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Early postoperative review and cardiac rehabilitation

Submission date 13/12/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/02/2024	**Overall study status** Ongoing	
Last Edited 07/08/2025	**Condition category** Circulatory System	

Plain English summary of protocol

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 controlled 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 in a 1:1 ratio to either the control (standard care) or the intervention arm. Participants in the control arm will receive standard post-sternotomy cardiac surgery care, which includes specialist review at 6 weeks after hospital discharge, followed by commencement of CR from 8 weeks. Participants in the intervention arm will have a specialist review at 3 weeks after hospital discharge, followed by the commencement of CR from 4 weeks. Both groups will receive 8 weeks of CR followed by a post-CR review. In addition to this, there will be a follow-up appointment for both groups at 6 months post-randomisation and a final questionnaire-only follow-up at 12 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:
1. Reducing muscle wasting, joint stiffness, and physical deconditioning
2. Facilitating early return to usual fitness levels
3. Improving post-sternotomy symptoms and
4. 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 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 completion and some clinical assessments/tests that 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?
York Trials Unit at the University of York (UK)

When is the study starting and how long is it expected to run for?
July 2023 to June 2027

Who is funding the study?
Health Technology Assessment (HTA) Programme, National Institute for Health and Care Research (NIHR152069) (UK)

Who is the main contact?
Chief Investigator: Prof Dumbor Ngaage (dumbor.ngaage@nhs.net)
Trial Manager: Dr Natasha Mitchell (natasha.mitchell@york.ac.uk)
York Trials Unit Team: farstercare-trial-group@york.ac.uk

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
334434

Protocol serial number
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 objectives
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 6 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 two-armed randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Early initiation of cardiac rehabilitation following cardiac surgery with sternotomy

Interventions
Current interventions as of 07/08/2025:
FARSTER-Care is a multi-centre, two-armed, randomised controlled trial (RCT) looking at the effects of early cardiac rehabilitation following cardiac surgery with sternotomy compared with the standard treatment. Eligible and consenting patients will be asked to complete a questionnaire (supported by the R&D team at the participating site) and have their blood pressure, weight, and height 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 3 weeks following hospital discharge followed by commencement of CR from 4 weeks. The standard care group will have their specialist outpatient appointment six weeks after hospital discharge, followed by commencement of CR from 8 weeks. Both groups will be offered CR for 8 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-5D5L 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.

At 6-months post-randomisation, participants will have a follow-up appointment. They will be asked to 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. At 12 months post-randomisation, participants will receive a final questionnaire (EQ-5D-5L and resource use questions).

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Those in the FARSTER-Care group will receive their specialist outpatient appointment three weeks following hospital discharge followed by commencement of CR from 4 weeks. The standard care group will have their specialist outpatient appointment 6 weeks after hospital discharge followed by commencement of CR from 8 weeks. Both groups will be offered CR for 8 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(s)
Current primary outcome measures as of 07/08/2025:
Aerobic fitness measured using the Incremental Shuttle Walk Test (ISWT) at the 6-month time point

Previous primary outcome measures:
1. Aerobic fitness measured using the Incremental Shuttle Walk Test (ISWT) before CR commences (pre-CR timepoint), once CR finishes (post-CR timepoint) and at the 6-month timepoint
2. Physical health assessed via the following variables at Baseline, Outpatient review, Pre-CR, Post CR, and at the 6-month timepoint
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 6-month timepoint

Key secondary outcome(s))
1. Physical health assessed via the following variables at Baseline, Outpatient review, Pre-CR, Post CR, and at the 6-month timepoint
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 Pre-CR, Post-CR, and at the 6-month timepoint
3. Psychological health measured using the Generalized Anxiety Disorder Scale (GAD-7) at Baseline, Pre-CR, Post-CR, and at the 6-month and 12-month timepoints
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 6-month and 12-month timepoints
5. Patient-reported NHS and personal social services (PSS) resource use will be collected using a bespoke questionnaire at Pre-CR, and at the 6-month and 12-month timepoints
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 number of sessions attended between Pre-CR and Post-CR timepoints

Completion date

30/06/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/08/2025:
1. Aged ≥18 years
2. Undergoing elective or urgent cardiac surgery through a sternotomy
3. Capable of giving informed consent.
4. Patients capable of completing, and willing to complete, the ISWT.
5. 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.

Previous inclusion criteria:
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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

Healthy volunteers allowed
No

Age group
All

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key 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.

Date of first enrolment
30/05/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

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
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
Hull University Teaching Hospitals NHS Trust

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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) or Alex Mitchell (alex.mitchell@york.ac.uk).

IPD sharing plan summary
Available on request