yours sincerely,

Ian Tindall
Chair, Human Research Ethics Committee
Central Adelaide Local Health Network

cc: Site Research Governance Officer

Health
Central Adelaide Local Health Network

Central Adelaide Local Health Network
Research Office
Level 3, Roma Mitchell House
North Terrace, Adelaide SA
Australia 5000

T : 08 7117 2209
T : 08 8222 6841
E : Health.CALHNResearchGovernance@sa.gov.au

16 February 2021

Professor Anthony Maeder
Flinders Digital Health Research Centre
FLINDERS UNIVERSITY

Dear Professor Maeder,

HREC Reference Number: 14079

Governance Reference Number: 14079

Project Title: Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation.

RE: Governance Review

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to commence at the SA Brain Injury Rehabilitation Service, SA.

Authorisation is valid from **12 February 2021 to 12 February 2023**. Proposed extensions beyond this term must be submitted as an amendment to the CALHN Research Office.

The following conditions apply to the authorisation of this research project. These are additional to those conditions imposed by the Human Research Ethics Committee (HREC) that granted ethical approval to this project:

1. Authorisation is limited to the site/s identified in this letter only.
2. Project authorisation is granted for the term specified above.
3. The study must be conducted in accordance with the conditions of ethical approval provided by the lead HREC, SA Health policies, and in conjunction with the standards outlined in the *National Statement on Ethical Conduct in Human Research* (2007) and the *Australian Code for the Responsible Conduct of Research (2007).*
4. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the HREC for review, are copied via email to the CALHN Research Office;
5. Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted via email to the CALHN Research Office;
6. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
7. Proposed amendments to the research protocol or conduct of the research which may affect both the ongoing ethical acceptability of the project and the site acceptability of the project are to be submitted to the CALHN Research Office after a HREC decision is made.
8. A copy of this letter should also be maintained on file by the Coordinating Principal Investigator as evidence of project authorisation.
9. Notification of completion of the study at this site is to be provided to the CALHN Research Office.

You are reminded that continuation of governance approval is contingent on submission of the Annual Progress Report to the reviewing HREC, a copy of which must be submitted to

the CALHN Research Office along with acknowledgement of the report by the reviewing HREC. Failure to comply may result in suspension of the project.

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.

We wish you every success in your research project.

Yours sincerely

Bernadette Swart
Manager, CALHN Research Office
Ph: 7117 2209
Email: Health.CALHNResearchGovernance@sa.gov.au

Appendix XV: Feasibility pilot trial – Information and consent form for clinicians

Flinders Digital Health Research Centre

Participant Information Sheet/Consent Form for Clinicians

Health/Social Science Research - *Adult providing own consent*

The Brain Injury Community and Home North Clinic, HRC; the Brain Injury Community and Home South Clinic, & the Concussion and Mild Brain Injury service, RGH.

Title	Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Using a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	14079
Principal Investigator	A/ Prof Belinda Lange
Associate Investigator(s)	Mrs Judith Hocking, Dr Maggie Killington, Prof David Powers, Dr Lua Perimal-Lewis, Prof Anthony Maeder
Locations	Brain Injury Rehabilitation Community and Home, North (BIRCH North), Hampstead Rehabilitation Centre, Lightsview SA; Brain Injury Rehabilitation Community and Home, South (BIRCH South) and Concussion and Mild Brain Injury service (CAMBI) Repatriation General Hospital, Daw Park SA.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project called **Using a motivational RehabChat App for Brain Injury Rehabilitation**. You are able to participate because you are working as a clinical therapist at BIRCH North, BIRCH South or CAMBI.

This Participant Information and Consent Form tells you about the research project and the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research. **Participation in this research is voluntary. If you don't wish to take part, you don't have to.**

Please read this information carefully. Ask questions about anything that **you don't understand or want to** know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or co-worker. If you decide you want to take part in the research project, you will be asked to sign the consent section.

By signing the Consent Form, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 About RehabChat

RehabChat is a conversation App that can be used on a tablet device. It has been designed using software developed by an Adelaide software company – Clevertar.

- RehabChat can have motivational conversations with a person about their rehabilitation.

- RehabChat has been developed by the researchers in consultation with clients and clinicians of BIRCH South and CAMBI. Motivation is important for brain injury rehabilitation.
- A motivational RehabChat App could help improve recovery after brain injury.
- This is the first time that a motivational Chat App has been developed for brain injury rehabilitation.

Using a hand-held device

How the RehabChat App looks

3 What is the purpose of this research?

The aims of this project are to investigate

- how useful the RehabChat App is in rehabilitation care at BIRCH North, BIRCH South and CAMBI, and
- how easy it is to use RehabChat.

The results of this research will be used by Judith Hocking to obtain a Doctor of Philosophy degree. This research has been initiated by, and will be conducted by, Judith Hocking and the Flinders Digital Health Research Centre, Flinders University (FDHRC).

4 What does participation in this research involve?

All participants will receive initial training in using RehabChat on a tablet device. Following this, RehabChat will be used by a client/s of yours for a 2-week trial alongside their usual rehabilitation care at BIRCH North, BIRCH South or CAMBI. You will provide clinical oversight of your client using RehabChat. All participants will provide feedback about their experience at the end of the trial.

- You will receive 1:1 training in using RehabChat and be able to practise using RehabChat until you feel confident. Judith Hocking will provide the training and then assess you for being proficient in using RehabChat. Following this, you will be asked to provide some feedback about RehabChat. This will take approximately one-hour.
- You will then screen your current clients (with whom you have been providing care for at least three appointment sessions) for eligibility to be involved in the pilot trial.
- You will supervise any of your clients that are recruited to the study whilst they use RehabChat for 2 weeks alongside their usual rehabilitation.

At the start and finish of RehabChat being used by your client/s, you will complete a series of questionnaire questions – this will take approximately 20 minutes each time. At the end of the trial, you will complete a short questionnaire about your experience supervising your client using RehabChat, and participate in a 1:1 interview with Judith Hocking to discuss your experience and views about using RehabChat in your clinic.

If you are interested in taking part in this research, you will be asked to read and sign a consent form before any part of the study is completed.

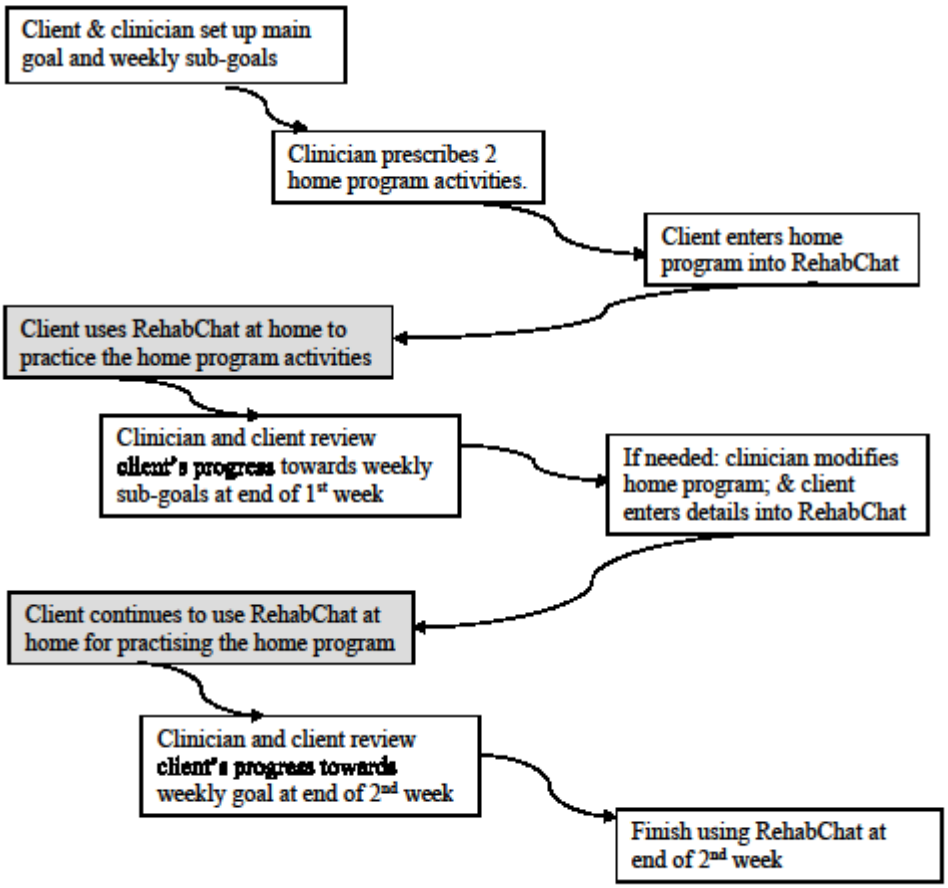
4. a) Details of the 2-week trial using RehabChat alongside usual care

RehabChat will be used on a tablet device provided by the researchers. You will provide clinical oversight of your client whilst they use RehabChat alongside their usual rehabilitation care.

