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Cardiac rehabilitation for people with chronic stable angina

Submission date 15/09/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/09/2021	**Overall study status** Completed	
Last Edited 12/05/2026	**Condition category** Circulatory System	

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 April 2026

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

Who is the main contact?
activate.trial@liverpool.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
300485

Central Portfolio Management System (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

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

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' (https://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(s)
Physical limitations measured using the UK Version of Seattle Angina Questionnaire (SAQ-7) Physical Limitation domain at baseline, 6, and 12 months

Key secondary outcome(s)
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

Completion date
22/04/2026

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
125 Years

Sex
All

Total final enrolment
101

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
18/09/2024

Locations

Countries of recruitment
United Kingdom

England

Wales

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

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

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

Study participating centre

Healthy Prestatyn
Rhuddlan Iach Ty Nant
Nant Hall Road
Prestatyn
Denbighshire
Wales
LL19 9LN

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

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

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

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

Study participating centre
Pendle View Medical Centre
47 Arthur Street
Brierfield
Nelson
England
BB9 5RZ

Study participating centre
Brownlow Group Practice
Primary Care Resource Centre
70 Pembroke Place
Liverpool
England
L69 3GF

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
The Pendle Medical Partnership
Edward Street
Earby
Barnoldswick
England
BB18 6QT

Study participating centre
The Village Practice
Thornton Medical Centre
Church Road
Thornton-cleveleys
England
FY5 2TZ

Study participating centre

West End Medical Centre
West End Medical Centre
Conway Road
Colwyn Bay
Wales
LL29 7LS

Study participating centre
Myrtle Group Practice
270 Telegraph Road
Heswall
Wirral
England
CH60 7RN

Study participating centre
St Georges Medical Centre
Field Road
New Brighton
Wallasey
England
CH45 5LN

Study participating centre
Llanedeyrn Health Centre
Llan Healthcare
Wellbeing Hub @ Maelfa
Round Wood, Llanedeyrn
Cardiff
Wales
CF23 9PF

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
England
L7 8XP

Study participating centre

Newton PLACE Surgery
Newton Road
Faversham
England
ME13 8FH

Study participating centre
The Ashgrove Surgery
Morgan Street
Pontypridd
Wales
CF37 2DR

Study participating centre
Mitcham Family Practice
55 Mortimer Road
Mitcham
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CR4 3HS

Study participating centre
Wirral Community Health and Care NHS Foundation Trust
Derby Road
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Study participating centre
Latchford Medical Centre
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Sponsor information

Organisation
University of Liverpool

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

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
Available on request, Stored in non-publicly available repository

Study outputs

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

Study website	Study website	11/11/2025	11/11/2025	No	Yes