The association between health literacy and knowledge, and self-care in heart failure patients

By

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Abstract

Background

Health literacy significantly contributes to a person's health and wellbeing, as it affects their ability to understand and act on health information. Heart failure (HF) is a global pandemic affecting 511,000 adults within the Australian population. It is a complex condition necessitating careful symptom self-management by patients to ensure quality of life and reduce the risk of hospitalisation and premature mortality. Therefore, health literacy is fundamental to positive outcomes in heart failure.

Methods

This study was a sub-analysis of data collected as part of a prospective multi-centre randomised controlled trial which evaluated the impact of heart failure knowledge and self-care by patients who used an innovative education tool using avatars. Participants were recruited from two metropolitan HF outpatient clinics. The association between health literacy and sociodemographic and clinical outcomes were reviewed.

Results

Thirty-six participants were recruited; the mean age was 67.5 ± (11.3) years. Thirty-three (89.9%) participants were classified as having adequate health literacy and the remaining four (11.1%) participants inadequate/marginal health literacy. Those with inadequate/marginal health literacy were significantly older, with a mean age of 84.7 ± (2.5) and those with adequate health literacy were younger, with a mean age of 65.5 ± (10.6). Those with a higher education level had adequate health literacy (96.6% of participants). Of the participants with inadequate/marginal health literacy, 100% had a comorbidity index score of > 3; those in the same health literacy group also had a body mass index (BMI kg/m_2) > 25 (100%). Participants with adequate health literacy who also had inadequate self-care management comprised 67.7% of this group. There was a statistically significant association between health literacy and HF knowledge (p = 0.014), and literacy and self-care maintenance (p = 0.029), literacy and self-care management (p = 0.027) and literacy self-care confidence (p = 0.035). Health literacy was associated with HF knowledge, while literacy was not. No association was found between health literacy and self-care; literacy had an association across the three self-care domains.

Conclusion

In this study participants health literacy, were significantly associated to HF patients' knowledge and self-care. Participants with inadequate/marginal health literacy who were older and had no schooling, had more comorbidities and a high BMI (kg/m$_2$). Participants with adequate health literacy demonstrated inadequate self-management. Therefore, health literacy and its impact on HF patients disease specific knowledge and self-care warrants focused research and clinical innovation in many of the specific demographic, clinical and associative variables discussed in this thesis.

Declaration

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

30 October 2019

Signature Date

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Heart failure with all its complexities and the people who live with it have been an important constant in my clinical life. Therefore, it has been a pleasure and honour to have had the opportunity to learn more about health literacy in this small population of HF patients.

Thank you!

List of Abbreviations

ALLS	Adult Literacy Life Skills Survey
BMI (kg/m_2)	body mass index
DHFKS	Dutch heart failure knowledge scale
EHFScBS_9	European heart failure self-care behaviour scale
ESL	English as a second language
GCP	Good Clinical Practice
H_0	null hypotheses
H_1	alternate hypotheses
HADS	hospital anxiety and depression scale
HF	heart failure
HFmEF	heart failure with moderate ejection fraction
HFpEF	heart failure with preserved ejection fraction
HFrEF	heart failure with reduced ejection fraction
LVEF	left ventricular ejection fraction
LVF	left ventricular failure
MMSE	mini mental state examination
MoCA	Montreal cognitive assessment
NYHA-FC	New York Heart Association functional class
OSC	American College of Cardiology and the American Heart Association’s stages of heart failure
PRCT	pragmatic randomised controlled trial

QOL	quality of life
RCT	randomised controlled trial
REALM	rapid estimate of literacy in medicine
REALM-SF	rapid estimate of literacy in medicine short form
S-TOFHLA	short test of functional health literacy
SA	South Australia
SCHFI	self-care of heart failure index
US	United States

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Chapter 1: Introduction

1.1 Introduction

Chapter 1 will examine the background, significance, aims and objectives of the study. It begins by outlining HF as a condition and its physiological effect while highlighting the need for focused self-care. Further to this it defines health literacy and its impact on patients with HF, and explores knowledge as it relates to HF and self-care. The epidemiological and financial impact of HF globally, nationally and locally is described, allowing for discussion and evaluation of the gaps in current research and strategies (particularly on a local level) that this study addresses.

1.2 Background

1.2.1 Heart failure

Heart failure is a complex and compounding condition that originates from abnormalities within the cardiac anatomy. It limits the heart's ability to fill with blood at the pressure required or release blood effectively to meet metabolising organ requirements (National Heart Foundation, 2018). Atherosclerotic coronary artery disease that precipitates myocardial infarction, chronic ischemia and hypertension represents the greatest risk factor for developing HF (Givens & Shulze, 2017). Other contributors to HF can be categorised into three groups: myocyte damage or loss, abnormal loading conditions and arrhythmias (Ledley et al., 2017; National Heart Foundation, 2018). Myocyte damage or loss, of which ischemia, inflammation and toxicity are the main contributors, encompasses many conditions. Abnormal loading conditions include hypertension as the most significant contributing factor to HF (National Heart Foundation, 2018). Arrythmias includes tachyarrhythmias, both atrial and ventricular, and sinus node or atrioventricular node dysfunction leading to a bradycardic arrhythmic state (National Heart Foundation, 2018).

Heart failure can be categorised into HF with reduced ejection fraction (HFrEF), HF with moderate ejection fraction (HFmEF) and HF with preserved ejection fraction (HFpEF) (National Heart Foundation, 2018). Patients with HFrEF will have clinical symptoms and signs of HF and a left ventricular ejection fraction (LVEF) under 40%. HFmEF patients will have LVEF of 40–49%. Finally, patients with HFpEF will have symptoms and signs of the condition, an ejection fraction of 50% or greater, and associated structural heart disease or diastolic dysfunction (National Heart Foundation, 2018).

Heart failure patients will experience life-limiting signs and symptoms ranging from dyspnoea, orthopnoea and nocturnal dyspnoea, to lethargy and palpitations (National Heart Foundation, 2018). Further, these patients will experience episodic periods of worsening HF in which they will demonstrate weight gain, peripheral oedema, pulmonary crackles, tachycardia and cardiac murmurs (National Heart Foundation, 2018). Given the complexities of HF as a clinical condition, strategic self-care requiring specific pharmacological and non-pharmacological interventions is imperative to help patients minimise hospitalisation, maintain QOL and reduce mortality risk (National Heart Foundation, 2018).

1.2.2 Health Literacy

Health literacy represents a person's ability to obtain, understand and act upon health information relating to the prevention and management of clinical conditions to improve and maintain their health and wellbeing (Australian Commission on Safety and Quality in Health Care 2014 & World Health Organization, 2016). This definition is among 17 derived by Sorensen et al. (2012) in their systematic review of 19 publications that identified the definitions and conceptual frameworks of health literacy. Magnani et al. (2018) identified 11 health literacy skills from the work of Sorensen et al. (2012) and Haun et al. (2014), as shown in Table 1.1.

Table 1.1

Classification of Health Literacy Skills

Skill	Integral Competencies and Abilities
Literacy	Perform basic reading tasks
Interaction	Engage in communication about health
Comprehension	Understand varied sources of information
Numeracy	Able to complete basic numerical tasks
Information seeking	Search for and access health information
Application/function	Understand and utilise current and changing health-related information
Decision-making/critical thinking	Able to make informed health-related decisions
Evaluation	Sort, translate and evaluate health information
Responsibility	Assume responsibility for decisions regarding health and wellbeing
Confidence	Able to improve personal and community health with confidence
Navigate	Successfully navigate society and health systems enabling positive self-care

Adapted from Magnani et al. (2018, p. 50).

In their systematic review, Cajita, Cajita and Han (2016) highlighted that HF patients with inadequate health literacy are unlikely to adopt and utilise health information and interventions as effectively as those with adequate health literacy. They reported that 39% of HF patients have inadequate health literacy. These findings are consistent with an Australian Bureau of Statistics (2019) report, in which 59% of Australians were deemed as having inadequate health literacy. This figure is based on a 2006 assessment of adults aged 15–74 years using the Adult Literacy Life Skills Survey (ALLS). The scores for this survey range from level 1 (lowest) to level 5 (highest), with level 3 recognised as the minimum score to achieve success in managing the complexities of life (Australian Bureau of Statistics 2019). This deficit in health literacy levels results in greater need of healthcare services with concurrent poorer health outcomes (Australian Commission on Safety and Quality in Health Care, 2014).

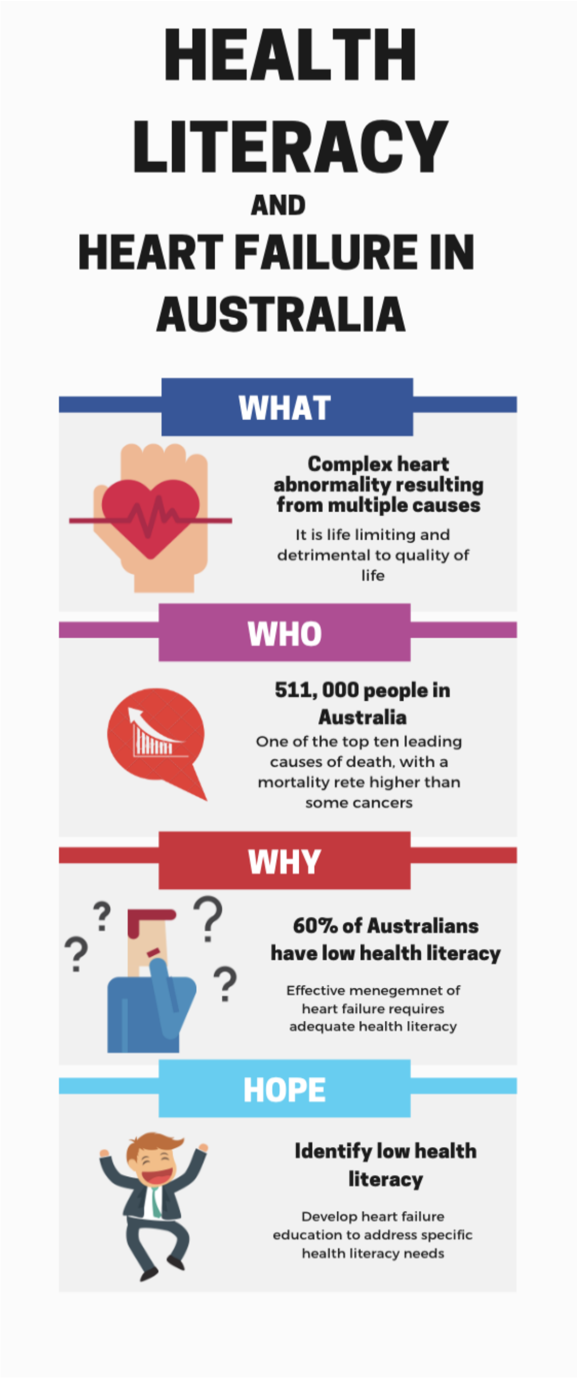
The disease-specific knowledge and self-care required of HF patients to manage their condition, and ensure quality of life (QOL) and longevity is dependent upon adequate health literacy (Mackey, Doody, Werner & Fullen, 2016). Magnani et al. (2018) described inadequate health literacy as an invisible barrier at the interface of patient and clinician encounters, at which healthcare interventions and strategies are applied. This can have a significant personal and financial cost to both individuals and the public healthcare system (Magnani et al., 2018). The American Heart Association (in its scientific statement on health literacy and cardiovascular disease, and how it relates to primary and secondary prevention) stated that increasing the awareness of health literacy, its implications and relevance to individual and public health, is essential to improve outcomes in cardiovascular health (Magnani et al., 2018). It is well reported that to reduce premature mortality and hospital admissions and improve QOL for HF patients, an adequate level of health literacy is essential (Ponikoswski et al., 2014).

1.2.3 Knowledge

Knowledge in the context of HF refers to a person's ability to remember health information, recall learned materials and apply them (Riegel, Dickson & Faulkner, 2016). Barnard, Napier and Zipperer (2014) outlined the three components that form human knowledge: explicit (knowing what); implicit (knowing how and being able to articulate it); and tacit (knowing how without being able to articulate it). This understanding of knowledge is significant in addressing HF patients' awareness of their condition; it allows healthcare providers to collaborate with patients to address knowledge acquisition through their explicit, implicit and tacit knowledge (Pols, 2014). Pols (2014) further elaborated that knowledge alone regarding patients' implementation of self-care may not always be a positive influence when considered alongside familial estrangement, lack of support, financial stressors or embedded routines.

1.2.4 Self-care

Self-care is the process of decision-making, influenced by life experience. It is a naturalistic process involving self-care maintenance, symptom perception and symptom management (Riegel et al., 2016). Self-care maintenance is the first process in self-care; it is any behaviour through which patients maintain physiological wellbeing by monitoring their symptoms and acting accordingly in a timely and positive manner (Riegel et al., 2016). The second process is self-care perception, through which HF patients have a physical awareness of changes and decipher meaning from this knowledge (Riegel et al., 2016). The final self-care process is management, through which HF patients respond to symptoms as they occur. This process indicates confidence in their ability to manage their HF (Riegel et al., 2016). Empowerment of HF patients to adopt positive self-care can be enhanced through shifting the focus from a multimorbid state to identifying positive domains that could include maintaining QOL, engaging in everyday activities and developing a *new* normal life (Chew & Lopez, 2018). Critical self-reflection, a powerful agitator of positive self-care, when integrated with education interventions, can help refocus HF patients' self-care (Chew & Lopez, 2018).



HEALTH LITERACY AND HEART FAILURE IN AUSTRALIA

WHAT

Complex heart abnormality resulting from multiple causes

It is life limiting and detrimental to quality of life

WHO

511, 000 people in Australia

One of the top ten leading causes of death, with a mortality rete higher than some cancers

WHY

60% of Australians have low health literacy

Effective menegemnet of heart failure requires adequate health literacy

HOPE

Identify low health literacy

Develop heart failure education to address specific health literacy needs

Figure 1.1 Health literacy infographic.

1.3 Significance of Heart Failure

Heart failure is a global pandemic affecting 26 million people worldwide (Ponikoswski et al., 2014). Heart failure mortality risk is high; 50% of the HF population die within the first five years of diagnosis, and experience reduced QOL and increased hospital admissions (Ponikoswski et al., 2014).

In Australia annually, 511,000 people live with HF, accounting for 158,000 admissions and 1.1 million hospital days of stay (Chen et al., 2017). This contributes to 61,000 HF-related deaths, with 9,300 within one year of de novo admission and a health cost of A$3.1 billion (Chen et al., 2017); A$2 million of this comprises hospital care costs (Chen et al., 2017). Heart failure is one of the top 10 leading causes of death in Australia, with 50% of patients with severe HF at risk of dying within one year of diagnosis (Australian Bureau of Statistics, 2016). The readmission rate for HF patients within 12 months of an incident hospitalisation for HF is greater than 10,000 separations, indicative of HF patients' complex disease state, multimorbidity and increasing age (Chan et al., 2016).

There are 41,000 HF cases in South Australia (SA) per year, representing a hospital burden of 87,000 days of stay. It is estimated that by 2025, the number of HF cases will rise to 50,000 (Chen et al., 2017). Adelaide has a population of 1,288,681 people, with HF cases falling within 5% of the Australian average (Chen et al., 2017). Within this HF population, of those aged over 45 years, there were 30,000 new cases of HF with 63,000 days of hospital stay and a health expenditure of A$176.5 million (Chen et al., 2017).

Due to the multimorbid state of HF patients and the resultant complexities of care, Mamas et al. (2017) compared survival outcomes in HF patients with those of patients living with the four most common cancers in men and women. Data were obtained from general practices in Scotland. Male HF patients' five-year survival rate was 55.8%, compared to males with prostate cancer whose five-year survival rate was 68.3%, and males with bladder cancer (57.3%) (Mamas et al., 2017). Females' HF five-year survival rate was 49.5%, while the breast cancer and colorectal cancer five-year survival rate was 77.7% and 51.5% respectively (Mamas et al., 2017). From this data, Mamas et al. (2017) concluded that HF can be considered as *malignant* as the cancers in men and women, despite advancements in the clinical management of HF (p.1103).

A study in the United States (US), in which temporal trends in the incidence of and mortality associated with HFrEF and HFpEF were compared, established that HFrEF and HFpEF had similar mortality rates that have remained static since studies prior to 2000 (Dunlay & Roger, 2014; Owan et al., 2006; Tsao et al., 2018). This lack of reduced mortality rates is interesting given that the across the study period (1990–2009), there was a concurrent increase in the prescription of medications for cardiovascular disease and HF. Heart failure knowledge and self-care as previously discussed are important components of HF patients' wellbeing. This considered, the findings from this study were attributed to poor medication adherence (Tsao et al., 2018). Further, both groups over this period had unchanged or less than ideal blood pressure, again reinforcing the issue of medication non-compliance or failure to follow prescription guidelines for target treatment (Tsao et al., 2018).

Health literacy, HF knowledge and self-care among HF patients has been studied extensively. Many interventional studies have had neutral outcomes, while other study designs have produced conflicting results in terms of measuring health literacy among HF patients (Cockayne et al., 2014; Dracup et al., 2014; Gonzalez et al., 2014; Peerson & Saunders, 2011, p. 125; Srisuk et al., 2016; Tung et al., 2013). These outcomes could arguably be attributed to the measurement of health literacy and application of interventions at a population level, given that health literacy is often specific to the context in which it is delivered, as is the content of health information itself (Nutbeam 2009).

Health literacy is recognised as a significant contributor to the determinants of population health. However, there remains a deficit in the translation of research into the assessment and understanding of the value of health literacy in clinical practice, influencing the current effectiveness of interventions (Duell et al., 2015). Further complicating this is the varying definitions and domains of health literacy, which affects the identification of specific measurements appropriate for HF patients. Therefore, it is timely and appropriate to assess the health literacy and literacy levels of a sample of HF patients in SA.

The outcomes of the study will provide a snapshot of the health literacy of HF patients in SA and highlight the association, if any, between HF knowledge and self-care. This project is part of a master's degree by research; it uses data to inform researchers on how to address deficits in health literacy through larger cross-sectional, case control and interventional studies that include further epidemiological data, correlations and interventional strategies and evaluations. Future initiatives this study can embolden could encompass the development of specific health literacy screening tools to inform decisions about management pathways after diagnosis and treatment plans for use in multiple clinical settings and locations, from metropolitan to regional and rural Australia.

1.4 Aims and Objectives

1.4.1 Aims

The aim of this study was to assess the health literacy of HF patients and determine the association between health literacy, HF knowledge and self-care.

1.4.2 Objectives

The specific objectives of this study were to:

1. describe sociodemographic and health literacy characteristics
2. describe clinical and health literacy characteristics
3. describe health literacy levels, literacy levels, HF knowledge and self-care
4. determine any associations between participants health literacy levels, literacy levels, HF knowledge and self-care.

1.5 Conclusion

Chapter 1 has introduced the premise for the study by defining HF, and health literacy and its relationship to HF patients, knowledge and self-care. Furthermore, it has described the current climate globally, nationally and locally (SA). The aims and objectives have been stated and justification for the study has been outlined. Chapter 2 will review the current literature on health literacy and HF, and its impact on HF knowledge and self-care.

Chapter 2: Literature Review

2.1 Introduction

Chapter 2 presents a summary of the literature on HF patients' health literacy. Given the prevalence of inadequate health literacy in Australia (as discussed in Chapter 1) and its effect on population wellbeing, a review of the literature is appropriate. This structured literature review also includes the search strategies and results, the appraisals thereof and the relevant studies presented. Following this, a thematic analysis outlines and discusses the findings, allowing for the development of both research and clinical practice recommendations.

2.2 Methods

This section outlines the literature search strategies, search results and appraisal.

2.2.1 Article selection process

Through a comprehensive database search and bibliographic scrutiny, 24 articles were selected for inclusion in the review of the literature (see Figure 2.1). The Cochrane, Scopus and PubMed databases were searched using several inclusion criteria: publication between 2013 and 2018; publication in English; and inclusion of participants over 18 years. The search terms included were health literacy and/or HF, HF and/or knowledge and self-care and S-TOFHLA. The initial search recovered 1,054 articles, of which 973 were excluded after applying further filters (excluding those with a clinical or pharmacological focus and those that measured all-cause mortality). From this search, 84 articles were selected as appropriate for title and abstract screening; 28 were excluded and 62 were retrieved for full-text screening. Bibliographic scrutiny provided a further 16 articles for abstract and full-text screening. Of these 78 articles, 54 were excluded, leaving 24 articles for inclusion in the literature review.

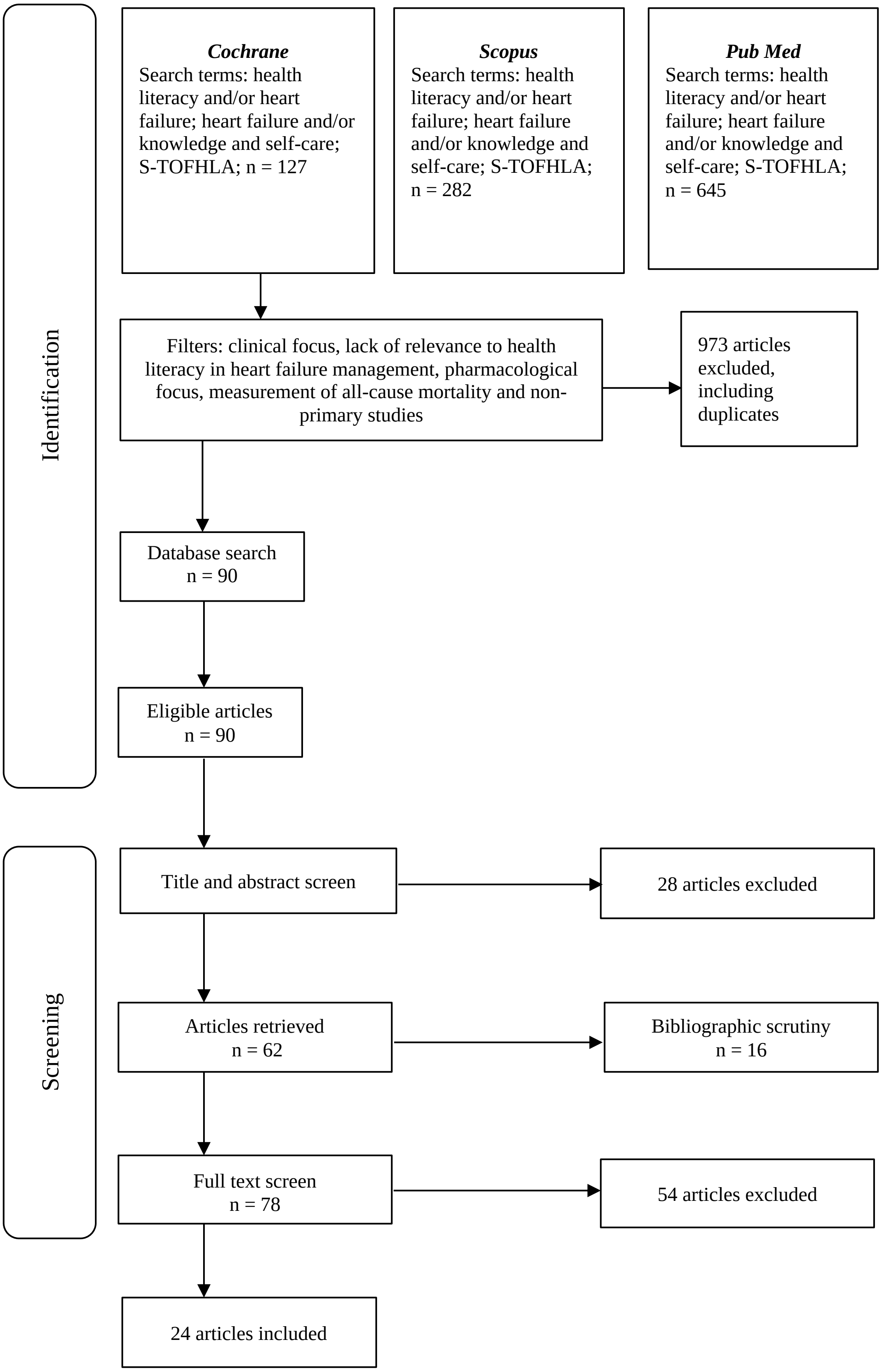


Figure 2.1 PRISMA flow chart.