The specific ways in which RehabChat will be used alongside usual care are:

1. Using RehabChat in your clinic appointment time, to
- Define the main rehabilitation goal, and enter these into RehabChat;
- Define weekly sub-goals to be achieved at the end of the 1st and 2nd weeks, and enter these into RehabChat;
- prescribe two home program activities relevant to the main rehabilitation goal
- enter the home program details into RehabChat
2. The client will use RehabChat at home to practise their home program
3. Using RehabChat in the clinic at the end of the 1st week and at the end of the 2nd week, to
- review **the client's progress towards achieving the**ir weekly sub-goals
- if needed, make changes to RehabChat, for example regarding the home program.
4. The client continues to use RehabChat at home to practise their home program in-between each clinic appointment
- finish using RehabChat after the view at the end of the 2nd week.

Flow-chart: using RehabChat alongside usual care: (grey shading = home-based use)



5 Other relevant information about the research project

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoid jumping to conclusions. We will audio record the 1:1 interviews so that the feedback can be accurately collected and analysed.

Results from the project may be included in publications or presentations. No identifying information of the participants will be shared outside of the project, nor in any report or other write-up or presentation of the project.

Your participation will not affect any rights you have to compensation under common law.

Following completion of the study, you will not have any follow-up from the research team.

There are no costs associated with participating in this research project.

Up to 21 participants will be taking part in this project at BIRCH North, and/or BIRCH South and/or CAMBI: up to 6 clinicians, and up to 15 clients.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your work at CAMBI, BIRCH North or BIRCH South, or your relationship with staff at CAMBI, BIRCH North or BIRCH South, or your relationship with the researchers.

7 What are the possible benefits of taking part?

There are no direct benefits to you from your participation in this research; however, your participation will contribute to developing a motivational RehabChat App which could be used by people with a traumatic brain injury.

RehabChat is in its early stages of development and is not yet proven to be clinically effective.

8 What are the possible risks and disadvantages of taking part?

When using RehabChat, you may become stressed. If so, please discuss any concerns with the research team who will aim to resolve any questions or issues promptly. You can tell us if you are stressed or feel uncomfortable about anything during the project. **If needed, you may like to contact 'Beyond Blue'** telephone counselling on Free call 1800 010 630. The research team will not provide any counselling.

Confidentiality

The research team will keep data and information confidential and secure.

9 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project,

- please notify a member of the research team before you withdraw
- **you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be** provided to you by the research team
- the researchers will not collect additional information from you
- information already collected will be retained to ensure that the results of the research project can be analysed properly and to comply with law.

You should be aware that data collected up to the time you withdraw be included in the research results.

10 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as research member/s becoming ill. As well, the researchers may recommend that you cease your involvement in this project if this is in your best interests.

11 What happens when the research project ends?

At the end of this study, we can provide you with a summary report of the research so that you can be aware of the outcomes. Individual results will not be available. If you are interested in receiving a summary of the study findings, please discuss with the researcher. The research team will otherwise not make any contact with you after the project ends.

Part 2 How is the research project being conducted?

12 What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The personal information collected in this project is individually identifiable, and will include: your name, contact details, age, gender, occupation, and details about your prior experiencing using rehabilitation technology and chatbots.

Audio recordings will be taken of the 1:1 interview conducted at the end of the trial. Any confidential information will be deleted form the audio file prior to it being transcribed into text. This ensures that no individual can be identified from the transcribed text.

Information and data obtained during this project will be stored securely and confidentially on the Flinders University Cloud drive under password control. Any paper records will be filed in a locked filing cabinet at the Flinders Digital Health Research Centre. Only the research team will have access to the data. All records and data from this project will be deleted or destroyed after five years from the completion of the project or from the date of publication of this research.

During this project, your client/s will use RehabChat. The software company – Clevertar - stores the data entered into **RehabChat. Clevertar's privacy** policy explains how information entered into RehabChat will be managed; this policy can be found at http://v2020.clevertar.com/privacy-policy/ .

It is anticipated that results of this project will be published and/or presented in a variety of forums and may inform future research. Confidentiality will be assured by not including any identifying information about you in published reports or presentations about this research project, or in future research which uses information and results from this project.

Any information obtained for the purpose of this research project and for the future research described that can identify you will be treated as confidential and securely stored.

In accordance with relevant Australian and/or South Australia privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

13 Complaints and compensation

If you suffer any distress or psychological stress as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support. You are welcome to discuss your needs by contacting your treating health professional, or Beyond Blue (ph. 1300 224 636). This research is covered by Flinders University Indemnity Insurance.

14 Who is organising and funding the research?

The FDHRC is organising this research. No funding is being received for this project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). You or your family will not benefit financially from participating in this research project even if, for example, knowledge gained from the project proves to be of commercial value to Flinders University, or leads to discoveries that are of commercial value to Flinders University, the researchers or their institutions.

15 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies. The Central Adelaide Local Health Network Human Research Ethics Committee has reviewed and approved this project.

16 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on (08) 8201 2226.

Research contact persons

Name	Judith Hocking
Position	Lead Researcher, PhD Candidate, FDHRC
Telephone	#######
Email	#######

Name	#######
Position	Research Coordinator, SABIRS including BIRCH North, BIRCH South and CAMBI
Telephone	#######
Email	#######

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	Executive Officer, contactable through the HREC Support Officer
Telephone	#######
Email	#######

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

HREC name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
HREC Executive Officer	Executive Officer, contactable through the HREC Support Officer
Telephone	#######
Email	#######

Local HREC Office contact

Name	#######
Position	Manager CALHN Research Office
Telephone	#######
Email	#######

Flinders Digital Health Research Centre

Consent Form - *Adult providing own consent*

Title	Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Using a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	14079
Principal Investigator	A/Prof Belinda Lange
Associate Investigator(s)	Mrs Judith Hocking, Dr Maggie Killington, Prof David Powers, Dr Lua Perimal-Lewis, Prof Anthony Maeder
Locations	Concussion and Mild Brain Injury service (CAMBI) and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA. Brain Injury Rehabilitation Community and Home, North (BIRCH North), Hampstead Rehabilitation Centre, Lightsview SA.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project. I understand that audio recordings will be taken of 1:1 interview and that the recording will be de-identified and transcribed to text.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I have had the opportunity to discuss my participation in this study with a family member, friend, or support person.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Flinders Digital Health Research Centre

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Using a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	14079
Principal Investigator	A/Prof Belinda Lange
Associate Investigator(s)	Mrs Judith Hocking, Dr Maggie Killington, Prof David Powers, Dr Lua Perimal-Lewis, Professor Anthony Maeder
Locations	Concussion and Mild Brain Injury service (CAMBI) and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA. Brain Injury Rehabilitation Community and Home, North (BIRCH North), Hampstead Rehabilitation Centre, Lightsview SA

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or BIRCH North, BIRCH South or CAMBI.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Appendix XVI: Feasibility pilot trial – Information and consent form for clients

Flinders Digital Health Research Centre

Participant Information Sheet/Consent Form for Clients

Health/Social Science Research - *Adult providing own consent*

The Brain Injury Community and Home North Clinic, HRC, Lightsview; the Brain Injury Community and Home South Clinic, & the Concussion and Mild Brain Injury service, RGH, Daw Park

Title	Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Using a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	14079
Principal Investigator	A/Prof Belinda Lange
Associate Investigator(s)	Mrs Judith Hocking, Dr Maggie Killington, Prof David Powers, Dr Lua Perimal-Lewis, Prof Anthony Maeder
Locations	Brain Injury Rehabilitation Community and Home, North (BIRCH North), Hampstead Rehabilitation Centre, Lightsview SA; Brain Injury Rehabilitation Community and Home, South (BIRCH South) and Concussion and Mild Brain Injury service (CAMBI), Repatriation General Hospital, Daw Park SA.

