ISRCTN10054455 https://doi.org/10.1186/ISRCTN10054455

Cardiac rehabilitation for people with chronic stable angina

Submission date	**Recruitment status**	[X] Prospectively registered
15/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/09/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/08/2024	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Angina is chest pain caused by a build-up of fats and cholesterol in the walls (atherosclerosis) of the blood vessels that supply the heart (coronary arteries), which restricts blood flow to the heart muscle, especially during exercise. Current management of angina consists of behaviour change, drug treatment and operations to improve blood flow to the heart (revascularization).

Cardiac rehabilitation is routinely offered to patients following a heart attack or revascularisation procedures, but not for chronic, stable angina. Cardiac rehabilitation consists of lifestyle change, exercise training, education and mental health interventions. The National Institute for Health and Care Excellence will not support cardiac rehabilitation for chronic stable angina until stronger evidence of effectiveness and cost-effectiveness is available.

The aims of the project are to improve the health of people with long-term angina chest pain, which is not getting worse and does not require an operation but still limits daily activities. We aim to assess whether a rehabilitation programme is more effective than usual care in improving the health of people with long-standing stable angina, whether the programme is good value for money, and whether it is delivered as intended. The programme uses behaviour change techniques such as goal-setting, self-monitoring, providing feedback on behaviour, graded tasks, social reward, providing information about health consequences and reducing negative emotions.

Who can participate?

Patients with chronic stable angina aged 18 years and older from four regions: Liverpool, Lancashire, Leicester and North Wales, which are all areas of high disease burden with socio-economic deprivation. Some of these areas include high proportions of BAME groups (Leicester, East Lancashire) and areas with low research activity in this field (Blackpool, North Wales).

What does the study involve?

Participants will be split into two groups randomly. by a computer. Group A will receive usual care from their GP plus a cardiac rehabilitation programme called ‘Activate Your Heart’. Group B will receive usual care from their GP. ‘Activate Your Heart’ is an interactive website for participants to use at home. It is secure and protected by a password. The programme was

developed by a team of health care professionals, people with angina and software designers. The programme includes education, promoting a healthy diet and physical activity, reducing risk factors for heart attack and improving mental wellbeing. The programme helps participants to set goals, monitor progress and gives feedback on how they are doing. It encourages participants to gradually increase their activity levels. A paper manual will be available for participants who are unable to use the online version or for those who feel they would prefer a paper version. We would also like participants to complete some questionnaires whilst taking part in the study and also wear a small device called an ActivPAL device which looks out how active participants are.

What are the possible benefits and risks of participating?
The risks of the online rehabilitation intervention 'Activate Your Heart' are minimal. There may be a small risk of injury or provoking an episode of angina when exercising, but to prevent this, the physical activity goals are carefully set. Participants can contact the cardiac rehabilitation therapists for advice and support via an online email link or by joining an online scheduled weekly chat room, participants will also be given a phone number to contact them on. Experience from using the 'Activate Your Heart' programme for cardiac rehabilitation has shown that it is very safe.

Where is the study run from?
The University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
From August 2021 to August 2024

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Farhiya Ashoor
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Study website
www.activate-trial.org.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
300485

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50446

Study information

Scientific Title
Cardiac rehabilitation for people with chronic stable angina (ACTIVATE): a randomised controlled trial

Acronym
ACTIVATE

Study objectives
Can a rehabilitation programme combined with usual heart care be better than usual heart care alone in improving the health of people with long-standing stable angina?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/09/2021, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 21/NS/0116

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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 pectoris

Interventions
People with long-term stable angina will be recruited and divided into two groups. One group will receive usual care; the other group will undertake a rehabilitation programme in addition to usual care. Participants in undertaking the rehabilitation programme will be given access to 'ActivateYourHeart' (www.activateyourheart.org.uk). The programme is tailored to individual needs and is in four stages, which can be completed in 8 weeks, but access to the site and its features continue for 12 months. Participants will complete the intervention with support from cardiac rehabilitation staff. The online programme called 'ActivateYourHeart' has already been developed. It was designed to be used by many kinds of people with heart disease including those who cannot or do not want to attend group rehabilitation sessions. It can be used at home and can be completed at the participant's own pace. An early preliminary study on people with stable angina indicates that it may be beneficial and that a larger trial is needed. People usually access this programme using their computer or their mobile device and the programme provides them with a tailored plan. However, before beginning the programme each participant receives face-to-face training using the website and a written user manual. A paper-based version will also be available if people are not comfortable using the website.

