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Improving physical and psychological symptoms in inpatients post heart attack through the symptom self-management programme

Submission date
18/06/2014

Recruitment status
No longer recruiting

Registration date
05/08/2014

Overall study status
Completed

Last Edited
12/08/2020

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Heart attack [acute myocardial infarction (AMI)] is the leading cause of death across the world. Generally, people with AMI have severe physical symptoms (such as chest pain, breathlessness, and vomiting) requiring immediate treatment and hospitalization. They are also at a risk for developing psychological symptoms such as stress, depression, and anxiety. Therefore, there is a need to develop nursing interventions to help people manage their physical and psychological symptoms after a heart attack. This study aims to find out if the symptom self-management program can help patients self-manage their physical and psychological symptoms after a heart attack.

Who can participate?
Adult patients admitted in the hospital, who have a confirmed diagnosis of acute myocardial infarction.

What does the study involve?
Enrolled participants will be randomly allocated to one of these treatment conditions: a) hospital standard care (control group), b) standard care with the symptom self-management program delivered through virtual reality device (IManage-VR) which has audio-visual presentations, and c) standard care with the symptom self-management program delivered through a face-to-face method (IManage-FF).

What are the possible benefits and risks of participating?
Those in the IManage-VR and IManage FF groups will have the opportunity to learn how to manage physical and psychological symptoms relating to heart attack. Risks are not expected from participating in this study. Participants in the control group will receive standard care provided by hospital.

Where is the study run from?
Cardiovascular wards at a tertiary hospital in Singapore

When is the study starting and how long is it expected to run for?
The study started in August 2013 and will run for two years

Who is funding the study?
National University of Singapore (NUS) (Singapore)

Who is the main contact?
Dr Piyanee Yobas
nurpk@nus.edu.sg

Contact information

Type(s)
Scientific

Contact name
Dr Piyanee Yobas

Contact details
Alice Lee Centre for Nursing Studies
National University of Singapore
Level 2, Medical Research Centre, MD11
10 Medical Drive
Singapore
Singapore
117597
+65 (0)65167789
nurpk@nus.edu.sg

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EudraCT/CTIS number

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Secondary identifying numbers
HSRNIG12nov005

Study information

Scientific Title
Improving physical and psychological symptoms in inpatients with acute myocardial infarction through the symptom self-management programme: a pilot randomised controlled trial

Study objectives
Hypothesis 1:
In comparison with the control group, inpatients post-acute myocardial infarction (post-AMI) who complete the symptom self-management programme will report significantly:

1.1. Lower levels of chest pain, stress, anxiety, depression, number of re-hospitalization and emergency visits, and health care cost
1.2. Greater levels of perceived relaxation and cardiac self-efficacy

Hypothesis 2:
Participants in the experiment and control groups will identify strengths, weaknesses, usefulness, areas for improvement, and undesirable effects of the programme they attend.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHG Domain Specific Review Board (DSRB); 31/10/2013; ref. 2013/00801

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Care for people post-myocardial infarction

Interventions
There are three treatment conditions in this study

1. The IManage-VR programme is a two one-hour individual-based symptom self-management intervention delivered in two consecutive days, four weekly follow-up telephone calls, a booster session, and homework assignment. This programme, delivered via a virtual reality (VR) device, comprises an educational component, the practice of relaxation techniques, and a homework assignment. The VR device is perceived to induce quicker and deeper relaxation as it simultaneously offers pleasant visual presentations (e.g., peaceful sceneries) and audio functions (e.g., music and voice instruction). Furthermore, the use of the VR device is perceived to better reduce distractions from the environment and thus may enhance learning outcomes.

2. The IManage-FF programme is a two one-hour individual-based symptom self-management intervention delivered in two consecutive days, four weekly follow-up telephone calls, a booster session, and homework assignment. It will also contain two major components: education and

the practice of relaxation techniques. However, this programme will be delivered using a conventional face-to-face method. Only audiotape instruction (i.e. relaxation CD) will be used to guide the practice of relaxation.