Part 1 What does my participation involve?

1 Introduction

- You are invited to take part in this project called **Developing a motivational RehabChat App for Brain Injury Rehabilitation**. You are able to participate because you are a current client of BIRCH North, BIRCH South or CAMBI and are aged 18 years or older,
- This Participant Information and Consent Form tells you about the research project, and what it means to take part in it. Knowing what is involved will help you decide if you want to take part.
- Please read this information carefully. You can **ask questions about anything that you don't** understand or want to know more about. Before you decide about taking part or not, you might want to talk about it with someone you trust. **If you don't want to take part, you don't have to.**
- If you decide you want to take part in the project, you will be asked to sign the consent form. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 About RehabChat

- RehabChat has been developed by the researchers in consultation with clients and clinicians of BIRCH South and CAMBI. Motivation is important for brain injury rehabilitation.
- A motivational RehabChat App could help improve recovery after brain injury.
- This is the first time that a motivational Chat App has been developed for brain injury rehabilitation.

Using a hand-held device

How the RehabChat App looks

3 What is the purpose of this research?

The aims of this project are to investigate

- how useful the RehabChat App is in rehabilitation care at BIRCH North, BIRCH South and CAMBI, and
- how easy it is to use RehabChat.

The results of this research will be used by Judith Hocking to obtain a Doctor of Philosophy degree. This research has been initiated by, and will be conducted by, Judith Hocking and the Flinders Digital Health Research Centre, Flinders University (FDHRC).

4 What does participation in this research involve?

All participants will receive initial training in using RehabChat on a tablet device. Following this, RehabChat will be used by a client/s of yours for a 2-week trial alongside their usual rehabilitation care at BIRCH North, BIRCH South or CAMBI. You will provide clinical oversight of your client using RehabChat. All participants will provide feedback about their experience at the end of the trial.

- You will receive 1:1 training in using RehabChat and be able to practise using RehabChat until you feel confident. Judith Hocking will provide the training and then assess you for being proficient in using RehabChat. Following this, you will be asked to provide some feedback about RehabChat. This will take approximately one-hour.
- You will then screen your current clients (with whom you have been providing care for at least three appointment sessions) for eligibility to be involved in the pilot trial.
- You will supervise any of your clients that are recruited to the study whilst they use RehabChat for 2 weeks alongside their usual rehabilitation.

At the start and finish of RehabChat being used by your client/s, you will complete a series of questionnaire questions – this will take approximately 20 minutes each time. At the end of the trial, you will complete a short questionnaire about your experience supervising your client using RehabChat, and participate in a 1:1 interview with Judith Hocking to discuss your experience and views about using RehabChat in your clinic.

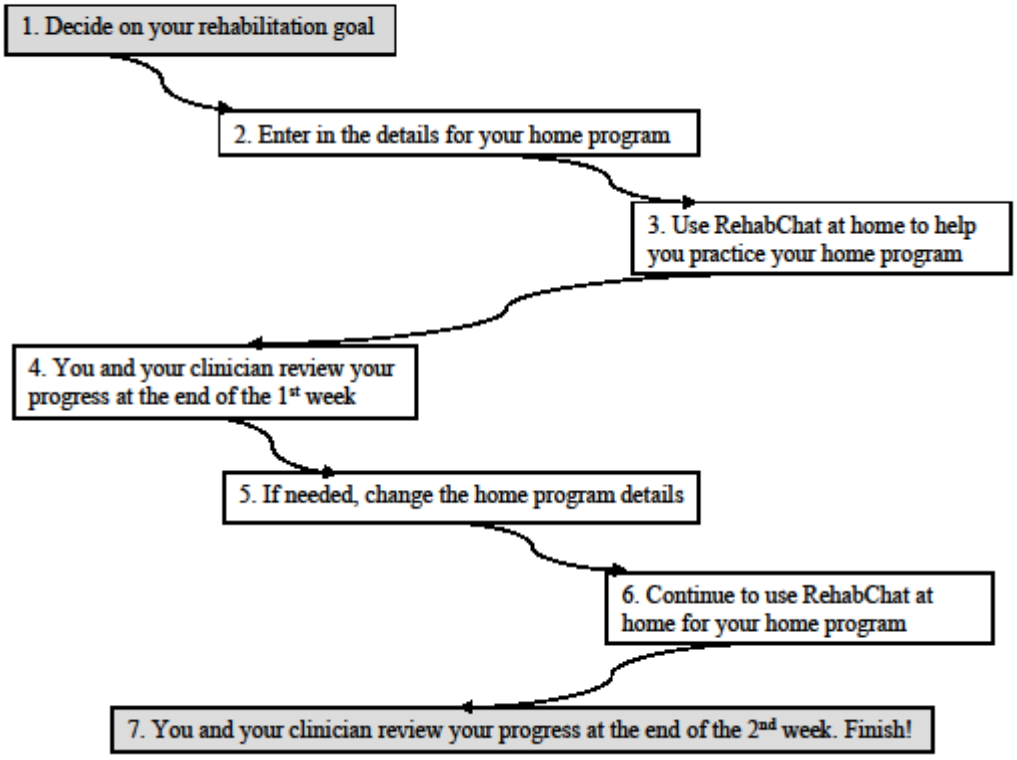
If you are interested in taking part in this research, you will be asked to read and sign a consent form before any part of the study is completed.

4. a) Details of the 2-week trial using RehabChat alongside usual care

- You will also **have an interview** with Judith to discuss your experiences of using RehabChat, and **what you thought about it. This interview will last about 45 minutes, and will be held just after you've** finished using RehabChat.
- You will use **RehabChat to do the following** (see the Flowchart below):

- Set a rehabilitation goal that you want to work towards
- Decide on some steps you can achieve in the 2 weeks, to help you work towards your goal
- Record the details of two activities that you will practice at home – your clinician will prescribe these
- Practice your home program activities at home
- Review your progress towards achieving your rehabilitation goal

Flow-chart: using RehabChat for 2 weeks alongside your usual rehabilitation care



5 Other relevant information about the research project

This research project has been designed to make sure the researchers interpret the results fairly, and **don't** jump to conclusions.

- Up to 21 participants will be taking part in this project at BIRCH North, and/or BIRCH South and/or CAMBI: up to 15 clients, and up to 6 clinicians.
- We will take an audio recording of the interview so that your feedback can be accurately collected and analysed.

- Results from this project may be included in publications or presented at conferences or in journal articles. No identifying information of the participants will be shared outside of the project, nor in any report or other write-up or presentation of the project.
- Your participation will not affect any rights you have to compensation under common law.
- There are no costs associated with participating in this research project.
- After this project is finished, you will not have any follow-up from the researchers.

6 Do I have to take part in this research project?

It is your choice if you want to take part in this project or not. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from being in the project at any time.

- If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.
- Whether you take part or not, or if you take part and then later withdraw, will not affect your clinical care at BIRCH North, BIRCH South or CAMBI. Also, it won't affect your relationship with staff at BIRCH North, BIRCH South or CAMBI, or your relationship with the researchers.

7 What are the possible benefits of taking part?

There are no direct benefits to you if you take part in this research; however, your participation will help develop a motivational RehabChat App which could be used by people with a traumatic brain injury. As well, all client-participants will be paid a $25 Coles-Myer gift card to acknowledge their efforts.

RehabChat is in its early stages of development and is not yet proven to be clinically effective.

8 What are the possible risks and disadvantages of taking part?

- When using RehabChat, you may become tired or stressed. If this does happen, please talk to your clinician, or discuss it with the research team.
- The research team will aim to resolve any questions or issues promptly.
- You can tell us if you are worried or feel uncomfortable about anything during the project.
- If needed, you may like to contact 'Beyond Blue' counselling on Free call 1800 010 630. The research team will not provide any counselling.