2.2.2 Appraisal of selected articles

The articles selected were critically appraised for their value, quality of evidence and relevance to knowledge and self-care as they relate to health literacy (Polit & Beck, 2016). Only one qualitative study was selected for review. This was appraised using the Joanna Briggs Institute Critical Appraisal Checklist for Qualitative Studies (Moola et al., 2017). The qualitative methodology was an appropriate design for this study and delivered outcomes that contribute to the review. The remaining studies were appraised using the Joanna Briggs Institute Critical Appraisal Checklist for Analytical Cross-Sectional Studies, Randomised Controlled Trials, Quasi-Experimental Studies and Cohort Studies (Lockwood, Munn & Porritt, 2015; Moola et al., 2017; Tufanaru et al., 2017).

2.3 Literature Review Findings

2.3.1 Study characteristics

The characteristics of the included studies are summarised in Appendix A. Of the 24 studies selected for review, two were published in 2013. At the time of reviewing the literature, these articles were five years old and were included based on their relevance to the topic. Only one article was older than five years (2011) at the time of the review; it provided a major outcome of all-cause mortality, which was an exclusion criterion in the search strategy. However, this article was included, as it directly measured health literacy with a validated tool and identified associations with cardiac events. It can be argued that HF knowledge and self-care are implicit in clinical outcomes, and are therefore relevant for inclusion in the review. The remaining 21 articles were published between 2014 and 2018. Sample sizes ranged from 12 to 2,647, with a mean age of 65.0 (± 6.6) years, and comprised 55.6% male participants. Twelve of the studies were undertaken in the US, two in Brazil, one in Australia, Jordan, Sweden, Spain, Thailand, Singapore, Taiwan, China, the United Kingdom and South Korea. Of the 24 studies, three were randomised controlled trials, one quasi-experimental, one prospective interventional, 10 cross-sectional, three cohort, two prospective, one retrospective and one qualitative.

2.3.2 Thematic synthesis

Health literacy, the predictors thereof and its association with HF knowledge and self-care are implicit in the research aims and objectives, with the literature reviewed highlighting specific related themes. Three themes were evident from the review: 1) cognitive function and educational status and its effect on health literacy, HF knowledge and self-care; 2) patient–carer dyads and the influence of health literacy on HF knowledge and self-care; and 3) health-related QOL, anxiety and depression and their interaction with patient health literacy, knowledge and self-care. These three themes highlight the predictors of health literacy levels and their impact on patients' HF knowledge and effective self-care.

2.3.2.1 Theme 1—Cognitive function and educational status

Cognitive function and or patients' educational status were directly linked to both positive and negative effects on health literacy (Chen et al., 2014; Da Conceicao, Dos Santos, Dos Santos & Da Cruz, 2015; Fabbri et al., 2018; Gonzalez et al., 2014; Hawkins et al., 2016; Linn, Azzolin & Nogueira de Souza, 2016; McNaughton et al., 2015; Peterson et al., 2011; Tawalbeh et al., 2017; Zeng et al., 2016; Zou et al., 2016). Of the 11 studies included in the review that examined cognitive function and educational status, seven identified a link between cognitive impairment and inadequate educational status. Dracup et al. (2014), in their RCT, tested the impact of an educational intervention program that included a control (usual care), Fluid Watchers LITE and Fluid Watchers PLUS, on HF rehospitalization and cardiac death. Both intervention groups received education sessions that were delivered by a nurse face to face with the LITE group having two follow-up phone calls and the PLUS group having bi-weekly calls (Dracup et al., 2014). Dracup et al. (2014) did not discern a difference in literacy levels across all three groups, the mean health literacy score ranged between 69.5 (± 24.7) to 73.0 (±

25.4). Their study had a neutral outcome at 24 months that was attributed to 49% of the patients having HFpEF (Dracup et al., 2014). There is a lack of evidence surrounding these patients and the effectiveness of interventions (Dracup et al., 2014). Dracup et al. (2014) do however acknowledge the importance of assessing health literacy when testing educational interventions. Chen et al. (2014) and Hawkins et al. (2016) both linked health literacy and knowledge, highlighting the blunting effect of this on patients' perceptions of the importance of self-care in HF. However, they did not establish a link between health literacy and self-care. The link between health literacy and knowledge was strengthened by Da Conceicao et al. (2015), in which 52% of the sample had cognitive impairment with a concurrent poor performance in self-care. Da Conceicao et al. (2015) study assessed HF patients, who if clinically decompensating during their hospital admission, received ongoing consultation from a nurse and/or doctor, and those that were clinically stable had no formal input. Those monitored by a nurse and physician had a higher score on the Self-Care of HF Index, regardless of cognitive function or educational level. Fabbri et al. (2017) studied a large sample, of which 261 had low health literacy and lower educational levels, providing a delineation between higher educational status versus lower and its impact on health literacy. Further, Peterson et al. (2011) associated low health literacy with patients that are older, from low socio-economic backgrounds, and who did not complete high school. Son, Shim, Seo and Seo (2018) supported these findings. Their study found that patients who were younger and had completed high school had higher levels of health literacy and subsequent positive self-care. In keeping with Peterson et al. (2011) and Son et al. (2018), Wu et al. (2016) discovered that 47 % of the sample who were older also had lower health literacy and were more likely to experience a cardiac event.

Gonzalez et al. (2014) identified an improvement in HF patients' self-care across all three educational levels. They assessed this via a nursing intervention of up to six face-to-face sessions guided by a structured booklet and the European HF self-care behaviour scale

(EHFScBS_9) at baseline and at one year. Educational levels were assessed at baseline with only 69 participants in the medium–high education group compared to 208 in the low education group (Gonzalez et al., 2014). The authors reported statistical significance for improvement in the higher education group at one year for six questions. Further, Likewise, Linn et al. (2016) reported that those with more years' education had higher self-care scores than those with inadequate or incomplete educational experiences. Conversely, Tung et al. (2013) only found improvements in self-care maintenance and mental and social QOL, without any corresponding improvement in self-care management. Interestingly, given the positive association between health literacy, HF knowledge and self-care across much of the literature, there is too weak an association in the review, following educational or self-management interventions, to prove changes to self-care (Cockayne et al., 2014; Dracup et al., 2014; Tung et al., 2013). In Dracup et al. (2014), this could be attributable to poor delineation between cardiovascular mortality and other causes of death, which limits the outcomes of their educational intervention. Further, Cockayne et al.'s (2014) participants received help in following the cognitive behaviour self-management manual, while Tung et al. (2013) only collected data at baseline, one month and two months. This could be a contributor to the neutral or negative outcomes.

Cognitive function and educational status, particularly years of education, can be directly linked to health literacy and subsequent HF knowledge and effective self-care. However, there is evidence to suggest that a variety of interventions can affect elements of HF patients' self-care. The strength of association around interventional content, structure and delivery of interventions, while understanding HF patients' baseline health literacy and its effect on HF knowledge and self-care, is yet to be addressed in the research.

2.3.2.2 Theme 2—Patient–carer dyads

The literature supports the positive impact that an HF patient's perception of support, particularly social, and the existence of patient–carer dyads can have on HF patients' health literacy, knowledge, self-care maintenance and confidence, while not significantly identifying any influence on their self-care management (Cameron, Rhodes, Ski & Thompson, 2015; Cene et al., 2013; Levin, Peterson, Dolansky & Boxer, 2014; Srisuk, Cameron, Ski & Thompson, 2016). Cene et al. (2013) discovered that perceived emotional, informational and educational support was positively linked to effective self-care maintenance and self-care confidence. Three other studies in the review also linked the patient–carer dyad interactional relationship and the positive self-care. Levin et al. (2014) found caregivers were younger than the patients, female, with higher health literacy skills and had more accurate label-reading skills than the patients. Both the randomised controlled trial (RCT) and qualitative analysis of interviews identified carers as an important element in positive self-care (Srisik et al., 2016; Cameron et al., 2015). In Srisik et al. (2016), the intervention group of carers and patients, who received a family-based education program, recorded increased knowledge scores and improved perceptions of patient symptom management at three and six months, increasing the level of self-care in HF patients. Further, Cameron et al.'s (2015) qualitative study provided carers' perceptions about their role in managing HF patients' self-care. They reported that impediments to positive self-care include 'mood and coping', 'memory loss' and 'fatigue and inactivity'. Wu et al.'s (2017) secondary analysis of data from an RCT uncovered that low health literacy in HF patients, in patient–carer dyads, was associated with low HF knowledge and poor medication adherence. Further, family members with low health literacy negatively affected both their own HF knowledge and patients' knowledge (Wu et al., 2017). Carers' relationships with patients are pivotal and could be further augmented to improve HF patients' health literacy while improving knowledge and self-care (Cameron et al., 2015).

2.3.2.3 Theme 3—Anxiety and depression

Heart failure can precipitate anxiety, emotional distress, depression and reduced QOL, contributing to the disruption of patients' functional health literacy (Bose et al., 2016; Cockayne et al., 2014; Hwang, Moser & Dracup, 2014; Nesbitt et al., 2014; Zou et al., 2016). This negatively affects symptom perception, HF knowledge and self-care. An RCT investigating the effectiveness of a cognitive behavioural self-management manual—in which the intervention group received a nurse-facilitated program and the control group received only the manual and their usual care—found that the intervention group had a higher score in the Hospital, Anxiety and Depression Scale (HADS) (Cockayne et al., 2014). It is suggested that this secondary outcome could have been influenced by the information imparted during the study, which may have increased anxiety around the symptoms and management of patients' conditions (Cockayne et al., 2014). However, with a larger sample size than those in Bose et al. (2016) and Cockayne et al. (2014), Hwang et al. (2014) found that higher HF knowledge contributed to lower depressive symptoms and a greater perception of perceived control predicting more effective self-care. In keeping with Hwang et al. (2014), Zou et al. (2016) identified a strong association between low health literacy, lower social support and depressive symptoms. Nesbitt et al. (2014) discovered a link between high or low QOL dependant on age and gender, and reported reduced QOL in younger male cohorts than in those who were older and/or female. While they did not find a robust association between educational levels and health-related QOL, they reported that baseline HF knowledge, either high or low, had a reciprocal effect on health-related QOL (Nesbitt et al., 2014).

2.4 Discussion of Findings

There is a clear link between cognitive function, years of education and adequate health literacy, resulting in increased HF knowledge with subsequent positive self-care. While those with poor cognitive function or fewer years of education experience inadequate health literacy and poorer HF knowledge, which leads to ineffective self-care, increased hospitalisations and mortality (Chen et al., 2014; Fabbri et al., 2018; Hawkins et al., 2016; Linn et al., 2016; McNaughton et al., 2015; Zou et al., 2016). The review also revealed the positive or negative role of patient–carer dyads in HF patient health literacy, HF knowledge and self-care (Cameron et al., 2015; Cene et al., 2013; Levin et al., 2014; Srisuk et al., 2016; Wu et al., 2017). Anxiety and depressive symptoms are predictors of low health literacy, poor HF knowledge and inadequate self-care (Bose et al., 2016; Hwang et al., 2014; Nesbitt et al., 2014; Zou et al., 2016).

There are conflicting data regarding the efficacy of HF interventional strategies. Of the five experimental studies reviewed, two showed no significant statistical improvement in HF patients' self-care, while the remaining three experimental studies reported positive outcomes (Cockayne et al., 2014; Dracup et al., 2014; Gonzalez et al., 2014; Srisuk et al., 2016; Tung et al., 2013). Dracup et al. (2014) acknowledged some inconsistences in delineating between cardiovascular mortality and other causes of death. The interventions applied in these experimental studies were similar. They all included initial face-to-face contact and telephone follow-ups. The only difference was that two studies involved patient use of a self-management manual.

Cameron et al. (2015) reported that self-care in HF patients was of importance to carers, who felt they could play a multifaced role in imparting knowledge and providing support in the wider context of patients' HF. Patients who felt a sense of support from caregivers or family members exhibited improvements in self-care, while carers and/or family members and HF patients with either adequate or inadequate health literacy had a reciprocal level of HF knowledge and self-care (Cene et al., 2013; Levin et al., 2014; Wu et al., 2017). This interactional relationship is significant to the successful acquisition of HF knowledge and the performance of positive self-care. There were also positive results from an interventional education program in which carers reported an improvement in their perceived control of the HF patient's management, further consolidating the notion that patient–carer dyads improve health literacy through knowledge and self-care (Srisuk et al., 2016). These studies used small sample sizes at single sites, limiting the ability to develop population generalisations (Cameron et al., 2015; Cene et al., 2013; Levin et al., 2014). The use of the Dutch HF knowledge scale (DHFKS) for assessing carers' health literacy must be considered in any review, as it is not validated for this purpose (Srisuk et al., 2016). However, statistical significance was addressed by assessing carers' changing responses over time (Srisuk et al., 2016).

Bose et al. (2016) argued that from their study outcomes, psychosocial interventions must be incorporated in the education and support of patients with HF. This suggestion was validated by Cockayne et al. (2014), who found in their secondary study outcomes that HADS scores increased in the intervention group, highlighting the possibility that HF, diagnosis and educational interventions can lead to a greater sense of anxiety regarding symptom management and life expectancy. Further, confounding bias was acknowledged, as HF symptoms and depressive symptoms can overlap (Hwang et al., 2014; Zou et al., 2016). Of the four studies reviewed, only one used an experimental design, with the primary study focus of the effectiveness of a cognitive behavioural self-management manual on health literacy, not anxiety and depression (Cockayne et al., 2014). The remaining two were non-experimental, secondary analyses of primary data using non-probabilistic sampling that acknowledged possible confounding bias (Hwang et al., 2014; Zou et al., 2016). Future studies would benefit from an experimental design and randomisation to control for potential confounders.

2.5 Limitations

The limitations of this review include the age of the literature. Except for one article, the studies reviewed were not older than five years at the time of the review, possibly excluding relevant studies. An expert librarian was not utilised and, as previously discussed, the dominance of cross-sectional and non-interventional study designs limited the establishment of causation between health literacy and HF knowledge and self-care and any generalisations about study outcomes. However, this does not diminish the findings given that the purpose of the review was to examine the literature for findings on health literacy and its association to HF knowledge and self-care.

2.6 Conclusion

The education of both patients and carers is central in the non-pharmacological management of HF. Patient education begins on admission to hospital, with frequent revision, to ensure adequate health literacy to enable an increase in HF knowledge and effective self-care. The review of the literature supports this, while identifying the predictors of poor health literacy and its influence on HF knowledge and self-care as cognitive function, educational status, and anxiety and depressive symptoms.

This review highlights the importance of understanding HF patient’s health literacy levels and how it interacts with knowledge and self-care. Therefore, a descriptive study in SA measuring these phenomena and how they are associated is warranted. Furthermore, the review identifies the benefits to transposing research-based health literacy tools, self-care scales and depression screens for use in general clinical settings. This would help ensure provision of appropriate inpatient education, discharge instructions and referrals.

Health literacy, HF knowledge and patients’ self-care are influenced by patients’ cognitive function and educational status, support networks, and anxiety and depressive symptoms. Future strategies to improve these predictors could include experimental research designs to explore anxiety and depressive symptoms in HF patients, while developing inclusive interventions for patient–carer dyads. Therefore, anxiety and depressive symptoms in HF patients could be addressed through further research, using experimental designs and randomisation of sampling to ensure statistically significant outcomes. Recognition of HF patients’ supports networks, specifically the patient–carer dyad, when developing and delivering interventions will ensure adequate health literacy and improvement in HF knowledge and self-care.

Chapter 3: Methods

3.1 Introduction

This chapter outlines the methodology used for this study. Ethics, governance and site-specific applications are discussed along with the ethical considerations addressed. Recruitment, including sampling and data collection, is described followed by discussion on the internal reliability and validity of the instruments used. Further, the external validity of the study is addressed. Finally, data analysis and the statistical methods used to address the aim and objectives are outlined.

3.2 Methodology

3.2.1 Research paradigm

This study used a positivist paradigm that includes deductive reasoning and empirical methods to assess human behaviour, enabling the refinement and confirmation of the phenomena studied (Williamson, 2018). Positivism seeks truth and facts through objective measurement through a quantitative research design, the objective of which is to establish a relationship between two variables, either through descriptive or interventional methodological approaches (Williamson, 2018). Typically, survey designs are descriptive, non-interventional approaches developed to collect data from a population or part thereof to establish the incidence of a phenomenon and associations between the variables in question (Tanner, 2018). Additionally, descriptive studies can be used in the planning and evaluation of health programs and policies (Setia, 2016). This study seeks to assess health literacy levels among a population of HF patients in SA while reporting any associations between health literacy levels, HF disease-specific knowledge and self-care. These descriptions and associations will be established using data analysed through the Statistic Package for Social Science (SPSS, Version 22). This study design can inform researchers on the need for larger cross-sectional, case control or interventional studies and assist in the design of studies to test specific hypotheses (Setia, 2016).

3.2.2 Fluid watchers pragmatic randomised controlled trial

This study was a sub-study of a pragmatic RCT (PRCT) Fluid Watchers, which developed and evaluated the effectiveness of an interactive avatar education application for improving HF patients' knowledge and self-care (Wonggom, Du & Clark, 2018). The PRCT randomised participants into a usual care or interventional group. The usual care group continued to consult their cardiologist and HF nurse, while the intervention group also received an avatar education application on a tablet (Wonggom et al., 2018).

This descriptive study was nested within the PRCT, in which baseline data were gathered and analysed, providing the data needed to meet the study aims and objectives.

3.3 Hypotheses

Two experimental hypotheses were tested:

Hypothesis (H_0)

There will be no association with health literacy and HF knowledge and self-care in this sample of HF patients.

Hypothesis (H_1)

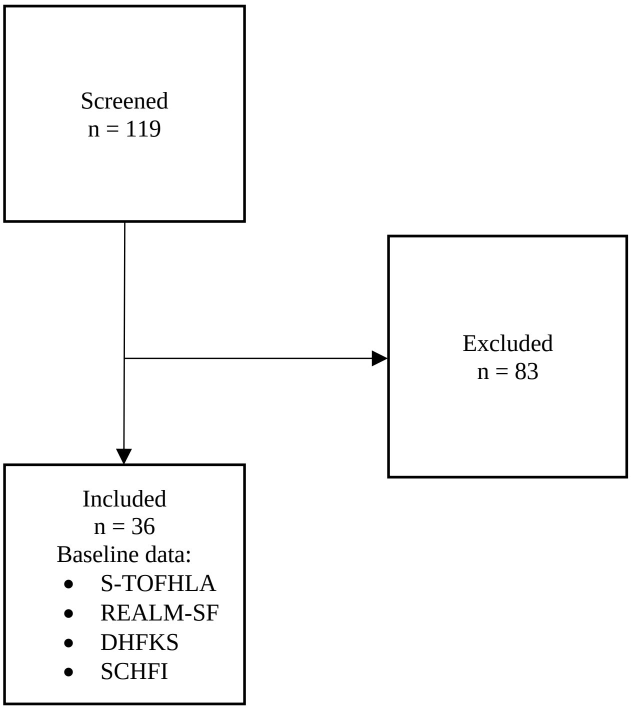
There will be an association with health literacy and HF knowledge and self-care in this sample of HF patients.

3.4 Study Design

3.4.1 Setting and Participant recruitment

Participant recruitment and data collection commenced in October 2018 and continued until March 2019. Recruitment and data collection were undertaken at three public outpatient

HF clinics in metropolitan Adelaide (see Appendices G–I). As shown in Figure 3.1, 36 participants were recruited for this sub-study.



Note: S-TOFHLA (short test of functional health literacy); REALM-SF (rapid estimate of adult literacy in medicine short form); DHFKS (Dutch HF knowledge scale); SCHFI (self-care of HF index).

Figure 3.1 Consort flow chart.

Recruitment was undertaken by the cardiologist or HF nurse specialist during a scheduled appointment on the day; consent was sought from the nurse researcher. Data were collected at one point during individual sessions. Participants completed the Montreal Cognitive Assessment (MoCA; see Appendix B); those with a score of ≥ 26 were included.

Prior to formal recruitment and data collection, the cardiologists and HF nurse specialists were inducted by the principal investigator and research team to inform them of the aim and objectives of the project, and the methods that would be used to achieve them. Further, they were given flyers to be distributed to potential participants to explain the purpose of the study and what their involvement would entail. They were given the inclusion criteria (see Table 3.1), allowing them to screen patients for suitability for the study. The nurse researchers were present during these clinics to approach participants at one time. However, occasionally, patients interested in participating and those who provided signed consent were not able to undertake the study requirements at the time. Instead, they elected to rebook either at the outpatient clinic, in a café or in their home with two nurse researchers present.

Table 3.1

Inclusion/Exclusion Criteria

Inclusion	Exclusion
Confirmed diagnosis of HF	Clinically unstable
Previous hospitalisation for HF	Cognitive impairment (< 26 MoCA)
Clinically stable	No English
Normal cognitive function (≥ 26 MoCA)	Unable to provide informed consent
NYHA-FC I-IV	
English	
Informed consent	

Note: MoCA (Montreal Cognitive Assessment); NYHA classification (New York Heart Association). Adapted from Wonggom et al. (2018, p. 5).

Inclusion criteria were modified during the recruitment process to include all those with a confirmed diagnosis. The original criteria, as outlined in the protocol for the PRCT, was a confirmed diagnosis within one year (Wonggom et al., 2018). This was modified due to the restrictive nature of the original inclusion criteria and its potential impact on achieving the study's established enrolment number. Participants were considered clinically unstable if they did not have a normal heart rate, systolic blood pressure, respiratory rate, oxygen saturations and temperature.

3.4.2 Variables

The variables for this study, based on the aim and objectives, were demographic, clinical, HF patients' health literacy level, literacy level, HF knowledge and self-care. Associations between health literacy and HF knowledge and self-care were reported based on apparent connections between these variables. Participants' health literacy was measured using the S-TOFHLA; literacy was assessed using the REALM-SF; HF knowledge was measured by the DHFKS; and self-care were assessed using the SCHFI (see Appendices C–E; Arozullah et al., 2007; Baker et al., 1999; Reigel et al., 2009; Van der Wal et al., 2005). Demographic and clinical baseline data (see Table 3.2) were collected from observations of the HF nurse specialist, patient medical records and patient interviews.

Table 3.2

Participant Baseline Data

Demographic	Clinical	Instruments
Age	Diagnosis	MoCA
Gender	Medical history	S-TOFHLA
Country of birth	Past procedures	REALM-SF
Marital status	Hospital admissions	DHFKS
Living arrangements	NYHA-FC	SCHFI
Occupation	Medications	
Educational level	LVF	
	Charlson comorbidity index	

Note: NYHA-FC (New York Heart Association functional class); LVF (left ventricular function); MoCA (Montreal Cognitive Assessment); S-TOFHLA (short test of functional health literacy); REALM-SF (rapid estimate of adult literacy in medicine short form); DHFKS (Dutch HF knowledge scale); SCHFI (self-care of HF index). Adapted from Wonggom et al. (2018, p. 5).

3.4.3 Measurement

Participant cognitive assessment was collected using the MoCA. It is an assessment tool designed to capture mild cognitive impairment in individuals who may score normally on the mini mental state examination (MMSE) (Nasreddine et al., 2005). It consists of 30 points of testing and should take 10 minutes to complete; a score of ≥ 26 is considered normal cognitive function. Although this measurement is not significant to the study’s aim or objectives, it is an inclusion or exclusion criteria and will be explored in the discussion.

Health literacy levels were measured using S-TOFHLA, as it is one the shortest instruments available that can comprehensively assess functional health literacy and is indicated for use in research (Baker et al., 1999; p. 39; Haun et al., 2014). The S-TOFHLA

(Version 3) is a prose-only version comprising 36 items. It uses the Cloze procedure in which the patients choose a word from a multiple-choice list that is omitted from the sentence (Baker et al., 1999). The sentences include health information and terminology that people encounter frequently in healthcare settings. The participant has seven minutes to complete the assessment and their health literacy is then categorised into inadequate (0–16), marginal (17–22) and adequate (23–26) (Baker, 1999).

The literacy level of study participants was measured using the REALM-SF. This is a shortened instrument based on the REALM tool, which is a 66-item literacy assessment (Arozullah et al., 2007). The short form is a simplified version used for assessing literacy in clinical, health and research settings (Arozullah et al., 2007). The short form requires participants to read seven words as they are shown to them. It is scored using conventional school grades: zero (Grade 3); 1–3 (Grades 4–6); 4–6 (Grade 7–8); and ≥ 7 (Grade 9) (Arozullah et al., 2007).

Heart failure knowledge was measured using the DHFKS, which is a questionnaire comprising 15 items covering general HF knowledge, HF treatment knowledge, and HF symptoms and recognition (Van der Wal et al., 2005). Its scoring system is based on a scale from 0–15, with 0 being no knowledge, 15 optimal knowledge, < 11 inadequate knowledge and ≥ 11 adequate knowledge (Van der Wal et al., 2005). It is a validated tool for use in research to establish the effect of health education messages and clinical practice input on HF patients' knowledge about their condition (Van der Wal et al., 2005).

The SCHFI measured participants' maintenance and management of their condition. (Reigel et al., 2009). It consists of five maintenance items, six management items and four confidence items. The SCHFI authors recommend that the self-care component—maintenance and management—is scored separately to the confidence component (Reigel et al., 2009). A score of 70 on each of the three scales is considered indicative of self-care adequacy (Reigel et al., 2009).

3.5 Approval and Ethical Standards

This study included participants with a diagnosis of HF attending HF outpatient clinics from two sites in metropolitan SA. The research was conducted in accordance with the *National Health and Medical Research Councils National Statement on Ethical Conduct in Human Research* (2018). Research Ethics Committee approval was sought in May 2017 and obtained from the Southern Adelaide Clinical Human Research Committee (HREC/17/SAC/286) in February 2018 (see Appendix H). Site-specific approval (SSA/17/SAC/278) was also sought in May 2017, as the project was conducted at the Queen Elizabeth Hospital and Noarlunga GP Plus, and granted in March 2018. An amendment for ethics approval was submitted in May 2018 to include the researcher as an associate investigator and ethics approval was granted in September 2018 (see Appendices I–J). Changes to the study were reported to the ethics committee in a timely manner. Risk of harm to participants was negligible due to the descriptive design of the study. The ethics approval letters and amendment approvals are available in Appendices F–J.

3.5.1 Privacy and participants' rights

Initial contact with participants was undertaken by the cardiologist or HF nurse specialist in the clinic. They gained consent for the research nurse to contact the patient, thus minimising intimidation, coercion or duress. The purpose of the study was explained to the patient, consent explained, including the voluntary nature of their consent, and that at no time would their usual treatment be affected if they did not consent or withdrew at a later time. Participant consent forms can be viewed in Appendix K. Participants were informed that any and all published material was deidentified and data statistically summarised with identifying information converted to numerical codes on all study documents to ensure confidentiality. This deidentification was completed in situ. Participant interviews were undertaken in an office in the clinic with the door closed; only the research nurses were present to facilitate the core principles recommended by the United Nations Educational, Scientific and Cultural Organization in its *Universal Declaration on Bioethics and Human Rights* (Schneider & Whitehead, 2016). Investigators signed a confidentiality agreement with the Office of Research (see Appendix L). These core principles are respect for autonomy and responsibility, respect for privacy, anonymity and confidentiality, respect for justice and beneficence, respect for human vulnerability and personal integrity and respect for cultural diversity (Schneider & Whitehead, 2016).

3.5.2 Data storage and protection

Data were collected through paper questionnaires and demographic forms. These data were entered into a digital format by manually entering the variables in Excel spreadsheets. Numerical codes were entered on all study documents in situ instead of names to ensure anonymity and confidentiality. For the duration of the study, all data collected will be kept in a locked filing cabinet in the researcher's office. Further, data were entered in a timely manner, to minimise the misplacement of data, into password-protected Excel spreadsheets. Weekly audits of data entered were conducted at scheduled meetings by range checks and random audits. Only those listed as investigators under ethics approval have password access to these documents. Any published material will be deidentified and all data will be statistically summarised. The data collected from this study will be kept for five years.

3.5.3 Ethics and governance application process

An application for ethical and governance approval was submitted as part of the preparation for the RCT in which this descriptive sub-study was embedded. This application was submitted in May 2017, with final approval received in February 2018. An amendment was submitted to include the updated RCT study protocol, S-TOFHLA and three months' follow-up document; approval was granted in April 2018. A final amendment was submitted in August 2018 to include Katie Nesbitt and Dr Paul Nolan as associate investigators. The descriptive study approval was received in September 2018.

3.6 Quantitative Variables

This study assessed participants from both groups in the PRCT and report as one group. As such, the variables were examined in singular groupings. The data collected were entered on an Excel spreadsheet with demographic variables entered as singular sets for each measure and the MoCA variable entered as a raw score of 0–30. The S-TOFHLA was entered with three variables based on participants' answers. The first variable was the answer the participant chose (A–D); the second indicated if the answer was *correct* or *incorrect* and a numerical identifier was recorded (0 = incorrect, 1 = correct and 999 = missing). These were entered for each question. The final two variables for the S-TOFHLA are the total score (0–36) and health literacy grouping (inadequate, marginal or adequate). The REALM-SF participants' answers were entered as either *correct* or *incorrect,* a total score and then the converted corresponding grade level. The DHFKS was entered as two variables—*correct* or *incorrect*—for each question and the total score. Finally, for the SCHFI, which requires participants to choose the correct word, five variables were entered—the word chosen for each question, a subtotal score for the three themes, and a total score.

3.7 Statistical Methods

The data collected in this study were analysed using IBM's Statistical SPSS (Version 25). Demographic and clinical characteristics, and health literacy scores were analysed using descriptive statistics. The mean age and standard deviation (SD) were calculated, and the data were expressed as participant numbers and percentages for all, and inadequate/marginal and adequate health literacy in tables. The description of health literacy scores, DHFKS scores and SCHFI scores were also calculated and expressed as participant numbers and percentages in a table. In addition, the mean and SD of participants' DHFKS scores, based on their health literacy level, were calculated and reported in the same table. This study further explored the relationships between health literacy, literacy, HF knowledge and self-care to discover and understand any associations. Correlational analysis was calculated using ordinal data and the Spearman's rho (Pallant, 2016; Polit & Beck, 2017). Correlations were analysed based on the value of the correlation coefficient ranging from – 1.0 to + 1.0, expressed in a table to reflect neutral, positive or negative correlation between health literacy, HF knowledge and self-care-behaviour (Cohen, 1988; Pallant, 2016; Schneider & Whitehead, 2016). Statistical significance was achieved at $p < 0.05$ (Pallant, 2016; Schneider & Whitehead, 2016). When conducting correlational analysis for ordinal data, such as health literacy levels, literacy levels, HF disease-specific knowledge and self-care, Spearman's rho is indicated, and as such, was used in this study (Cohen, 1988; Pallant, 2016; Polit & Beck, 2017).

3.8 Rigour

3.8.1 Validity and reliability

This study used five instruments to establish if participants met the inclusion criteria and provided data to meet the aim and objectives. The psychometric properties of these instruments establish their reliability, validity and worthiness to accurately assess the variables nominated in this study. The psychometric properties of the MoCA establish reliability, validity and accuracy in measuring impaired cognitive function. Reliability was established with a test–retest correlation coefficient of 0.92; internal consistency was established for the standardised items with a Cronbach's alpha of 0.83 (Nasreddine et al., 2005). Sensitivity compared well to the MMSE, with mild cognitive impairment and Alzheimer's disease identification rates of 90% and 100% respectively, while the MMSE was 18% and 78% respectively (Nasreddine et al., 2005). The MMSE specificity identified 100% of the elderly controls who had a score above 26 and the MoCA identified 87% (Nasreddine et al., 2005).

The validity through internal consistency of the S-TOFHLA was established using Cronbach's alpha from a sample of 211, while validity was reported from correlations between the S-TOFHLA and the REALM (Baker, 1999). The S-TOFHLA Cronbach’s alpha for the 36 items in the prose-only version was 0.97 and the correlation coefficient was 0.80 (Baker, 1999).

The REALM-SF is validated through correlation with the REALM, with a correlation coefficient of r = 0.95 for development samples and r = 0.94 for validation samples (Arozullah et al., 2007). These results were correlated with the wide-range achievement test (WRAT-R) for field validation testing at r = 0.83 (Arozullah et al., 2007).

Internal consistency was established for the DHFKS after assessing a population of 902 HF patients from 17 Dutch hospitals (Van der Wal et al., 2005). Cronbach’s alpha was 0.62 and was not able to be improved by deleting any of the 15 items (Van der Wal et al., 2005). Content validity was achieved after assessment by 10 HF nurses and two cardiologists; nothing was added or deleted, while face validity was established after the instrument was assessed by six HF patients selected for their current HF knowledge (Van der Wal et al., 2005). They too made no additions or changes. Construct validity showed that the instrument can detect the difference between patients with higher HF knowledge and those with lower HF knowledge (Van der Wal et al., 2005).

Finally, the SCHFI reliability was reported with a test–retest correlational coefficient of 0.89 for self-care maintenance, 0.70 for symptom perception and 0.84 for self-care management (Riegel et al., 2018). Internal consistency for the same measures were 0.71, 0.81 and 0.66 respectively, and the global reliability index results were 0.75, 0.85 and 0.70 respectively (Riegel et al., 2018). Predictive validity was supported by correlations between the SCHFI and the 36-item survey short form (SF-36) (Riegel et al., 2018). The psychometric properties of the SCHFI showed an improved instrument that is reliable and valid (Riegel et al., 2018, p. 190).

External validity, through the study’s generalisations, will be difficult to achieve due to the non-probabilistic sampling method used, the small sample size and access to participants across only two sites. However, external validity could be achieved futuristically by replicating the study and using non-random sampling, achieving a more representative sample over different periods in a variety of settings (e.g., regional and rural).

3.8.2 Investigators

All investigators completed their *Good Clinical Practice* training with certification of completion available in Appendix M. *Good Clinical Practice* online training was developed to inform researchers undertaking studies involving human participants on how to conduct clinical trials (National Drug Abuse Treatment Clinical Trials Network, 2018). Some of the topics covered in the course are institutional review boards, informed consent, quality assurance, the research protocol and, documentation and record keeping (National Drug Abuse Treatment Clinical Trials Network, 2018).

3.8.3 Bias

There were four potential biases, which were controlled for in this descriptive sub-study (Smith & Noble 2014). First, confounding bias whereby the contact participants have with the HF nurse specialist and cardiologist immediately prior to participating in the study could transiently falsely increase their HF knowledge. As opposed to an alternative sample and setting in which HF patients had no prior clinical or educational encounters before having their HF knowledge and self-care assessed. Second, data collection bias was controlled for by following the study protocol, ensuring the nurse researchers were trained in data collection prior to starting. Further, the research team met weekly for governance meetings to discuss data collection and entry among other logistical and clinical issues (Wonggom et al., 2018). Third, measurement bias was inherently addressed using validated instruments, as discussed previously. The fourth bias that was addressed was analysis bias, in which the Excel document was a shared single document accessed by the research team; weekly audits and double checks were undertaken. Furthermore, data analysis was supervised by a statistician who was not involved in any part of the descriptive sub-study or PRCT.

3.8.4 Study size

There was no power analysis conducted for this descriptive sub-study. However, the PRCT within which this study was conducted was to enrol 88 participants (Wonggom et al., 2018). This sample size was determined by a previous study measuring HF knowledge using the DHFKS and calculated using PASS 14 power analysis and sample-size software by a statistician (Wonggom et al., 2018).

3.9 Conclusion

Chapter 3 has set out the methodology used in the study, developing the groundwork for data analysis and the discussion to follow in Chapters 4–5. The ethical application process, approval and considerations have been discussed, followed by the sampling method, data collection process and measurements used. Rigour was established by discussing the psychometric properties of the instruments used to prove reliability and validity. Finally, data analysis was discussed, which will provide the basis for the findings presented in Chapter 4.

Chapter 4: Results

4.1 Introduction

This results chapter will present the sociodemographic and clinical characteristics of the participants in tandem with their health literacy scores as measured by the S-TOFHLA. This will be followed by a description of health literacy scores, literacy scores and a comparison of these with participants' HF knowledge and self-care as measured by the DHFKS and the SCHFI. Finally, associations were explored between these three variables and the REALM-SF, enabling a discussion of the analysis in Chapter 5.

4.2 Participants' Characteristics

The participants characteristics and health literacy levels are reflected in Table 4.1. There were 36 participants with a mean age of 67.5 ± (11.3) years. Of these, four had inadequate/marginal health literacy (11.1%) and 32 had adequate health literacy (88.9%).

Of the 36 participants 29 were men (80.6%) and seven were women (19.4%). Thirty-four spoke English (94.4%). Regarding marital status 19 were married (52.8%) and 27 lived with a spouse or carer (75%). There were 14 participants that had completed a certificate education level (38.9%), 25 were born in Australia (69.4%) and 23 were retired (63.9%).

The four participants who had inadequate/marginal health literacy had a mean age of 84.7 ± (2.5) of which three were men (75%) and four spoke English (100%). Regarding marital status two were married (50%) and two were widowed (50%), while four lived with a spouse or carer (100%). Participants either had no schooling (2, 50%) or a certificate level education (2, 50%). All participants were born in Australia and retired (4, 100% respectively).

Table 4.1

Participant Characteristics and Short Test of Functional Health Literacy Scores

Characteristics	All n = 36 n (%)	Inadequate/Marginal n = 4 n (%)	Adequate n = 32 n (%)
Age, mean (SD)	67.5 ± (11.3)	84.7 ± (2.5)	65.5 ± (10.6)
Sex			
Male	29 (80.6)	3 (75.0)	26 (81.3)
Female	7 (19.4)	1 (25.0)	6 (18.8)
Language spoken:			
English	34 (94.4)	4 (100)	30 (93.8)
ESL	2 (5.6)	0 (0.0)	2 (6.3)
Marital status:			
Single	10 (27.8)	1 (25.0)	9 (28.1)
Married	19 (52.8)	2 (50.0)	17 (53.1)
De facto	1 (2.8)	0 (0.0)	1 (3.1)
Divorced	2 (5.6)	0 (0.0)	2 (6.3)
Widowed	4 (11.1)	1 (25.0)	3 (9.4)
Living status:			
Alone	8 (22.2)	0 (0.0)	8 (25.0))
Spouse/carer	27 (75.0)	4 (100)	23 (71.8)
other	1 (2.8)	0 (0.0)	1 (3.1)
Education level:			
No schooling	3 (8.3)	2 (50.0)	1 (3.1)
Primary/high school	6 (16.7)	0 (0.0)	6 (18.8)
Trade	8 (22.2)	0 (0.0)	8 (25.0)
Certificate	14 (38.9)	2 (50.0)	12 (37.5)
Degree	5 (13.9)	0 (0.0)	5 (15.6)
Country of birth:			
Australia	25 (69.4)	4 (100)	21 (65.6)
United Kingdom	8 (22.2)	0 (0.0)	8 (25.0)
Germany	1 (2.8)	0 (0.0)	1 (3.1)
Ukraine	1 (2.8)	0 (0.0)	1 (3.1)
Holland	1 (2.8)	0 (0.0)	1 (3.1)
Occupation:			
Retired	23 (63.9)	4 (100)	19 (59.4)
Employed	7 (19.4)	0 (0.0)	7 (21.9)
Unemployed	6 (16.7)	0 (0.0)	6 (18.3)

Note: S-TOFHLA (short test of functional health literacy); marginal/inadequate (0–22), adequate (23–36); SD (standard deviation).

The 32 participants who had adequate health literacy had a mean age of 65.5 ± (10.6), 26 were men (81.3%) and 30 spoke English (93.8%). Regarding participants marital status, 17 were married (53.1%) and 23 lived with a spouse or carer (71.8%). Those participants that had achieved a certificate level education were 12 (37.5%). Over half of the participants were born in Australia (21, 65.1%), eight were born in the UK (25%) and 19 were retired (59.4%).

4.3 Participants' Clinical Characteristics

The clinical characteristics and health literacy levels of participants is reflected in Table 4.2. Of the 36 participants', 12 had HFrEF (33.3%) and 13 HFpEF (36.1%). Just under half the participants had been diagnosed with HF longer than five years (17 participants, or 47.2%). HF aetiology was primarily attributed to dilated cardiomyopathy (15 participants, or 41.7%) and idiopathic cardiomyopathy (10 participants, or 27.8%).

Of the four New York Heart Association classifications (NYHA), there was a closely distributed number of participants in Class I and Class II, with 18 participants with Class I (50%) and 15 with Class II (41.7%). The American College of Cardiology and the American Heart Association stages of HF (OSC) findings were identical to the NYHA classifications. Participants with a Charlson comorbidity index ≤ 2 numbered 20 (55.6%) of the total group. Participants with a family history of heart disease were relatively even; there were 19 (52.8%) with a history, and 17 (47.2%) without.

Smoking status was distributed among non-smokers 16 (44.4%) and ex-smokers 14 (41.7%). Just under half of participants were occasional or rare drinkers (15, 41.7%). Most participants were either overweight or obese; 16 participants were overweight and 13 obese, constituting 44.4% and 36.1% respectively.

Table 4.2

Clinical Characteristics and Short Test of Functional Health Literacy Scores

Characteristics	All n = 36 / n (%)	Inadequate/Marginal n = 4 / n (%)	Adequate n = 32 / n (%)
Type of HF:			
HFrEF(LVEF < 40%)	12 (33.3)	0 (0.0)	12 (37.5)
HFmEF (LVEF 40–49%)	11 (30.6)	3 (75.0)	8 (25.0)
HFpEF (LVEF ≥ 50%)	13 (36.1)	1 (25.0)	12 (37.5)
HF (number of years):			
< 1 years	10 (27.8)	0 (0.0)	10 (31.3)
1–5 years	9 (25.0)	1 (25.0)	8 (25.0)
> 5 years	17 (47.2)	3 (75.0)	14 (43.8)
Aetiology of HF:			
Dilated cardiomyopathy	15 (41.7)	1 (25.0)	14 (43.8)
Idiopathic cardiomyopathy	10 (27.8)	2 (50.0)	8 (25.0)
Viral cardiomyopathy	1 (2.8)	0 (0.0)	1 (3.1)
Ischaemic cardiomyopathy	5 (13.9)	0 (0.0)	5 (15.6)
Tachymyopathy	2 (5.6)	0 (0.0)	2 (6.25)
Hypertension	2 (5.6)	1 (25.0)	1 (3.1)
Myocardial infarction	1 (2.8)	0 (0.0)	1 (3.1)
NYHA classification:			
I	18 (50.0)	1 (25.0)	17 (53.1)
II	15 (41.7)	3 (75.0)	12 (37.5)
III	3 (8.3)	0 (0.0)	3 (9.4)
IV	0 (0.0)	0 (0.0)	0 (0.0)
OSC classification:			
Class A	18 (50.0)	1 (25.0)	17 (53.1)
Class B	15 (41.7)	3 (75.0)	12 (37.5)
Class C	3 (8.3)	0 (0.0)	3 (9.4)
Class D	0 (0.0)	0 (0.0)	0 (0.0)
Charlson comorbidity index:			
≤ 2	20 (55.6)	0 (0.0)	20 (62.5)
3–4	14 (38.9)	3 (75.0)	11 (34.4)
≥ 5	2 (5.5)	1 (25.0)	1 (3.1)
Family history of heart disease:			
Yes	19 (52.8)	0 (0.0)	19 (59.4)
No	17 (47.2)	4 (100)	13 (40.6)
Smoking status:			
Non-smoker	16 (44.4)	2 (50.0)	14 (43.8)
Current Smoker	5 (13.9)	0 (0.0)	5 (15.6)
Ex-smoker	15 (41.7)	2 (50.0)	13 (40.6)
Alcohol consumption:			
Non-drinker	9 (25.0)	1 (25.0)	8 (25.0)
Occasional/rare drinker	15 (41.7)	1 (25.0)	14 (43.8)
Regular drinker	9 (25.0)	0 (0.0)	9 (28.1)
Ex-drinker	3 (8.3)	2 (50.0)	1 (3.1)
BMI (kg/m²):			
18.5–24.9 (healthy)	7 (19.4)	0 (0.0)	7 (21.9)
25–29.9 (overweight)	16 (44.4)	1 (25.0)	15 (46.9)
≥ 30 (obese)	13 (36.1)	3 (75.0)	10 (31.3)

Note: S-TOFHLA (short test of functional health literacy); marginal/inadequate (0–22), adequate (23–36); HFrEF (HF with reduced ejection fraction); HFmEF (HF with moderate ejection fraction); HFpEF (HF with preserved ejection fraction); HF, HF, NYHA classification, New York Heart Association, OSC classification, the American College of Cardiology and the American Heart Association stages of HF.

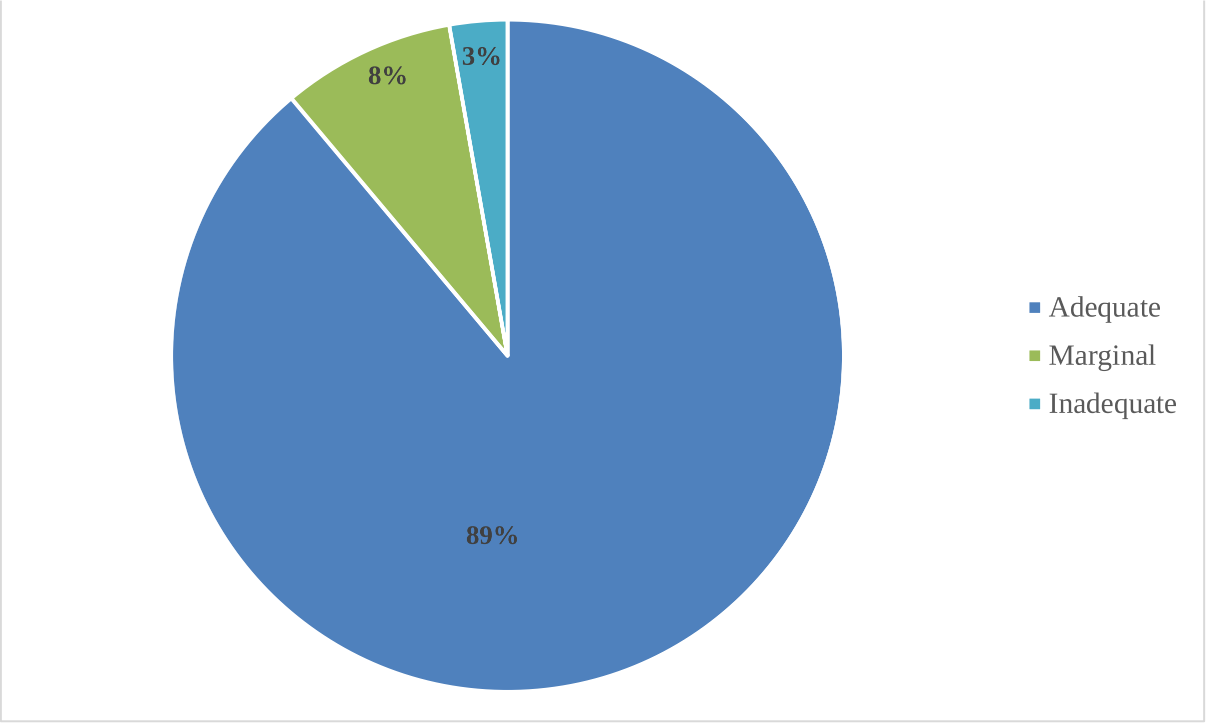
Of the four participants with inadequate/marginal health literacy, three had been diagnosed with HF ≥ 5 years (75%) with one having dilated cardiomyopathy (25%) and three having idiopathic cardiomyopathies (75%). Of the four New York Heart Association classifications (NYHA) one participant was Class I (5%) and three were Class II (75%). The American College of Cardiology and the American Heart Association stages of HF (OSC) findings were identical to the NYHA classifications. Three participants had a Charlson comorbidity index score of 3-4 (75%) and one had a score ≥5 (25%). There were no participants with a history of heart disease (100%). Smoking status was evenly distributed among the inadequate/marginal health literacy group; there were two non-smokers (50%) and two former smokers (50%) with two participants (50%) former drinkers. Most participants were either overweight or obese; one was overweight (25%) and three were obese (75%).

Of the 32 participants in the adequate health literacy group their type of HF was evenly distributed; HFrEF (12, 37.5%), HFmEF (8, 25%) and HFpEF (12, 37.5%). Those diagnosed with HF ≥ five years were 14 (43.8%), while HF aetiology was primarily attributed to dilated cardiomyopathy (14 participants, or 43.8%) and idiopathic cardiomyopathy (8 participants, or 25%). Of the four New York Heart Association classifications (NYHA), the distributions were —17 had Class I (53.1%) and 12 had Class II (37.5%). The American College of Cardiology and the American Heart Association stages of HF (OSC) findings were identical to the NYHA classifications.

Participants with a Charlson comorbidity index score of ≤2 were (20, 62.5%) and 3–4 (11, 34.4%). Regarding family history of heart disease 19 had a family history (59.4%), and 13 had no family history (40.6%). Smoking status was evenly distributed in the adequate group, which comprised 14 non-smokers (43.8%) and 13 ex-smokers (40.6%). Of these participants alcohol consumption was occasional or rare 14 (43.8%). Most participants were either overweight or obese; this was reflected by 15 participants being overweight (46.9%) and 10 obese (31.3%).

4.4 Participants' Health Literacy, HF Knowledge and Self-care

The S-TOFHLA measured participants' health literacy levels by categorising them as adequate, marginal or inadequate. As previously discussed, marginal and inadequate are reported as one dichotomous variable in Tables 1–3. However, Figure 4.1 shows a detailed breakdown of the health literacy of the 36 participants; 89% had adequate health literacy, 8% had marginal literacy and 3% had inadequate literacy.



Note: S-TOFHLA (short test of functional health literacy); inadequate (0–16), marginal (17–22), adequate (23–36).

Figure 4.1 Short test of functional health literacy results of study participants.

Table 4.3 outlines the mean and median sores and compares the DHFKS and SCHFI scores with participants' S-TOFHLA scores. The mean DHFKS score for the inadequate and marginal group was 10.3 ± (1.7) and the adequate group was 12.0 ± (2.5). The median score was similar in the inadequate and marginal group at 10.5, as it was with the adequate group at 13.0.

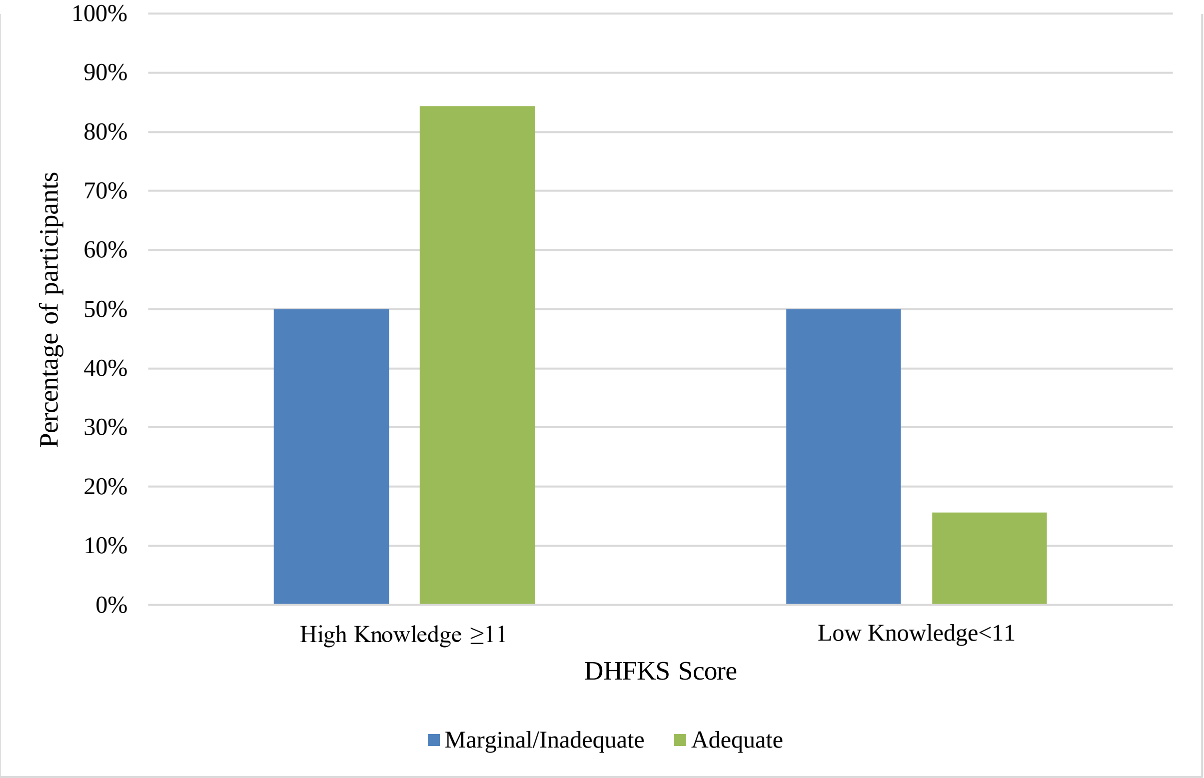
Table 4.3

Comparison Between Dutch HF Knowledge Scores, Self-Care HF Index Scores and Short Test of Functional health Literacy Scores

		Inadequate/Marginal n = 4 / n (%)	Adequate n = 32 / n (%)
HF knowledge (DHFKS):			
Mean score (SD)		10.3 ± (1.7)	12.0 ± (2.5)
Median score (SE)		10.5 (0.9)	13.0 (0.4)
High knowledge ≥ 11		2 (50.0)	27 (84.4)
Low knowledge < 11		2 (50.0)	5 (15.6)
Self-care (SCHFI)			
Self-care maintenance			
	Inadequate < 70%	0 (0.0)	6 (18.8)
	Adequate ≥70%	4 (100)	26 (81.3)
Self-care management			
	Inadequate < 70%	4 (100)	21 (67.7)
	Adequate ≥70%	0 (0.0)	10 (32.3)
Self-care confidence			
	Inadequate < 70%	0 (0.0)	6 (18.8)
	Adequate ≥70%	4 (100)	26 (81.3)

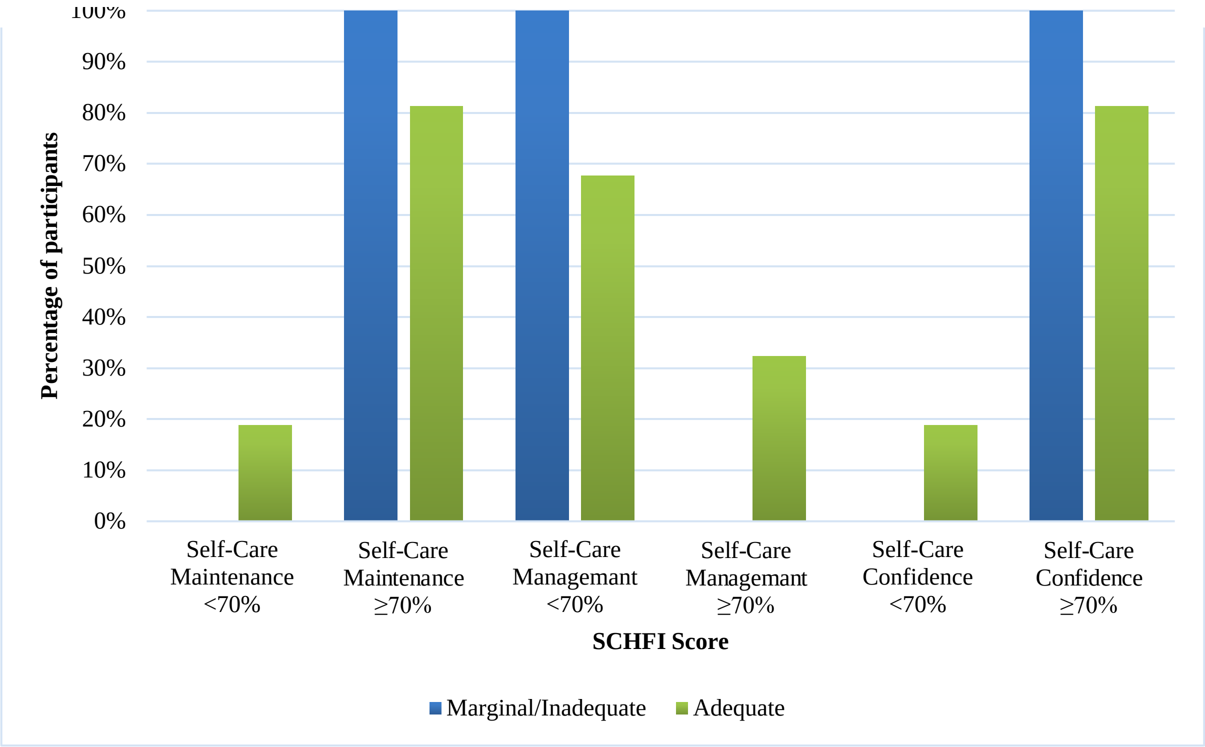
Note: S-TOFHLA (short test of functional health literacy); marginal/inadequate (0–22), adequate (23–36); DHFKS (Dutch HF knowledge scale); SD (standard deviation); DHFKS cut-off scores: high knowledge ≥ 11, low knowledge 11; SCHFI (self-care of HF index); SCHFI cut-off scores: inadequate < 70%, adequate ≥ 70%.

Table 4.3 and Figure 4.2 show the number of participants with marginal or low health literacy who scored ≥ 11 and ≤ 11 in the DHFKS (two participants, or 50% respectively). There were 27 participants with adequate health literacy who scored ≥ 11 (84.4%), while there were five who scored ≤ 11 (15.6%). Therefore, 29 participants (80.6%), regardless of health literacy level, scored ≥ 11. Regarding self-care, as shown in Table 4.3. and Figure 4.3, as measured by the SCHFI, six participants (18.8%) with adequate health literacy had inadequate self-care maintenance. Four (100%) of those with marginal and inadequate health literacy had inadequate self-care maintenance. In the adequate self-care maintenance group, 26 participants (81.3 %) had adequate health literacy. Four (100%) of participants with marginal or inadequate health literacy, and 21 (67.7%) of those with adequate health literacy, had inadequate self-care management. Only 10 (32.3%) of the adequate health literacy group had adequate self-management. Self-care confidence reflected the same outcomes as self-care maintenance in both groups.



Note: S-TOFHLA (short test of functional health literacy); DHFKS (Dutch HF knowledge scale).

Figure 4.2 Participants' Dutch HF knowledge scores compared to short test of functional health literacy scores.



Note: S-TOFHLA (short test of functional health literacy); SCHFI (self-care of HF index).

Figure 4.3 Participants' self-care HF index scores compared to short test of functional health literacy scores.

4.5 Associations Between Health Literacy, Literacy, HF Knowledge and Self-care

Spearman's correlation was used to explore the strength of association between the health literacy levels of participants and their disease-specific knowledge and self-care, as shown in Table 4.4 and Figures 4.4–4.7. Correlations were analysed based on the value of the correlation coefficient ranging from – 1.0 to + 1.0, to reflect a neutral, positive or negative correlation between health literacy, HF knowledge and self-care (Cohen, 1988).

Table 4.4

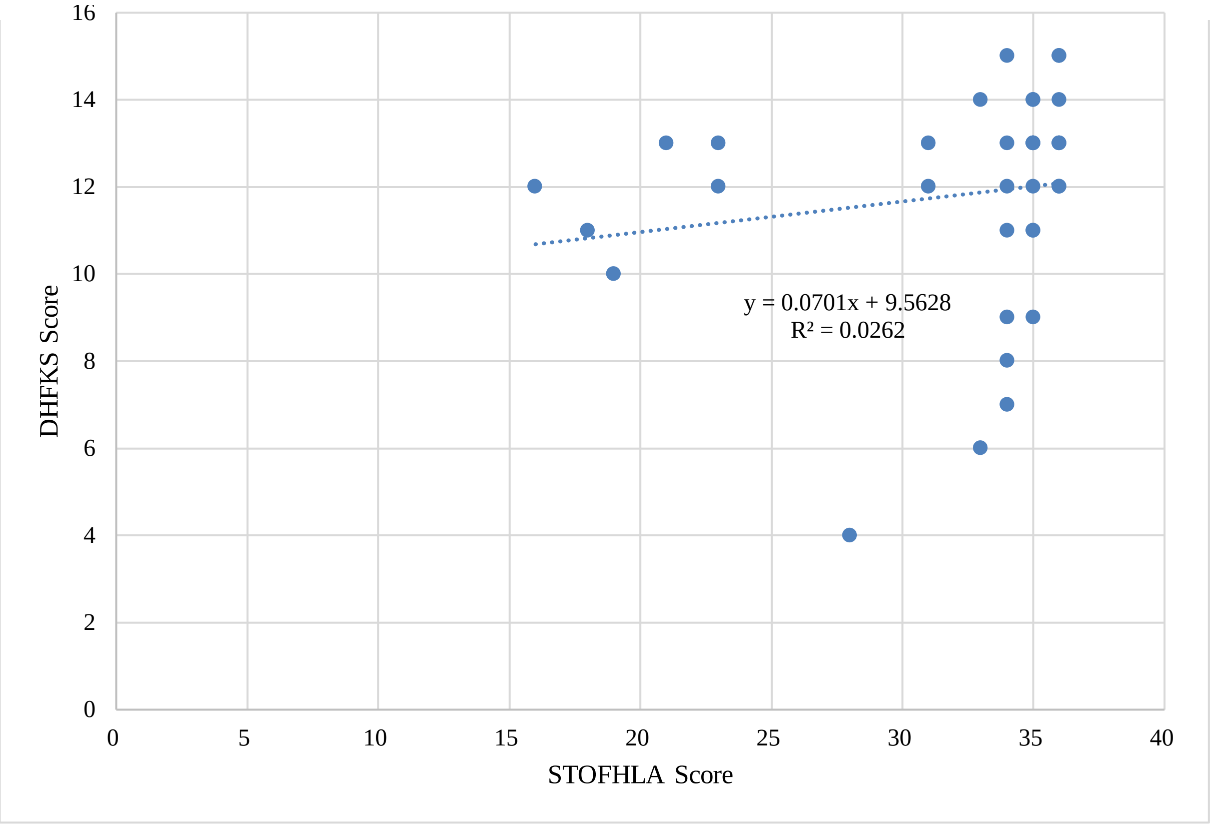
Correlation Between Health Literacy Levels, Literacy Levels, HF Knowledge and Self-care

	HF Knowledge		Self-Care Maintenance		Self-Care Management		Self-Care Confidence	
		p-value		p-value		p-value		p-value
S-TOFHLA	0.404	0.014*	0.125	0.468	0.252	0.138	0.192	0.263
REALM-SF	0.018	0.918	–0.363	0.029*	0.281	0.027*	–0.353	0.035*

Note: S-TOFHLA (short test of functional health literacy); REALM-SF (rapid estimate of adult literacy in medicine short form); Spearman's: *p <0.05 statistically significant.

Table 4.4 outlines the associations between health literacy, literacy, HF knowledge and self-care. There was a medium positive correlation between the S-TOFHLA score and HF knowledge (*r* = 0.404; *p* = 0.014, 95% CI, 0.088, 0.646), suggesting statistical significance This was a stronger association than the REALM-SF score and HF knowledge results, which had a small positive correlation (*r* = 0.018; *p* = 0.918; 95% CI, –0.312, 0.344).

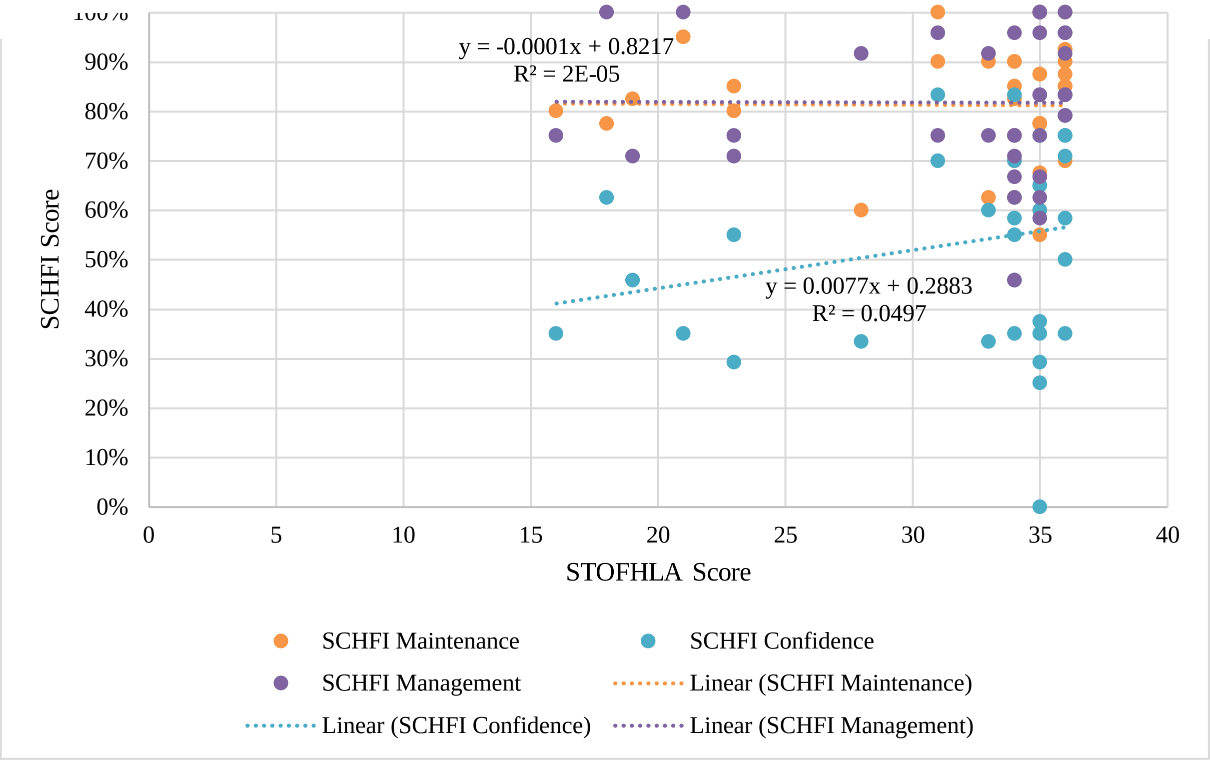
The S-TOFHLA score and self-care maintenance had a small positive correlation (*r* = 0.125) with no statistical significance (*p* = 0.468; 95% CI, –0.212, 0.435). The REALM-SF and self-care maintenance had a medium negative correlation of the (*r* = –0.363; *p* = 0.029; 95% CI, –0.617, –0.04). There was a small positive correlation of no statistical significance between the S-TOFHLA and self-care management (*r* = 0.252; *p* = 0.138; 95% CI, 0.083, 0.536). This small positive correlation was repeated with the REALM-SF and self-care management (*r* = 0.281; *p* = 0.027; 95% CI, –0.052, 0.558). There was a small positive correlation between the S-TOFHLA and self-care confidence (*r* = 0.192; *p* = 0.263; 95% CI –0.145, 0.489) with no statistical significance. There was a medium negative correlation with the REALM-SF and self-care confidence (*r* = –0.353; *p* = 0.035; 95% CI, –0.61, –0.028).



Note: S-TOFHLA (short test of functional health literacy); S-TOFHLA cut-off scores: marginal/inadequate (0–22), adequate (23–36); DHFKS (Dutch HF knowledge scale); DHFKS cut-off scores: high knowledge ≥ 11, low knowledge < 11.

Figure 4.4 Correlation between health literacy and HF knowledge.

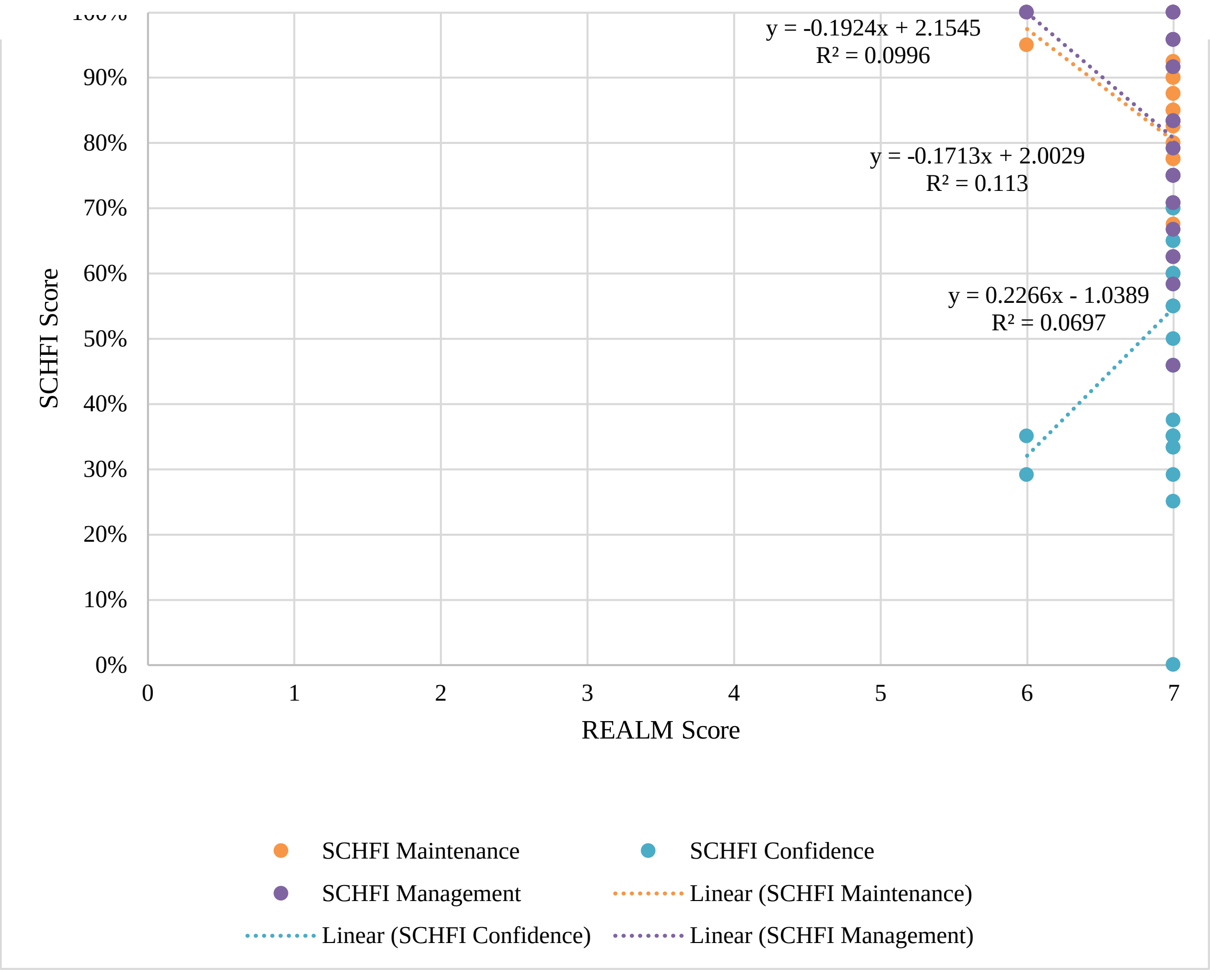
Health literacy, literacy and HF knowledge and self-care and their relationship have already been outlined in Table 4.4; however, Figures 4.4–4.6 provide a visual presentation of these associations. Figure 4.4 shows a positive relationship between health literacy and HF knowledge indicating a link between higher health literacy levels and HF knowledge.



