

**PROTOCOL**

Evaluation of the effectiveness of an interactive avatar-based education application for improving heart failure patients' knowledge and self-care behaviours: A pragmatic randomized controlled trial protocol

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Abstract

Aim: The aim of this study was to evaluate the effectiveness of an avatar-based education application for improving knowledge and self-care behaviour in patients with heart failure (HF).

Background: Avatar-based technologies for supporting education are an innovative approach for patients with low literacy, low health literacy and English as a second language. The use of avatar technologies for patient education has shown benefits in improving knowledge, self-care behaviours and quality of life in chronic diseases such as cancer, diabetes and depression. Research has demonstrated positive outcomes in clinical practice. However, the effectiveness of this technology has not been evaluated among patients with HF.

Design: A multi-centred, non-blinded randomized, two-armed parallel pragmatic, controlled trial.

Method: Eighty-eight participants will be recruited from the HF clinics at three public hospitals and randomized into either control or intervention groups. The intervention group will receive the avatar-based education plus usual care. The control group will receive usual care. The primary outcome is HF knowledge, secondary outcomes include; improved self-care behaviours, readmission and satisfaction. Data will be collected at the baseline and at 1- and 3-month follow-ups.

Discussion: This study will measure the effectiveness of avatar-based education on patients' knowledge and self-care behaviours following HF. The evidence will be evaluated in terms of the reduction in patients' readmission.

KEYWORDS

avatar-based education, heart failure, knowledge, nursing, patient satisfaction, randomized controlled trial, readmission, self-care behaviours

1 | INTRODUCTION

Heart failure (HF) is a global pandemic that affects at least 26 million people worldwide and its prevalence is increasing due to an ageing

population and improvements in treatment (Savarese & Lund, 2017). Adherence to self-care recommendations is essential for preventing avoidable hospitalisation and achieving optimal patient outcomes (Lainscak et al., 2011). However, self-care is challenging, particularly for people with low health literacy levels (Cajita, Cajita, & Han, 2016). HF patients can find it challenging when faced with all that is

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required to be learnt to best take care of themselves (Harkness, Spaling, Currie, Strachan, & Clark, 2015).

Educational interventions for HF are an important part of treatment, to develop, maintain and change the self-care behaviours (Boyde, Turner, Thompson, & Stewart, 2011; Ditewig, Blok, Havers, & van Veenendaal, 2010). A variety of educational programmes have been developed and evaluated to improve patients' knowledge, self-care behaviours and other health outcomes (Boyde et al., 2011; Clark et al., 2015; Dinh, Bonner, Clark, Ramsbotham, & Hines, 2016).

Patient education using Avatars has been used in the management of chronic diseases, such as cancer, diabetes and depression. These studies have shown improvements in patients' knowledge, self-care behaviours and quality of life (Bedra, Wick, Brotman, & Finkelstein, 2013; Johnson et al., 2013; Pinto, Hickman, Clochesy, & Buchner, 2013). However, no studies have been conducted to evaluate this technology in HF education. Therefore, this paper will present the study protocol of a pragmatic randomized controlled trial to evaluate the effectiveness of an avatar-based education application (app) for improving HF patients' knowledge and self-care behaviours.

1.1 | Background

Health literacy is defined as the ability to read and understand health information materials to care for one's own health and to make effective health decisions (Wayne, 2009). On average, 39% of HF patients have low levels of health literacy (Cajita et al., 2016). Systematic reviews have reported that low levels of health literacy are associated with poor knowledge and self-care behaviour, poor health outcomes and under-use of healthcare services (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011; Cajita et al., 2016). A lack of self-care, such as non-adherence to medication and lifestyle recommendations as well as failure to detect deterioration, can lead to potentially preventable hospitalisation (Kollipara et al., 2008; Vaughan Dickson, Lee, & Riegel, 2011).

Self-care is a naturalistic decision-making process that influences actions to maintain physiological stability, facilitate the perception of symptoms and direct the management of symptoms (Riegel, Dickson, & Faulkner, 2016). An important determinant of self-care is knowledge, which is required in both making a decision and acting decisively to carry out successful self-care behaviours. The relationship between knowledge and behaviours is also significantly mediated by self-efficacy, which is concerned with how people judge their capabilities and how, through their self-percepts of efficacy, they affect their actions (Bandura, 1977). Other factors related to self-care in HF include experiences and skills, individual motivation, habits, cultural beliefs and values, functional and cognitive abilities, confidence, support and access to care; these are all important considerations when developing interventions to support self-care of patients with HF (Jaarsma, Cameron, Riegel, & Stromberg, 2017).

With the rapid development of information and communication technologies, innovative interventions have been developed to support self-care and improve health outcomes in people with chronic diseases (Azevedo, de Sousa, Monteiro, & Lima, 2015; Franklin,

Why is this research needed?

- Heart failure is a major public health issue associated with poor clinical outcomes and substantial economic burden to the healthcare system.
- There were no studies that have investigated the effectiveness of avatar-based patient education on the improvement of knowledge of heart failure and related self-care behaviours.
- An interactive avatar-based education application, such as the one developed in this study, should be considered as an alternative patient education tool for improving knowledge and health outcomes particularly for those with low literacy, low health literacy or English as a second language.

2015). Interactive patient education technology and serious game platforms can overcome low health literacy using visual and auditory signals, promoting disease knowledge and having an impact on patient health outcomes (Annam, Lassiter, Viera, & Ferris, 2015; Charlier et al., 2016). An avatar is an icon or a figure that represents a person in a computer game, on an Internet forum, etc. (Peterson, 2005). Avatar technology is particularly useful for patients with low literacy and low health literacy because it is more engaging than printed education materials and it supports learning through the use of audio and visual aids. Avatar-based technologies in patient education are now widespread and their use is increasing (Duncan, Miller, & Jiang, 2012). It has been showed to be beneficial to people with chronic diseases, including over-active bladder, ileostomy stoma care and smoking cessation (Andrade, Anam, Karanam, Downey, & Ruiz, 2015; Bedra et al., 2013; Krebs et al., 2009).

While the current body of literature has suggested that avatar technology has a positive impact on knowledge, self-care behaviours and self-efficacy in chronic diseases, each intervention must be developed and evaluated based on the characteristics and needs of its intended patient population (Annam et al., 2015; Bedra et al., 2013; Friedman, Cosby, Boyko, Hatton-Bauer, & Turnbull, 2011; Constance Johnson et al., 2014; Kato, Cole, Bradlyn, & Pollock, 2008; Ruggiero et al., 2014). To date, no previous study has evaluated the use of avatar-based patient education in HF. The authors have developed an interactive avatar-based education app, in collaboration with HF patients, clinical experts and information technology (IT) experts, to support patients' self-care. This interactive avatar-based education app will be evaluated in this study.

2 | THE STUDY

2.1 | Aim

The aim of this study was to evaluate the effectiveness of avatar-based education as an innovative way to teach patients about HF.

2.2 | Objectives

The objectives of this study were to:

1. Evaluate the effectiveness of an avatar-based education app on HF knowledge.
2. Evaluate the effectiveness of an avatar-based education on patients' self-care behaviours.
3. Evaluate the impact of the avatar teaching on heart failure related readmissions.
4. Compare outcomes between patients with low health literacy level and patients with an adequate health literacy level.

3 | METHODOLOGY

3.1 | Design

The study is a multi-centred, non-blinded, randomized, two-armed parallel pragmatic, controlled trial.

3.2 | Study setting

This study will be conducted at three HF out-patient clinics in three public hospitals in South Australia.

3.3 | Eligibility criteria

Inclusion criteria for the participants are as follows: (a) a confirmed diagnosis of HF within 1 year; (b) have had a previous hospitalization for HF; (c) in New York Heart Association Functional Class (NYHA-FC) I-IV; (d) normal cognitive function. Normal cognitive function is defined as a score of 26 or higher on the Montreal Cognitive Assessment (MoCA) test (Nasreddine et al., 2005); (e) sufficient English language capabilities to communicate and to follow the study procedure and (f) must be willing to give informed consent. Exclusion criteria for the participants are as follows: (a) those who are clinically unstable. Clinically unstable is defined as patients who do not achieve the five normal vital signs (i.e. heart rate, systolic blood pressure, respiratory rate, oxygen saturation and temperature) and normal mental status and ability to eat for at least 24 hr prior to enrolling in the study; and (b) cognitive impairment.

3.4 | Sample size

The Dutch HF knowledge scale (DHFKS) was used as the primary outcome measure in this study. On the basis of a previous HF study (Delaney et al., 2013) to measure HF knowledge using the DHFKS with a standard deviation of 2.075, we estimated a sample size of 40 per group is needed with a two-sided 5% significance level and 80% power (calculated using PASS 14 Power Analysis and Sample Size Software by a statistician). When taking into account a loss to follow up of 10%, 88 participants (44 per group) are required to be enrolled in this study.

