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Examining the effectiveness of a self-help psychoeducation programme on outcomes of outpatients with coronary heart disease (CHD)

Submission date
03/01/2014

Recruitment status
No longer recruiting

Registration date
21/01/2014

Overall study status
Completed

Last Edited
11/02/2021

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Rehabilitation programmes run in hospitals can improve the quality of life of patients with heart disease. However, most patients do not participate in these programmes, while those who do participate do not complete the programme. A different approach to deliver the cardiac rehabilitation programme should be considered to improve patients' recovery. The aim of this study is to develop and examine the effectiveness of a home-based self-help psychoeducation programme on the quality of life, stress level, anxiety and depression symptoms, cardiac risk factors, and health service use of outpatients with heart disease.

Who can participate?
Adult outpatients of the participating hospital who have been diagnosed with coronary heart disease will be recruited in this study.

What does the study involve?
Once the patients have been enrolled into the study, they will be randomly allocated to either a home-based self-help psychoeducation programme group or another group without this programme. Study participants in both groups will be given the same questionnaires three times during the four-month study period. The research assistant will meet the study participants to give these questionnaires. At the end, participants who underwent the home-based self-help psychoeducation programme will be invited for individual face-to-face interviews.

What are the possible benefits and risks of participating?
There may be several benefits for the participants who receive the home-based self-help psychoeducation programme. These include a more positive perception of quality of life, lower stress levels, lesser symptoms of anxiety and depression, greater self-efficacy and a decrease of cardiac risk factors. There are no foreseeable risks for study participants.

Where is the study run from?
This study is run from the National University Heart Centre based in the National University Hospital, Singapore.

When is the study starting and how long is it expected to run for?
The recruitment is planned to start in January 2015 and end in December 2015.

Who is funding the study?
Ministry of Education (Singapore) will be funding this study.

Who is the main contact?
Dr Wang Wenru, wenru_wang@nuhs.edu.sg
Mr Aloysius Chow, nurca@nus.edu.sg

Contact information

Type(s)
Scientific

Contact name
Dr Wenru Wang

Contact details
Alice Lee Centre for Nursing Studies
Yong Loo Lin School of Medicine
National University of Singapore
10, Medical Drive, Block MD11
Clinical Research Centre, Level 2
Singapore
Singapore
117597
+65 6601 1761
wenru_wang@nuhs.edu.sg

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized controlled trial of the effectiveness of a self-help psychoeducation programme on outcomes of outpatients with coronary heart disease

Study objectives
When compared with study participants who are randomised into the group without the self-help psychoeducation programme, study participants in the group with the self-help

psychoeducation programme will report a more positive perceived health-related quality of life, lower stress levels, lesser anxiety and depression symptoms, greater self-efficacy, lesser cardiac risk factors (i.e. levels of lipids, body mass index, blood pressure, and tobacco use) and also lower reported use of health services (e.g. cardiac-related hospital re-admission).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Domain Specific Review Board of the National Healthcare Group, Singapore, October 2013, NHG DSRB reference number: 2013/007270

Study design
Two groups randomised controlled trial at a single site

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Coronary Heart Disease

Interventions
Participants are randomised to two groups:

1. Intervention group: the intervention used in this study is the the self-help psychoeducation programme, which includes an education booklet, an accompanying DVD and an education session conducted by a member of the research team.
2. Control group: will not receive any additional intervention

All study participants will continue to receive their usual care from the hospital during their participation in this study.

Intervention Type
Behavioural

Primary outcome measure
1. The cardiac risk factors (i.e. levels of lipids, body mass index, blood pressure, and tobacco use) will be recorded by a form designed by the research team

2. The amount of health service use (e.g. cardiac-related hospital re-admission) will be recorded by a form designed by the research team
3. Health-related Quality of Life (HRQoL) will be assessed using the 12-item Short Form Health Survey (SF-12v2). The SF-12 is a shorter version of the SF-36v2 (Ware, Kosinski & Keller, 1996).
4. The Perceived Stress Scale (PSS) measures the perception of stress of an individual (Cohen, Kamarck & Mermelstein, 1983)
5. Hospital Anxiety and Depression Scale (HADS) assesses for the presence of anxiety or depression in physically ill patients (Zigmond & Snaith 1983)
6. Self-efficacy will be assessed by the General Self-efficacy Scale, which measures the competency to manage challenging events (Schwarzer & Jerusalem, 1995)

The measures will be administered at baseline, the 4th week from baseline and the 12th week from baseline.

Secondary outcome measures
A process evaluation which utilises a qualitative approach using in-depth focused, individual face-to-face interviews will be used to measure the suitability, strengths and weaknesses of the self-help psychoeducation programme at baseline, the 4th week from baseline and the 12th week from baseline.

Overall study start date
02/01/2015

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Has a medical diagnosis of CHD
2. Has been discharged from the hospital and lives at home
3. Does not intend to attend hospital-based cardiac rehabilitation programmes
4. At least 21 years old
5. Can communicate on the telephone
6. Can speak and understand English

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
128

Total final enrolment
129

Key exclusion criteria
1. Suffers from complications (e.g. uncontrolled arrhythmias)
2. Has undergone cancer treatment, and other illnesses that will limit participation
3. Has a known history of major psychiatric illness
4. Has pre-existing mobility difficulties
5. Has major auditory and vision problems

Date of first enrolment
02/01/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Singapore

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

Sponsor information

Organisation
National University Health System (Singapore)

Sponsor details
NUHS Research Office
1E Kent Ridge Road
NUHS Tower Block
Level 6
Singapore
Singapore
119228
+65 6772 3718
medv951@nus.edu.sg

Sponsor type
Government

ROR
https://ror.org/05tjjsh18

Funder(s)

Funder type
Government

Funder Name
Ministry of Education (Singapore) - Academic Research Fund Tier 1, Grant Number: T1-2013 Apr -05

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	01/10/2015		Yes	No
Results article	results	01/10/2018	11/02/2021	Yes	No