ISRCTN12160517 https://doi.org/10.1186/ISRCTN12160517

Improving attendance at cardiac rehabilitation: a randomized controlled trial

Submission date
06/07/2011

Recruitment status
No longer recruiting

Registration date
08/08/2011

Overall study status
Completed

Last Edited
10/02/2016

Condition category
Circulatory System

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

Plain English summary of protocol
Background and study aims
Phase III cardiac rehabilitation is a program of supervised exercise, relaxation and education for people with heart disease. It improves fitness and reduces the likelihood of future heart attacks, but attendance rates are low. We set out to increase the proportion of people attending cardiac rehabilitation using a specially designed invitation letter and supportive leaflet, using wording that theoretically should encourage people to attend.

Who can participate?
People were recruited to the study while in hospital following a heart attack or heart surgery.

What does the study involve?
Participants are randomly allocated to either receive either the new letter or the previously used letter. Similarly, participants are randomly allocated to receive the new leaflet or not. We then count how many of each group attend cardiac rehabilitation.

What are the possible benefits and risks of participating?
There were no risks to participants.

Where is the study run from?
Aberdeen Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
January 2007 to December 2008

Who is funding the study?
University of Aberdeen (UK)

Who is the main contact?
During the study: Dr Sultan Mosleh (s.m.mosleh@abdn.ac.uk)
After study completion: Dr Neil Campbell (n.campbell@abdn.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Dr Sultan Mosleh

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of theory based interventions to improve attendance at cardiac rehabilitation: a randomized controlled trial

Study objectives
A theory-based invitation letter and leaflet will increase attendance at phase III cardiac rehabilitation above that attained by the usual invitation letter

Ethics approval required
Old ethics approval format

Ethics approval(s)
Grampian Research Ethics Committee,17/11/2006, ref: 06/S0802/119

Study design
2x2 factorial design single centre blind randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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. Specifically post myocardial infarction and post cardiac surgery.

Interventions
1. Letter of invitation to cardiac rehabilitation designed with theory based wording
2. Supportive leaflet to accompany letter of invitation to cardiac rehabilitation designed with theory based wording
3. The control was the previously used letter of invitation to cardiac rehabilitation

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Attendance at least one session of a Phase III CR programme

Secondary outcome measures
1. To identify the factors associated with CR attendance
2. The independent measures of CR attendance were determined by a baseline self-report questionnaire which covered socio-demographical and medical factors, Hospital Anxiety and Depression Scale (HAD) (Zigmond and Snaith, 1983), Theory of Planned Behaviour (TPB) scale (Blanchard et al, 2002; Blanchard et al, 2003) and Illness Perception questionnaire (Weinman et al. 1996)

Overall study start date
01/01/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria

Consecutive patients who were admitted with myocardial infarction (MI) or post cardiac surgery between January 2007 and December 2007 at Aberdeen Royal Infirmary were invited to participate in the study if they were referred to the cardiac rehabilitation (CR) programme in the city of Aberdeen or the area of Aberdeenshire.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
412 patients were required in total to enable comparison between all of the four cells, or 206 to enable two-group comparisons (theoretical letter vs. the standard letter, or leaflet vs. no leaflet)

Key exclusion criteria
1. Patients who had not had MI
2. Patients who were terminally ill
3. Patients who had cardiac valve stenosis
4. Patients who had arrhythmia
5. Patients who abuse alcohol or drugs
6. Patients who are mentally or physically disabled
7. Those referred to the CR programme from out of Aberdeen area

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Research and Innovation
University of Aberdeen
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Sponsor type
University/education

Website
http://www.abdn.ac.uk/

ROR
https://ror.org/016476m91

Funder(s)

Funder type
University/education

Funder Name
University of Aberdeen

Alternative Name(s)
ABDN

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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?
Results article	results	01/09/2009		Yes	No