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An evaluation of a cardiac rehabilitation programme based on the internet

Submission date	Recruitment status	[X] Prospectively registered
26/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/08/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/09/2014	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of an interactive web-based cardiac rehabilitation programme in terms of the programme's effectiveness and acceptability in patients with angina

Acronym
OSCAR (Online Study of CArdiac Rehabilitation)

Study objectives
Angina is the pain associated with coronary heart disease. Often described as a heaviness, tightness or pain in the centre of the chest, which may spread to the arms, neck, and jaw, between the shoulder blades or stomach. Some people often describe a dull, persistent ache. For some people the pain or tightness is severe; for others it is not much more than a mild discomfort. Symptoms will often start intermittently on exertion, generally lasting for about 3 to 5 minutes and should be relieved by rest and glycerine trinitrate (GTN). This is known as stable angina.

Hypotheses:
1. The interactive web-based cardiac rehabilitation (CR) programme is effective at favourably influencing physical activity and other risk factor profiles for patients with angina
2. The interactive web-based CR programme is acceptable for patients with angina

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Coventry National Research Ethics Service (NRES) on the 23rd June 2008 (ref: 08/H1210/84). However, this approval was subject to making slight adjustments to the study invitation letter and participant information sheet.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Angina

Interventions
Cardiac rehabilitation is an intervention for patients with coronary heart disease to achieve their optimal physical, emotional, social and vocational status. Typically cardiac rehabilitation programmes include exercise training, behavioural changes, education and psychological support. Past research and reviews suggest cardiac rehabilitation to be an acceptable intervention of follow up after acute myocardial infarction (AMI). The overall aim of cardiac rehabilitation is to help patients to be physically active and modify lifestyle to reduce risk factors of coronary heart disease.

Intervention:
Those participants which have been randomised to the intervention group will receive the internet based cardiac rehabilitation programme for a period of 6 weeks. The researcher will provide these participants with an introductory session to the web based programme. This session will involve giving patients access to the website, describing how the website works and setting up a username and password for the participant. These participants will then be expected to follow the online cardiac rehabilitation programme for a period of 6 weeks.

Control:
Participants in the control group will be required to follow treatment as usual which will consist of continuing with regular GP visits without receiving any other intervention. They will also be required to follow this for a period of 6 weeks in order to match those in the intervention group.

Both the intervention and control group will be required to complete study measures at baseline, 6 weeks and 6 months after randomisation. All participants will receive two telephone calls during the study period to check on patient progress. It is envisaged that the researcher will contact each patient in the intervention group at week 2 and week 4 of the study. Moreover, 10 - 15 participants completing the web-based intervention will be interviewed. Overall a purposeful sampling technique will be employed, however, the specific sampling technique utilised will be maximum variation sampling. This will involve purposefully picking a wide range of patients varying in demographic variables such as age, ethnic background and gender. These interviews will be recorded and transcribed.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure is the assessment of physical activity. Physical activity will be measured using a SenseWear Pro3 Armband. This physical activity monitor is an armband which will be used to assess participants' walking activity. Participants will be required to wear the armband on three separate occasions:
1. For a period of one week, before randomisation
2. For a period of one week, 6 weeks after randomisation
3. For a period of one week, at a 6 month follow-up

Secondary outcome measures

Secondary outcome measures include measuring:
1. Body fat
2. Weight
3. Blood pressure
4. Dietary intake, measured using the Dietary Instrument for Nutrition Education (DINE)
5. Patients' level of anxiety and depression, measured using Hospital Anxiety and Depression Scale (HADS)

Other outcome measures include:
6. Assessing patients' perceived health status, measured with the Seattle Angina Questionnaire
7. Ability to interpret their illness positively, measured using the Silver Lining Questionnaire (SLQ)
8. Quality of life, measured using the MAC Quality of Life Scale
9. Self efficacy, measured using the Generalised Self Efficacy Scale
10. Healthcare costs (sub-scale taken from a larger questionnaire)

Further, patients' attitudes and experiences of the programme will be explored using qualitative interviews. All secondary outcome measures will be taken at baseline, 6 weeks and 6 months after randomisation.

Overall study start date
01/09/2008

Completion date
01/03/2010

Eligibility

Key inclusion criteria
1. Patients anticipated to be aged from 45 to 70 years, either sex
2. A history of stable angina
3. Undergone coronary angioplasty treatment
4. Fluent in English
5. No prior cardiac rehabilitation in the previous year
6. Regular access to the internet

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria

1. Severely anxious or suffering from depression
2. Experiencing unstable angina
3. Significant cardiac arrhythmia
4. Co-morbidities which prevent physical activity
5. Any cardiac rehabilitation treatment in the previous year

Date of first enrolment
01/09/2008

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Pulmonary and Cardiac Rehabilitation
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Sponsor information

Organisation
Coventry University (UK)

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Sponsor type
University/education

Website

http://www.coventry.ac.uk/

ROR
https://ror.org/01tgmhj36

Funder(s)

Funder type
Government

Funder Name
Warwick and Coventry Primary Care Research (WC-PCR) (UK)

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	12/09/2014		Yes	No