3. Standard care includes usual evidence-based treatments and services provided by the hospital. All patients also receive a single-session, individual-based, one-hour long patient education. This session teaches patients about AMI and management of AMI (such as healthy diet and exercise)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1.Chest pain will be measured by the perceived chest pain scale. On the single-item Numeric Rating Scale (a 10-centrimetre continuum line), participants will give a number corresponding to their pain level between 0 (no pain) and 10 (unbearable pain).
2. Objective stress will be measured by bio-physiological instruments. Heart rate will be assessed in beats/min. Blood pressure will be measured by using the B-PRO device, a lightweight wristwatch-like blood pressure machine (Dasrao, Yeo, Sim, 2001). Oxygen saturation will be measured by C3G Finger Tip Pulse Oxymeter (Devon Medical, 2011). Skin temperature will be measured by Stress ThermometerTM #SC911 (Biofeedback instrument cooperation, 2003) and lower skin temperature reflects a higher level of stress. Salivary alpha amylase will be analysed using an ELISA method.
3. Subjective stress will be measured with the 7-item Depression subscale of the Depression, Anxiety, and Stress scale (DASS; Lovibond & Lovibond, 1995). The subscale has four response categories ranging from 0 (did not apply to me at all) to 3 (applied to me most of the time). Possible scores of each subscale are in the range of 0 - 21 with higher scores indicating higher stress levels. Cronbachs alphas of the subscale in the range of 0.86 0.90 (Mahmoud et al., 2010).

Secondary outcome measures
1. Anxiety and depression will be measured with corresponding subscales of the DASS (Lovibond & Lovibond, 1995). Each subscale has seven items with four response categories ranging from 0 (did not apply to me at all) to 3 (applied to me most of the time). Possible scores of each subscale are in the range of 0 - 21 with higher scores indicating higher anxiety or depression levels. Cronbachs alphas of the anxiety subscale (0.86-0.90), and depression (0.82 - 0.90) are in acceptable ranges (Mahmoud et al., 2010).
2. Cardiac self-efficacy (participants confidence in their ability to take care of their health) will be assessed by the 13-item Cardiac Self-efficacy Scale (Sullivan, et al., 1998). Patients will rate on a 5-point scale, from 0 (not at all confident) to 4 (completely confident). Total scores range from 0 to 52 with higher scores indicating greater levels of cardiac self-efficacy. The scale has high internal consistency (= 0.87) with good discriminant/convergent validity (Sullivan, et al., 1998).
3. Perceived relaxation will be measured by the perceived relaxation scale. Participants will rate their relaxation level on a single-item Numeric Rating Scale: a 10-centimetre continuum line starting from 0 (very tensed) to 10 (very relaxed).
4. The number of rehospitalisation and emergency visits within six months following the current hospitalisation will be retrieved from patients records.
5. Length of hospital stay associating with the current episode of AMI will be recorded in number of days.

6. Healthcare cost will be retrieved from patients records. All medical expenses relating to the treatments of AMI within six months will be collected. Patients will also be asked about healthcare expenses relating to AMI treatments they receive at other healthcare facilities during the first follow-up visit (one month) and six months later.
7. Perception of interventions will be obtained through open-ended questions. Participants will describe how they feel about the programmes, identify strengths/weaknesses, list most helpful /least helpful aspects, indicate undesirable effects (if any), and provide suggestion for improvement.
8. Demographic information (including age, gender, education, religion, housing arrangement, occupation, family income) and clinical data (medical diagnoses, length of medical diagnoses, and treatments) will be collected.

Overall study start date
22/08/2013

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Adult inpatients of any gender aged between 21 to 65 years old
2. Having a confirmed diagnosis of AMI by their attending physician
3. Having an ability to communicate in English
4. Having access to a computer, tablet, or smartphone at home (to review VCD/CD)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Are less than 21 or older than 65 years old
2. Present with severe comorbidity (such as congestive heart failure)
3. Have been diagnosed with mental disorders (such as schizophrenia)

Date of first enrolment
22/08/2013

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
Singapore

Study participating centre
Alice Lee Centre for Nursing Studies
Singapore
Singapore
117597

Sponsor information

Organisation
National Medical Research Council (Singapore)

Sponsor details
Ministry of Health
#09-10/11 Helios
11 Biopolis Way
Singapore
Singapore
136667
+65 (0)63258130
MOH_NMRC@moh.gov.sg

Sponsor type
Research council

Website
http://www.nmrc.gov.sg

ROR
https://ror.org/04x3cxs03

Funder(s)

Funder type
University/education

Funder Name
National University of Singapore (NUS) (Singapore) - Health Service Research, New Investigator Grant

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2015		Yes	No