Note: S-TOFHLA (short test of functional health literacy); S-TOFHLA cut-off scores: marginal/inadequate (0–22), adequate (23–36); SCHFI (self-care of HF index); SCHFI cut-off scores: inadequate < 70%, adequate ≥ 70%.

Figure 4.5 Correlation between health literacy and self-care.

Figure 4.5 also shows a positive relationship between adequate health literacy and self-care maintenance and management, indicating the higher the health literacy level the better the self-care maintenance and management. There is however no relationship with self-care confidence.



Note: REALM (rapid estimate of adult literacy in medicine short form); REALM-SF cut-off scores: 0– (Grade 3), 1–3 (Grade 4–6), 4–6 (Grade 7–8), 7 (Grade 9); SCHFI (self-care of HF index); SCHFI cut-off scores: inadequate < 70%, adequate ≥ 70%.

Figure 4.6 Correlation between literacy and self-care.

Finally, Figure 4.6 reflects a similar relationship between literacy levels and self-care maintenance and management, but no relationship with self-care confidence.

4.6 Conclusion

Chapter 4 has outlined the findings from the data collected from HF clinics in SA. The data outcomes outlined established the sociodemographic and clinical characteristics of the participants and their concurrent health literacy scores based on the short test of functional health literacy. This chapter further explored the impact of health literacy on HF patients' HF knowledge and self-care by describing their health literacy scores and comparing them with their HF knowledge (as measured by the DHFKS) and their self-care using the SCHFI. Finally, health literacy scores and literacy scores were correlated with the DHFKS and SCHFI to demonstrate any associations. These findings will be discussed in Chapter 5.

Chapter 5: Discussion

5.1 Introduction

Chapter 5 will discuss the findings from the previous analysis of the data. This chapter commences by restating the aims and objectives of the study and summarising the key outcomes. This will be followed by a discussion on the demographic and clinical characteristics and health literacy levels of participants. Following this, health literacy scores will be compared with HF knowledge and self-care. The discussion will continue, identifying any associations between health literacy, literacy and HF knowledge and self-care. The discussion will refer to the literature reviewed in Chapter 2 and other literature to address the relevance of this study's findings. Therefore, the discussion will reiterate the pertinent findings, interpretations and implications for clinical practice and future research. Finally, it will conclude by acknowledging the strengths and limitations of the study and offer recommendations for future research.

5.2 Aims of the Study

The aim of this study was to assess the health literacy of HF patients while determining any association between health literacy, literacy, HF knowledge and self-care. This was achieved by describing the sociodemographic, clinical characteristics and health literacy characteristics of participants. It also correlated the health literacy levels, literacy levels, HF knowledge and self-care to determine any associations.

5.3 Health Literacy Levels

The health literacy of participants in this study was higher than reported in the literature, with a concurrent positive impact on HF knowledge, self-care maintenance and self-care confidence but not self-care management. Health literacy was correlated with HF knowledge, those with inadequate/marginal health literacy had lower levels of HF knowledge. Whereas those with adequate health literacy had higher levels of HF knowledge. There was no correlation with health literacy and the three self-care domains. There was no correlation between literacy and HF knowledge; however, there was a correlation with the three self-care domains.

Those participants with adequate health literacy in this study were represented by the majority. This was supported in the literature reviewed in Chapter 2. Studies that measured health literacy using the S-TOFHLA included Hwang et al. (2016), who reported a mean health literacy score of 25.5, Chen et al. (2013), who reported 68.3% with adequate health literacy and Dracup et al. (2014) with 61.3% having adequate health literacy. Fabbri et al. (2018) and Peterson et al. (2011) found that 10.5% and 17.5% (respectively) of their participants had low health literacy. Levin et al. (2014) and Wu et al. (2016) also reported a smaller percentage of participants with low health literacy using the Newest Vital Sign and the REALM. This differed from Son et al. (2018), who confirmed a prevalence of low health literacy (54.8%) using a three-item set of brief screening questions.

The literature reviewed in chapter two also highlights that greater than 80% of participants had completed high school or achieved a tertiary qualification, positively influencing their health literacy levels (Hwang et al., 2016; Chen et al., 2013; Dracup., 2014; Fabbri et al., 2018; Peterson et al., 2011; Levin et al., 2014; Wu et al., 2016). Son et al. (2018) however found that 62% of participants in their study had not completed high school. The link between years of education and health literacy is supported by this study and the literature reviewed, therefore an important consideration when providing HF patients with information and interventions to improve their knowledge and self-care.

5.4 Demographic and Health Literacy Characteristics

5.4.1 Age

The results from the study reflected an average age of HF affliction that is consistent with current Australian statistics. The Australian Institute of Health and Welfare (2019) reported that two-thirds of adults with HF are aged 65 years and over. Similarly, a study from Canberra (Australia) reported a mean age of 69.4 years (Abhayaratna et al., 2006). This finding is consistent with the literature, where Peterson et al. (2011), described that 17.5% of participants who had low health literacy were older. In Wu et al. (2016), 47 % of those who were older had low health literacy

The findings suggest a difference in the mean age of those with inadequate/marginal health literacy who are older, compared to those with adequate health literacy who are younger. This can be attributed to age-related cognitive decline and frailty; as such, the findings emphasise the need for both research and clinical practice to address and include those with cognitive impairment.

5.4.2 Gender

It was difficult to assess any difference between male and female health literacy, as the participants in this study comprised 80.6% males, with an even distribution among the health literacy levels. This was significantly higher than the 65% of men represented in the literature.

5.4.3 Marital/living status

There were similar outcomes for both the inadequate/marginal and adequate health literacy groups in terms of marital status. Those who were married or lived with a spouse or carer comprised the larger portion of those with adequate health literacy. However, within their groups, results were statistically similar. This confirms what is already known in the literature—HF patients who are either married or in a patient–carer dyad manage their HF more effectively than those who are not (Cameron et al., 2015; Levin et al., 2014; Srisuk et al., 2016). Together with the findings from this study, the importance of engaging family and/or carer in HF management is apparent.

5.4.4 Education level

The education levels of the participants in this study and their health literacy group was consistent with the literature. Of note, the small number of participants with adequate health literacy had no schooling, compared to half of the inadequate/marginal group who had no schooling. Fabbri et al. (2018) reported a similar outcome with 30.3% of those who had not gradated high school had low health literacy, compared to 9.6% with adequate health literacy. Son et al. (2018) reported a lower mean health literacy score for those who completed below primary school (7.24) as opposed to those who completed high school who had a higher mean health literacy score (10.29). These findings reinforce what is already known—HF education must encompass those with educational deficits and a probable inadequate health literacy level.

5.5 Clinical and Health Literacy Characteristics

5.5.1 HF type

The clinical characteristics and health literacy levels of participants who have HFmEF and HFpEF were very similar. There were no participants with HFrEF in the inadequate/marginal health literacy group. This is consistent with Peterson et al.'s (2011) sample, in which there was a 0.7% variation between the types of HF and health literacy levels. Bose et al. (2016), Cene et al. (2018) and Fabrri et al. (2018) did not measure health literacy against HF types. However, they reported the percentage of these subsets—HFpEF (13.6% and 16.2% respectively) and HFmEF (26.4% and 32% respectively). Son et al. (2018) found that participants with HFpEF were the group in their study that recorded the lowest health literacy scores. Although not included in the review, Cheng et al. (2014) confirmed the predominance of HFpEF in their large study, of which 47% of participants were categorised as. Both this study and the literature reviewed have little to report regarding these two groups of HF patients. However, the relationship between HF type and heath literacy could be further investigated.

5.5.2 Years with HF

Almost half of the participants had been diagnosed with HF over five years prior to the study. Those with inadequate/marginal health literacy had been diagnosed with HF at least one year before the study. This pattern was also evident in the adequate group. Son et al. (2018) reported that almost 50 % of their participants were diagnosed with HF one to two years prior to the study. However, across all health literacy levels and years duration, no differences were discovered. These findings are also reflected in Boyde et al. (2012), in which their participants years since diagnosis were distributed evenly from under one year, to over five years and health literacy levels equally reflected in both adequate and inadequate/marginal. Although the findings from his study and the literature reviewed are not conclusive, they are important to consider. Is there a mediation between years with HF and health literacy and its effect on HF knowledge and self-care? Does the length of time from diagnosis improve HF patient's engagement with their self-care or does increasing frailty, frequently associated with HF, comprise this?

5.5.3 HF classification (NYHA/OSC)

Both the NYHA and OSC classifications were the same for all participants and their health literacy groupings. Class I and II and A and B were the most common groupings. Hwang et al. (2014) also had 65% of participants with either Class I or II; 66% had low HF knowledge and good self-care, and 71% had high knowledge and good self-care. Cene et al. (2013) provided a comparative population of 74% with Class I and II. Despite the lack of any link in this study between HF classification and health literacy, it is interesting to note that in Son et al. (2018), participants with a Class I HF classification had a mean health literacy score of 9.9 while those with Class II and III had mean health literacy scores of 7.29 and 7.88. This score is based on a three-item set of brief screening questions, with 11–12 being adequate health literacy, 7–10 marginal and ≤ 6 inadequate.

This may indicate that a younger age and educational status have a positive effect on health literacy. It also highlights the mediation between age and cognitive function and worsening HF classification and health literacy level.

5.5.4 Charlson comorbidity index

The participants in this study with inadequate/marginal health literacy had higher Charlson comorbidity index scores than the adequate group, whose index scores were lower. Fabbri et al. (2018) reported that 52.1% of their total sample scored ≥ 3 on the Charlson comorbidity index (50.8% in the adequate health literacy group and 63.2% in the inadequate/marginal health literacy group). Multimorbidity is commonly found in HF patients, and is often precipitated by the aetiology of the HF itself. It presents due to the older age of HF patients and the complexities of managing HF (Wiley et al., 2018). In their study on multimorbidity and 30-day readmission risk in HF patients, Wiley et al. (2018) reported a mean Charlson comorbidity index score of 6.6.

Given the larger number of participants with inadequate/marginal health literacy and higher Charlson comorbidity index scores in this study (and the literature reviewed), a concerted focus on the mediation between multimorbidity and health literacy on HF patients is warranted. This is particularly true if innovation in both physiological and education interventions can improve patient outcomes.

5.5.5 Smoking status

Smoking status was similar across the inadequate/marginal and adequate health literacy groups for non-smokers or former smokers, with only a small number of current smokers included in the study. The literature only reported on current smoking status. However, this is valuable comparison data given their total percentage of smokers was larger than in this study. Therefore, it could possibly be interrelated to health literacy status and understanding and acting upon health-related information on smoking cessation (Cockayne et al., 2014; Dracup et al., 2014; Linn et al., 2016; Nesbitt et al., 2014; Zeng et al., 2016). These studies reported a sample current smoking population range of 11.6%–28.3% (Cockayne et al., 2014; Dracup et al., 2014; Linn et al., 2016; Nesbitt et al., 2014; Zeng et al 2016).

5.5.6 Alcohol consumption

The data for alcohol consumption was inconclusive for any interaction with health literacy, except for half the inadequate/marginal group being former drinkers.

5.5.7 Body mass index

This study's findings that participants were either overweight or obese (with the greater number being obese in the inadequate/marginal group and overweight in the adequate group) and is consistent with the literature reviewed. Of the three studies that measured participants' BMI (kg/m$_2$), two reported BMI (kg/m$_2$) > 25 in 74.6% of the sample. These were an RCT and a sub-study within the RCT. In the other study, a BMI (kg/m$_2$) of > 25 was reported for 45% of the sample. The other studies in the review did not measure BMI. Further to this study's findings and the reviewed literature, Campbell et al.'s (2019) cohort study of a community-based population found that those who were obese or overweight were at a greater risk of HFpEF. Participants in this study with both inadequate/marginal and health literacy had either HFmEF or HFpEF and a concurrent BMI (kg/m$_2$) of either 25–29.9 or ≥ 30.

Therefore, due to the association between BMI, HF and health literacy, this could be a clinical characteristic that is measured more routinely in research and clinical practice.

5.6 Health Literacy, HF Knowledge and Self-care

5.6.1 Health literacy and HF knowledge

The mean and median score for HF knowledge in the inadequate/marginal group indicated low HF knowledge, while the adequate group had high HF knowledge. However, half of those with inadequate/marginal health literacy had high HF knowledge. This study analysed and presented the data in such a way that HF knowledge and health literacy could be compared. The literature featured mixed results compared to this study. Hawkins et al. (2016) reported a mean DHFKS score of 11.54, while Tawalbeh et al. (2017) reported a score of 5.29. This may be partly attributable to the difference in education status across the two studies; 34% of Tawalbeh et al.'s (2017) sample was illiterate. Chen et al. (2013) also had an alternative HF knowledge score. Although they used the HF knowledge questionnaire, they reported a mean score of 8.1, based on a 0–15 scoring scale. This was against a background of a mean health literacy score of 27.4. Although this study reported a low HF knowledge mean score, it had an adequate health literacy score.

5.6.2 Health literacy and self-care

All participants with inadequate/marginal health literacy and most with adequate health literacy had adequate self-care maintenance and confidence. All inadequate/marginal health literacy group participants had inadequate self-care management and over half of the adequate health literacy group also had inadequate self-care management. This phenomenon is attributable to multiple and complex triggers. These triggers vary in studies on health literacy, cognitive function, social support and anxiety and depression. Self-care management is an elusive component of the triad of self-care for patients to achieve and researchers to understand. The data presented here are consistent with this ongoing dilemma, reflecting the multifaceted nature of self-care in HF patients (Cene et al., 2013; Chen et al., 2014; Hwang et al., 2014; Tung et al., 2013; Wu et al., 2017).

5.7 Health Literacy, Literacy and Association with HF Knowledge and Self-care

5.7.1 Health literacy and HF knowledge

Adequate health literacy and HF knowledge have been positively linked in this study. Chen et al. (2014) reported a positive correlation ($p < 0.001$) between health literacy and HF knowledge. Further, Hawkins et al. (2016) found health literacy directly affected HF knowledge. Dennison et al. (2011) and Macabasco-O’Connell et al. (2011) supported these outcomes, reporting a higher mean HF knowledge score in the adequate health literacy group compared to the inadequate or marginal literacy group ($p < 0.000$, CI 0.39–1.04). Hawkins et al. (2016) only excluded from those with a diagnosis of Alzheimer’s disease, stroke or severe head injury. Hence, 68% of the participants with impaired health literacy also had cognitive impairment.

It is well established that adequate health literacy has a positive impact on HF knowledge. This study supports this; however, the exclusion of those with poor cognitive function in some studies is potentially misleading. This study excluded those with a MoCA score under 26; thus, it cannot fully represent the true and total cohort of HF patients. Poor cognitive function is often an exclusion criterion in studies therefore, this is an important area for future research to explore in terms of the number of HF patients with cognitive impairment and the potential impact of this on their health literacy.

5.7.2 Health literacy and self-care

There was no relationship between health literacy and all three of the self-care domains. This was consistent with Chen et al. (2014), who found no positive correlation across all three domains. Conversely, Son et al. (2018) reported that health literacy was strongly associated with self-care ($p = 0.029$), which is also consistent with studies not included in Chapter 2 (Macabasco-O’Connell et al., 2011; Matsuoka et al., 2016). The issue with these positive results is that these studies did not use the SCHFI. Rather, they used an adapted Japanese version of the European HF self-care scale (EHFScBS), adapted telephone questionnaire and the EHFScBS. Therefore, comparing outcomes is problematic. Further clarifying this issue of consistency in instruments is an earlier study by Chen et al. (2011), which identified a strong association between health literacy and self-care maintenance, with no association to self-care management or confidence (using the SCHFI).

Therefore, consistency of instrument measure is essential to obtain comparable data to claim strength of association across studies aiming to measure health literacy and association to self-care.

5.7.3 Literacy and HF knowledge

In this study, literacy was not associated with HF knowledge. Wu et al. (2017) measured HF knowledge using the Atlanta HF knowledge test, which found those from the participants who had low literacy also had low HF knowledge ($p < 0.001$).

5.7.4 Literacy and self-care

Literacy was negatively associated with self-care maintenance, positively with self-care management and negatively with self-care confidence. This is interesting given it conflicts with the data presented in Table 4.3. To this effect, Wu et al. (2017) reported that those with low literacy also had poor medication adherence and higher sodium intake. This was the only study to compare literacy against self-care using the REALM-SF. However, this study highlights the need to explore the lack of correlation between literacy and self-care. Furthermore, it reinforces the need to consider patients' literacy levels when developing interventions to improve self-care.

5.8 Strengths

There were several strengths in this study. This study was part of a multi-centre PRCT that engaged cardiac nurses as researchers. Although the sample size was small the demographic and clinical characteristics suggest this sample is representative of the HF population. Investigators working on the study had *Good Clinical Practice* accreditation. The study used recognised, reliable and valid instruments to measure health literacy, literacy, HF knowledge and self-care.

5.9 Limitations

A few limitations should be considered when interpreting the study results. As a descriptive study causal relationship between health literacy and self-care cannot be established. Second, the statistical outcomes must be interpreted with caution due to the small sample size. Third, a possible selection bias may have resulted in the recruitment of participants who were more likely to be engaged with their care due to the HF nurse and cardiologist pre-screening for inclusion.

Only a small number of participants spoke ESL, and non-English speaking HF patients were excluded. Therefore, the sample is not representative of cultural diversity. The study was conducted at metropolitan HF clinics; thus, the findings may not be generalisable to regional or rural SA. Finally, the predominance of adequate health literacy among the participants in this study limits any exploration of outcomes in the inadequate/marginal health literacy group. Therefore, the results cannot be generalised in populations with low health literacy.

5.10 Implications for Future Research

This study was conducted within the PRCT Fluid Watchers study, which developed and tested an avatar application for improving knowledge and self-care in HF patients. This avatar education application does not assess patients' health literacy but could address the secondary component by providing comprehensive and ongoing discharge instructions. This application is applicable for all literacy levels due to the graphic and audio presentation of the information. This could be further tested in a larger population to establish its efficacy in contributing to HF patients' knowledge and self-care.

It is known that health literacy is a barrier to effective self-care and interventions targeting health literacy have the potential to support self-care. This present sub-study adds to the literature by providing a snapshot of the demographic and clinical characteristics of HF patients with both adequate and inadequate/marginal health literacy. Emphasising the importance of tailored interventions.

A further implication within research (highlighted in Chapter 2) concerns the consistency of instruments used to assess health literacy, HF knowledge and self-care. For comparative purposes and accuracy of results for both non-interventional and interventional studies, a standardised instrument that is both reliable and valid should be a criterion for reporting study outcomes.

This study highlighted the disparity between age and inadequate health literacy that was supported in the literature. HF patients are an increasingly ageing population and future studies should focus on this disparity, specifically to understand the contributing phenomena. These studies could include, rather than exclude, those with cognitive dysfunction.

In this study there is a link between BMI (kg/m_2) > 25, HF and inadequate/marginal health literacy. This prevalence of high BMI (kg/m_2) in the HF population is supported in the literature. Thus, it is worthy of a specific larger cross-sectional study to report on this in the context of SA.

Patient education and self-care are key to effective QOL and reduced hospital readmissions. Are we measuring the effectiveness of interactions with patients, particularly in the outpatient setting where patients are stable and well? To better understand this, an evaluative tool that measures the effectiveness of HF nurse practice in education and empowering patients to manage their condition would enable clinicians to reflect on their own practice and outcomes.

5.11 Implications for Clinical Practice

This study highlights the need to screen the older HF patient for health literacy levels in order to provide appropriate education. Furthermore, those HF patients who indicate lower educational levels may exhibit lower health literacy levels and as such consideration of this should include evaluating educational levels prior to management strategies being implemented. In addition to these, it is important for clinicians to recognise the need to assess HF patients' health literacy as part of their discharge information exchange and in the outpatient setting to provide optimal patient-centred care.

The development and use of a patient feedback tool of the current educational and interventional strategies (i.e., brochures and written information) would provide valuable information for clinicians and researchers when planning the above.

Finally, there is a need to address the complexities of synchronising the separation between health-literate HF patients with inadequate self-care management. Self-efficacy could be part of the nurse and patient exchange to better understand the psychosocial drivers of this anomaly.

5.12 Conclusion

Adequate and inadequate/marginal health literacy had no association with HF knowledge however, literacy was associated with all three self-care domains. It is well established that over half the Australian population has inadequate health literacy with a concurrent significant burden of HF. A descriptive study of the health literacy of a sample HF patient population in SA and its effect on and association with HF knowledge and self-care was assessed and reported on. Thus, the aims and objectives of this study have been met. The findings from this have shown a predominantly health-literate population. However, those with inadequate/marginal health literacy are older, and have lower educational levels with higher comorbidity scores and BMI.

The literature supports the outcomes in this study. However, accurate comparison between these studies and this study's findings was problematic given the variety of instruments used to assess health literacy, literacy, HF knowledge and self-care.

Health literacy and its association with the demographic and clinical characteristics, highlight the possible need to further investigate age and education specifically, and the role of these variables in HF patients' health literacy. Clinical characteristics such as multimorbidity and higher BMI (kg/m_2) are also worthy of focused research to establish their role in inadequate/marginal health literacy.

Health literacy had a positive association with HF knowledge and those with adequate health literacy had adequate self-care maintenance and confidence, but not self-care management, partly supporting the H_1. Further, literacy did not correlate to HF knowledge, but did have a negative association to self-care maintenance and self-care confidence and a positive association to self-care management.

Health literacy and its impact on HF patients warrants focused research and clinical innovation in many of the specific demographic, clinical and associative variables discussed in this thesis.