3.5 | Recruitment

The medical and nursing staff will assist the research nurse to identify potential participants from the HF out-patient clinics at the participating hospitals. The medical and nursing staff will be provided with the study's inclusion and exclusion criteria. The medical and nursing staff will obtain each patient's permission to be contacted by the research nurse. With the patient's permission, a research nurse will approach the patient. At that time, the study's purpose and its protocol will be explained. Once consent is obtained, the participants will be screened to determine if they meet the eligibility criteria.

3.6 | Randomization

3.6.1 | Sequence generation

Participants will be randomly assigned to either a control or intervention group with a 1:1 ratio. A block randomization sequence will be generated by an independent clinical trial management centre using a computer randomization system. Two random block sizes will be used.

3.6.2 | Allocation concealment mechanism

Randomization will occur after consent and completion of baseline assessment. Allocation concealment will be ensured, as the automatic randomization system will not release the randomization code until the patient has been recruited into the trial, which takes place after all baseline measurements have been completed. Two block sizes will be used to ensure concealment of the allocation at any time during the trial.

3.6.3 | Implementation

In this study, an interactive voice response system (IVRS) will be used for randomization. The IVRS provides an immediate response, collects and responds to caller inputs and is available 24 hr a day, 7 days a week and has a 24-hr emergency unblinding and backup service. The confirmation of each randomization will be emailed to the chief investigator.

Participants are randomly allocated to a study group; the research nurse will inform these participants of their allocation group. This may be the intervention group or the usual care group. Neither the research nurse nor the participant can decide which group they will be in.

3.7 | Blinding

As the avatar-based education application is an education intervention, blinding of the participants and the researchers who conducted telephone follow-up data collection will not be possible.

3.8 | Intervention: The Avatar-based Education App

This section presents the details of the intervention based on the template for intervention description and replication (TIDieR) checklist to provide sufficient details (Hoffmann et al., 2014). At baseline, after the participants are assigned to the avatar-based education group, the research nurse will provide them with a tablet installed with the avatar-based education app. The research nurse will instruct the participants on how to use the app. The participants will be asked to review the app once at baseline. They will also complete the study questionnaires that assess HF knowledge and self-care behaviour before and after using the app, and a satisfaction survey after using the app to collect participants' feedback on the app. This session will be conducted in the out-patient clinic and is expected to take approximately 45 min.

Participants will then be asked to take the app home and to use it as much as they like during the 3-month study period. The app software will automatically record the frequency of use and most visited sections (Figure 1).

The intervention is a self-administered avatar-based education app that is installed on a tablet and that does not require the Internet for operation. The avatar-based education app will be provided to participants and they can use the app at any time and at any location that is convenient for them.

The content of the avatar-based education app is based on the National Heart Foundation of Australia's booklet, *Living Well with Heart Failure* (National Heart Foundation of Australia 2016). The content of the app consists of four main sections, including (a) understanding heart failure, (b) looking after yourself, (c) things to do every day and (d) emergency action plan. Each main section also includes sub-sections, for example, section 2 includes fluid, salt, medicines, alcohol and smoking, sleeping, talking with your doctor, vaccinations and etc.

When using the app, the participants can make and customise their own avatar. They can skip or repeat sections of the app and access or stop the app at any point based on their individual needs. The participant will be prompted to do a quiz at the start of the app and after completing each sub-section. To maintain the interest of the participants, the question at the end of each sub-section is randomly selected from a question bank each time the participant reviews that section.

The education application was developed in collaboration with clinical and academic HF experts, patients with HF and IT experts. Any errors and glitches in the app reported by research nurses or the participants will be forwarded to the IT experts for immediate modification. The authors do not foresee that the content of the education app will need to be modified during the trial.

3.8.1 | Usual care

Participants in the control group will receive usual care. Usual care at the study site includes care from HF nurses or regular nurses who will be responsible for bedside education to reinforce the diagnosis,

treatment, self-care, self-monitoring and follow-up provided by HF nurses at the HF clinic. As part of usual care, all patients will be provided with the educational booklets from the National Heart Foundation of Australia. Patients will be followed up at 1- and 3-months (Figure 1).

3.9 | Outcome measures

The timeline of study measurement is shown in Table 1. Recruitment will run between June 2018-December 2018.

3.9.1 | Primary outcome

The primary outcome for this study will be Heart Failure knowledge measured by the Dutch Heart Failure Knowledge (DHFKS) (Figure 1).

The DHFKS consists of 15 multiple choice items concerning HF in general (four items), HF treatment (six items on diet, fluid restriction and activity) and symptoms and symptom recognition (five items). The DHFKS is a self-administered questionnaire. For each item, participants can choose from three options, with one option being the correct answer. The correct answer for each question accrues one point (the wrong answer has zero points). Therefore, the scale has a minimum score of zero points (no knowledge) and a maximum score of 15 points (optimal knowledge). The scale has been able to differentiate between HF patients with high and low levels of HF knowledge. Cronbach's α of the knowledge scale was 0.62 (van der Wal, Jaarsma, Moser, & van Veldhuisen, 2005).

3.9.2 | Secondary outcomes

The secondary outcomes for this study will include evaluation of HF Self-care behaviours, HF related readmission and satisfaction (intervention group only).

HF self-care behaviours

The Self-care of Heart Failure Index (SCHFI) version 6.2 will be used to assess self-care behaviours. The SCHFI consists of a 22-question survey used to measure patient activation regarding maintenance (nine items), management (seven items) and confidence (self-efficacy) (six items) with respect to HF self-care. Each of these components has been tested for reliability (maintenance: coefficient alpha = 0.55; confidence: coefficient alpha = 0.83; and management: coefficient alpha = 0.6–0).

The possible total range for maintenance, confidence and management scores is 0–100. In self-care maintenance, the lowest possible raw scale score is 10 and the raw score indicating the best self-care maintenance is 40. For self-care management, the highest possible raw score is 24 and the lowest possible raw scale score is 4. Self-care confidence, the highest possible score is 24 and the lowest possible scale score is 6. The raw score for each sub-scale is transformed to a standardized score of 100 to make them comparable across the three sub-scales. A score of ≥ 70 can be used as the cut-point to judge self-care adequacy (Riegel, Lee, Dickson, & Carlson, 2009).

