Southern Adelaide Clinical Human Research Ethics Committee

Government of South Australia
SA Health

Flinders UNIVERSITY

General research application form

Project Title:	The effectiveness of a **S**imple avatar-based **A**pplication for impro**V**ing Heart Attack symptom **E**ducation: A Pragmatic randomised controlled trial
Investigator Details:	
Chief Investigators	
Name:	Robyn Clark
Qualifications:	Professor
Department/address:	School of Nursing and Midwifery Flinders University Bedford Park South Australia 5042
Contact details: phone and email	08 8201 3266
The Chief Investigator is to provide either a signature or an email to confirm they are part of the study with this application. Please do not send separately.	YES- an email is included confirming I am part of the study (See attached)
Name:	Huiyun Du
Qualifications:	PhD
Department/address:	School of Nursing and Midwifery Flinders University Bedford Park South Australia 5001
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The Chief Investigator is to provide either a signature or an email to confirm they are part of the study with this application. Please do not send separately.	YES- an email is included confirming I am part of the study (See attached)
Name:	Jintana Tongpeth

Qualifications:	PhD candidate
Department/address:	School of Nursing and Midwifery Flinders University Bedford Park South Australia 5001
Contact details: phone and email	08 8201 5135
The Chief Investigator is to provide either a signature or an email to confirm they are part of the study with this application. Please do not send separately.	YES- an email is included confirming I am part of the study (See attached)
Co-investigators	
Name:	Derek Chew
Qualifications:	Professor
Department/address:	Cardiology
Contact telephone number:	08 8404 2001
Co-investigator agreement All co investigators are to provide either a signature or an email to confirm they are part of the study.	YES- an email is included confirming I am part of the study;
Name:	Sharon Burns
Qualifications:	Head of Cardiac care unit
Department/address:	Cardiac Care Unit
Contact telephone number:	08 8204 4315
Co-investigator agreement All co investigators are to provide either a signature or an email to confirm they are part of the study.	YES- an email is included confirming I am part of the study;
Contact Person	If other than an investigator
Name:	Jintana Tongpeth
Position:	PhD candidate
Department/address:	School of Nursing and Midwifery Flinders University Bedford Park

	South Australia 5001
Contact telephone number:	08 8201 5135
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Are you requesting a waiver of consent?	NO
Genetic Analysis Will there be any genetic (DNA/RNA) analyses?	NO
Financial interest Does the principal investigator have a financial interest in this study?	NO
Is this study commercially sponsored*? A commercial sponsor is the organisation or company that will be invoiced for the SAC HREC review of this application. **Details for invoicing:** Sponsor or coordinating company: ABN: Australian postal address and contact person: Sponsor protocol number for this study:	NO
Is this study funded by a grant? Is this study investigator driven? Is this study part of a cooperative trial group?	NO Yes NO

Where is this research being done in Australia?

Cardiac Care Unit, Flinders Medical Centre, South Australia

SA public health sites: Flinders Medical Centre, South Australia

Interstate public health sites: Nil

Letter of endorsement from the head of department

Please see attached letter from Prof Derek Chew the Director of Cardiology Department, Flinders Medical Centre.

Project Details

1. Background

Cardiovascular disease remains the leading cause of death and disability worldwide [1]. Each year there are more than 48,000 heart attacks in Australia, half of which are fatal. Much of the morbidity and many of the potential preventable complications associated with heart attack are linked with pre-hospital delay in seeking medical treatment [2-4]. Reducing the time from symptom onset to reperfusion therapy in people who are having a heart attack, can decrease the damage to heart muscle and reduce death rate. Reperfusion therapy within the first one to two hours can reduce death rate up to 50% [5]. Longer delay from symptom onset to treatment is associated with higher in-hospital mortality. Transportation and the time from patient's hospital arrival to treatment (in-hospital delay), is decreasing and only contributes to

a small percentage of the total delay time [6]. However the median pre-hospital delay time is 6.4 hours in Australia [7]. The time taken, by patients to decide to seek medical help, accounts for the largest portion of pre-hospital delay, and it is where the greatest improvement is needed in order to optimize patients' outcomes [8].

Evidence-based guidelines recommend that an ambulance should be called within 10 minutes of symptom onset [9]. Unfortunately, warning signs of a heart attack are inconsistent from person to person, and they can be mistaken as symptoms of another non-urgent and non-cardiac conditions (e.g. heartburn), therefore delaying appropriate response. Inadequate knowledge of symptom recognition and symptom management has been documented in the literature and it appears to be consistent with the observed patterns in patients' delay observed [10]. In one study in the United States, individuals with a history of heart disease had five to seven times the risk of having a heart attack or dying, however, 43% of those high-risk patients inappropriately rated their risk of having a heart attack as low. Moreover, 44% of the 3,522 patients (average age 67) with a history of heart attack had a low level of knowledge on heart disease [11]. A research study has shown that 78.15% of the patients (n=254) identified chest discomfort as a symptom of heart attack, 66.7% mistakenly thought the chest discomfort would be severe, sharp and stabbing pain. Almost 50% of the participants identified symptoms of a stroke (e.g. weakness on one side, severe headache, etc.) as the symptoms of a heart attack [8]. People with a history of heart disease need continuous reinforcement of both the nature of the symptoms, and the benefits of early medical treatment [8, 10].

Changes in the health care delivery system have led to shorter length of stay, and reduced the amount of time available for education. Patients are often provided with pamphlets, and booklets for reading; however, a mismatch often exists between the reading levels of health-related materials and the reading skills/health literacy level of the intended audience. Despite these being the groups with the most to gain from education interventions, the existing patient education programs have had limited reach to this population. The use of jargon and technical language has often made educational materials unnecessarily difficult for patients. A recent report showed that three quarters of Australian and New Zealand patients who have had a heart attack, were discharged to home without receiving basic follow-up advice and preventive care [12]. The large US study called the REACT study was conducted to test community based educational interventions, showed only a slight decrease in delay time in the interventions group [13]. Since this disappointing result, there have been few insights to further the development in the area of preventing pre-hospital delay using educational interventions [14]

2. Rationale

Limited health literacy is associated with high health system costs, and it is a challenge to the healthcare system globally. In 2011 the Australian Bureau of Statistics reported that 47% of the Australians are functionally illiterate. This means they cannot read the instructions on a medicine bottle, or even a map, or a recipe. Lack of knowledge regarding the symptoms of a

heart attack is recognized as a major obstacle to timely medical treatment and it is associated with potentially preventable death and complications.

Recent research in neuroscience and in cognitive functioning has increased our understanding of how people learn and how desired outcomes can be achieved through innovative interventions. Factors such as health literacy, numeracy, cognitive capacity and cultural needs influence the patient's learning experience and their capacity to adopt information for decision-making [15-17]. Specifically, cognitive capacity is an important consideration in understanding the design, feasibility and acceptability of patient education interventions [18, 19]. Interactive patient education interventions have been used to overcome barriers such as low literacy and low health literacy, among people living with a variety of conditions, including depression [20], diabetes [21, 22], breast cancer [23] and ileostomy [24]. In recent decades, the use of information technology in education has grown exponentially, such as the use of avatar [24] and simulation [25] Patients are increasingly access information from computer-based and multimedia sources. While positive outcomes of interactive education in different conditions existing in the literature [23], there is no published study on the development and evaluation of interactive education intervention for people at risk of a heart attack. Given the evident knowledge deficiency and pre-hospital decision delay, this interactive patient education approach may have a significant impact on the outcome of people experiencing a heart attack and could revolutionize the way that health information is communicated to patients.

The proposed project has the potential to replace the traditional booklets, brochures and complex medical language in patient education and is one of the first to address the issue of low literacy and low health literacy when communicating with patients who are at risk of heart attack. Our approach will improve patients' ability to recognize and manage heart attack symptoms, therefore improving patient outcome.

3. Objective

The aim of this project is to evaluate the effectiveness of an avatar-based education application for improving patients' knowledge of and responses to chest pain and other heart attack symptoms, through a pragmatic randomised controlled trial.

The specific objectives are:

1. To evaluate the effect of an avatar-based education application on knowledge of heart attack symptoms among patients who have experienced heart attack symptoms.
2. To evaluate the effect of an avatar-based education application on patients' responses to heart attack symptoms and healthcare service utilisation.
3. To compare the effect of an avatar based education application (aimed at improving patients' knowledge of and response to heart attack symptoms), between patients with low health literacy level and patients with an adequate literacy level.

Proposed Methods

1. Study design

A pragmatic randomised controlled trial design, with two parallel groups, will be used to achieve the study's aim.

2. Study duration 1 January 2016 to 30 December 2017

3. Participants

Potential participants will be identified by the nursing shift coordinator, during their hospital stay in the Cardiac Care Unit (CCU) of Flinders Medical Centre. Once consented, participants will undergo a screening phase to assess their eligibility. The study design will include a six-month follow-up period. It is anticipated that approximately 25 participants per week will be recruited.

4. Inclusion criteria and exclusion criteria

Inclusion Criteria	Exclusion Criteria
○ Admitted with any cardiac diagnosis where chest pain or other heart attack symptoms have been experienced previously	○ Clinically unstable
○ Clinically stable*	○ Cognitive impairment
○ Normal cognitive function	○ Failure to give informed consent
○ Sufficient English language ability to communicate and to follow the study procedure	

*Clinically stable is defined as the achievement of five normal vital signs (i.e. heart rate, systolic blood pressure, respiratory rate, oxygen saturation, and temperature) plus normal mental status and ability to eat, for at least 24 hours prior to enrolment in the study.

The nursing shift coordinator will identify potential participants based on his/her clinical judgement of patients' English language ability, cognitive capacity and clinical stability. If a potential participant agrees to be contacted by the study research nurse, the nursing shift coordinator will then introduce the research nurse to the patient at an agreed time. After obtaining consent, the research nurse will screen the potential participant based on the inclusion and exclusion criteria. Participants who are clinically unstable, whose MMSE score is less than 27 or who do not have the language skills to follow the study protocol will be excluded from this study.

5. Withdrawal criteria

Participation in this study is voluntary. Participants are free to withdraw from the study at any time without consequence.

6. Intervention

6.1 Usual care group

"Usual care" in this study means care specific to a patient's diagnosis. Usual care at the study site will include bedside education in order to reinforce the diagnosis, procedures and risk factor management by bedside nurse. Bedside nurses will provide education about emergency chest pain and heart attack symptom action plans and about how to use the angina medicine. As part of usual care, the educational booklet (Heart Foundation's *My heart, my Life*)[26] and/or *Living well with chronic heart failure*) [27] will be provided to all patients. Moreover, the patients will be introduced to the cardiac rehabilitation co-ordinator for information regarding phase I and phase II cardiac rehabilitation programs before they are discharged from the hospital. The usual care group in this study will receive two telephone follow-ups (at one month and six months) after they are discharged from the hospital. Research nurse will contact the Cardiac Rehabilitation Nurse Team before telephone follow-up in order to avoid unknowingly contacting patient's families that the patients have passed away. The purpose of the telephone follow-up is to obtain information on implementation of the heart attack action plan and administer the Acute Coronary Syndrome (ACS) Response Index, Chest Pain Action Plan Survey and Health Services Utilisation questionnaires.

6.2 Intervention group

The education tool (i.e., the app) that will be used in this project is a simple and interactive avatar-based education application. An avatar is an icon or figure representing a particular person in a computer, tablet or smart phone. The app will enhance patient learning by minimising the need for reading, and by using modern computerized tools such as animation, voice and touch screen response; also, there will be no complex medical terminology used in the app (Figure 1).

Participants in the intervention group will receive the usual care plus the avatar-based education application (the app). Once randomisation, an iPad style tablet will be provide to all intervention group participants to view the app and to take home for the study period. The research nurse will provide explanations and instructions to participants on how to use the avatar-based education application. Participants in this group will be asked to use the app before they are discharged from hospital. It will take approximately 10 minutes to go through the app and an additional 10 minutes to complete the associated baseline surveys (i.e., ACS index and satisfaction survey).

Participant will be encouraged to use the app after hospital discharge, during the follow-up period. Two telephone follow-up calls (at one month and six months) will be scheduled with the participants before they are discharged from the hospital. The purpose of the telephone follow-up is to obtain information on implementation of the heart attack action plan and administer the Acute Coronary Syndrome (ACS) Response Index, Heart Attack Action Plan Survey and Health Services Utilisation questionnaires.

Regardless of group allocation, all patients consenting to participate in the study will undertake baseline assessment, including the following:

From the participant's medical record:

- Demographics data
- Clinical information and history
- The Global Registry of Acute Coronary Events (GRACE) Risk Score [28],

From the participant's interview:

- Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF) [29],
- Heart Attack Action Plan Survey,
- Health Services Utilisation, and
- Acute Coronary Syndrome Response Index (ACS Response Index) [30].

Both the intervention and usual care group will receive one-month and six-month telephone follow ups.

Details about each study measurement will be provided in a later section of this document. The Trial schema is illustrated in Figure 2.

8. Outcomes

Primary outcome

- Knowledge of heart attack symptoms as assessed by the Knowledge sub-scale of the ACS Response Index [30].

Secondary outcomes

- Attitudes and beliefs sub-scales of the ACS Response Index [30].
- Response to heart attack symptoms as assessed by the investigator-developed questions based on the Heart Foundation Heart Attack Action Plan [31]. (See Attached Heart Attack Action Plan Survey)
- Health Services Utilisation as assessed by the investigator-developed questions.(See attached Health Services Utilisation Survey)
- Participants' satisfaction as assessed by SAVE Satisfaction Questionnaire (adapted from two validated surveys) [32,33].

