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A web-based cardiac rehabilitation alternative for those declining or dropping out of conventional rehabilitation

Submission date
28/04/2015

Recruitment status
No longer recruiting

Registration date
01/09/2015

Overall study status
Completed

Last Edited
22/11/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Coronary heart disease (CHD) affects over 2.3 million people in the UK. There is a very large cost to both the individual, in terms of loss of quality of life, and to society, in terms of healthcare costs and loss of productivity. It has been estimated that the cumulative cost of cardiovascular disease (CVD) to the UK economy is about £30 billion per year. The management of people with CHD has been outlined in many national and international guidelines and acknowledges the importance of cardiac rehabilitation (CR). CR is a programme of exercise and information sessions to help patients after a heart attack, heart surgery or procedure. Despite national guidance a significant number of eligible patients do not receive or take up the offer of CR. Factors related to nonattendance include employment commitments, difficulties with transport, lack of time, distance to travel to rehabilitation, and embarrassment related to attending group rehabilitation sessions. This study will assess the feasibility of delivering an alternative web-based CR intervention ('Activate your Heart') for those who decline or drop out from conventional supervised CR. Our program has not yet been tested with these groups and therefore we are aiming to examine the practicalities of conducting a large scale study with this population.

Who can participate?
Adult patients (aged over 18) with a confirmed diagnosis of CHD who have recently declined or dropped out of conventional CR.

What does the study involve?
Participants will be randomly allocated to one of two groups: the web-based CR group or the control group. Those allocated to web-based CR will have access to the 'Activate your Heart' online programme for 12 months (although the programme can be completed within 4 weeks). The programme is individually tailored and supervised by the local CR team. Patients in the control group will recieve usual care for their region: a referral back to general practice and standard advice and guidance booklets.

What are the possible benefits and risks of participating?
There may not be any direct benefit to participants. However, we would hope that taking part in the research may help patients' understanding of exercise and rehabilitation and inform both present and future cardiac rehabilitation programmes, therefore benefiting other CHD patients. There are minimal identified risks to taking part in this study. Patients experience some muscle aching and general tiredness after performing the walking tests and if allocated to the web-based exercise programme. This is usually mild and wears off after a couple of days. Participants in the control group will not receive any form of rehabilitation. This would be standard care if you declined rehabilitation classes or dropped out during a conventional CR programme. Participants will be asked to make additional visits to hospital over the 6-month study period. This is a potential inconvenience but, in our experience, most patients are happy to attend. Travel expenses will be reimbursed or a taxi provided for these assessment visits.

Where is the study run from?
University Hospitals of Leicester (UHL) NHS Trust and Lincoln Community Health Service NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2015 to October 2017

Who is funding the study?
The study is being funded by the Research for Patient Benefit (RFPB) programme, which is part of the funding body National Institute for Health Research (NIHR). The study is also supported by the NIHR Leicester Respiratory Biomedical Research Unit (BRU).

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
Research for Patient Benefit (RfPB) Programme: PB-PG-1013-32059

Study information

Scientific Title
A Web-based cardiac REhabilitatioN alternative for those declining or dropping out of conventional rehabilitation: the WREN feasibility study

Acronym
WREN

Study objectives
The study is a feasibility randomised controlled trial, which aims to assess the feasibility of delivering an alternative web-based Cardiac Rehabilitation (CR) intervention for those who decline or drop out from conventional supervised CR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Leicester Central, 06/08/2015, REC ref: 15/EM/0291

Study design
Feasibility randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary heart disease (CHD)

Interventions

Intervention group: web-based cardiac rehabilitation using the 'Activate your Heart' online programme.
Control group: usual care.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome measured in this study is the feasibility of recruiting/retaining people who meet our inclusion and exclusion criteria; those who have declined/dropped out of traditional cardiac rehabilitation.