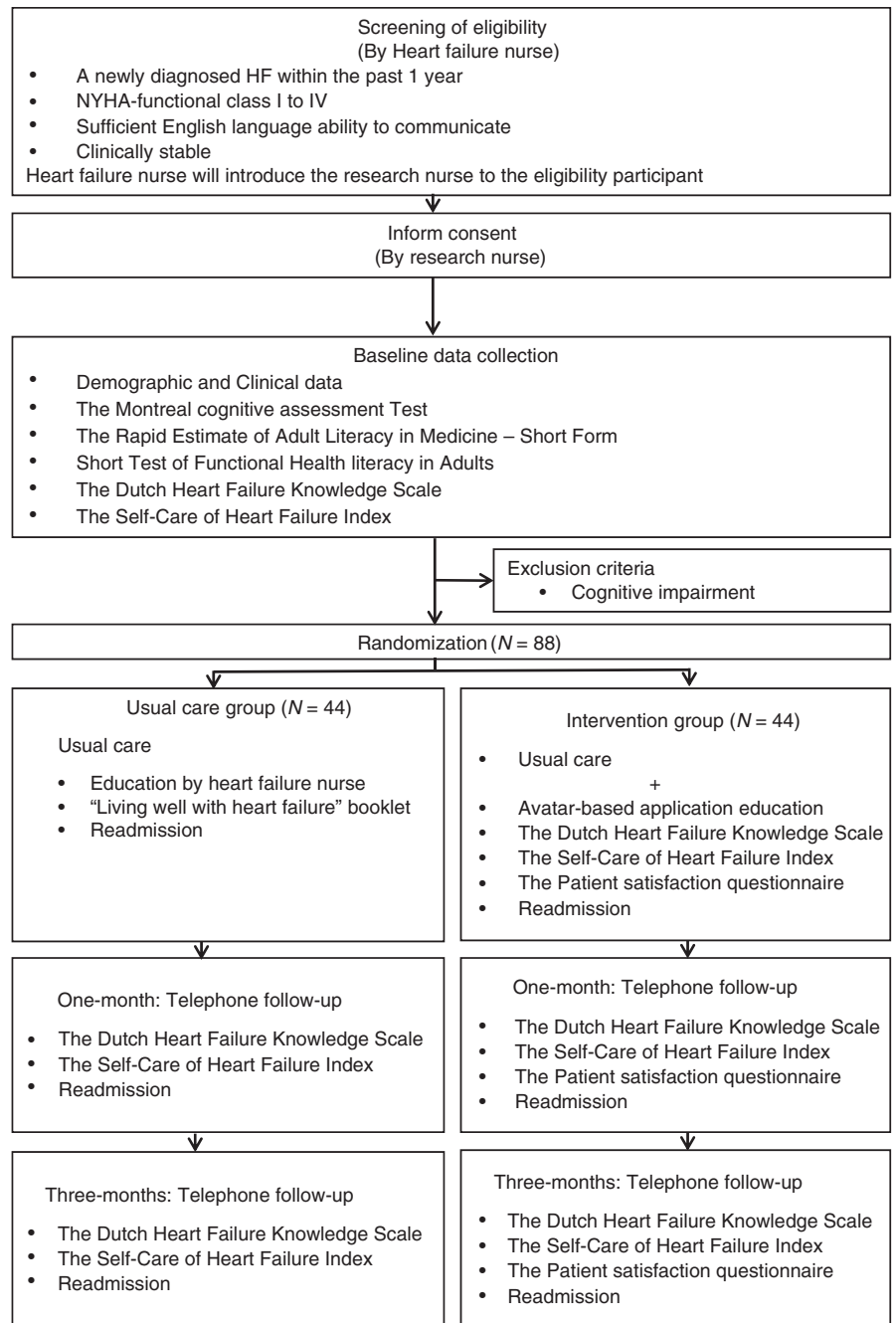


FIGURE 1 The schedule of enrolment, intervention and assessment content

HF related readmission

Readmission will be assessed for HF-caused readmission including both emergency and elective admissions to hospital and unplanned visits to general physician units as measured by self-reporting and a review of medical records for verification of the information.

Satisfaction

Satisfaction will be assessed by the investigator developed avatar-based application satisfaction questionnaire, which is adapted from validated education material acceptability surveys (Clark et al., 2015; Wakefield et al., 2008).

3.9.3 | Baseline data

In addition to the data collected to measure outcomes, at baseline, demographic and clinical information, The Montreal cognitive assessment (MoCA), The Montreal cognitive assessment (MoCA) and Short Test of Functional Health literacy in Adults (STOFHLA) will be collected.

Demographic and clinical information

The demographics data sheet will be used to collect information from patient interviews and medical records. The demographic data

TABLE 1 Timeline of study measurement

Measure	Baseline	1 Month	3 Months
Demographic information	X		
Clinical information	X		
MOCA (Nasreddine et al., 2005)	X		
REALM-SF (Arozullah et al., 2007)	X		
STOFHLA (Baker et al., 1999)	X		
DHFKS (van der Wal et al., 2005)	X	X	X
SCHF1 (Riegel et al., 2009)	X	X	X
Satisfaction	X	X	X
Readmission	X	X	X

Note. MOCA: The Montreal cognitive assessment; REALM-SF: Rapid Estimate of Adult Literacy in Medicine—Short Form; STOFHLA: Short Test of Functional Health literacy in Adults; DHFKS: The Dutch Heart Failure Knowledge; SCHFI: The Self-care Heart Failure Index.

includes gender, date of birth, country of birth, language spoken at home, contact details, marital status, living status, occupation and level of education. The clinical information includes diagnosis, previous medical history, past procedures, family history, smoking status, past admissions, the Charlson Comorbidity Index, left ventricular function, the New York Heart Association functional class, aetiology of HF and cardiac medications.

The Montreal cognitive assessment

The MoCA is a brief 30-question test. The MoCA assesses different types of cognitive abilities, including orientation, short-term memory, executive function, language abilities, attention and visuospatial ability. The MoCA is a relatively simple, brief test that helps health professionals determine quickly whether a person has abnormal cognitive function and may need a more thorough diagnostic work-up. It may predict dementia in people with mild cognitive impairment and because it tests for executive function, it is useful in people with scores of 26 or higher. The MoCA will be used in this study to evaluate potential participants' cognitive function, as a part of assessing their eligibility (Nasreddine et al., 2005).

Rapid Estimate of Adult Literacy in Medicine—Short Form

The Rapid Estimate of Adult Literacy in Medicine—Short Form (REALM-SF) provides researchers with a brief, validated instrument for assessing patient literacy in diverse research settings in the health-care system. It has been widely used in the healthcare settings. In the proposed study, the REALM-SF will be used to assess the health literacy level of study participants at baseline (Arozullah et al., 2007).