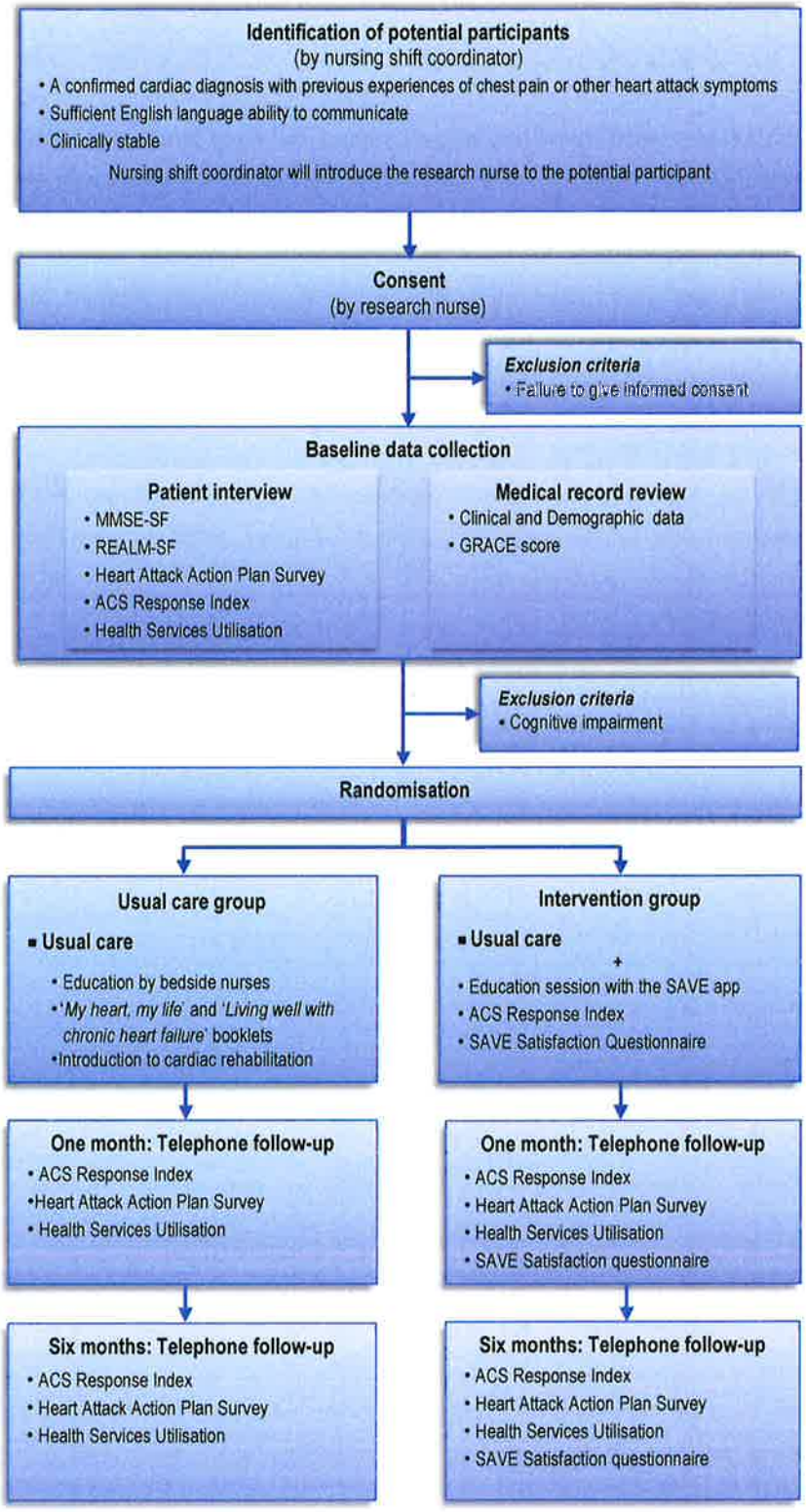

Figure 2: Trial schema

9. Study measurements

The mini mental state examination (MMSE)

The MMSE is the most commonly used instrument for screening cognitive function [34]. This examination is not suitable for making a diagnosis but can be used to indicate the presence of cognitive impairment, such as in a person with suspected dementia or following a head injury. The following cut off levels be used for classification purposes: normal cognitive function =27-30, mild cognitive function impairment = 21-26, moderate cognitive function impairment = 11-20, and severe cognitive function = 0-10 [32]. The MMSE will be used in this study to evaluate potential participants' cognitive function, as a part of assessing their eligibility.

Clinical and Demographic data

Information on the study participants' age, gender, education, domiciliary and employment status, medical history, clinical status, past procedures, other admissions, vital signs, and cardiac biochemistry, including in-hospital risk score (GRACE Risk Score) [28], will be collected at baseline.

The Global Registry of Acute Coronary Events Risk Score (GRACE Risk Score)

The GRACE Risk Score [28], designed to predict in-hospital mortality, was developed from an earlier cohort of GRACE patients. The components of the GRACE RS are age, history of heart failure, history of acute myocardial infarction, heart rate at admission, systolic blood pressure at admission, ST segment deviation, serum creatinine at admission, and elevated troponin and cardiac arrest at admission. In this proposed study, the GRACE Risk Score will be used to provide information on participants' clinical status at baseline.

Rapid Estimate of Adult Literacy in Medicine – Short Form (REALM-SF)

The REALM-SF [35] provides researchers with a brief, validated instrument for assessing patient literacy in diverse research settings in the healthcare 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.

