

# Early postoperative review and cardiac rehabilitation

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<b>Registration date</b> 29/02/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/06/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

In the UK, heart operations have steadily increased since 2010, and 36,166 heart operations were performed in 2016. Following cardiac surgery, patients currently attend their first outpatient review six weeks after hospital discharge, where recovery is assessed and fitness to commence cardiac rehabilitation (CR) is determined. CR is then started from eight weeks. In a survey we conducted in May/June 2017, 35 of the 42 UK cardiac centres responded, and confirmed this as current practice. The long interval before postoperative review and CR extends the period of vulnerability and inactivity for patients, with patients often seeking medical attention for surgery-related complications during this period. In a prospective observational study, we found that 38.9% of patients sought further medical help during these 6 weeks, and 44.4% would like an earlier review. Our proposed randomised control trial (RCT) aims to determine if early CR leads to improved outcomes and is cost-effective compared to standard CR.

### Who can participate?

Adult patients aged 18 years and older undergoing elective or urgent cardiac surgery through a sternotomy at UK centres

### What does the study involve?

The recruitment period will last for 24 months and eligible and consenting participants will be randomised, a 1:1 ratio, to either the control (standard care) or intervention arms. Participants in the control arm will receive standard post-sternotomy cardiac surgery care which includes specialist review at six weeks after hospital discharge, followed by commencement of CR from eight weeks. Participants in the intervention arm will have a specialist review at three weeks after hospital discharge, followed by the commencement of CR from four weeks. Both groups will receive eight weeks of CR followed by a post-CR review. In addition to this there will be follow-up appointments for both groups at six and twelve months post-randomisation. The outcomes will be measured through a variety of standard clinical tests as well as questionnaires.

### What are the possible benefits and risks of participating?

Individual participants may not benefit directly from this research. However, participants randomly allocated to the novel treatment arm may benefit from the advantages of early

commencement of graded and supervised exercise which include;

- reducing muscle wasting, joint stiffness, and physical deconditioning,
- facilitating early return to usual fitness levels,
- improving post-sternotomy symptoms and,
- improving cardiac function.

There are no foreseen areas for clinical concern. In the context of a lack of robust evidence to determine the best time frames for post-operative review and CR, risks are not increased through participation in the study. Risks and burdens to patients have been considered during the study design process. Study patients will undergo clinical assessment after discharge following surgery, and be certified fit for cardiac rehabilitation (CR) by the surgical team. Before commencing exercise-based CR they will undergo exercise testing, and CR will be tailored to their fitness levels. After CR, they would have another assessment and exit consultation. Burdens include questionnaire and diary completion, and some clinical assessments/tests which are not part of the normal patient pathway. However, these additional tests may not involve attending any extra hospital visits.

Where is the study run from?

Hull University Teaching Hospitals NHS Trust

When is the study starting and how long is it expected to run for?

December 2023 to June 2027

Who is funding the study?

Health Technology Assessment (HTA) Programme, National Institute for Health and Care Research (NIHR152069)

Who is the main contact?

Chief Investigator: Prof Dumbor Ngaage ([dumbor.ngaage@nhs.net](mailto:dumbor.ngaage@nhs.net))

Trial Manager: Dr Natasha Mitchell ([natasha.mitchell@york.ac.uk](mailto:natasha.mitchell@york.ac.uk))

Trial Coordinator: Ms Radwa Abdelatif ([radwa.abdelatif@york.ac.uk](mailto:radwa.abdelatif@york.ac.uk))

## Contact information

### Type(s)

Scientific, Principal Investigator

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

334434

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

IRAS 334434, CPMS 60242

## Study information

### Scientific Title

A Multi-centre Randomised Controlled trial of standard care versus an accelerated care pathway after cardiac surgery (FARSTER-care).

### Acronym

FARSTER-Care

### Study hypothesis

The objectives are:

1. Undertake a randomised parallel group comparison to determine the effects of early CR on physical functional capacity using the incremental shuttle walk test (ISWT) at six months post-randomisation
2. Undertake an 8-month internal pilot to obtain robust estimates of recruitment and retention ensuring trial viability.
3. Undertake a randomised parallel group comparison to determine the effects of early CR on outcomes related to physical health and psychological health at 6- and 12-months post-randomisation.
4. Conduct a detailed economic evaluation to assess the cost-effectiveness of early CR.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 07/03/2024, North West - Liverpool Central REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8118; liverpoolcentral.rec@hra.nhs.uk), ref: 24/NW/0036

**Study design**

Multicenter 2-armed randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

**Condition**

Early initiation of cardiac rehabilitation following cardiac surgery with sternotomy

**Interventions**

FARSTER-Care is a multi-centre, 2-armed, randomised control trial (RCT) looking at the effects of early cardiac rehabilitation following cardiac surgery with sternotomy compared with the standard treatment. Eligible and consenting patients be asked to complete a questionnaire (supported by the R&D team at the participating site) and have their blood pressure, weight, height, and waist circumference measured. Participants will then be randomised on a 1:1 basis to either the FARSTER-Care group (n = 294) or the usual care group (n = 294) using block randomisation stratified by site. The allocation schedule will be generated by a trial statistician not otherwise involved in the recruitment or randomisation of patients, and implemented via a central, web-based randomisation system designed and managed by the YTU. Sites will be provided access to the randomisation system which will automatically send the research team at the site and the trial team at YTU the treatment allocation.

Those in the FARSTER-Care group will receive their specialist outpatient appointment three weeks following hospital discharge followed by commencement of CR from four weeks. The standard care group will have their specialist outpatient appointment six weeks after hospital discharge followed by commencement of CR from eight weeks. Both groups will be offered CR for eight weeks and can be completed in person, remotely, or a hybrid of both.

At the first CR session, participants will be provided with advice and leaflets on cardiac risk factor reduction. They will also undergo an assessment by a physiotherapist which will involve exercise testing using the Incremental Shuttle Walk Test (ISWT) which measures aerobic fitness. Participants will also be given a pre-rehabilitation questionnaire to complete containing EQ-5D-5L and resource use questions. Following completion of CR, participants will complete a post-rehabilitation questionnaire (EQ-5D-5L and resource use questions) and have a repeat ISWT.

After 26 weeks from surgery, participants will have a follow-up appointment. Here participants will complete a questionnaire (EQ-5D-5L and resource use questions), and undergo a final ISWT. Study participants will be examined for sternal wound complications, including sternal

instability. Medical records will be checked for hospital readmissions and Accident and emergency department attendance for surgery-related complications. After 52 weeks from surgery, Participants will receive a final questionnaire (EQ-5D-5L and resource use questions).

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

1. Aerobic fitness measured using the Incremental Shuttle Walk Test (ISWT) before CR commences (pre-CR time point), once CR finishes (post-CR time point) and at the six-month time point
2. Physical health assessed via the following variables at Baseline, Outpatient review, Pre-CR, Post CR, and at the six-month time point
  - 2.1. Heart rate measured in beats per minute using a pulse oximeter
  - 2.2. Blood pressure (systolic and diastolic) measured using standard trust procedure and recorded in mmHg
  - 2.3. Oxygen saturation measured using a pulse oximeter
3. Perceived exertion (RPE) measured using the Borg Scale at Pre-CR, Post-CR, and at the six-month time point

## **Secondary outcome measures**

1. Physical health assessed via the following variables at Baseline, Outpatient review, Pre-CR, Post CR, and at the six-month time point
  - 1.1. Heart rate measured in beats per minute using a pulse oximeter
  - 1.2. Blood pressure (systolic and diastolic) measured using standard trust procedure and recorded in mmHg
  - 1.3. Oxygen saturation measured using a pulse oximeter
2. Patient outcomes measured using a Patient Reported Outcome Measure - Cardiac Rehabilitation (PROM-CR) at [timepoint]: Pre-CR, Post-CR, and at the six-month time point
3. Psychological health measured using the Generalized Anxiety Disorder Scale (GAD-7) at Baseline, Pre-CR, Post-CR, and at the six-month and twelve-month time points
4. Quality of life measured using the EQ-5D-5L validated generic patient-reported outcome measure at Baseline, Pre-CR, Post-CR, and at the six-month and twelve-month time points
5. Patient-reported NHS and personal social services (PSS) resource use will be collected using a bespoke questionnaire at Pre-CR, and at the six-month and twelve-month time points
6. Complications measured using data collected in the documentation at baseline and 6 months, and throughout the trial in the form of adverse events.
7. Cardiac rehabilitation uptake measured using data recorded in the CR session logs by the end of the study [measured using] at measured using number of sessions attended between Pre-CR and Post-CR timepoints

## **Overall study start date**

13/12/2023

## **Overall study end date**

30/06/2027

## **Eligibility**

### **Participant inclusion criteria**

1. Aged  $\geq 18$  years
2. Undergoing elective or urgent cardiac surgery through a sternotomy
3. Capable of giving informed consent.
4. Patients who are taking part in other research studies can still enter the trial as long as the first study does not include an intervention or element that may affect the FARSTER-care trial outcomes or would be overly burdensome for patients.

**Participant type(s)**

Patient

**Age group**

All

**Lower age limit**

18 Years

**Upper age limit**

100 Years

**Sex**

Both

**Target number of participants**

588

**Participant exclusion criteria**

Patients with postoperative sternal wound complications like sternal instability, or postoperative complications requiring further specialised care, such as stroke rehabilitation and regular dialysis.

**Recruitment start date**

30/05/2024

**Recruitment end date**

31/12/2026

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Hull University Teaching Hospitals NHS Trust

Hull Royal Infirmary

Anlaby Road

Hull

United Kingdom  
HU3 2JZ

**Study participating centre**

**South Tees Hospitals NHS Foundation Trust**  
James Cook University Hospital  
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## **Sponsor information**

**Organisation**

Hull University Teaching Hospitals NHS Trust

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**Sponsor type**

University/education

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA



**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

We plan to report and disseminate the results of the study via the below methods:

1. Peer reviewed scientific journals
2. Conference presentations
3. Submission to regulatory authorities

The final report will also be submitted to the Funder.

**Intention to publish date**

01/01/2028

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Natasha Mitchell ([natasha.mitchell@york.ac.uk](mailto:natasha.mitchell@york.ac.uk)) or Alex Mitchell ([alex.mitchell@york.ac.uk](mailto:alex.mitchell@york.ac.uk)).

**IPD sharing plan summary**

Available on request