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Appendices

Appendix A: Literature Review

Study	Publication/ Country	Objective	Methods	Sampling Strategy	Sample Patient (M/F)	Mean Age	Description	Limitations
1	Bose et al. 2016 (Sweden)	Links between/mediating role of illness perception/poor coping mechanisms in HF patients with depression and anxiety	Cross- sectional study	Convenience	n = 103 71/32	71	Avoidant coping was significantly linked to anxiety and depression *(CI 0.52–1.04), (CI 0.13–0.60)*	Non-experimental Cross-sectional in design
2	Cameron, Rhodes, Ski & Thompson 2015 (Australia)	Examine carers' views on HF patient self-care	Qualitative approach	Purposive	n = 12 4/8	67	Qualitative approach allows carers to share their experiences of supporting someone living with HF Insight into how HF management can be strengthened through carers	Small sample size Single site
3	Cene et al. 2013 (US)	Association between patient perception of support/self-care	Cross-sectional survey	Convenience	n = 150 74/76	61	Perception of greater emotional/social/educational support significant in improving self-care management/maintenance *(p = 0.04)*	Cross-sectional design Single site
4	Chen et al. 2014 (US)	Test a model explaining relationships between health literacy/HF/knowledge/self-care	Cross-sectional, correlational	Convenience	n = 63 33/30	62.1	Health literacy and knowledge linked, health literacy not related to self-care (*p < 0.001), (< 0.05)*	Naturalistic setting Patient self-reporting Single site

5	Cockayne et al. 2014 (United Kingdom)	Compare effectiveness of cognitive behavioural self-management manual	RCT	Randomisation	n = 260 188/72	70.6	No statistical significance between groups and hospital admission *(CI – 0.54–1.49)* HADS depression score in self-management group ($p = 0.003$)	Patients received help in following the manual
6	Da Conceicao, Dos Santos, Dos Santos & Da Cruz 2015 (Brazil)	Describe self-care	Descriptive cross-sectional observational	Non-probabilistic	n = 116 63/53	57.7	↓LVEF ($p = 0.001$), length of time from diagnosis ($p = 0.05$), nurse/ physician follow-up ($p = 0.007$) all scored high on the self-care HF index Overall self-care was inadequate	52% of sample cognitive impairment
7	Dracup et al. 2014 (US)	Quantify the impact of an educational intervention on HF rehospitalisation and death	RCT	Randomisation	n = 602 353/249	66	Over a 2-year follow-up period, no difference in the 3 groups' clinical outcomes ($p = 0.06$)	Rural sample Poor delineation between cardiovascular mortality and other
8	Fabbri et al. 2017 (US)	The impact of health literacy on hospitalisations and death	Prospective survey	Convenience	n = 2647 1333/1314	73.5	Inadequate health literacy linked with hospitalisations *(95% CI, 1.17–1.86,* $p = 0.001$*).* Cohort representative of general population in Minnesota	White, higher than average education sample
9	Gonzalez et al. 2014 (Spain)	Assessment of educational levels at baseline and changes one year later following intervention	Prospective educational intervention study	Convenience	n = 335 245/90	67	Independent of educational levels, all 3 improved in self-care 1-year post intervention ($p < 0.001$)	Nurses assisted with completion of questionnaire
10	Hawkins et al. 2016 (US)	Determine relationship between cognitive function and	Prospective observational cohort study	Convenience	n = 330 200/130	68.45	Health literacy ($p = < 0.001$) and cognition ($p = <0.001$) were associated with the DHFKS score Link between cognitive function and HF knowledge	Directional relationships not established over time in HF population

		health literacy in HF knowledge						
11	Hwang, Moser & Dracup 2014 (US)	Identify barriers to/factors promoting, self-care among HF patients with or ↓level of HF knowledge	Cross-sectional design Secondary analysis of primary data	Purposive	n = 612 359/253	65.9 ± 12.9	HF knowledge linked to *(p = < 0.001)* □ lower depressive symptoms *(p = < 0.001). Perceived control* *(p = <0.002) predicted better self-care*	Causation not established due to study design Variables limited to data collected from primary study
12	Levin, Peterson, Dolansky & Boxer 2014 (US)	Assess health literacy and the relationship with HF self-care in HF pt/caregiver dyads	Prospective observational survey	Convenience	n = 34 07/10	80 ± 5 Patient (80.2 ±5.1) Carer (66. 9± 10. 46)	Caregivers had higher health literacy in response to health literacy questions and label reading *(p = 0.001), (p = 0.001)*	Small sample size
13	Linn, Azzolin & Nogueira de Souza 2016 (Brazil)	Assess association between self-care and number of readmissions of HF patients and test applicability of 2 self-care assessment tools	Retrospective longitudinal study	Convenience	n = 82 47/35	61.85 ± 12. 33	Patients with a low self-care score had more readmissions	Scores from EHFScBS showed weak–moderate due to inpatient status
14	McNaughton et al. 2015 (US)	Test hypotheses that patients hospitalised for AHF have an increased risk of mortality and rehospitalisation	Retrospective cohort study	Convenience/ purposive	n = 1,379 813/566	63.1	Death in 38.3% < 9 BHLS. Death in 26.5%>9 BHLS No strong link with rehospitalisation	Adjusted age/race/sex/level of education/comorbidity confounders: HD, depression, frailty

15	Nesbitt et al. 2014 (US)	Measurement of baseline factors and their association with baseline QOL measurements in rural HF patients	Secondary analysis of RCT	Purposive	n = 612 58.7%/41.3%		Older age QOL. Younger ↓ QOL. Male ↓ QOL. No association between education and HRQoL Association between HF knowledge and HRQoL both -/+	Only targeted rural populations Patient fatigue due to number of tests
16	Peterson et al. 2011 (US)	Evaluate association between HL and all-cause mortality and hospitalisations of HF outpatients	Retrospective cohort study	Purposive	n = 1,494 699/795	74.9 ± 10.7	17.5% sample had low HL, were older, ↓ socio-economic and < high school education. Low HL associated with mortality ($p = 0.001$)	Did not use a more detailed health literacy assessment tool. Specific population group, limiting generalisations
17	Son, Shim, Seo & Seo 2018 (South Korea)	Identify impact of HL and frailty on self-care in patients with HF	Cross-sectional	Convenience/purposive	n = 281 171/110	68.7 ± 11.1	HL younger age ($p = < 0.001$). HL men ($p = < 0.001$). HL higher level education ($p = < 0.001$) HL +ve correlation to self-care ($p = <0.001$) Education levels predict self-care	Longitudinal associations could not be established Single site
18	Srisuk, Cameron, Ski & Thompson 2016 (Thailand)	Evaluate HF education program developed for patients and carers	RCT	Consecutive, randomisation	n = 100 47/53	62	Carers from intervention group perceived improved control of managing patients' HF symptoms over time ($p = < 0.001$) After 3 months, CAS-R score was higher than control group ($p = 0.018$)	Use of the DHFKS not been validated for carers
19	Tawalbeh et al. 2017 (Jordan)	Describe associations between knowledge, sociodemographic and self-care	Cross-sectional descriptive-correlational design	Convenience	n = 226 140/86	56.92	Significant predictors of maintenance, management self-care confidence ($p = < 0.001$), ($p = < 0.001$), ($p = < 0.001$)	Cross-sectional design

20	Tung et al. 2013 (Taiwan)	Test the effectiveness of a self-management intervention, examine the relationship between self-care/QOL	Quasi-experimental design	Convenience	n = 82 61/21	61.5	+ve changes at baseline, 1 month, 2 months after intervention in self-maintenance, mental and social QOL $(p = < 0.001)$, $(p = < 0.001)$, $(p = 0.001)$	Self-management score remained below 70
21	Wu et al. 2016 (US)	Test association between age/health outcomes and severity of HF, evidenced based medicine use and HL in patients with HF	Sub-study within RCT	Purposive	n = 575 341/234	66 ± 13	36% sample had inadequate HL and more likely to have cardiac event $(p = 0.006)$ 47% sample (older participants) had lower HL than younger (21%); median HL 25.6. Older age associated with frequent hospitalisation/cardiac mortality	Only measured reading ability, not numeracy
22	Wu et al. 2017 (US)	Relationship among family members and patients HL and HF knowledge and self-care	Secondary data analysis from RCT	Purposive	n = 113 pairs 72/41	56.1 ± 10.5	Low literacy associated with low HF knowledge $(p < 0.001)$, poor medication adherence ($p = 0.077$), higher Na intake $(p = 0.072)$. FM low literacy affects their own HF knowledge and patients' knowledge	Small sample size medication measure self-reported Only reading assessed, not numeracy
23	Zeng et al. 2016. (Singapore)	Measure HF knowledge on disease/self-care management and factors influencing knowledge level	Quantitative study, descriptive nature	Convenience	n = 187 147/40	> 50 years	Factors affecting HF knowledge were education level $(p = < 0.001)$; HF knowledge score 10.1 lower than expected for patients receiving inpatient HF education	Single site
24	Zou et al. 2016 (China)	Examines how socio-economic status/depressive	Secondary analysis Cross-sectional Study	Convenience	n = 321 165/156	63.6 ± 10.6	Lower health literacy associated with depressive symptoms, lower social	Possible confounding bias (HF symptoms)

	symptoms in HF patients affect access to health care, health literacy/social support	support linked to depressive symptoms *($p = < 0.001$), ($p = 0.007$)*

Appendix B: Montreal Cognitive Assessment

https://www.parkinsons.va.gov/resources/MOCA-Test-English.pdf
https://www.parkinsons.va.gov/resources/MoCA-Instructions-English.pdf

Appendix C: Short Test of Functional Health Literacy in Adults

https://flinders-my.sharepoint.com/:w:/g/personal/nesb0023_flinders_edu_au/EYclML9HyWxGugzE_1xIB7QBMNOnv72xWcVRVPYUf3-Jfw?e=4%3aBY777l&at=9

Appendix D: Dutch HF knowledge scale

https://flinders-my.sharepoint.com/:w:/g/personal/nesb0023_flinders_edu_au/ETDX-YqscmVHnRBMNr5YYOUBB4vaEmhue9XCVPuHtjlnig?e=4%3aQHQ7Oo&at=9

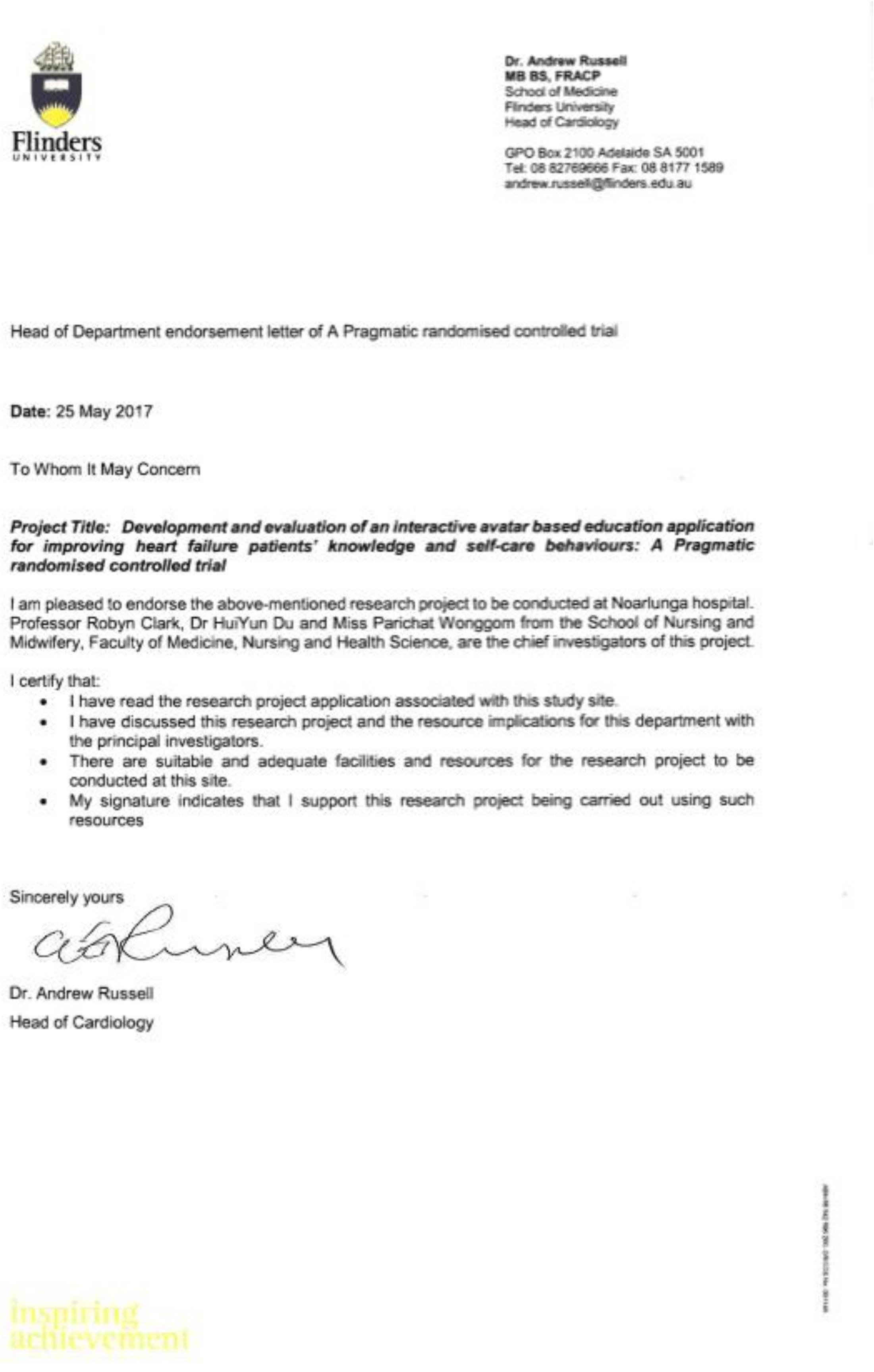
Appendix E: Self-Care of HF Index

https://flinders-my.sharepoint.com/:w:/g/personal/nesb0023_flinders_edu_au/EXhRImbXDyJNmQHQEl3JHPoBiKtFfypjBFnF4qJqhJy_Lw?e=4%3aUeH2AV&at=9

Appendix F: Rapid Estimate of Adult Literacy in Medicine Short Form

https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/quality-resources/tools/literacy/realm.pdf

Appendix G: Letter of Endorsement



Dr. Andrew Russell
MB BS, FRACP
School of Medicine
Flinders University
Head of Cardiology

GPO Box 2100 Adelaide SA 5001
Tel: 08 82769666 Fax: 08 8177 1589
andrew.russell@flinders.edu.au

Head of Department endorsement letter of A Pragmatic randomised controlled trial

Date: 25 May 2017

To Whom It May Concern

Project Title: Development and evaluation of an interactive avatar based education application for improving heart failure patients' knowledge and self-care behaviours: A Pragmatic randomised controlled trial

I am pleased to endorse the above-mentioned research project to be conducted at Noarlunga hospital. Professor Robyn Clark, Dr HuiYun Du and Miss Parichat Wonggom from the School of Nursing and Midwifery, Faculty of Medicine, Nursing and Health Science, are the chief investigators of this project.

I certify that:

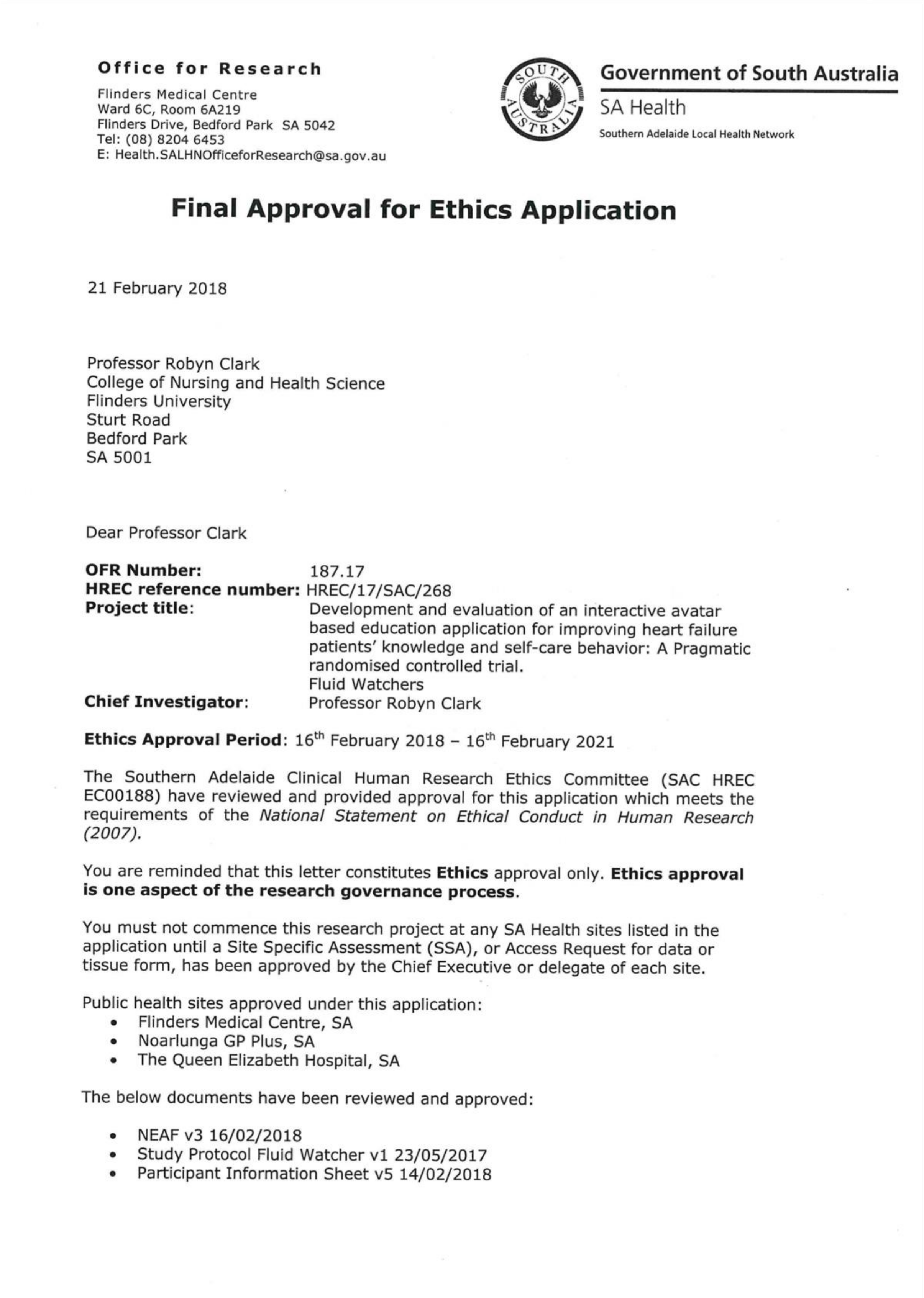
- I have read the research project application associated with this study site.
- I have discussed this research project and the resource implications for this department with the principal investigators.
- There are suitable and adequate facilities and resources for the research project to be conducted at this site.
- My signature indicates that I support this research project being carried out using such resources

Sincerely yours

Dr. Andrew Russell
Head of Cardiology

inspiring
achievement

Appendix H: Ethics Approval



Office for Research
Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final Approval for Ethics Application

21 February 2018

Professor Robyn Clark
College of Nursing and Health Science
Flinders University
Sturt Road
Bedford Park
SA 5001

Dear Professor Clark

OFR Number:	187.17
HREC reference number:	HREC/17/SAC/268
Project title:	Development and evaluation of an interactive avatar based education application for improving heart failure patients' knowledge and self-care behavior: A Pragmatic randomised controlled trial. Fluid Watchers
Chief Investigator:	Professor Robyn Clark

Ethics Approval Period: 16th February 2018 – 16th February 2021

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided approval for this application which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007).*

You are reminded that this letter constitutes **Ethics** approval only. **Ethics approval is one aspect of the research governance process**.

You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form, has been approved by the Chief Executive or delegate of each site.

Public health sites approved under this application:
- Flinders Medical Centre, SA
- Noarlunga GP Plus, SA
- The Queen Elizabeth Hospital, SA

The below documents have been reviewed and approved:

- NEAF v3 16/02/2018
- Study Protocol Fluid Watcher v1 23/05/2017
- Participant Information Sheet v5 14/02/2018

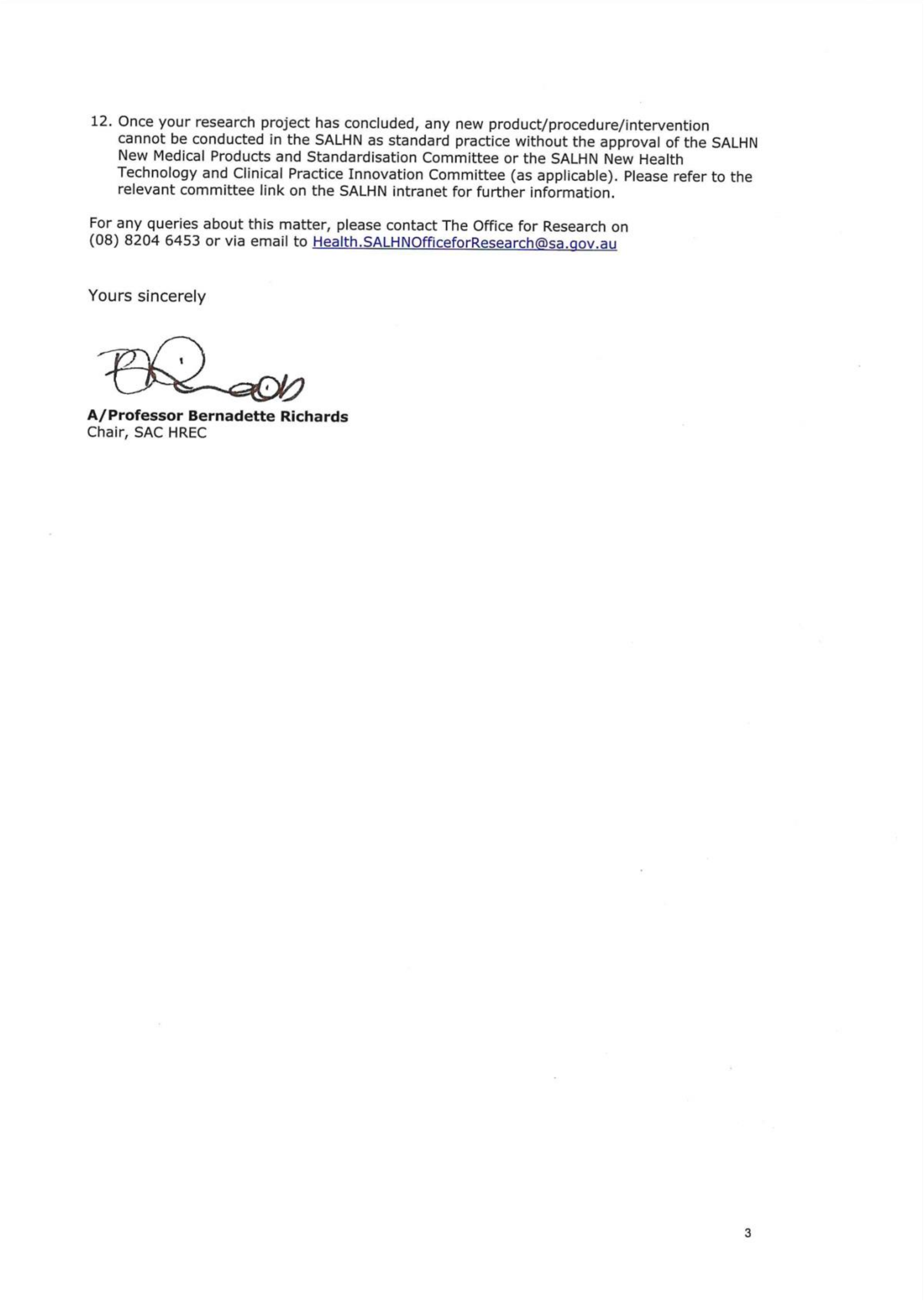
- Baseline questionnaire v1 23/05/2017
- Montreal Cognitive Assessment MoCA v1 23/05/2017
- REALM SF v2 29/01/2018
- 1 Month follow up v2 29/01/2018
- 6 Month follow up v2 29/01/2018
- Cover Letter 23/05/2017
- Endorsement letter from Dr Julian Vaile 28/06/2017
- Endorsement letter from Dr Daniel Ninio 25/05/2017
- Endorsement letter from Dr Andrew Russell 25/05/2017
- Storyboard – Fluid Watchers v5 05/02/2018
- Question Bank – Fluid Watchers v4 03/01/2018
- Email confirmation to use Monkeystack logo 07/11/2017
- Confirmation to use Flinders logo v1 25/09/2017
- Response to the reviewers 05/02/2018
- Response to reviewers 29/01/2018
- Response to reviewer for study 187.17 29/11/2017
- 187.17 Researcher response to sub committee

Terms and Conditions Of Ethics Approval:

It is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval only covers the science and ethics component of the application. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. 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.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.