Confidentiality

The research team will keep data and information confidential and secure.

9 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time.

If you decide to withdraw from the project,
- please notify a member of the research team before you withdraw
- you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team
- the researchers will not collect additional information from you
- information already collected will be retained to ensure that the results of the research project can be analysed properly and to comply with law.

You should be aware that data collected up to the time you withdraw be included in the research results.

10 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons such as research member/s becoming ill. As well, the researchers may recommend that you cease your involvement in this project if this is in your best interests.

11 What happens when the research project ends?

At the end of this study, we can provide you with a summary report of the research so that you can be aware of the outcomes. Individual results will not be available. If you are interested in receiving a summary of the study findings, please discuss with the researcher. The research team will otherwise not make any contact with you after the project ends.

Part 2 How is the research project being conducted?

12 What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

- The personal information collected in this project is individually identifiable, and will include: your name, contact details, age, gender, occupation/vocation, and details about your prior experiencing using technology and chatbots. During this project, your medical / health records will not be reviewed at all. When using RehabChat, you will only use your first name or nickname, and not enter any confidential information.
- Audio recordings will be taken of the interview. Any confidential information will be deleted form the audio recording prior to it being transcribed into text. This ensures that no individual can be identified from the transcribed text.
- Information and data gathered during this project will be stored securely and confidentially on the Flinders University Cloud drive under password control or in a locked filing cabinet at the Flinders Digital Health Research Centre (FDHRC). Only the research team will have access to the data. All records and data from this project will be deleted or destroyed after five years from when the project is completed, or from when this research is published.
- The software company – Clevertar - stores the data entered into **RehabChat. Clevertar's privacy** policy explains how information entered into RehabChat will be managed; this policy can be found at http://v2020.clevertar.com/privacy-policy/ .
- Results of this project may be published and/or presented in a variety of forums and may help plan future research. Confidentiality will be assured by not including any identifying information about you in published reports or presentations about this research project, or in future research which uses information and results from this project. Any information obtained for the purpose of this research project and for the future research described that can identify you will be treated as confidential and securely stored.
- In accordance with relevant Australian and/or South Australia privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

13 Complaints and compensation

If you suffer any distress or psychological stress as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support. You are welcome to discuss your needs by contacting your treating health professional, or Beyond Blue (ph. 1300 224 636). This research is covered by Flinders University Indemnity Insurance.

14 Who is organising and funding the research?

The FDHRC is organising this research. No funding is being received for this project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). You or your family will not benefit financially from participating in this research project even if, for example, knowledge gained from the project proves to be of commercial value to Flinders University, or leads to discoveries that are of commercial value to Flinders University, the researchers or their institutions.

15 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies. The Central Adelaide Local Health Network Human Research Ethics Committee has reviewed and approved this project.

16 Further information and who to contact

The person you may need to contact will depend on the nature of your query – see below for details. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on (08) 8201 2226.

Research contact person

Name	Judith Hocking
Position	Lead Researcher, PhD Candidate, FDHRC
Telephone	#######
Email	#######

Name	########
Position	Research Coordinator, SABIRS including BIRCH North, BIRCH South and CAMBI
Telephone	########
Email	########

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Executive Officer, contactable through the HREC Support Officer
Telephone	########
Email	########

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Executive Officer, contactable through the HREC Support Officer
Telephone	########
Email	########

Local HREC Office contact

Name	########
Position	Manager CALHN Research Office
Telephone	########
Email	########

Flinders Digital Health Research Centre

Consent Form - *Adult providing own consent*

Title	Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Using a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	14079
Principal Investigator	A/Prof Belinda Lange
Associate Investigator(s)	Mrs Judith Hocking, Dr Maggie Killington, Prof David Powers, Dr Lua Perimal-Lewis, Prof Anthony Maeder
Locations	Brain Injury Rehabilitation Community and Home, North (BIRCH North), Hampstead Rehabilitation Centre, Lightsview SA; Concussion and Mild Brain Injury service (CAMBI), and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project. I understand that audio recordings will be taken of 1:1 interview and that the recording will be de-identified and transcribed to text.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I have had the opportunity to discuss my participation in this study with a family member, friend or support person.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Flinders Digital Health Research Centre

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Using a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	14079
Principal Investigator	A/Prof Belinda Lange
Associate Investigator(s)	Mrs Judith Hocking, Dr Maggie Killington, Prof David Powers, Dr Lua Perimal-Lewis, Prof Anthony Maeder
Locations	Brain Injury Rehabilitation Community and Home, North (BIRCH North), Hampstead Rehabilitation Centre, Lightsview SA; Concussion and Mild Brain Injury service (CAMBI), and Brain Injury Rehabilitation Community and Home, South (BIRCH South), Repatriation General Hospital, Daw Park SA.

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or BIRCH North, BIRCH South or CAMBI.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Appendix XVII: Feasibility pilot trial – Promotional poster

Promotional poster. HREC Ref. No. 14079 Version 4. 16/11/21

Would you like to try using a RehabChat App during your rehabilitation?

Would you like to use RehabChat for two weeks alongside your usual rehabilitation care at BIRCH North, BIRCH South or CAMBI?

We want to hear your thoughts about what you think about RehabChat.

Using a hand-held device

How the RehabChat App looks

- Are you a client at BIRCH North, BIRCH South or CAMBI?
- Are you English-speaking?
- Are you aged 18 years or older?

Please contact Judith Hocking:

Ph. (08) 8201 2226; 0466 275 004. Judith.hocking@flinders.edu.au

- Clients with traumatic brain injury, and clinicians of BIRCH South (Brain Injury Rehabilitation Community and Home, South), BIRCH North and Concussion and Mild Brain Injury (CAMBI) service are invited to try using RehabChat for 2 weeks.
- All participants will receive initial training in how to use RehabChat. Client-participants will then use RehabChat for 2 weeks with their clinician providing support for this.
- Client-participants will receive a $25 Coles-Myer gift card to acknowledge their efforts.
- Client-participants must be able to use a hand-held tablet device and be able to provide their own consent.

Project title: Using a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation. This research is being conducted by researchers from Flinders University and South Australian Brain Injury Rehabilitation Service (SABIRS). This research has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. Ethics approval number 14079.

Rehab Chat App. Judith Hocking
Ph. 08 8201 2226; 0466 275 004
Judith.hocking@flinders.edu.au

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Judith.hocking@flinders.edu.au

Appendix XVIII: Feasibility pilot trial – Repeated measures screening questions

Domain	Question	0 - 10 self-rating scale*										
		0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Anxiety	How anxious / stressed do you feel today?	0 = not at all anxious / stressed										10 = extremely anxious / stressed
Depression	How depressed / sad do you feel today?	0 = not at all depressed / sad										10 = extremely depressed / sad
Motivation	How motivated / enthusiastic do you feel today?	0 = not at all motivated / enthusiastic										10 = extremely motivated / enthusiastic
Energy	How energetic / active do you feel today?	0 = not at all energetic / active										10 = extremely energetic / active

Appendix XIX: Feasibility pilot trial – User testing question guide

Main themes	Main questions
RehabChat: impressions and feedback	What do you like about RehabChat? What don't you like about RehabChat? What was easy to use in RehabChat? What was difficult to use in RehabChat? [Consider: how the ECA dialogues were phrased and presented conversationally to the user as a language/dialogue mechanism]What features of the user guide are helpful?
RehabChat: meeting client needs	How do you think your clients will find using RehabChat? In order to optimise how well your clients can use RehabChat, what needs to be changed?
User guide: impressions and feedback	What features of the user guide are helpful? What features of the user guide were not helpful?
User guide: meeting client needs	How do you think your clients will find using the user guide? In order to optimise how well your clients can use the User Guide, what needs to be changed?
Using in clinic setting	How do you think it will go using RehabChat alongside usual rehabilitation care at your clinic? In order to optimise how well it will go using RehabChat alongside usual rehabilitation care at your clinic, what needs to be changed?
Other	Is there anything else you would like to say about RehabChat?

Appendix XX: Feasibility pilot trial – User guide

Flinders Digital Health Research Centre

RehabChat: User guide for clients & clinicians

Open RehabChat on the iPad

1. Keep iPad well charged
2. Turn on iPad
3. Check that there are no internet browser screens open
4. **Click to open RehabChat**

   a. <u>For training module:</u> click on **'RehabChat Training'** RehabChat Training

   b. <u>For rehabilitation module:</u> click on **'RehabChat'** Rehab Chat

   c. RehabChat will then launch on your iPad like this:

351

Quick tips for your RehabChat conversation

a. **Scroll** through your conversation: use 2 fingers to scroll

b. **To hear the same dialogue read again:** if the avatar has finished reading the dialogue, click on the avatar to hear it read out again.

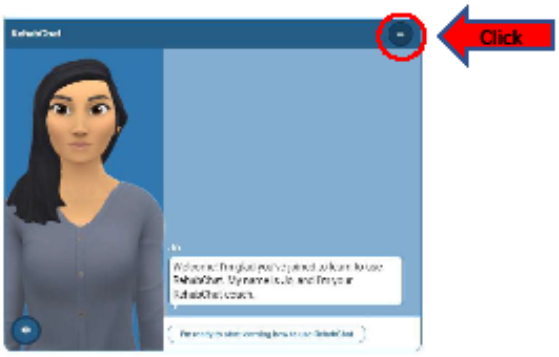
c. **If the avatar is speaking the dialogue and you want silence:** Click on the avatar to stop the talking just for that dialogue

d. **To silence the avatar for longer:** Click on the mute button. Click again to restart talking

352

Close RehabChat

1. **Minimise RehabChat** while you have a rest break: **click** '-' in top corner



   a. It will then appear as a simple icon: 

   b. Click on this icon to open RehabChat again after your rest

2. **Close RehabChat for the day**

   a. click on the iPad home button; this will close RehabChat fully

3. **Keep your iPad fully charged**

Please contact Judith Hocking with any queries

- Phone ######
- Email ######

Appendix XXI: Feasibility pilot trial – Interview question guide for clinicians

Main themes	Main question	Secondary questions / points to consider
What liked?	What did you like about RehabChat?	- aspects regarding RehabChat on the tablet - aspects regarding how RehabChat was used alongside usual care
What not liked?	What didn't you like about RehabChat?	- aspects regarding RehabChat on the tablet - aspects regarding how RehabChat was used alongside usual care
Client's motivation (and energy levels)	Do you think RehabChat changed how motivated your client felt with their rehabilitation? Please explain.	Do you think using RehabChat changed how energetic your client felt? Please explain.
Client's stress (anxiety and depression)	Do you think using RehabChat caused any stress for your client? Please explain.	Do you think using RehabChat caused any anxiety or depression symptoms for your client? Please explain.
Context – clinic	How well does RehabChat help to meet the needs of clients receiving care at clinic? In what ways does RehabChat address the needs of clients at [your] clinic?	Ensure are asking just for the clinic from which the participant comes. - give examples of needs being considered - examples of how RehabChat helps meet specific need/s
Context – home	How well does RehabChat meet the needs of a client when practising a home program?	- give examples of needs being considered - examples of how RehabChat helps meet specific need/s
WCAG – Operable	How easy did you find using RehabChat on the tablet device? Please explain. How easy was it for you to support your client using RehabChat on the tablet device?	- ease of typing and clicking - amount of typing, clicking - reaction to needing to use tablet keyboard for all interactions with RehabChat - sense of any time pressure - can revisit previously entered data - progress/navigate through conversation in correct order
WCAG – Perceivable	How clear was the design of RehabChat clear to look at and to listen to?	- audio clarity - text content easy to read - text content able to be understood

Main themes	Main question	Secondary questions / points to consider
		- visual design of avatar - HCI display clarity
WCAG – Understandable	How easily could you understand the RehabChat conversations? How much did you need to support your client/s to understand the RehabChat conversations? Please give examples.	- how well could you understand what was said? / the written text? - did you know how well did you know how to navigate and use the screen display? - how useful were the help hints in RehabChat? - after you had entered your responses, did you feel you could check what you'd entered? – How/why?
UTAUT – Performance expectancy	How do you think using RehabChat benefits your clients?	- clinician: optimise engagement in my clients
UTAUT – Effort expectancy	How much effort do you think your client needs to expend to use RehabChat? What parts of using RehabChat do your clients need to expend more effort?	- amount of effort for each area of effort mentioned - areas of effort may relate to training needed, needing to juggle RehabChat as another variable in care journey
UTAUT – Attitude toward using technology	Do you think using RehabChat is a beneficial thing for your clients to do? Why?	- level of enjoyment using RehabChat - does using RehabChat make rehabilitation more interesting? - does using RehabChat make rehabilitation more fun?
UTAUT – Social influence	How much did the clinical or home environment influence how your client used RehabChat? How much did the clinical environment influence your use of RehabChat? Why/how?	- who were the people that had an opinion on you using RehabChat? (e.g. clinic staff, family, friends etc.) : and what were their opinions? : and how have these options affected your client's use of RehabChat?
UTAUT – Facilitating conditions	Do you feel you had everything you needed to use RehabChat well? Do you feel you had everything you needed to support your client to use RehabChat well?	- enough training - enough practice time prior to independent use - able to contact the research team for support - able to ask questions and get answers in a timely way

Main themes	Main question	Secondary questions / points to consider
UTAUT – Self-efficacy	In what way does RehabChat help you to support your client to achieve rehabilitation goal? What extra resources or help do you need so that you can best support your client to achieve their rehabilitation goal using RehabChat?	- being left to do things independently - having someone to call on when I needed help - having enough time to work through the steps of using RehabChat - having new/more resources in / in-built into RehabChat for helping me when needed - having someone to guide you through it
UTAUT – Anxiety	Do you have any concern about supervising clients to use RehabChat? – please explain Were you worried about supervising clients to use RehabChat? – please explain Did anything in the training or intervention aspects of this study cause you to feel anxiety?	- anything specifically that may have caused anxiety, or worry - if RehabChat makes the user feel inferior or intimidated
UTAUT – Behavioral intention to use the system	Have you thought whether you would like to continue using RehabChat in your clinical work if you had the opportunity? – why/why not? If so, for how long do you think you would like to use RehabChat in your clinical work in the future?	- for how long would you like to continue using RehabChat? - Why would you like/not like to continue using RehabChat? - ask in months
Context – workflow	How does using RehabChat impact upon your work?	- workload - workflow - style of work
Context – quality/effectiveness of care delivered	How does RehabChat impact (or may impact upon) the quality of the care that they deliver? How does RehabChat impact (or may impact upon) the effectiveness of the care that they deliver? How well did you think you were able to provide clinician oversight of your client using RehabChat? Please explain	- care activities which use RehabChat as being those areas most likely to be directly affected - other areas may be indirectly affected by attention being drawn away from these

Main themes	Main question	Secondary questions / points to consider
Context – client/clinician relationship	How has using the ECA impacted upon the relationship you have with your client?	- rapport level - time available in sessions - sense of understanding client's needs
Clinical – safety	Do you have any concerns about the safety of RehabChat? Do you have any concerns about confidentiality when using RehabChat?	Could the ECA cause any safety concerns? Could the ECA exacerbate any symptoms? Are you concerned about data safety? Do you think RehabChat details are kept safe and confidential?
Recommendations for change	What should be changed in the design of RehabChat? What should be changed in the way RehabChat is used alongside usual care at your clinic?	Ensure that are asking about the clinic from which the participant is from - how it functions on the tablet - using a tablet device - how it works alongside usual care
Other	Is there anything else you would like to comment on about your experience of using RehabChat?	