Acute Coronary Syndrome Response Index (ACS Response Index).

The ACS Response Index [30] is a validated instrument for assessing patients' knowledge, attitudes and beliefs about heart attack symptoms. It includes 21 knowledge subscales, six attitudes subscales and seven beliefs subscales. In the proposed study, the ACS Response Index will be used to assess the knowledge, attitudes and beliefs regarding heart attack symptoms of the study participants.

Heart Attack Action Plan Survey

The Heart Attack Action Plan Survey is an investigator-developed questionnaire for assessing participants' response to heart attack symptoms. It is adapted from the Heart Foundation's Heart Attack Action Plan, including participants' symptoms experiences and their behavioural

responses (STOP, TALK and CALL) (Figure 3) [31]. This information will be collected at baseline, one-month and six-month follow-ups. The purpose of this questionnaire is to evaluate the effect of the app on participants' response to heart attack symptoms.

Figure 3 Heart Attack Action Plan

Health Services Utilisation

Health Services Utilisation is an investigator-developed questionnaire for assessing participants' health-behaviour (including emergency services or GPs). This information will be collected at baseline, and at one-month and six-month follow-ups. The purpose of this questionnaire is to evaluate the effect of the app on participants' response to heart attack symptoms.

Simple avatar-based Application for ImproVing Heart Attack Education (SAVE)-Satisfaction Questionnaire

Intervention Satisfaction Questionnaire is a 15-item Likert scale. This survey is adapted from validated education material acceptability surveys [32, 33]. The aim of this survey is to assess the participants' perception of the avatar-based education application in terms of audio-visuals, content, usefulness and user-friendliness.

7. Statistical analysis (including justification of sample size, if relevant):

Sample size

The change in the knowledge sub-scale of the ACS Response Index [30] between the control and the intervention groups in a previously published study was used to calculate the required sample size [36]. A sample size calculation was performed using a standard deviation of 2.9 and an effect size of 0.42 for ACS Response Index, which was determined from a previously published study [36]. The require sample size per group was calculated to be 31 (alpha=0.05, power=0.95) this calculation was performed using the independent sample t-test and test by Power Analysis and Sample Size (PASS) software [37, 38]. When taking into account a 10% attrition rate, 70 participants (35 per group) must be enrolled in the study.

8. Recruitment and randomisation

Recruitment

The research nurse will not approach potential participants directly. Potential participants will be identified during their hospital stay in the CCU at Flinders Medical Centre by the nursing shift coordinator. The inclusion and exclusion criteria will be provided to the nursing shift coordinator. The nursing shift coordinator will identify potential participants and obtain their permission to be contacted by the research nurse, as well as the patient's preferred time to be contacted. With the patient's permission, a research nurse (JT or HYD) will approach the patient with the nursing shift coordinator to provide the Patient Information and Consent Form (PICF) and to further explain the purpose and the protocol of this study.

Once consent is obtained, participants will undergo a screening phase to assess their eligibility. Based on current admission statistics it is anticipated that approximately 25 participants per week will be recruited. A study log will be maintained where all individuals screened and their reasons for not participating will be documented.

Randomisation

Randomisation will occur after consent and completion of baseline assessment (See Figure 2). This is to ensure that the baseline assessment will not be affected by the participant's group allocation. The design of this type of patient education research means that the participant's group allocation will be obvious to the researcher and the participants after randomisation.

Upon completion of the baseline assessment, the research nurse will contact the telephone randomisation service to obtain group allocation.

Block randomisation sequence will be generated in blocks of 10 by the Excel computer software program. Participants' detail will be recorded with their group allocation in a secure file only accessible to the administrative assistant responsible for randomisation.

9. Allocation concealment mechanism

The Excel file containing allocation sequences will be password protected and only accessible to an administrative assistant (randomisation service) who is based externally to the study

site and who will not be involved in the process of recruitment, implementation and data analysis.

10. Blinding

As the avatar-based education application is an education intervention, blinding of the participants and the researcher who will conduct telephone follow-ups is not possible. Thus, a non-blinded pragmatic randomised control trial will be used.

11. Statistical methods

Data from this study will be analysed according to the intention-to-treat principle, in order to provide unbiased assessment of intervention effectiveness. Data will be analysed by using the statistics software - Statistic Package for Social Science (SPSS), version 22 [39].