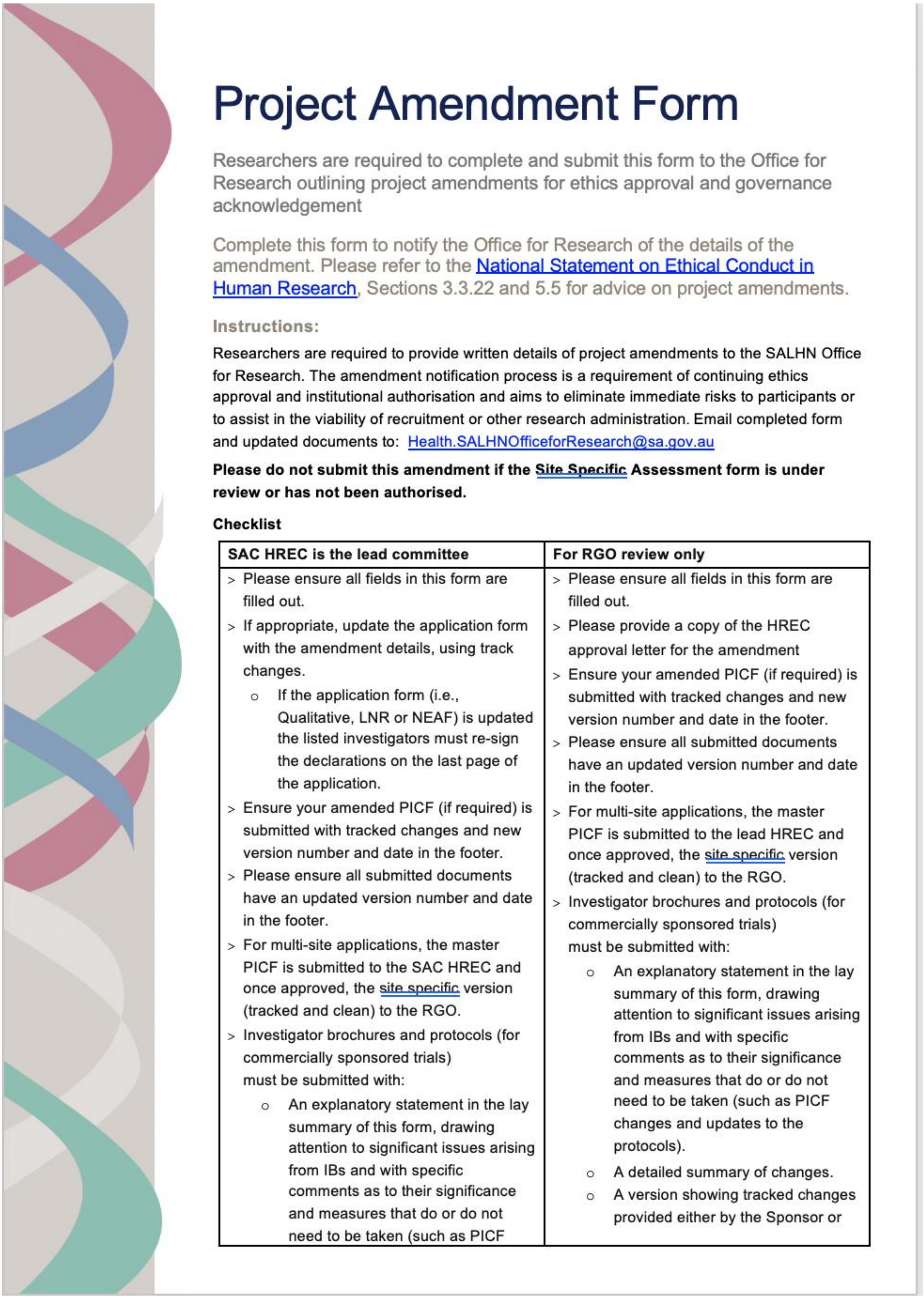
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.

For any queries about this matter, please contact The Office for Research on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au

Yours sincerely

A/Professor Bernadette Richards
Chair, SAC HREC

Appendix I: Amendment Application



Project Amendment Form

Researchers are required to complete and submit this form to the Office for Research outlining project amendments for ethics approval and governance acknowledgement

Complete this form to notify the Office for Research of the details of the amendment. Please refer to the National Statement on Ethical Conduct in Human Research, Sections 3.3.22 and 5.5 for advice on project amendments.

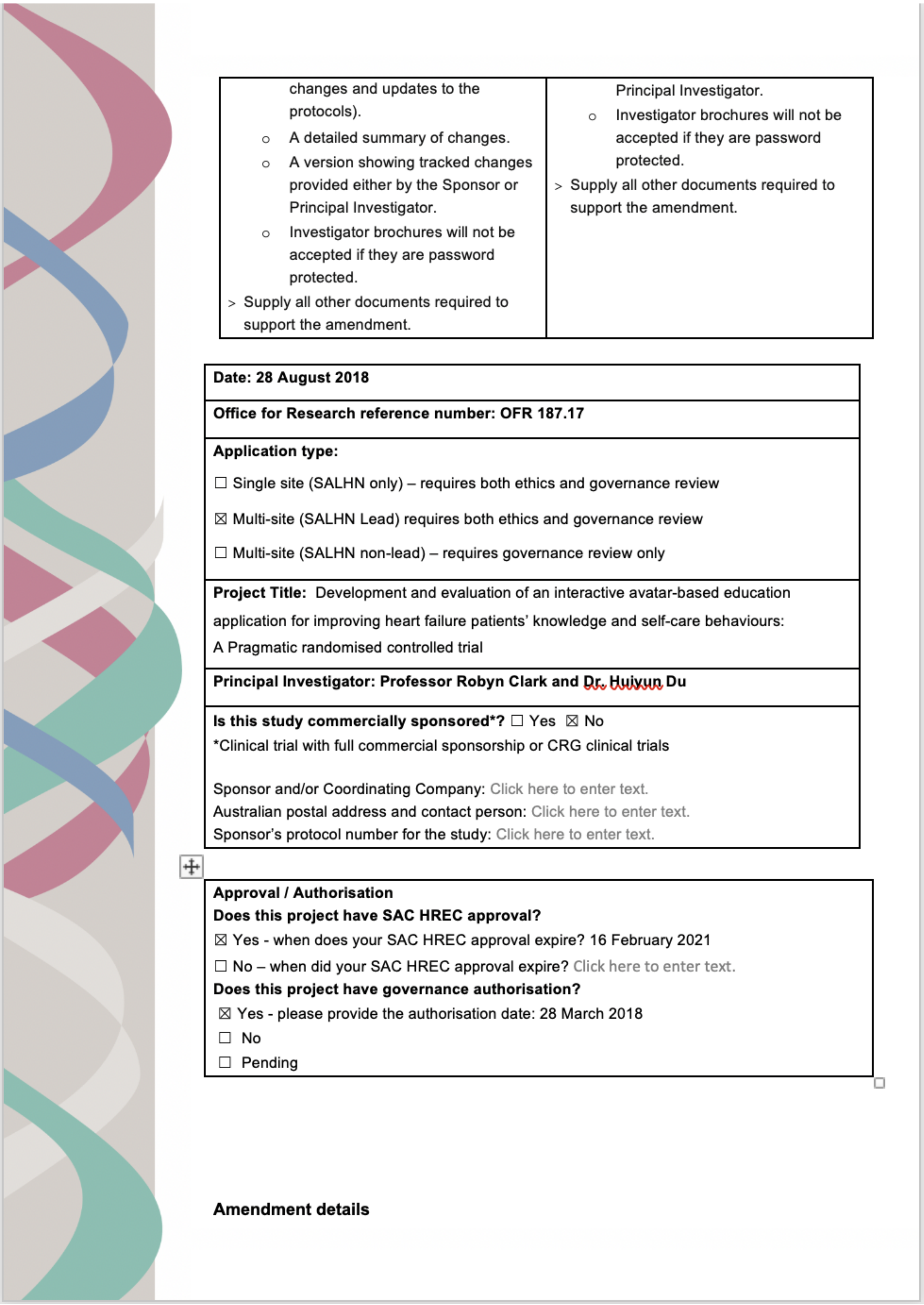
Instructions:

Researchers are required to provide written details of project amendments to the SALHN Office for Research. The amendment notification process is a requirement of continuing ethics approval and institutional authorisation and aims to eliminate immediate risks to participants or to assist in the viability of recruitment or other research administration. Email completed form and updated documents to: Health.SALHNOfficeforResearch@sa.gov.au

Please do not submit this amendment if the Site Specific Assessment form is under review or has not been authorised.

Checklist

SAC HREC is the lead committee	**For RGO review only**
> Please ensure all fields in this form are filled out. > If appropriate, update the application form with the amendment details, using track changes. ○ If the application form (i.e., Qualitative, LNR or NEAF) is updated the listed investigators must re-sign the declarations on the last page of the application. > Ensure your amended PICF (if required) is submitted with tracked changes and new version number and date in the footer. > Please ensure all submitted documents have an updated version number and date in the footer. > For multi-site applications, the master PICF is submitted to the SAC HREC and once approved, the site specific version (tracked and clean) to the RGO. > Investigator brochures and protocols (for commercially sponsored trials) must be submitted with: ○ An explanatory statement in the lay summary of this form, drawing attention to significant issues arising from IBs and with specific comments as to their significance and measures that do or do not need to be taken (such as PICF	> Please ensure all fields in this form are filled out. > Please provide a copy of the HREC approval letter for the amendment > Ensure your amended PICF (if required) is submitted with tracked changes and new version number and date in the footer. > Please ensure all submitted documents have an updated version number and date in the footer. > For multi-site applications, the master PICF is submitted to the lead HREC and once approved, the site specific version (tracked and clean) to the RGO. > Investigator brochures and protocols (for commercially sponsored trials) must be submitted with: ○ An explanatory statement in the lay summary of this form, drawing attention to significant issues arising from IBs and with specific comments as to their significance and measures that do or do not need to be taken (such as PICF changes and updates to the protocols). ○ A detailed summary of changes. ○ A version showing tracked changes provided either by the Sponsor or



changes and updates to the protocols). ○ A detailed summary of changes. ○ A version showing tracked changes provided either by the Sponsor or Principal Investigator. ○ Investigator brochures will not be accepted if they are password protected. > Supply all other documents required to support the amendment.	Principal Investigator. ○ Investigator brochures will not be accepted if they are password protected. > Supply all other documents required to support the amendment.

Date: 28 August 2018

Office for Research reference number: OFR 187.17

Application type:

☐ Single site (SALHN only) – requires both ethics and governance review

☒ Multi-site (SALHN Lead) requires both ethics and governance review

☐ Multi-site (SALHN non-lead) – requires governance review only

Project Title: Development and evaluation of an interactive avatar-based education application for improving heart failure patients' knowledge and self-care behaviours: A Pragmatic randomised controlled trial

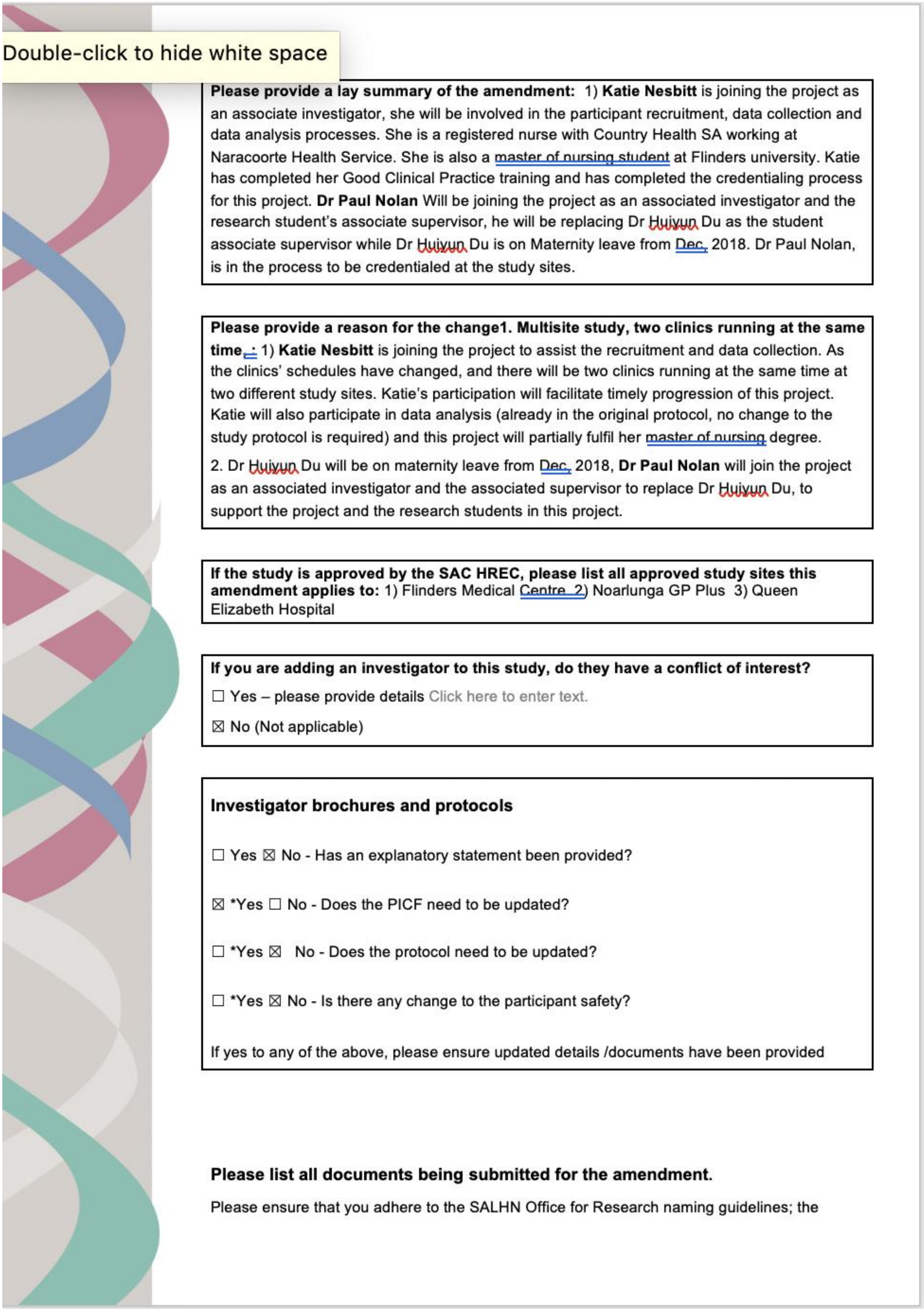
Principal Investigator: Professor Robyn Clark and Dr. Huiyun Du

Is this study commercially sponsored*? ☐ Yes ☒ No
*Clinical trial with full commercial sponsorship or CRG clinical trials

Sponsor and/or Coordinating Company: Click here to enter text.
Australian postal address and contact person: Click here to enter text.
Sponsor's protocol number for the study: Click here to enter text.

Approval / Authorisation
Does this project have SAC HREC approval?
☒ Yes - when does your SAC HREC approval expire? 16 February 2021
☐ No – when did your SAC HREC approval expire? Click here to enter text.
Does this project have governance authorisation?
☒ Yes - please provide the authorisation date: 28 March 2018
☐ No
☐ Pending

Amendment details



Please provide a lay summary of the amendment: 1) **Katie Nesbitt** is joining the project as an associate investigator, she will be involved in the participant recruitment, data collection and data analysis processes. She is a registered nurse with Country Health SA working at Naracoorte Health Service. She is also a master of nursing student at Flinders university. Katie has completed her Good Clinical Practice training and has completed the credentialing process for this project. **Dr Paul Nolan** Will be joining the project as an associated investigator and the research student's associate supervisor, he will be replacing Dr Huiyun Du as the student associate supervisor while Dr Huiyun Du is on Maternity leave from Dec, 2018. Dr Paul Nolan, is in the process to be credentialed at the study sites.

Please provide a reason for the change1. Multisite study, two clinics running at the same time.: 1) **Katie Nesbitt** is joining the project to assist the recruitment and data collection. As the clinics' schedules have changed, and there will be two clinics running at the same time at two different study sites. Katie's participation will facilitate timely progression of this project. Katie will also participate in data analysis (already in the original protocol, no change to the study protocol is required) and this project will partially fulfil her master of nursing degree.

2. Dr Huiyun Du will be on maternity leave from Dec, 2018, **Dr Paul Nolan** will join the project as an associated investigator and the associated supervisor to replace Dr Huiyun Du, to support the project and the research students in this project.

If the study is approved by the SAC HREC, please list all approved study sites this amendment applies to: 1) Flinders Medical Centre 2) Noarlunga GP Plus 3) Queen Elizabeth Hospital

If you are adding an investigator to this study, do they have a conflict of interest?

☐ Yes – please provide details Click here to enter text.

☒ No (Not applicable)

Investigator brochures and protocols

☐ Yes ☒ No - Has an explanatory statement been provided?

☒ *Yes ☐ No - Does the PICF need to be updated?

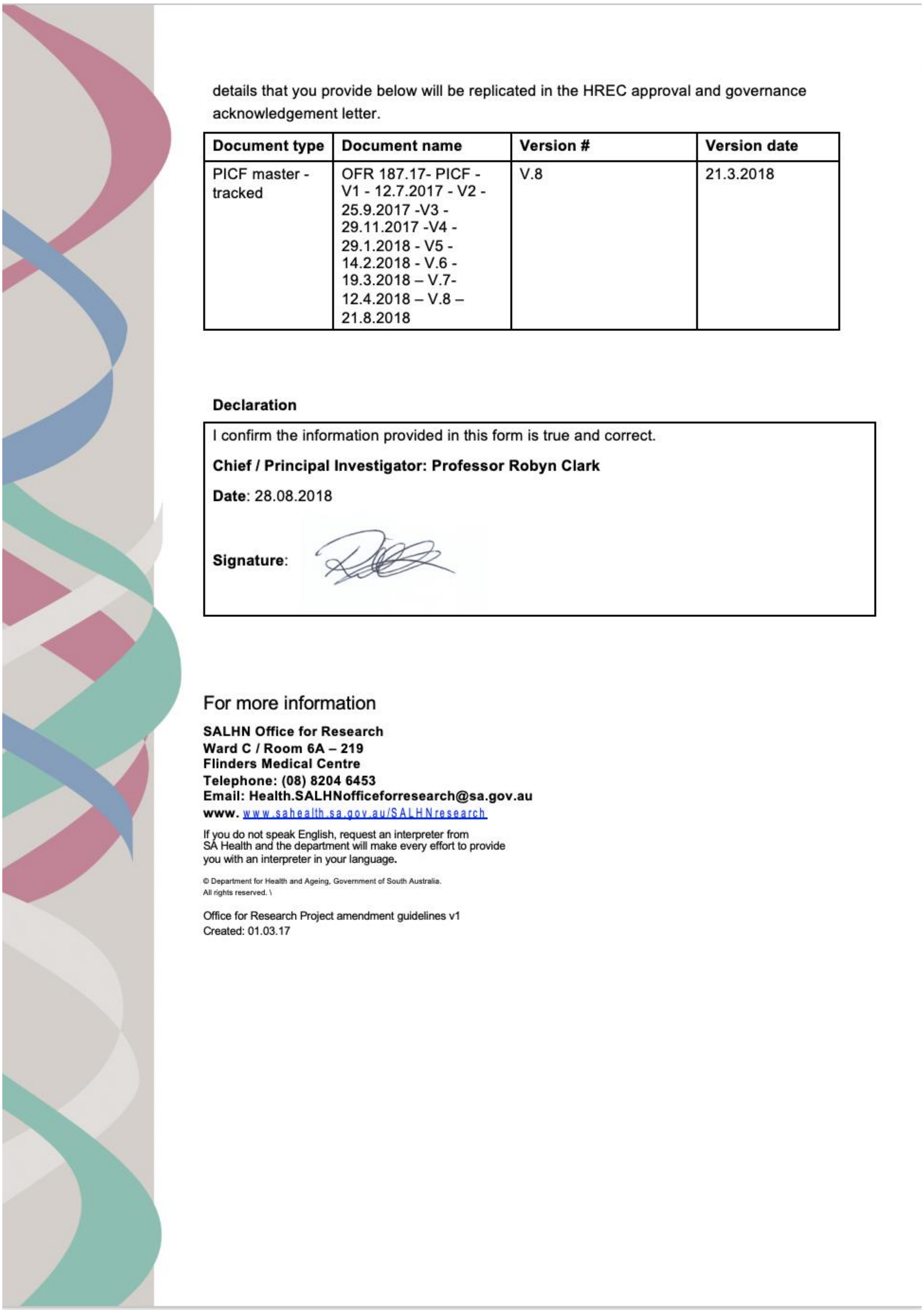
☐ *Yes ☒ No - Does the protocol need to be updated?

☐ *Yes ☒ No - Is there any change to the participant safety?

If yes to any of the above, please ensure updated details /documents have been provided

Please list all documents being submitted for the amendment.

Please ensure that you adhere to the SALHN Office for Research naming guidelines; the



details that you provide below will be replicated in the HREC approval and governance acknowledgement letter.

Document type	Document name	Version #	Version date
PICF master - tracked	OFR 187.17- PICF - V1 - 12.7.2017 - V2 - 25.9.2017 -V3 - 29.11.2017 -V4 - 29.1.2018 - V5 - 14.2.2018 - V.6 - 19.3.2018 – V.7- 12.4.2018 – V.8 – 21.8.2018	V.8	21.3.2018

Declaration

I confirm the information provided in this form is true and correct.