Legend: WCAG = Website Content Accessibility Guidelines (20); UTAUT = Unified Theory of Acceptance and Use of Technology (142)

Appendix XXII: Feasibility pilot trial – Interview question guide for clients

Main themes	Main question	Secondary questions / points to consider
What liked?	What did you like about RehabChat? Why?	- aspects regarding RehabChat on the tablet - aspects regarding how RehabChat was used alongside usual care
What not liked?	What didn't you like about RehabChat? Why?	- aspects regarding RehabChat on the tablet - aspects regarding how RehabChat was used alongside usual care
Motivation (and energy levels)	Did RehabChat change how motivated you felt with your rehabilitation? Please explain.	Did using RehabChat change how energetic you felt? Please explain.
Stress (anxiety and depression)	Did using RehabChat cause any stress for you? Please explain.	Did using RehabChat cause any anxiety or depression symptoms for you? Please explain.
Context – clinic	How well did RehabChat meet your needs at [your] clinic? How well do you think RehabChat can generally meet the needs of clients at [your] clinic?	Ensure are asking just for the clinic from which the participant comes. - give examples of needs being considered - examples of how RehabChat helps meet specific need/s
Context – home	How well did RehabChat meet your needs when you were practising your home program?	- give examples of needs being considered - examples of how RehabChat helps meet specific need/s
WCAG – Operable	How easy was it to use RehabChat on the tablet device? Please explain.	- ease of typing and clicking - amount of typing, clicking - reaction to needing to use tablet keyboard for all interactions with RehabChat - sense of any time pressure - can revisit previously entered data - progress/navigate through conversation in correct order
WCAG – Perceivable	How clear was the design of RehabChat to look at and to listen to?	- audio clarity - text content easy to read - text content able to be understood

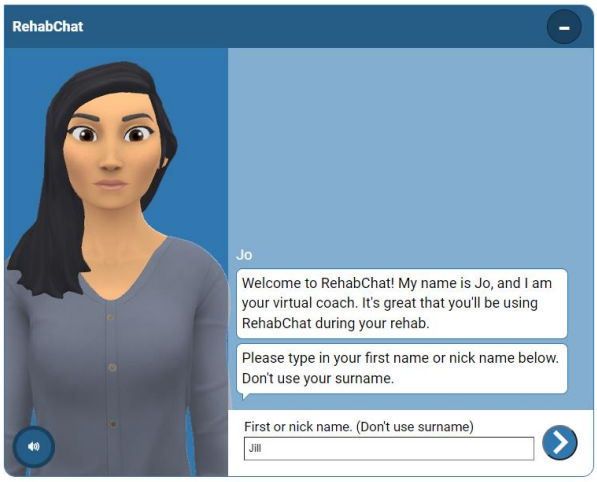
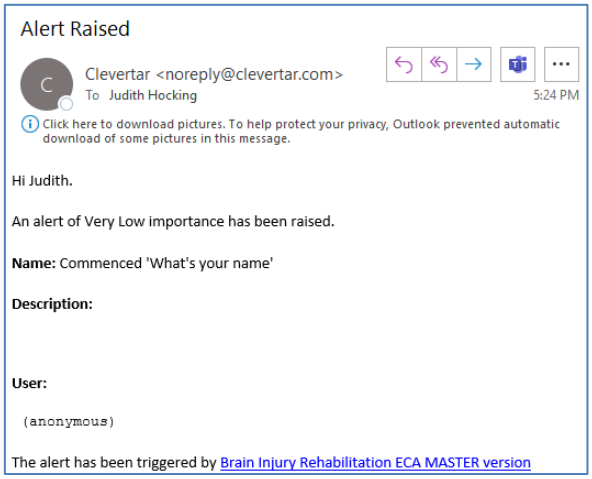
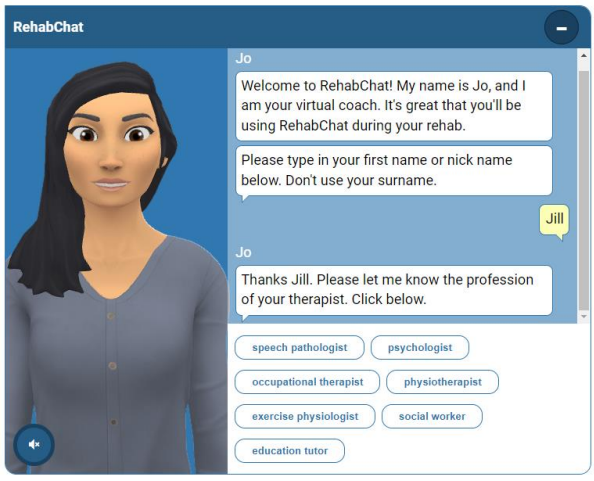
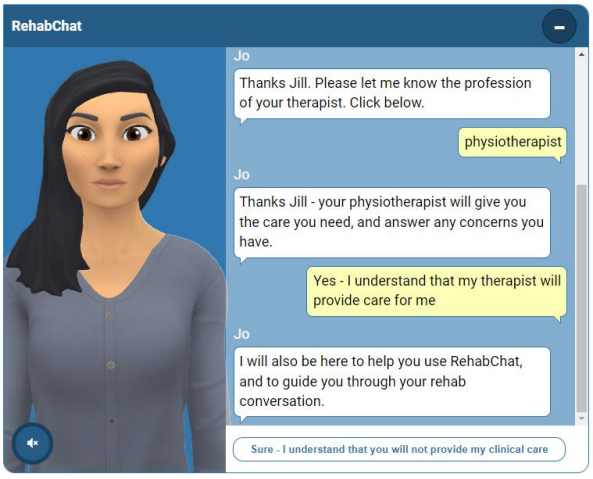
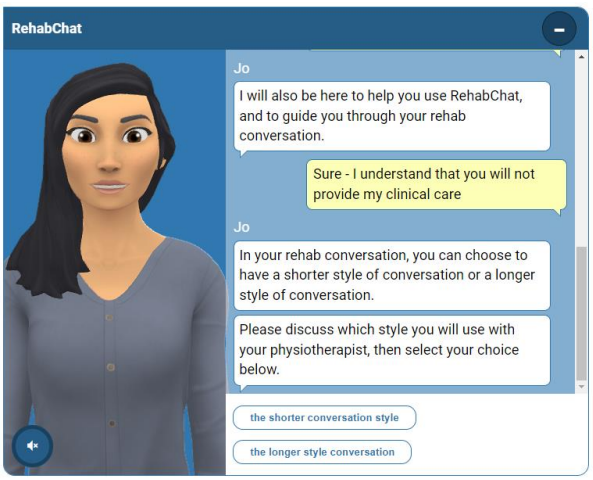
		- visual design of avatar - HCI display clarity
WCAG – Understandable	How easily could you understand the RehabChat conversations? How well could you check your answers entered into RehabChat, and also change your answers if you needed to? What did you think of the prompts that RehabChat gave you about the types of answers you need to enter?	- how well could you understand what was said? / the written text? - did you know how well did you know how to navigate and use the screen display? - how useful were the help hints in RehabChat? - after you had entered your responses, did you feel you could check what you'd entered? – How/why?
UTAUT – Performance expectancy	How do you think using RehabChat has benefited or could benefit you in the future?	- client: help me practice rehab tasks/exercises more regularly - clinician: optimise engagement in my clients
UTAUT – Effort expectancy	How much effort do you need when using RehabChat? What parts of using RehabChat need effort?	- amount of effort for each area of effort mentioned - areas of effort may relate to training needed, needing to juggle RehabChat as another variable in care journey
UTAUT – Attitude toward using technology	Do you think using RehabChat is a beneficial thing to do? Why?	- level of enjoyment using RehabChat - does using RehabChat make rehabilitation more interesting? - does using RehabChat make rehabilitation more fun?
UTAUT – Social influence	How much did the clinical environment influence you using RehabChat? How much did the home environment influence you using RehabChat?	- who were the people that had an opinion on you using RehabChat? (e.g. clinic staff, family, friends etc.) : and what were their opinions? : and how have these options affected you and your use of RehabChat?
UTAUT – Facilitating conditions	Do you feel you had everything you needed so that you could use RehabChat well?	- enough training - enough practice time prior to independent use - able to contact the research team for support - able to ask questions and get answers in a timely way