Descriptive statistics will be used to summarise the baseline demographic, clinical status, health literacy and mental status of participants. Continuous data will be summarised using mean, median, standard deviation and standard error of the mean scores, whilst categorical data will be summarised in terms of percentages. The demographics of the participants in the intervention and usual care groups will be compared using the independent sample t-test or Pearson's Chi-square test, to measure differences including age and gender. Continuous data with normal distribution will be analysed using the independent t-test, and the Mann-Whitney U test will be used for non-normally distributed data. Association between categorical data will be analysed using the Chi-square test. When comparing the change in ACS Response Index subscale scores overtime and between groups, ANCOVA will be used. The Mann-Whitney U test will be used for data that does not meet the assumptions of ANCOVA. Statistical significance will be considered at $P<0.05$ unless otherwise specified. All test result reported will be two-tailed. Data analysis will be supervised by a statistician who is not involved in the screening, recruitment or follow-up of the study participants.

Assessment of Participants

1. Clinical Assessment (Medical record review):

Routine clinical data includes: height and weight, previous medical history, risk factors, past cardiac procedure, smoking status, past admission in previous 12 months, GRACE Risk Score, Charlson index of comorbidity, vital sign and cardiac biochemistry.

2. Pathology: Participants will not undertake additional laboratory tests for this project. Cardiac biochemistry will be recorded. Cardiac biochemistry will not be done specifically for this research.

3. Other (e.g. radiological) Assessment: Participants will not undertake other assessment.

4. Monitoring adverse effects

Serious Adverse Effect (SAE) will be defined as any untoward medical, emotional, psychological occurrence resulting in hospitalisation or prolongation of hospitalisation, SAE will be defined as any untoward occurrences in study participants, potentially related to

implementation of the study protocol. Information regarding SAE will be collected during telephone follow-ups.

5. Significant adverse effects should be reported to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)

   SAEs for clinical research study at Flinders Medical Centre site will be reported to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) via the Executive Officer within 48 hours of the event becoming known to the local investigator.

Research relating specifically to the Aboriginal community:

This study is not specificlly related to Aboriginal community.

Important information for researchers intending to undertake research in South Australian schools. N/A

Researcher indemnity

Please see attached documentation from the Insurance Officer, Flinders University

Registration of Clinical Trials N/A

Administrative Aspects

1. Name of a contact person, the company name and the ABN of the commercial sponsor MUST be included on page 1. A commercial sponsor is the organisation or company that will be invoiced for the SAC HREC review of this application

   Ms Jintana Tongpeth is the contact person for this study.

   This study is not commercially sponsored.

2. Provision of source and details of funding (Grant, investigator driven, CTG) including payment per participant.

   N/A

3. Clinical data sheets

   The following documents are attached with your application:

   1. Baseline assessment form (Demographic and Clinical information, GRACE Risk Score, MMSE,REALM-SF, ACS Response Index, Heart Attack Action Plan Survey, and Health Services Utilisation)
   2. Post intervention survey for intervention group (ACS Response Index, and SAVE Satisfaction Questionnaire)
   3. One-month follow-up form (ACS Response Index, Heart Attack Action Plan Survey, and Health Services Utilisation, SAVE Satisfaction Questionnaire)
   4. Six-month follow-up form for intervention group (ACS Response Index, Heart Attack Action Plan Survey, Health Services Utilisation, and SAVE Satisfaction Questionnaire

5. Six-month follow-up form for usual care group (ACS Response Index, Heart Attack Action Plan Survey, and Health Services Utilisation)

4. Maintenance of records

All data will be collected in a de-identified form. Data collected through this study will be stored in a locked filing cabinet in the researcher's office within the School of Nursing and Midwifery, Flinders University. Electronic data will be kept on the Flinders University network computer in the School of Nursing and Midwifery, Flinders University, which is password protected. All study-related data will only be accessible to the researchers listed at the beginning of this document. All data will be retained for seven years, and then it will be destroyed permanently.

5. Special facilities required and use of hospital facilities: No

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). Ethical approval for this study will be obtained from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC), which is a joint committee of the Southern Adelaide Local Health Network and Flinders University. The overall project coordination will occur from School of Nursing and Midwifery.

1. Benefits anticipated from study.

The aim of this project is to evaluate an education application to help patients, particularly those with low literacy, to gain knowledge on heart attack symptoms and the appropriate responses to those symptoms.

2. Risks of any harm - including physical disturbance, discomfort, anxiety or pain.

The research team does not foresee any physical or emotional risk from taking part in this research.

3. Research involving dependent relationships-that includes patients of the researcher, staff, and student, children, mentally ill, intellectual impaired.
N/A

4. Separation of research and clinical responsibilities

N/A

5. Treatment of control group

N/A

6. Use of placebo

N/A

7. Source of payment for normal participants.

   Participants will not be paid for their participation in this study. All participants will be offered the avatar education application to keep for their use after completion of the study.

8. Protection of privacy and preservation of confidentiality.

   Protection of privacy

   Data protection at the School of Nursing and Midwifery meets all standards and follows all steps to protect other people's personal information under the Information Privacy Principles. The system and processes with respect to privacy and data protection comply with Health Records and Information Privacy Act (NSW) 2002, and Privacy Act (1988) and the Information Privacy Principles. Data access is limited to the authorised researchers listed at the beginning of this document.