Chief / Principal Investigator: Professor Robyn Clark

Date: 28.08.2018

Signature:

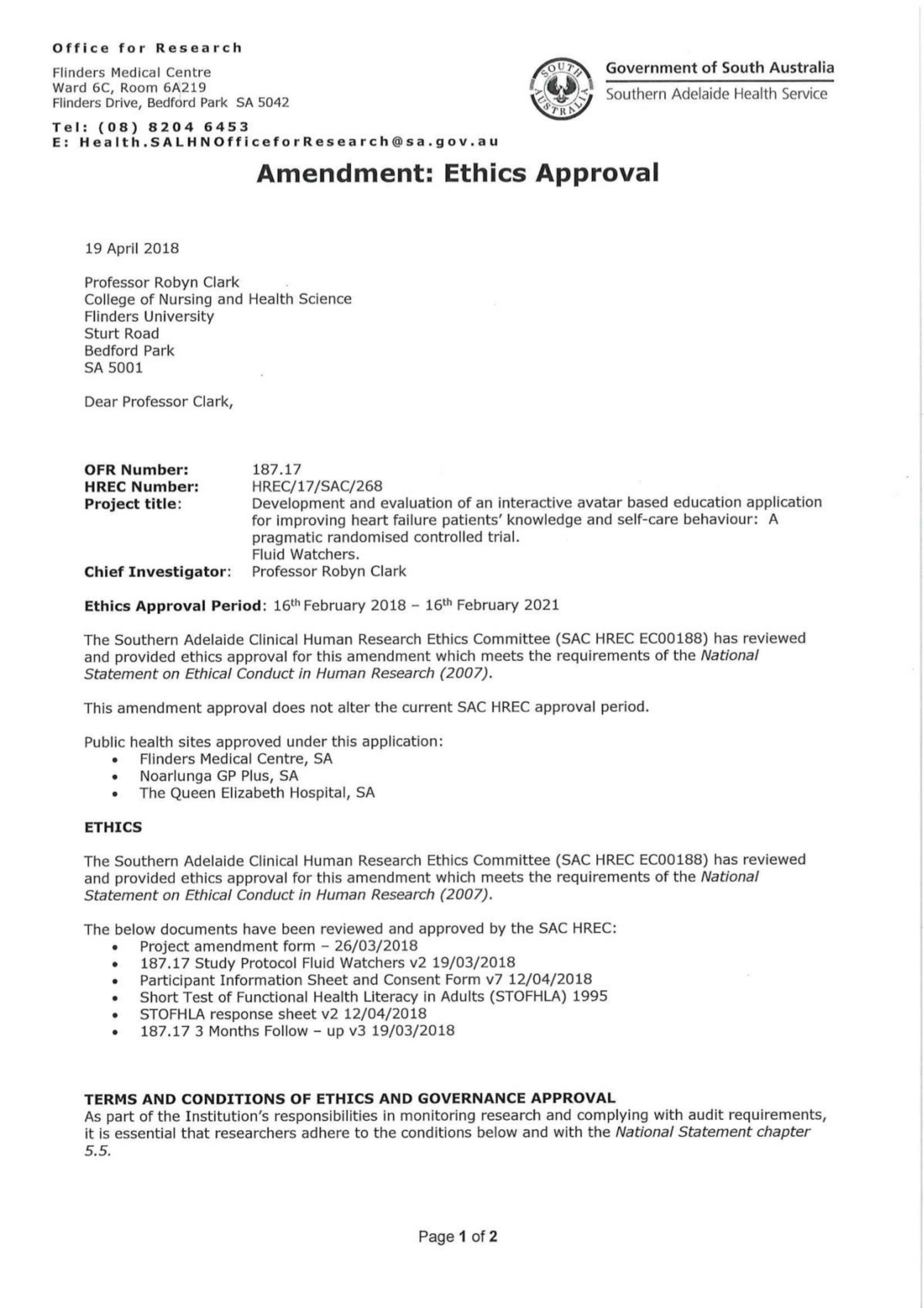
For more information

SALHN Office for Research
Ward C / Room 6A – 219
Flinders Medical Centre
Telephone: (08) 8204 6453
Email: Health.SALHNofficeforresearch@sa.gov.au
www. www.sahealth.sa.gov.au/SALHNresearch

If you do not speak English, request an interpreter from SA Health and the department will make every effort to provide you with an interpreter in your language.

Office for Research Project amendment guidelines v1
Created: 01.03.17

Appendix J: Amendment Approvals



Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042

Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
Southern Adelaide Health Service

Amendment: Ethics Approval

19 April 2018

Professor Robyn Clark
College of Nursing and Health Science
Flinders University
Sturt Road
Bedford Park
SA 5001

Dear Professor Clark,

OFR Number:	187.17
HREC Number:	HREC/17/SAC/268
Project title:	Development and evaluation of an interactive avatar based education application for improving heart failure patients' knowledge and self-care behaviour: A pragmatic randomised controlled trial. Fluid Watchers.
Chief Investigator:	Professor Robyn Clark

Ethics Approval Period: 16th February 2018 – 16th February 2021

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) has reviewed and provided ethics approval for this amendment which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

This amendment approval does not alter the current SAC HREC approval period.

Public health sites approved under this application:
- Flinders Medical Centre, SA
- Noarlunga GP Plus, SA
- The Queen Elizabeth Hospital, SA

ETHICS

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) has reviewed and provided ethics approval for this amendment which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

The below documents have been reviewed and approved by the SAC HREC:
- Project amendment form – 26/03/2018
- 187.17 Study Protocol Fluid Watchers v2 19/03/2018
- Participant Information Sheet and Consent Form v7 12/04/2018
- Short Test of Functional Health Literacy in Adults (STOFHLA) 1995
- STOFHLA response sheet v2 12/04/2018
- 187.17 3 Months Follow – up v3 19/03/2018

TERMS AND CONDITIONS OF ETHICS AND GOVERNANCE APPROVAL

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

- 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.
- Compliance with the National Statement on Ethical Conduct in Human Research (2007) & the Australian Code for the Responsible Conduct of Research (2007).
- To immediately report to the Office for Research anything that may change the ethics or scientific integrity of the project.
- Report Significant Adverse events (SAEs) as per SAE requirements available on the Office for Research website.
- Submit an annual report on each anniversary of the date of final approval and in the correct template from the Office for Research website.
- Confidentiality of research participants MUST be maintained at all times.
- A copy of the signed consent form must be given to the participant.
- Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
- All requests for access to medical records at any SALHN site must be accompanied by this approval letter.
- Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.
- Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

For any queries about this matter, please contact the Executive Officer on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au.

Yours sincerely

A/Professor Bernadette Richards
Chair
SAC HREC

Office for Research
Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
Southern Adelaide Health Service

Amendment: Ethics and Governance Approval

18 September 2018

Professor Robyn Clark
College of Nursing and Health Science
Flinders University
Bedford Park
SA 5001

wong0752@flinders.edu.au

Dear Professor Clark

OFR Number:	187.17
HREC reference number:	HREC/17/SAC/268
Project title:	Development and evaluation of an interactive avatar based education application for improving heart failure patients' knowledge and self-care behavior: A Pragmatic randomised controlled trial. Fluid Watchers
Chief Investigator:	Professor Robyn Clark

Ethics Approval Period: 16th February 2018 – 16th February 2021

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) has reviewed and provided ethics approval for this amendment which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

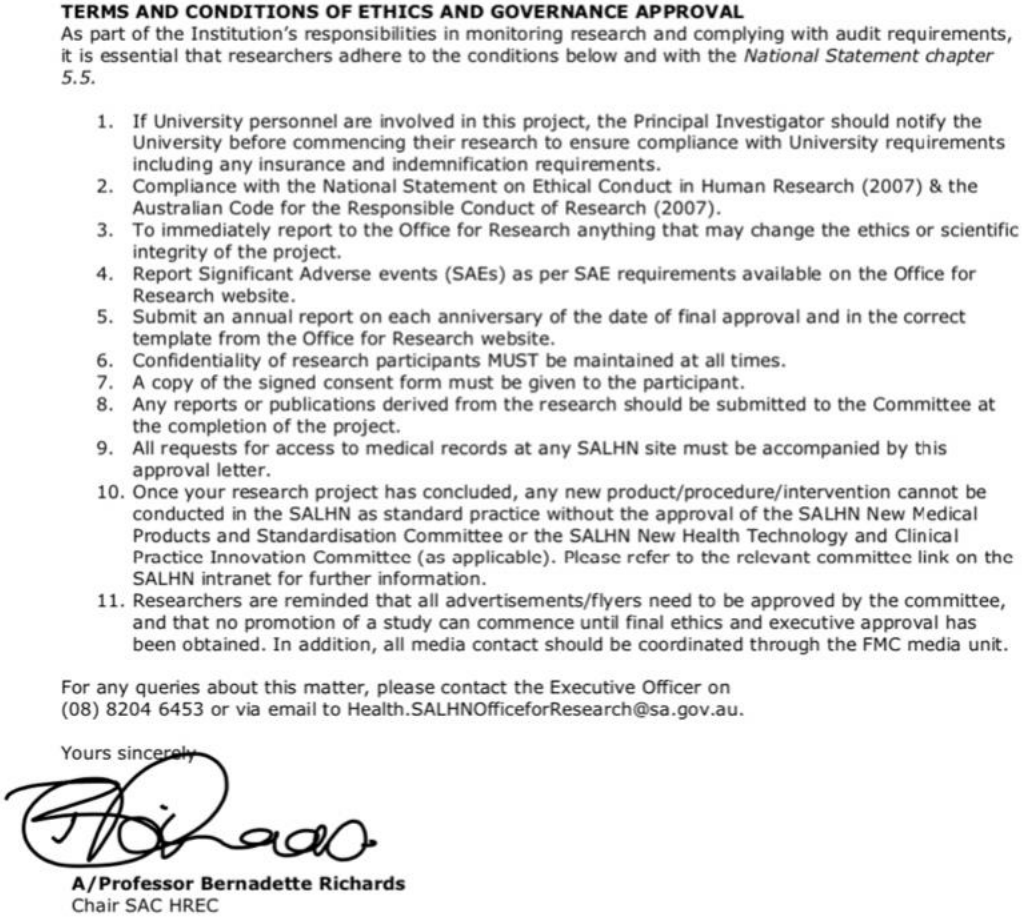
This amendment approval does not alter the current SAC HREC approval period.

Public health sites approved under this Ethics amendment application:

- Flinders Medical Centre, SA
- Noarlunga GP Plus, SA
- The Queen Elizabeth Hospital, SA

The below documents have been reviewed and approved by the SAC HREC:

- Project Amendment Form – addition of investigators – dated 28 August 2018
- NEAF v4 dated 03 September 2018
- Participant information sheet /consent form v8 dated 21 August 2018



TERMS AND CONDITIONS OF ETHICS AND GOVERNANCE APPROVAL

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

1. 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.
2. Compliance with the National Statement on Ethical Conduct in Human Research (2007) & the Australian Code for the Responsible Conduct of Research (2007).
3. To immediately report to the Office for Research anything that may change the ethics or scientific integrity of the project.
4. Report Significant Adverse events (SAEs) as per SAE requirements available on the Office for Research website.
5. Submit an annual report on each anniversary of the date of final approval and in the correct template from the Office for Research website.
6. Confidentiality of research participants MUST be maintained at all times.
7. A copy of the signed consent form must be given to the participant.
8. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
9. All requests for access to medical records at any SALHN site must be accompanied by this approval letter.
10. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.
11. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

For any queries about this matter, please contact the Executive Officer on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au.

Yours sincerely

A/Professor Bernadette Richards
Chair SAC HREC

Appendix K: Participant Consent

Participant Information Sheet/Consent Form

Interventional Study—*Adult providing own consent*

Flinders Medical Centre, Noarlunga GP Plus and Queen Elizabeth Hospital

Title	Development and evaluation of an interactive avatar-based education application for improving HF patients' knowledge and self-care: A Pragmatic randomised controlled trial
Short Title	Fluid Watchers
Coordinating Principal Investigator	Professor Robyn Clark
Principal Investigator	Professor Robyn Clark Dr Huiyun Du
Associate Investigator(s) (if required by institution)	Ms Parichat Wonggom Dr Christine Burdeniuk Associate Professor Carmine De Pasquale Dr Andrew Russell Dr Aaron Sverdlov Dr Paul Nolan
Location (where CPI/PI will recruit)	Flinders Medical Centre Noarlunga GP Plus Queen Elizabeth Hospital

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Part 1 What does my participation involve?

1. Introduction

You have been invited to take part in this research study because you have a new diagnosis of HF (within 1 year). This research project aims to evaluate an interactive educational tool for assisting people to learn more about HF and self-care.

This Participant Information Sheet/Consent Form tells you about the research project. It explains what participation in this research project involves and this will help you decide whether you want to take part in this research.

Please read this information carefully and ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part in this study, you are welcome to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing this, you are telling us that you:

- Understand what you have read.
- Consent to take part in the research project.
- Consent to allow us the use of your personal and health information as described.

You will be given a copy of the Participant Information Sheet/Consent Form to keep for your record.

2. What is the purpose of this research?

HF can be a burdensome illness. Managing multiple medications and following recommendations from your healthcare providers can be complex and challenging. You may have been given booklets and pamphlets to read about how you can better take care of yourself. However, reading and understanding medical information in a traditional booklet can be time consuming, daunting and difficult. In this research study, our research team aims to evaluate an interactive educational tool that provides information on HF and self-care, using animation, videos, voice, and without complex medical language. This study aims to evaluate whether this health educational tool is effective in teaching HF knowledge and self-care.

3. What does participation in this research involve?

If you agree to participate in this study:

- You will be asked to sign the Consent Form. This is to tell us that you understand what you have read and consent to take part in the research project, as well as to allow us the use of your personal and health information as described.
- A research nurse will assess your eligibility to participate in this study by reviewing your medical record and assessing your cognitive function.
- If you are eligible, the research nurse will collect information about your current medical condition and past medical history from your medical records.
- You will also be asked to fill out an assessment of your ability to understand complex and medical information.
- You will be randomly allocated to a study group; this may be the interactive educational tool group or the usual care group. Neither the research nurse nor you can decide which group you will be put into.
- If you are assigned to the interactive educational tool group, you will meet with a research nurse, who will provide you the interactive educational tool on a handheld computer and show you how to use it. It will take approximately 15 minutes to review the educational tool.
- After that, the research nurse will ask you some questions regarding the information provided by the educational tool. It will take approximately 20 minutes in total. The research nurse will give you a handheld computer to take home for reviewing the interactive educational tool for the next three months. You will need to return a handheld tablet computer to the researchers once the study is finished after the three-month follow-up.
- You will have two telephone appointments with the research nurse during the next three months. The first telephone appointment will be at one month and the second telephone appointment will be at three months. During the telephone follow-up, the research nurse will ask you some questions about your heart condition. These questions will be similar to what you have been asked in the HF clinic, to see if you remembered what you have learned. Each phone call will take approximately 20 minutes.
- If you are assigned to the usual care group, the research nurse will contact you by telephone after one month and at three months to ask some questions regarding your heart condition and how well you are going.
- *Regardless of the group you are allocated to, you will be provided with a Heart Foundation booklet about managing your condition*. The research nurse will contact you by telephone at one month and three months. The usual care you receive for your medical condition will not be affected because of your participation in this study.

4. Do I have to take part in this research project?

Participation in this research study 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 study at any stage.

Your decision to take part in this research study will not affect your routine treatment, your relationship with those treating you or your relationship with Flinders Medical Centre, Noarlunga GP Plus or Queen Elizabeth Hospital.

5. What if I withdraw from this research project?

You are free to withdraw from the study at any time without consequence.

6. What are the possible benefits of taking part?

Your participation will help the researchers to evaluate a simple and interactive educational tool. Viewing the educational tool during this study may help you gain a better understanding of HF, and how to better manage your HF.

7. What are the possible risks and disadvantages of taking part?

We do not foresee any physical or emotional risks from taking part in this research. All we need is a few hours of your time.

8. Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything nor will you be paid. Regardless of which group you are allocated to, you will be offered the opportunity to install the interactive educational tool on your handheld computer or smart phone at the completion of this study.

9. What happens to my treatment when the study is finished?

Your current and future medical treatment and the care you receive from the hospital will not be affected by your participation in this study.

10. How will my confidentiality be protected?

Data collected through this research project is not individually identifiable. Completed surveys will be stored in a locked cabinet in the researcher’s office within the College of Nursing and Health Sciences building, Flinders University and will only be accessible to the researchers listed at the beginning of this document.

Part 2 How is the research project being conducted?

11. What will happen to information about me?

Any information or comments provided by you will be collected in a de-identified form.

The survey will be stored in a locked filing cabinet in the researcher's office within the College of Nursing and Health Sciences, Flinders University. Electronic data will be kept on the Flinders University network computer in the College of Nursing and Health Sciences, Flinders University, which is password protected. All study-related data will only be accessible to the researchers listed at the beginning of this document.

After completion of the study, the paper-based data will be stored for five years and destroyed by means of shredding. After five years, the electronic data files will also be deleted from the Flinders University network computer.

12. Complaints and compensation

If you suffer any injuries or complications as a result of this research study, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

13. 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 study 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.

This research project has been approved by the Southern Adelaide Clinical HREC.

14. Who should I contact if I have concerns about the conduct of this study?

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project you can contact any of the following people:

Clinical contact person

Name	*Robyn Clark*

Position	*Professor, College of Nursing and Health Sciences, Flinders University*
Telephone	*8 82013266*
Email	*robyn.clark@flinders.edu.au*

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	*Villis Marshall*
Position	*Director, Office for Research*
Telephone	*8204 6453*
Email	*health.salhnofficeforresearch@sa.gov.au*

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	*Southern Adelaide Clinical*
Position	*Executive Officer*
Telephone	*8204 6453*
Email	*health.salhnofficeforresearch@sa.gov.au*

Local HREC Office contact (Single Site—Research Governance Officer)

Position

Telephone

Email

Consent Form—*Adult providing own consent*

Title	Development and evaluation of an interactive avatar-based education application for improving HF patients' knowledge and self-care: A Pragmatic randomised controlled trial
Short Title	Fluid Watchers
Coordinating Principal Investigator	Professor Robyn Clark
Principal Investigator	Professor Robyn Clark Dr Huiyun Du
Associate Investigator(s) (if required by institution)	Ms Parichat Wonggom Dr Christine Burdeniuk Associate Professor Carmine De Pasquale Dr Andrew Russell Dr Aaron Svedlov Dr Paul Nolan Mrs Katie Nesbitt
Location (where CPI/PI will recruit)	Flinders Medical Centre Noarlunga GP Plus Queen Elizabeth Hospital

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 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 health care.

I understand that I will be given a signed copy of this document to keep.

Signature ____________________ Date ____________________

Declaration by Senior 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 Senior Researcher[†]
(please print) ____________________

Signature ____________________ Date ____________________

[†] A senior 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.

Form for Withdrawal of Participation—*Adult providing own consent*

Title	Development and evaluation of an interactive avatar-based education application for improving HF patients' knowledge and self-care: A Pragmatic randomised controlled trial
Short Title	Fluid Watchers
Coordinating Principal Investigator/ Principal Investigator	Professor Robyn Clark Dr Huiyun Du
Associate Investigator(s) (if required by institution)	Ms Parichat Wonggom Dr Christine Burdeniuk Associate Professor Carmine De Pasquale Dr Andrew Russell Dr Aaron Svedlov Dr Paul Nolan Mrs Katie Nesbitt
Location (where CPI/PI will recruit)	Flinders Medical Centre Noarlunga GP Plus Queen Elizabeth Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Flinders Medical Centre, Noarlunga GP Plus and Queen Elizabeth Hospital.

Signature ______________________ Date ______________________

Declaration by Senior 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

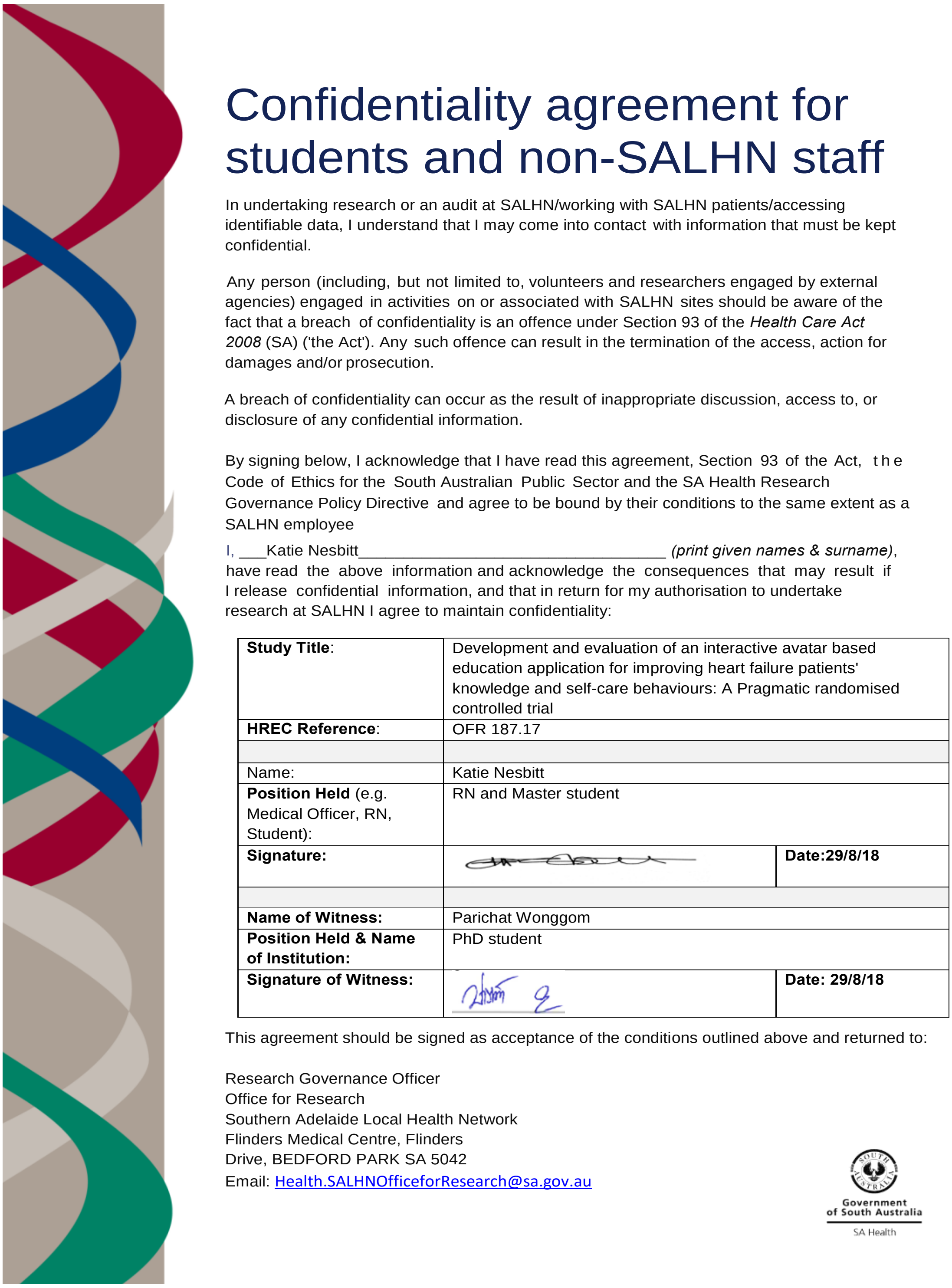
Senior Researcher† (please print) ______________________________

Signature ____________________ Date ____________________

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Appendix L: Confidentiality Agreement



Confidentiality agreement for students and non-SALHN staff

In undertaking research or an audit at SALHN/working with SALHN patients/accessing identifiable data, I understand that I may come into contact with information that must be kept confidential.

Any person (including, but not limited to, volunteers and researchers engaged by external agencies) engaged in activities on or associated with SALHN sites should be aware of the fact that a breach of confidentiality is an offence under Section 93 of the *Health Care Act 2008* (SA) ('the Act'). Any such offence can result in the termination of the access, action for damages and/or prosecution.

A breach of confidentiality can occur as the result of inappropriate discussion, access to, or disclosure of any confidential information.

By signing below, I acknowledge that I have read this agreement, Section 93 of the Act, the Code of Ethics for the South Australian Public Sector and the SA Health Research Governance Policy Directive and agree to be bound by their conditions to the same extent as a SALHN employee

I, ___Katie Nesbitt___________________________________ *(print given names & surname)*, have read the above information and acknowledge the consequences that may result if I release confidential information, and that in return for my authorisation to undertake research at SALHN I agree to maintain confidentiality:

Study Title:	Development and evaluation of an interactive avatar based education application for improving heart failure patients' knowledge and self-care behaviours: A Pragmatic randomised controlled trial	
HREC Reference:	OFR 187.17	
Name:	Katie Nesbitt	
Position Held (e.g. Medical Officer, RN, Student):	RN and Master student	
Signature:		**Date:29/8/18**
Name of Witness:	Parichat Wonggom	
Position Held & Name of Institution:	PhD student	
Signature of Witness:		**Date: 29/8/18**

This agreement should be signed as acceptance of the conditions outlined above and returned to:

Research Governance Officer
Office for Research
Southern Adelaide Local Health Network
Flinders Medical Centre, Flinders
Drive, BEDFORD PARK SA 5042
Email: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health

Appendix M: Good Clinical Practice Certificate of Completion

NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Katie Nesbitt

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:	**STATUS:**
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 21 May 2018

CTN Expiration Date: 21 May 2021

Tracee Williams, Training Coordinator
NIDA Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.