Before the start of the programme, participants will review the participant information sheet and provide written informed consent at their GP surgery and questionnaires will be used to measure physical limitations, the frequency and severity of chest pain, shortness of breath, quality of life, anxiety, depression, and the use of health services. Participants will complete assessment questionnaires at baseline, 6, and 12 months either via phone or in their GP surgery. Additionally, physical activity will be measured with the ActivPAL accelerometer device, which participants will collect from their GP surgery and take home with them to be worn continually for 7 days at each assessment point, and return to their GP surgery after 7 days. The Incremental Shuttle Walk Test will be completed at the participant's GP surgery under the supervision and

guidance of the research staff. As well as comparing the effectiveness of the rehabilitation programme between the two groups, the study will also assess its value for money, and whether the rehabilitation was delivered as intended.

Intervention Type
Behavioural

Primary outcome measure
Physical limitations measured using the UK Version of Seattle Angina Questionnaire (SAQ-7) Physical Limitation domain at baseline, 6, and 12 months

Secondary outcome measures
1. Dyspnea measured using the Rose Dyspnea Scale at baseline, 6, and 12 months
2. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 6, and 12 months
3. Perceived self-efficacy measured using the Generalised Self-Efficacy scale at baseline, 6, and 12 months
4. Physical activity measured with the ActivPAL accelerometer over 7 days at baseline, 6, and 12 months
5. Health–related physical activity measured using the International Physical Activity Questionnaire (IPAQ) at baseline, 6, and 12 months
6. Exercise capacity measured using the Incremental Shuttle Walk Test at baseline, 6, and 12 months
7. Quality of life measured using the EuroQol 5-Dimension 5-Level Quality of Life questionnaire (EQ-5D-5L) at baseline, 6, and 12 months
8. Service utilisation measured using the Client Service Receipt Inventory (CSRI) at baseline, 6, and 12 months

Overall study start date
01/08/2021

Completion date
01/08/2024

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Chronic stable angina with at least 2 out of 3 of the following features:
2.1. Constricting central chest pain
2.2. Precipitated by exertion or emotional stress
2.3. Relieved by rest or glyceryl trinitrate spray
3. Documented coronary artery disease on angiography with ≥70% stenosis of coronary arteries based on invasive coronary angiography, computerised tomography angiography, or reversible myocardial ischaemia on myocardial perfusion testing
4. Revascularisation procedures not planned and treated with medical treatments only. Including people with previous MI, or previous revascularisation procedure who may have attended cardiac rehabilitation in the past.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 518; UK Sample Size: 518

Key exclusion criteria
1. History of myocardial infarction (MI) within the last 12 months on electronic health record search
2. History of revascularisation procedure within the last 12 months, or planned at the time of study consent
3. Participation in cardiac rehabilitation programme within the last 12 months, or planned at time of study recruitment
4. Significant co-morbidities (as deemed by person confirming eligibility) that would limit participation in the exercise based rehabilitation programme
5. Refractory angina on maximal medical therapy

Date of first enrolment
01/12/2021

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Clarence Medical Centre
West Kinmel Street
Rhyl
Denbighshire
United Kingdom
LL18 1DA

Study participating centre
Plas Menai Surgery
Penmaenmawr Road
Llanfairfechan
Conwy
United Kingdom
LL33 0PE

Study participating centre
Corwen Health Centre
Green Lane
Corwen
Denbighshire
United Kingdom
LL21 0DN

Study participating centre
Healthy Prestatyn
Rhuddlan Iach Ty Nant
Nant Hall Road
Prestatyn
Denbighshire
United Kingdom
LL19 9LN

Study participating centre
Marshalls Cross Medical Centre
St Helens Hospital
Marshalls Cross Road
St Helens
Merseyside
United Kingdom
WA9 3DA

Study participating centre
Vauxhall Health Centre
Limekiln Lane
Vauxhall
Liverpool
United Kingdom
L5 8XR

Study participating centre
Fishergate Hill Surgery
50 Fishergate Hill
Preston
Lancashire
United Kingdom
PR1 8DN

Study participating centre
Lancaster Medical Practice
8 Dalton Square
Lancaster
Lancashire
United Kingdom
LA1 1PN

Sponsor information

Organisation
University of Liverpool

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Sponsor type
University/education

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

ROR
https://ror.org/04xs57h96

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 15/02/2024:
The datasets generated and analysed during this study will be stored in a non-publicly available repository. These datasets will be available upon request from 31/07/2026. For access to these datasets, please contact Prof. Nefyn H Williams (nefyn.williams@liverpool.ac.uk). Consent was required and obtained from all participants. Data will be anonymised before it is shared. There are no ethical or legal restrictions.

Previous IPD sharing plan:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		25/03/2024	27/03/2024	Yes	No