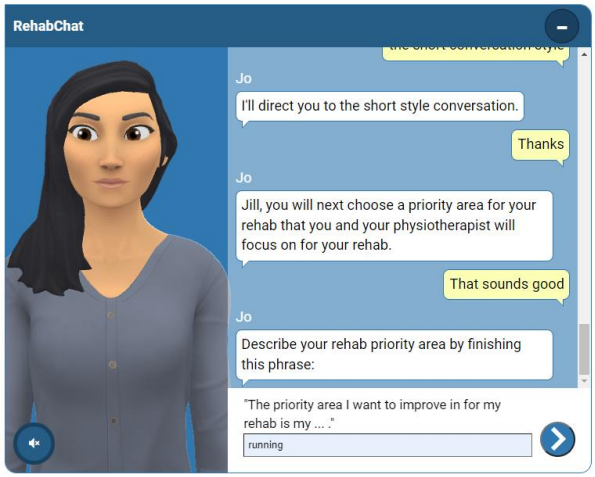
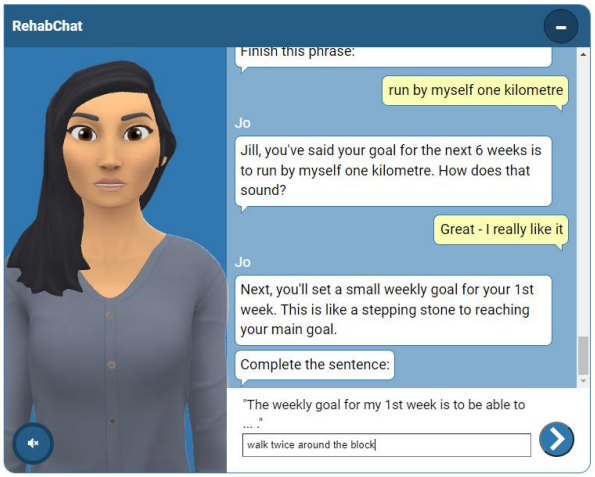
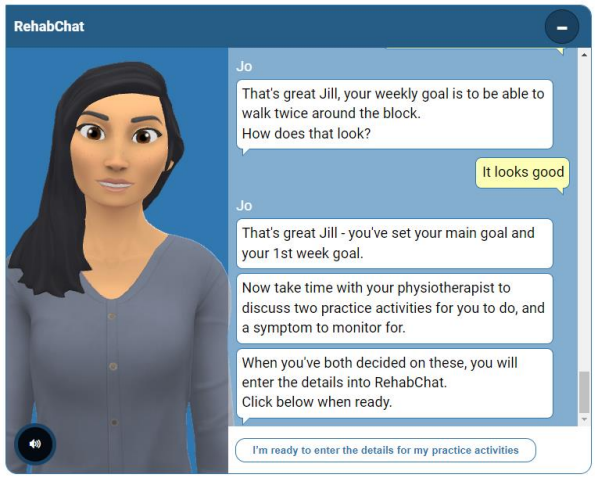
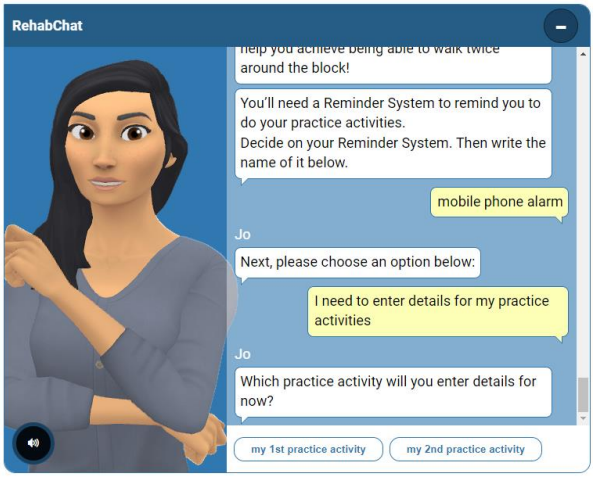
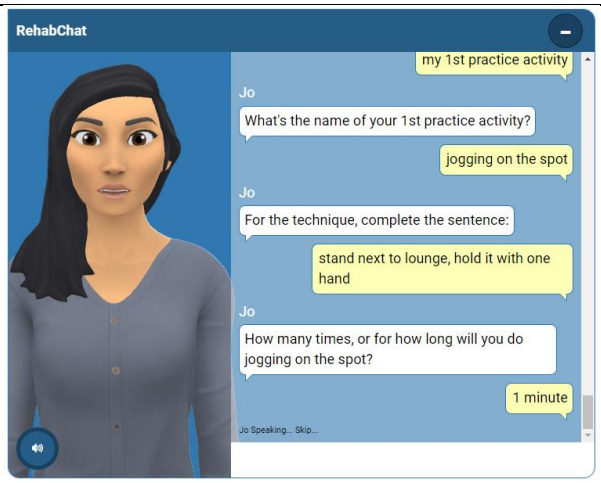
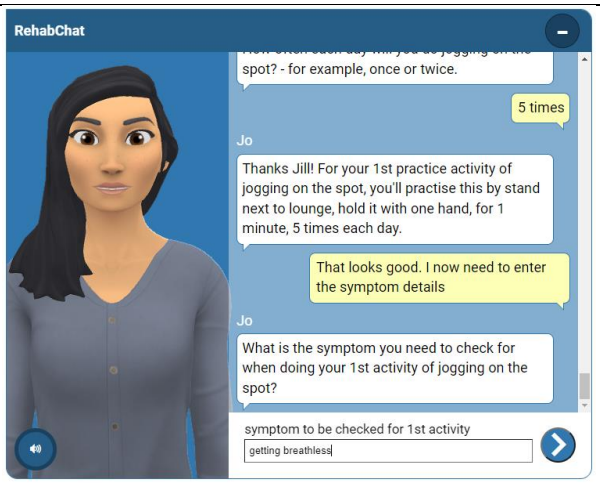
UTAUT – Self-efficacy	In what way has or could RehabChat help you achieve your rehabilitation goal? What extra resources or help do you need so that you can achieve your rehabilitation goal using RehabChat?	- being left to do things independently - having someone to call on when I needed help - having enough time to work through the steps of using RehabChat - having new/more resources in / in-built into RehabChat for helping me when needed - having someone to guide you through it
UTAUT – Behavioral intention to use the system	Have you thought whether you would like to continue using RehabChat if you had the opportunity? – why/why not? If so, for how long do you think you would like to use RehabChat for in the future?	- for how long would you like to continue using RehabChat? - Why would you like/not like to continue using RehabChat? - ask in months
UTAUT – Anxiety	Do you have any concern about using RehabChat? – please explain Were you worried when you were using RehabChat? Please explain Would you be worried about using RehabChat again in the future? Please explain	- anything specifically that may have caused anxiety, or worry - if RehabChat makes the user feel inferior or intimidated
Context – rehabilitation effort	Does RehabChat change how much effort you need to put in for your rehabilitation? If so, how much and why?	- what areas in rehabilitation need effort?
Context – quality/effectiveness of care delivered	How does RehabChat impacts (or may impact upon) the quality of the care that you or other clients may receive? How does RehabChat impacts (or may impact upon) the effectiveness of the care that you or other clients may receive?	- care activities which use RehabChat as being those areas most likely to be directly affected - other areas may be indirectly affected by attention being drawn away from these
Context – client/clinician relationship (client perspective)	How has using the ECA impacted upon the relationship you have with your clinician?	- rapport level - time available in sessions - sense of understanding clinician's information to client
Clinical – safety	Do you have any concerns about the safety of the ECA?	Could the ECA cause any safety concerns?

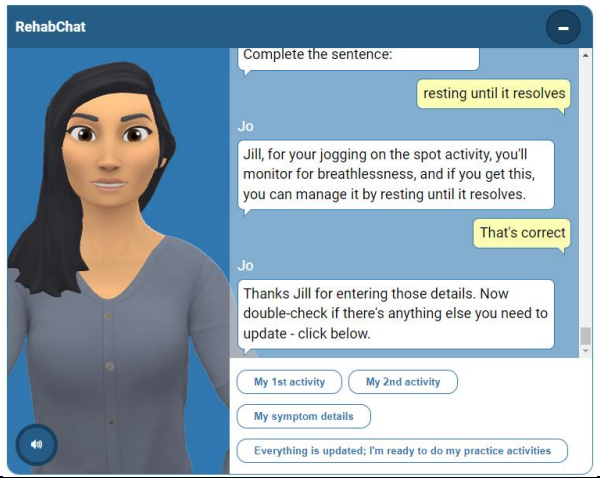
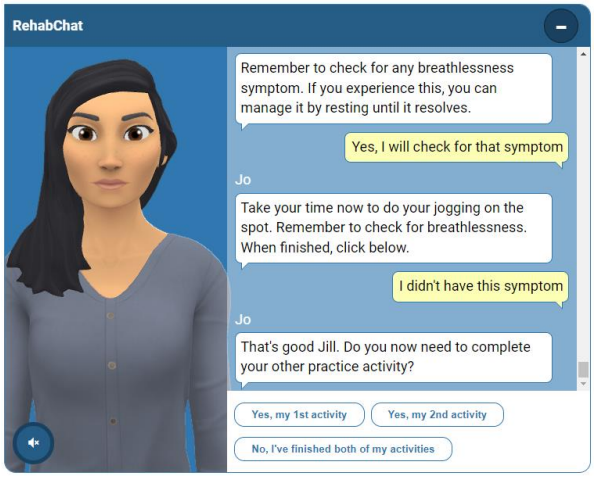
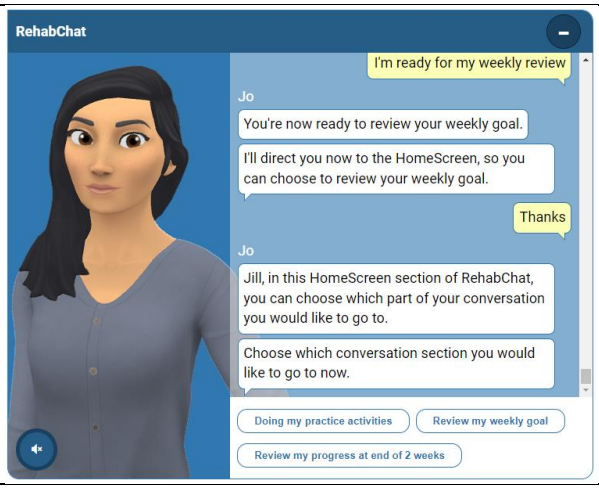
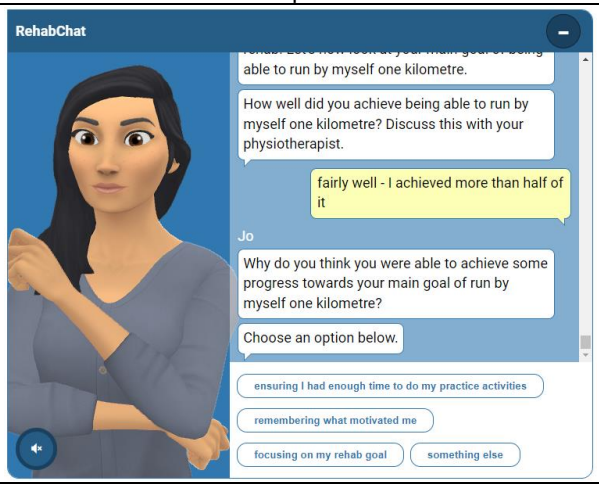
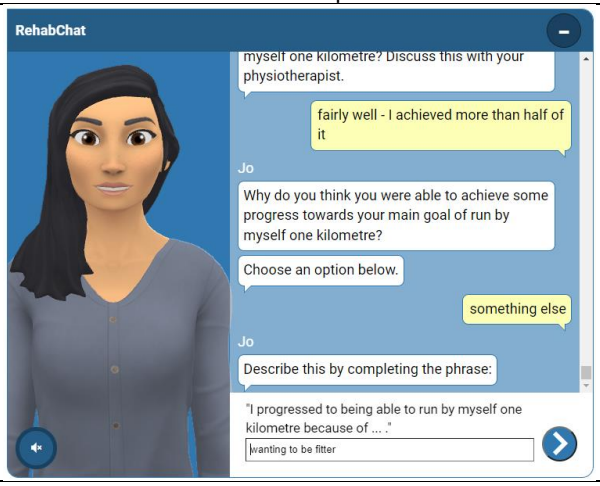
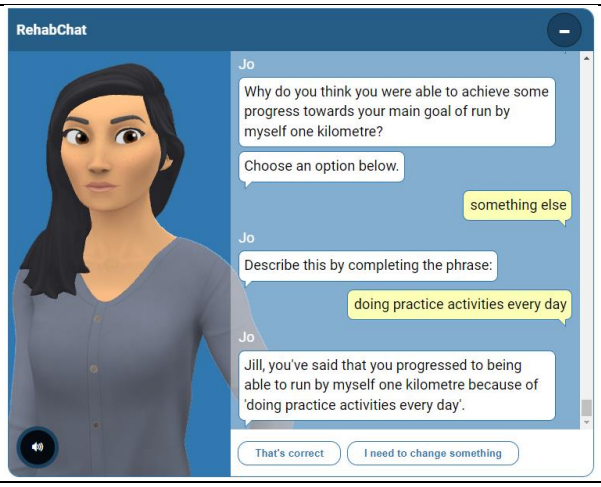
	Do you have any concerns about confidentiality when using RehabChat?	Could the ECA exacerbate any symptoms? Are you concerned about data safety? Do you think RehabChat details are kept safe and confidential?
Recommendations for change	What should be changed in the design of RehabChat? What should be changed in the way RehabChat is used alongside usual care at your clinic?	Ensure that are asking about the clinic from which the participant is from - how it functions on the tablet - using a tablet device - how it works alongside usual care
Other	Is there anything else you would like to comment on about your experience of using RehabChat?	

Appendix XXIII: Feasibility pilot trial – final version of RehabChat

18 screenshots of final ECA version of showing key aspects of conversation and user interface

<table>
<tr><th colspan="2">Final version of RehabChat used in feasibility pilot trial: key points of conversation & features of UI</th></tr>
<tr><td></td><td> 
</td></tr>
<tr><td>1) Launch button: simple design; single click to launch UI</td><td>2) UI: larger buttons & text, androgenous avatar name, & smaller screen for avatar; Conv: opening dialogues</td></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td>3) Generated alert emailed; separate alert for end of each sub-conversation; Conv: alert is for opening dialogues</td><td>4) UI: MCQs, scroll bar, mute button on; Conv: rapport building by ‘Thanks’ and introduce by name</td></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td>5) UI: Re-use entered variables (user name; therapist profession); Conv: emphasis on therapist role</td><td>6) UI: MCQs; Conv: emphasis on ECA not providing care; option to choose long or short conversation style</td></tr>
</table>

Final version of RehabChat used in feasibility pilot trial: key points of conversation & features of UI	
	
7) UI: placeholder above text entry box reduces amount of dialogue spoken by avatar; **Conv:** rehab priority area	**8) UI:** short dialogues of 2-3 lines; **Conv:** SMART aspects for main goal and 1st week sub-goal
	
9) UI: use of confirmation click button to help pace flow of conversation; **Conv:** advise on next steps	**10) UI:** Avatar shows subtle idling gesturing & smile; **Conv:** user can confirm each step of dialogues
	
11) UI: 'skip' visible as Jo speaks, click it to mute Jo for one dialogue & go to text; **Conv:** practice activity details	**12) UI:** Placeholder focuses user attention on key point; **Conv:** practice activity summary; symptom to check for

Final version of RehabChat used in feasibility pilot trial: key points of conversation & features of UI	
	
13) UI: extra MCQs require larger section in lower right corner of screen; **Conv:** use of variables in summary	**14) UI:** mute allows just text to be read with no speaking by Jo, & conv progresses more quickly; **Conv:** cues for home practice
	
15) UI: Multiple choice gives time for user to pause & think; **Conv:** 'HomeScreen' offers redirection options for next step	**16) UI:** predictable wording & structure e.g. 'choose an option below' precedes MCQs; **Conv:** review progress at end of 6/52
	
17) UI: Placeholder content uses sentence stem; **Conv:** partial success built upon by focusing on what helped progress	**18) UI:** option of reviewing entered content & being able to confirm or change it; **Conv:** reinforce useful strategies

Legend: UI = user interface capabilities; Conv= conversation content; MCQ = multiple choice question.