   Confidentiality

   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 will be removed prior to analysis. Any information or comments provided by participants will be collected in a de-identified form. Data collected through this study will be stored in a locked filing cabinet in the researcher's office within the School of Nursing and Midwifery, Flinders University. Electronic data will be kept on the Flinders University network computer in the School of Nursing and Midwifery, Flinders University, which is password protected. All study-related data will only be accessible to the researchers listed at the beginning of this document. Paper based data will be stored for seven years and then shredded; electronic data will be deleted permanently from the Flinders University network computer.

9. Restriction of use of data.

   Data ownership and publication: Ownership of the data collected during the Pragmatic Randomised Control Trial is retained by the School of Nursing and Midwifery under Flinders University. Persons contributing to the design, analysis or the writing process will be listed as authors on publications associated with this study. Data collected through this project will only be used for the purpose of this project.

Consent Process

The key ethical issue in this study population concerns the vulnerability of the participants who have heart conditions. To minimise coercion, the nursing shift coordinator will first approach patients in cardiac care unit, Flinders Medical Centre. 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 that have a low level of literacy 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.

Each patient will be asked to read the Patient Information sheet and consent form (PICF), and the research nurses (JT, HYD) will answer any questions that the patient may have. The patient does not have to provide consent immediately. He or she will be encouraged to think about the project and discuss it with others if they wish to. The contact details of the researchers will be provided to the patient. Once the patient agrees to participate in this study, they will be asked to sign the written consent form, in the presence of a witness.

A copy of the signed consent form is to be filed in the participant's medical record

The signed consent will be filed in the participant's medical record.

How will the study be promoted or advertised?

The research team will introduce the research project through the Director of Cardiology Department, and CCU manager, Flinders Medical Centre and through in-service sessions on the ward.

Statement of compliance with NH&MRC National Statement on Ethical Conduct in Human Research (2007) & the Australian Code for the Responsible Conduct of Research (2007)

By submitting this application the applicant(s) will comply with both of the above documents. All researchers are expected to be familiar with their responsibilities under each document. The application must include a statement that the project complies with the above documents.

STATEMENT: I hereby declare that " The effectiveness of a Simple avatar-based Application for improVing Heart Attack symptom Education: A Pragmatic Randomised Controlled Trial" trial complies with the above documents

Signed: 

Print name: Professor Robyn Clark

Dated: 26 / 09 / 2016

References

1. Fihn, S.D., et al., 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: executive summary: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. Circulation, 2012. 126(25): p. 3097-137.
2. Lloyd-Jones, D., et al., Heart disease and stroke statistics—2010 update A report from the American Heart Association. Circulation, 2010. **121**(7): p. e46-e215.
3. Furie, K.L., et al., *Guidelines for the prevention of stroke in patients with stroke or transient ischemic attack a guideline for healthcare professionals from the American Heart Association/American Stroke Association.* Stroke, 2011. **42**(1): p. 227-276.
4. Mays, N., *Origins and development of the National Health Service.* Sociology as applied to medicine, 2008: p. 221-251.
5. C.-H, R., *Patient delay from onset of chest pain suggesting acute coronary syndrome to hospital admission.* Scandinavian Cardiovascular Journal, 2003. **37**(4): p. 183-186.
6. Gersh, B.J., et al., *Pharmacological facilitation of primary percutaneous coronary intervention for acute myocardial infarction: is the slope of the curve the shape of the future?* Jama, 2005. **293**(8): p. 979-986.
7. Nestler, D.M., et al., *Sustaining Improvement in Door-to-Balloon Time Over 4 Years The Mayo Clinic ST-Elevation Myocardial Infarction Protocol.* Circulation: Cardiovascular Quality and Outcomes, 2009. **2**(5): p. 508-513.
8. Dracup, K., S.M. McKinley, and D.K. Moser, *Australian patients' delay in response to heart attack symptoms.* Medical Journal of Australia, 1997. **166**(5): p. 233-236.
9. Poomsrikaew, O., C.J. Ryan, and J.J. Zerwic, *Knowledge of heart attack symptoms and risk factors among native Thais: A street intercept survey method.* International journal of nursing practice, 2010. **16**(5): p. 492-498.
10. Foundation, N.H., *Will you recognise your heart attack? .* In: Foundation NH 2010. **editor**
11. Goff Jr, D.C., et al., *Prehospital delay in patients hospitalized with heart attack symptoms in the United States: The REACT trial.* American Heart Journal, 1999. **138**(6): p. 1046-1057.
12. Dracup, K., et al., *A randomized clinical trial to reduce patient prehospital delay to treatment in acute coronary syndrome.* Circ Cardiovasc Qual Outcomes, 2009. **2**(6): p. 524-32.
13. S., S., *Majority of MI patients discharge with out follow-up advice* mEDICAL oBSERVER 2014.
14. Luepker, R.V., et al., *Effect of a community intervention on patient delay and emergency medical service use in acute coronary heart disease: The Rapid Early Action for Coronary Treatment (REACT) Trial.* Jama, 2000. **284**(1): p. 60-67.
15. Tsai, S.-T. and F.-H. Chou, *The effectiveness of multimedia nursing education on reducing illness-related anxiety and uncertainty in myocardial infarction patients after percutaneous coronary intervention [Chinese].* Journal of Nursing, 2012. **59**(4): p. 43-53.
16. Dennison, C.R., et al., *Adequate health literacy is associated with higher heart failure knowledge and self care confidence in hospitalized patients.* The Journal of cardiovascular nursing, 2011. **26**(5): p. 359.
17. McNaughton, C.D., et al., *Low numeracy is associated with increased odds of 30-day emergency department or hospital recidivism for patients with acute heart failure.* Circulation: Heart Failure, 2013. **6**(1): p. 40-46.
18. Davidson, P.M., S.C. Inglis, and P.J. Newton, *Self-care in patients with chronic heart failure.* 2013.
19. Dickson, V.V., N. Tkacs, and B. Riegel, *Cognitive influences on self-care decision making in persons with heart failure.* American heart journal, 2007. **154**[1]: p. 424-431.
20. Bennett, S.J. and M.J. Sauvé, *Cognitive deficits in patients with heart failure: a review of the literature.* Journal of Cardiovascular Nursing, 2003. **18**[1]: p. 219-242.
21. Pinto, M.D., et al., *Avatar-based depression self-management technology: promising approach to improve depressive symptoms among young adults.* Appl Nurs Res, 2013. **26**(1): p. 45-8.
22. Boren, S.A., et al., *Computerized learning technologies for diabetes: a systematic review.* Journal of diabetes science and technology, 2008. **2**(1): p. 139-146.
23. Heinrich, E., et al., *Evaluation of the web-based Diabetes Interactive Education Programme (DIEP) for patients with type 2 diabetes.* Patient education and counseling, 2012. **86**(2): p. 172-178.