Key secondary outcome(s))
Secondary outcome measures as of 20/12/2016:
1. Feasibility of our randomisation process and willingness to be randomised
2. Retention rate of participants to the study at 8 weeks, and 6 months follow-up
3. Feasibility of conducting outcome measures which are proposed for the final trial:
3.1. Health-related quality-of-life; 'MacNew Heart Disease Questionnaire', measuring physical, emotional, and social aspects of quality-of-life
3.2. Exercise Capacity; measured using the 'Incremental Shuttle Walking Test (ISWT)', which is a test used to assess cardio-respiratory fitness
3.3. Anxiety and Depression; measured using the 'Hospital Anxiety and Depression Scale (HADS)'
3.4. Self-efficacy; measured using 'The General Self-Efficacy Scale'
3.5. Health utility; measured using the 'EQ-5D' questionnaire.
3.6. 'Seattle Angina Questionnaire' (SAQ)
3.7. Angina Symptoms; Symptoms and medication use diary kept by the patient for 2 week, recording the frequency of episodes of angina and the number of glyceryl trinitrate (GTN) pills or 'puffs' of sub-lingual spray taken each day
3.8. Resource use: Including: use of hospital and community services; social care; and personal costs
3.9. Web usage: weekly and total web usage statistics for patients assigned to the web-based programme will be monitored as will any technical problems participants encounter
3.10. Intervention completion rates amongst intervention group participants

Outcomes will be assessed at baseline, 8 weeks and 6 months in both groups.

Original secondary outcome measures:
1. Feasibility of our randomisation process and willingness to be randomised
2. Retention rate of participants to the study at 8 weeks, and 6 months follow-up
3. Feasibility of conducting outcome measures which are proposed for the final trial:
3.1. Health-related quality-of-life; 'MacNew Heart Disease Questionnaire', measuring physical, emotional, and social aspects of quality-of-life
3.2. Exercise Capacity; measured using the 'Incremental Shuttle Walking Test (ISWT)', which is a test used to assess cardio-respiratory fitness
3.3. Anxiety and Depression; measured using the 'Hospital Anxiety and Depression Scale (HADS)'
3.4. Self-efficacy; measured using 'The General Self-Efficacy Scale'
3.5. In order to conduct an economic evaluation, impact on health utility will be assessed using the 'EQ-5D' questionnaire. This measures health on five dimensions and a tariff is available for deriving a single utility score based on time trade-off utility scores
3.6. 'Seattle Angina Questionnaire' (SAQ)
3.7. Angina Symptoms; Symptoms and medication use diary kept by the patient for 2 week,

recording the frequency of episodes of angina and the number of glyceryl trinitrate (GTN) pills or ‘puffs’ of sub-lingual spray taken each day
3.8. Web usage: weekly and total web usage statistics for patients assigned to the web-based programme will be monitored as will any technical problems participants encounter
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Outcomes will be assessed at baseline, 8 weeks and 6 months in both groups.

Completion date
07/10/2017

Eligibility

Key inclusion criteria
1. Confirmed primary diagnosis of coronary heart disease (CHD)
2. Eligible for conventional CR (eligibility as described in NICE CR commissioning guidelines 2013, section 3)
3. Access to internet. Questions will be asked to establish familiarity with the internet, e.g. use of either online shopping/online banking
4. People who have recently (<12 months) declined an invitation to rehabilitation. These people are defined as those at stage 2 (patient assessment) or stage 3 (when the patient care plan is developed) expressing an unwillingness to attend any further stages of the programme (stages defined in NICE commissioning guidelines 2013, section 1). People who prospectively decline at these stages will also be included
5. People who have recently (<12 months) ‘dropped-out’ of rehabilitation. These people are defined as those not attending 2 consecutive sessions of stage 4 comprehensive rehabilitation sessions (stages defined in NICE commissioning guidelines 2013, section 1)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. No access to the internet (it would be unrealistic to recruit people without access to the internet; it is beyond the scope of the project to provide the hardware to participants)
2. Individuals who have completed rehabilitation for a previous admission in the last 12 months
3. Those demonstrating high levels of depression (defined by baseline HADS score >11 [moderate depression]) and poor exercise capacity (defined by poor performance on the Incremental Shuttle Walking Test, level achieved <3 – equivalent to walking 120 metres). These patients will require a more supervised approach
4. Unable to read English. The website is currently only available in English

Date of first enrolment

07/12/2015

Date of final enrolment
07/04/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
Trust Headquarters
Gwendolen House
Gwendolen Road
Leicester
United Kingdom
LE5 4QF

Study participating centre
Lincoln Community Health Service NHS Trust
Bridge House
Unit 16
Sleaford
United Kingdom
NG34 8GG

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes