

# Cardiac rehabilitation for people with chronic stable angina

<b>Submission date</b> 15/09/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/12/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 October 2025

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

activate.trial@liverpool.ac.uk

## Contact information

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Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

300485

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **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

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**

30/10/2025

## **Eligibility**

### **Key inclusion criteria**

1. Aged  $\geq 18$  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  $\geq 70\%$  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  
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L7 8XP

**Study participating centre**  
**Newton PLACE Surgery**  
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ME13 8FH

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

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

**Study participating centre**  
**Wirral Community Health and Care NHS Foundation Trust**  
Derby Road  
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CH42 0LQ

**Study participating centre**  
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WA4 1LJ

# 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](mailto: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?
<a href="#">Protocol article</a>		25/03/2024	27/03/2024	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes