

# Feasibility of early cardiac rehabilitation after coronary artery bypass grafting

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<b>Registration date</b> 24/01/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/05/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In the UK, heart operations have steadily increased since 2010. Of 36,134 operations performed in 2013, 17,630 were isolated coronary artery bypass grafting (CABG). Following CABG, 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. There is no research to support the timings of either the outpatient check-up or the start of cardiac rehabilitation. The long interval before postoperative review and CR extends the period of vulnerability and inactivity for patients. The aim of this study is to examine the feasibility of bringing forward outpatient review and CR, in order to facilitate recovery, physical fitness and quality of life.

### Who can participate?

Patients 18 to 75 years of age undergoing a planned CABG through a median sternotomy

### What does the study involve?

Half of the participants are randomly assigned to a new shortened pathway including a postoperative review three weeks after hospital discharge, followed by commencement of CR from four weeks. The remainder continue with usual treatment. CR for both groups involves exercise classes once or twice a week for 8 weeks, and fitness tests. Patients then have a final assessment at 26 weeks, with clinical examination, fitness and breathing tests, and completion of a general health questionnaire. Outcomes are measured through a variety of standard clinical tests as well as questionnaires. Additionally, data is collected through interviews, diary entries and focus group meetings with consenting participants and clinical staff. Patients' and staff experiences, patient fitness levels, delivery of the trial, quality of life and costs associated with each pathway are all analysed.

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

Individual participants may not benefit directly from this research but the information gained from this study may help to answer the question as to whether one of these treatments pathways is better than the other. There are no foreseen areas for clinical concern. In the context of lack of robust evidence to determine the best time frames for postoperative review and CR, risks are not increased through participation in the study.

Where is the study run from?

1. East Yorkshire Cardiothoracic Centre (UK)
2. James Cook University Hospital (UK)

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

August 2018 to July 2020

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

1. Dumbor Ngaage
2. James Illingworth

## Contact information

### Type(s)

Scientific

### Contact name

Mr Dumbor Ngaage

### ORCID ID

<http://orcid.org/0000-0003-2378-7160>

### Contact details

East Yorkshire Cardiothoracic Centre  
Castle Hill Hospital  
Castle Road  
Kingston-Upon-Hull  
United Kingdom  
HU15 6JQ

### Type(s)

Public

### Contact name

Mr James Illingworth

### Contact details

R&D Department  
Castle Hill Hospital  
Castle Road  
Kingston-Upon-Hull  
United Kingdom  
HU16 5JQ

## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

NCT03551015

**Secondary identifying numbers**

40546; PB-PG-0317-20047

## **Study information**

**Scientific Title**

Feasibility study of early outpatient review and early cardiac rehabilitation after coronary artery bypass grafting: mixed methods research design

**Acronym**

FARSTER

**Study objectives**

An early postoperative outpatient review followed by early commencement of cardiac rehabilitation is feasible, and would lead to quicker recovery of physical fitness and better quality of life.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

East Midlands - Derby Research Ethics Committee, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, Tel: +44 (0)207 104 8109 / (0)207 104 8237, Email: NRESCcommittee.EastMidlands-Derby@nhs.net, 10/01/2019, REC ref: 18/EM/0391

**Study design**

Randomised; Interventional; Design type: Process of Care, Rehabilitation

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Specialty: Surgery, Primary sub-specialty: Cardiothoracic Surgery; Health Category: Cardiovascular; Disease/Condition: Diseases of arteries, arterioles and capillaries

## **Interventions**

Participants will undergo 1:1 randomisation to either: current (control arm) or the proposed pathway (intervention arm). Randomisation will be undertaken using a centralised randomisation service provided by a York Trials Unit statistician not involved in recruiting patients, and will be stratified by site using randomly permuted variable block sizes.

Control (current practice): postoperative outpatient review 6 weeks after hospital discharge, followed by commencement of cardiac rehabilitation from 8 weeks.

Intervention: postoperative outpatient review 3 weeks after hospital discharge, followed by commencement of cardiac rehabilitation from 4 weeks.

The structure of outpatient review and cardiac rehabilitation will be the same for both arms of the trial, as in current practice, specifically:

1. First postoperative outpatient review: Specialist surgical team will perform postoperative outpatient clinical review, as is standard practice, for all study patients. Postoperative history, clinical examination including sternal stability assessment, chest x-ray, electrocardiogram and medication review will be undertaken and, patients that are certified fit would be referred to cardiac rehabilitation programme. This review will take place at six weeks post hospital discharge in the control arm, and at three weeks in the intervention arm.
2. Outpatient exercise-based cardiac rehabilitation (CR): Patients referred for CR will be offered a comprehensive programme. A first appointment would be made with a cardiac specialist nurse who provides the patient with advice and leaflets on cardiac risk factor reduction. This will typically include information on medication, diet, exercise and physical activity as well as psychosocial wellbeing and smoking cessation. Patients will be invited to a group education session on cardiac risk factor reduction. This will be delivered by specialist cardiac rehabilitation staff. At this first appointment, referral to other healthcare professionals such as specialist counsellors, pharmacists and dieticians may also be considered when necessary. Unless contraindicated, referral to the exercise component of the CR programme will be made. Before joining the CR exercise class, patients will receive a holistic assessment from a specialist physiotherapist or exercise professional. This will involve exercise testing using the incremental shuttle walk test (ISWT). This baseline test will help to personalise exercise prescription for each patient. Following this assessment, patients will be enrolled in exercise programmes. CR exercise training will consist of supervised low-to-moderate intensity exercise performed weekly or twice a week for eight weeks, as is usual practice. Exercise will be prescribed according to standards published by the British Association for Cardiac Prevention and Rehabilitation and, the Association of Chartered Physiotherapists in Cardiac Rehabilitation. Exercise training will be performed in a gym-like environment with other patients. Interval circuit training is the most commonly prescribed mode of exercise with each individual exercise programme tailored to patients' specific needs and fitness level. The following equipment will be used; heart rate monitors, treadmill, static bikes, and hand weights. At the end of CR, a reassessment, including exercise testing using incremental shuttle walk test will be conducted. The pre and post CR tests will be recorded. A discharge letter would be sent to patients' General Practitioners summarising their treatment. The control arm will commence CR at 8 weeks as is the current practice, while the intervention arm will start at 4 weeks.

## **Intervention Type**

Other

### **Primary outcome measure**

The feasibility of delivering outpatient review three weeks after discharge post-CABG, followed by CR from four weeks, assessed using:

1. Recruitment rates and drop-out to follow-up: recruitment rates measured by summarising number of patients screened, eligible, consenting and randomised during the 5 month recruitment period, and drop-out to follow-up measured by number of questionnaires completed at week 4 or 8 (pre-CR), week 12 or 16 (post-CR), and 6-months post randomisation
2. Compliance to treatment group allocation, measured by the number of participants attending their outpatient review appointment and number of Cardiac Rehabilitation sessions attended
3. Acceptability of patient recruitment, early outpatient review and CR to patients, clinicians and NHS organisations, measured via face-to-face interviews with a sample of participants at outpatient review appointment (3 weeks or 6 weeks post randomisation and 6 month follow-up appointment) and focus group(s) with research nurses and clinical staff at end of 6-month follow up period. Diaries will also be completed by participants (throughout their 8-week cardiac rehabilitation period), Research nurses (throughout the recruitment phase) and Cardiac rehabilitation staff (for the period study participants are attending cardiac rehabilitation)

### **Secondary outcome measures**

1. Physical fitness assessed by dynamic testing with incremental shuttle walk test (ISWT) at commencement and end of CR, and 6 months after surgery
2. Cardiopulmonary fitness assessed by cardiopulmonary exercise testing (CPET) at baseline and at 6 months, for 25 patients in each study group
3. Quality of life assessed with EuroQol five dimensions (EQ-5D-5L) at beginning of the study, end of CR and 6 months after surgery
4. 30- and 90-day mortality, surgical site complications and hospital readmission rates: data collected through outpatient review appointment (3 or 6 weeks), the final assessment (6 months) and AE/SAE reporting. Any such events recorded will be broken down into 'before first appointment' and 'between first appointment and 6 months assessment' and summarised by specific event (i.e. hospital readmission rates).
5. Costs or cost savings associated with the proposed pathway: a full cost-effectiveness analysis will not be undertaken as part of this feasibility study; rather, the work will identify the data, and the feasibility of collecting the data (at week 4 or 8 (pre-CR), week 12 or 16 (post-CR), and 6-months post randomisation), needed for an economic analysis of a full scale trial

### **Overall study start date**

15/01/2019

### **Completion date**

15/07/2020

## **Eligibility**

### **Key inclusion criteria**

1. Patients undergoing elective and urgent CABG
2. Having full median sternotomy
3. Capable of giving Informed consent
4. 18 to 75 years of age

### **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 100; UK Sample Size: 100

**Total final enrolment**

50

**Key exclusion criteria**

1. Body Mass Index greater than 40kg/m<sup>2</sup>
2. Heart failure with left ventricular ejection fraction of <30%
3. Early postoperative sternal wound complications such as infection and sternal instability
4. Postoperative complications resulting in prolonged hospital stay greater than 14 days after surgery

**Date of first enrolment**

20/05/2019

**Date of final enrolment**

20/12/2019

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**East Yorkshire Cardiothoracic Centre**

Castle Hill Hospital

Castle Road

Cottingham

Kingston-Upon-Hull

United Kingdom

HU15 6JQ

**Study participating centre**

**James Cook University Hospital**  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

## Sponsor information

### Organisation

Hull University Teaching Hospitals NHS Trust

### Sponsor details

Anlaby Road  
Kingston-Upon-Hull  
England  
United Kingdom  
HU3 2JZ  
+44 (0)148275875  
james.illingworth@hey.nhs.uk

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/01b11x021>

## 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

The protocol will be available once published. Planned publication of the results in a high-impact peer reviewed journal (and presentation at conference).

## Intention to publish date

01/07/2021

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Jenny Roche, trial statistician (jenny.roche@york.ac.uk). The trialists shall make data available to the scientific community with as few restrictions as feasible, while retaining exclusive use of the data until the publication of major outputs. Consent will be obtained from participants to share data anonymously with other researchers.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	29/12/2019	01/12/2020	Yes	No
<a href="#">Results article</a>	results	11/05/2023	15/05/2023	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No