Short Test of Functional Health literacy in Adults

The STOFHLA will be used to assess participants' capability to read and understand health information materials. The STOFHLA consists of four Numeracy items and two prose passage. The Cronbach's alpha was 0.68 for the 4 Numeracy items and 0.97 for the 37 items in the two prose passages. The total raw score is 0–36 score. There are three functional health literacy levels including inadequate (0–16

score), marginal (17–22 score) and adequate (23–36 score) (Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

3.10 | Data collection procedure

Data will be collected at baseline using medical record review and face-to face interview and by telephone at the 1- and 3-month follow-up period. Data will be entered into a password protected Excel spreadsheet, which is only accessible to the listed researchers. Data entered will be audited during each week's study meeting by range checks and random audit.

3.11 | Statistical methods

Data from this study will be analysed according to the intention-to-treat principle to provide unbiased assessment of intervention effectiveness. Data will be analysed using the statistics software, Statistic Package for Social Science (SPSS), version 22.

Descriptive statistics will be used to summarize the baseline demographic, clinical status, health literacy and mental status of participants. Continuous data will be summarized using mean, median, standard deviation and standard error of the mean scores, while categorical data will be summarized in terms of percentages. The demographics of the participants in the intervention and usual care groups will be compared by parametric or non-parametric tests.

When comparing the change in knowledge, self-care behaviours, readmission and satisfaction scores over time and between groups, inferential statistics will be used (see details below). A p value of <0.05 is considered statistically significant and all tests are two tailed. Data analysis will be supervised by a statistician who is not involved in the screening, recruitment or follow-up of study participants.

3.11.1 | Primary outcome: HF knowledge

When comparing the change in knowledge scores over time within groups and between the baseline and each follow-up point, paired t test and independent sample t test will be used. To compare a change in participants' knowledge scores from the baseline, the 1-month period and the 3-month period, one-way repeated measures ANOVA will be used. The Kruskal–Wallis test will be used for data that does not meet assumptions of one-way repeated measures ANOVA.

3.11.2 | Secondary outcomes: self-care behaviours, HF related readmission and satisfaction

When comparing the change in self-care behaviour scores over time within groups and between baseline and each follow-up point, paired t test and independent sample t test will be used. To compare a change in self-care behaviour scores from the baseline—the 1-month period and the 3-month period—one-way repeated measures ANOVA will be used. The Kruskal–Wallis test will be used for data

that does not meet assumptions of one-way repeated measures ANOVA. When comparing group differences in terms of HF-caused readmission, Pearson's chi-square test will be used. When comparing the change in knowledge and self-care behaviour scores between patients with low health literacy levels and patients with adequate literacy levels, paired *t* test and independent sample *t* test will be used. When evaluating how satisfied intervention group participants are with the app, the paired *t* test will be used.

4 | ETHICAL CONSIDERATIONS

The ethical principles on which this study will be conducted are based on the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007). Research Ethics Committee approval has been obtained from the Southern Adelaide Clinical Human Research Ethics Committee (HREC/17/SAC/268) in February 2018. The overall project coordination will occur from the College of Nursing and Health Sciences at Flinders University.

The key ethical issue in this study population concerns the vulnerability of participants who have heart conditions. To minimize coercion, the medical and nursing staff will first approach patients in three HF out-patient clinics. The research nurse will then be introduced to individuals who have indicated their willingness to participate. The research nurse will explain the study procedure and provide the Participant Information and Consent Form (PICF). The research nurse will read out aloud the PICF and explain the study in detail to any potential participants so that they can provide informed consent. Participants will be reminded that they can withdraw at any time during the study and that withdrawal from the study will not affect their current or future treatment. Once the patient agrees to participate in this study, they will be asked to sign the written consent form.

A safety monitoring committee will be established by the principal investigators and the research nurse. The safety monitoring committee will meet weekly and will review patient enrolment, site status and other commitments. The data and safety monitoring will consist of three physicians from HF clinics who will review the report of the recruitment and data collection process. If they have any points or suggestions, including the need of stopping the study, the principal investigators will arrange a meeting for discussion.

Any modification to the protocol will be reported to the ethics committee. Such amendments will be agreed on by the research team and approved by the SAC HREC prior to implementation and the health authorities will be notified in accordance with local regulation.