24. Jibaja-Weiss, M.L., et al., *Entertainment education for breast cancer surgery decisions: a randomized trial among patients with low health literacy.* Patient education and counseling, 2011. **84**(1): p. 41-48.
25. Bedra, M., et al., *Avatar-Based Interactive Ileostomy Education in Hospitalized Patients.* Informatics, Management and Technology in Healthcare, 2013. **190**: p. 83.
26. Australia, National Heart Foundation., My heart my life. 2012.
27. Australia, National Heart Foundation., Living well with chronic heart failure. 2011
28. Goodacre, S.W., et al., *Evaluation of Global Registry of Acute Cardiac Events and Thrombolysis in Myocardial Infarction scores in patients with suspected acute coronary syndrome.* The American Journal of Emergency Medicine, 2012. **30**(1): p. 37-44
29. Arozullah, A.M., et al., *Development and validation of a short-form, rapid estimate of adult literacy in medicine.* Medical care, 2007. **45**(11): p. 1026-1033.
30. Riegel, B., et al., *Psychometric evaluation of the acute coronary syndrome (ACS) response index.* Research in nursing & health, 2007. **30**(6): p. 584-594.
31. Foundation, N.H., Will you recognise your heart attack? . In: Foundation NH 2010.
32. Gwadry-Sridhar, F., et al., *Instruments to measure acceptability of information and acquisition of knowledge in patients with heart failure.* European journal of heart failure, 2003. **5**(6): p. 783-791.
33. Fredericks, B., et al., *Using participatory action research to assist heart failure self-care amongst indigenous Australians: a pilot study.* ALAR: Action Learning and Action Research Journal, 2013. **19**(2): p. 40.
34. Folstein, M.F., S. Folstein, and P. Mc Hugh, Mini-mental state examination: MMSE-2. 2010: Psychological Assessment Resources.
35. Ibrahim, S., et al., *Validation of a health literacy screening tool (REALM) in a UK population with coronary heart disease.* Journal of public health, 2008. **30**(4): p. 449-455.
36. Tullmann, D.F., et al., *A randomized controlled trial to reduce delay in older adults seeking help for symptoms of acute myocardial infarction.* Research in Nursing & Health, 2007. **30**(5): p. 485-497.
37. Julious, S.A. and M.J. Campbell, *Tutorial in biostatistics: sample sizes for parallel group clinical trials with binary data.* Statistics in medicine, 2012. **31**(24): p. 2904-2936.
38. Suresh, K. and S. Chandrashekara, *Sample size estimation and power analysis for clinical research studies.* Journal of human reproductive sciences, 2012. **5**(1): p. 7.
39. Wagner III, W.E., *Using IBM® SPSS® statistics for research methods and social science statistics*. 2014: Sage Publications.