Confidentiality will be ensured by replacing participants' names with numerical codes on all study documents. Data linking each participant's identifying information and participant code will be kept separately and removed prior to analysis. Data collected through this study will be stored in a locked filing cabinet in the researcher's office. Electronic data will be kept on the university network

computer, which is password protected and only accessible to listed researchers.

The researchers intend to publish and present the study results in high impact peer reviewed journals, conferences and research seminars. Only de-identified, aggregated data will be presented. The researchers will provide feedback to key stakeholders such as the South Australian State Health department by presenting outcomes at seminars and conferences.

5 | VALIDITY AND RELIABILITY

Four possible biases associated with a pragmatic randomized controlled trial will be controlled for the study (Borglin & Richards, 2010). First, performance bias will be minimized by strictly following the study protocol by training and supporting the research nurse in data collection processes. Second, the independent, computerized randomization process will be used to control for selection bias, whereas allocation concealment and the use of valid and reliable measurement instruments for outcome assessments will minimize detection bias. Third, data analysis will be performed using an intention-to-treat analysis to prevent possible attrition bias. This study protocol follows the SPIRIT statement (Chan et al., 2013) in conjunction with the TIDieR checklist (Hoffmann et al., 2014).

6 | DISCUSSION

The burden of HF is a continuing global challenge for the healthcare system. Adherence to self-care recommendations is essential for optimal patient outcomes. Poor self-care often leads to acute deterioration and frequent hospitalisation (Jaarsma et al., 2017). Knowledge is the main factor that influences patients' self-care behaviours. Intervention, using a variety of strategies, improves patients' knowledge about self-care, increases patient satisfaction and quality of life and prevents avoidable hospitalisations such as teach back method, telemonitoring, virtual world, interactive multimedia program and a web-based videogame (Dinh et al., 2016; Inglis, Clark, Dierckx, Prieto-Merino, & Cleland, 2017; Kato et al., 2008; Rosal et al., 2014; Strömberg, Dahlström, & Fridlund, 2006). Learning how to practice self-care is challenging, particularly for people with low levels of health literacy. Patients are often provided with printed informational materials they can read; however, a mismatch often exists between the reading levels of those materials and the reading skills and health literacy levels of the intended audience. The previous studies have reported that avatar-based technologies can improve knowledge, self-care behaviours and self-efficacy of patients with chronic diseases (Bedra et al., 2013; Clark et al., 2015; Constance Johnson et al., 2014; Kato et al., 2008; Strömberg et al., 2006). However, there is a lack of evidence regarding the effectiveness of interactive avatar-based education apps for improving knowledge and self-care behaviours in HF patients. If our approach is successful, it can potentially improve the learning experiences of HF patients. In

addition, the use of technology means the content of the app can be easily translated into different languages to assist clinical education of patients from linguistically diverse background.

6.1 | Limitations

This study has some limitations. First, because the avatar-based education app is an education intervention, it will not be possible to blind the participants and the researcher who will conduct the telephone follow-ups. However, data analysis will be supervised by a statistician who is not involved in the screening, recruitment or follow-up of the study participants. Second, both the intervention and the control groups will be treated at the same time at the same clinic. The interactive avatar-based app will be provided to the intervention group in a separate room; however, it will be difficult to prevent contamination between the participants in the intervention group and the participants in the control group. Third, the involvement of only English-speaking participants might limit the generalisation of the study's findings; to address this issue, future research should involve the more commonly spoken local languages of culturally and linguistically diverse groups. Fourth, a systematic bias of participant attrition is likely to occur during the study period of 3 months; to address this concern, participants will be informed the tentative dates of follow-ups and they will receive a message reminder prior to the tentative dates. Our sample size was calculated with the consideration of a 10% attrition rate.

7 | CONCLUSION

This pragmatic randomized controlled trial will be the first study to evaluate the effectiveness of an avatar-based education app for improving HF patients' knowledge and self-care behaviours.

The intervention is a consumer designed, self-administered avatar-based education app that is installed on a tablet and that does not require the Internet for operation. Participants can review the application at any time and at any location that is convenient to them.

This approach will increase accessibility to healthcare information and if successful, interactive avatar-based technology is likely to support and enhance HF patients' education and improve their knowledge and health outcomes particularly for those with low literacy, low health literacy or English as a second language or those without access to specialist HF services.

AUTHOR CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE [<http://www.icmje.org/recommendations/>]):

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

- drafting the article or revising it critically for important intellectual content.

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CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

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