

THE 'FARSTER-CARE' STUDY

A randomised controlled trial for patients after cardiac surgery:
standard care versus an accelerated care pathway (FARSTER-care).

Participant Information Sheet

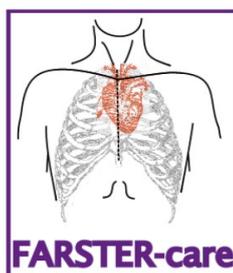
Version 2.0 (11.10.2024)

We would like to invite you to take part in our research study

- In order to make an informed decision, we would like to ask you to read the following document.
- Please do not hesitate to ask for any clarification or further information at any point in time.
- Feel free to take the time to discuss any of this with your family and friends.
- You will be given as much time as you want to make a decision.

Contents

1. What is the purpose of the study?
2. Why have I been invited?
3. How will I know if I am eligible to take part?
4. Do I have to take part?
5. What will happen if I decide to take part?
6. What will happen while I am in hospital?
7. What are the two treatment groups?
8. What will happen at my outpatient appointment?
9. Where will I have my cardiac rehabilitation?
10. What will happen at cardiac rehabilitation?
11. Is there anything different about the cardiac rehabilitation?
12. How and when will I be asked to complete questionnaires?
13. Are there any 'extra' appointments?
14. What is the total time commitment?
15. Will it cost me money to be involved?
16. Are there any risks or burdens involved?
17. Are there any benefits to taking part?
18. Who is organising the research?
19. Confidentiality
20. Your rights
21. What if there is a problem?
22. How to contact us



1. What is the purpose of the study?

Currently, patients who have had a heart operation have their first outpatient appointment at around 6 weeks after being discharged from hospital. They then start cardiac rehabilitation at around 8 weeks or later after discharge. However, there is no research to support these timings.

Our feasibility study (this is where we run the study on a much smaller scale to see what works and what doesn't) called 'FARSTER' found that starting cardiac rehabilitation earlier at 4 weeks was acceptable to patients and no complications were reported during the study. Patients in the feasibility welcomed the opportunity to start cardiac rehabilitation earlier.

We want to do a larger study following on from FARSTER called 'FARSTER-care'. Doing a larger study will help provide more reliable results to show whether an earlier outpatient appointment and cardiac rehabilitation after having a heart operation is better or not. For this larger study, we are recruiting 588 patients. Half will attend their outpatient appointment and cardiac rehabilitation at the usual times. The other half will receive attend these earlier.

2. Why have I been invited?

You have been invited to take part in this study because you will soon be having a heart operation where attending an outpatient appointment and cardiac rehabilitation are common practice. Your care team will also need to check whether you are eligible to take part (see Section 3).

3. How will I know if I am eligible to take part?

Your care team will check whether you are eligible to take part and let you know.

To take part in the study, you need to meet the following criteria:

- be aged ≥ 18 years;
- be having a 'sternotomy' which means having the operation through a cut in your breastbone;
- be offered cardiac rehabilitation as part of your care;
- be able to follow the detailed verbal instructions required for the clinical assessments;
- be able to, and agree to complete the exercise tests involved.

You are unable to take part in the study if you:

- have any sternal wound problems such as sternal instability after your operation;
- have any complications requiring further specialised care after your operation;

If you are not eligible to take part, you will continue to receive usual care.

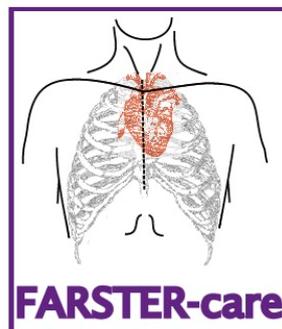
4. Do I have to take part?

Participation in this study is entirely voluntary. You may decline to take part or withdraw from the study at any time should you change your mind about taking part. You do not need to tell the researchers why you do not want to take part and your future treatment will not be affected.

5. What will happen if I decide to take part?

After you have talked about the study with a research nurse, and you have received enough information about the study, you can decide if you would like to take part. If you decide that you would like to take part, you will be asked to complete a consent form.

If you consent before your surgery, your baseline measures will be collected after your surgery. At this point you will also be asked to confirm you are still willing to participate in the trial. The following sections include details of what will happen next.



6. What will happen while I am in hospital?

After you have agreed to take part, you will be asked to complete your first questionnaire (this will take between 20-30 minutes to complete). Your care team will conduct a number of clinical assessments. These are part of your usual care and not just because you have decided to take part in this study. Information from these assessments and your medical records will be recorded by the research nurse or your care team.

You will then be placed into **one of two groups at random**. This is done by a computer and the research nurse or your care team have no control over which group you will be placed in. You will be told which group you are in. The timings of your outpatient appointment and cardiac rehabilitation will be determined by which group you are in (see Section 7).

7. What are the two treatment groups?

Group 1: Usual care group

If you are placed randomly into the usual care group, you will have an outpatient appointment at around **6 weeks** after you have been discharged from hospital. You will then start cardiac rehabilitation **2 weeks later** (at around **8 weeks** after discharge from hospital).

These timings are the same as those for usual care (the same as if you were not taking part in the study).

Group 2: FARSTER-care group

If you are placed randomly into the FARSTER-care group, you will have an outpatient appointment at around **3 weeks** after you have been discharged from hospital. You will then start cardiac rehabilitation **1 week later** (at around **4 weeks** after discharge from hospital).

These timings are earlier than usual care.

8. What will happen at my outpatient appointment?

At your outpatient appointment, you will be seen by a clinical specialist for a full clinical assessment. This would happen even if you were not taking part in the study and is the same for whichever treatment group you are in. The only thing that is different between the two treatment groups is the timings (i.e. the number of weeks after you have been discharged from hospital before attending this outpatient appointment—see Section 7).

9. Where will I have my cardiac rehabilitation?

You may be offered a choice of where to go for your cardiac rehabilitation. This will depend on the hospital where you had your operation and the services available where you live. Options may include:

- **Hospital-based** cardiac rehabilitation, either at the hospital where you had your operation, or at another hospital closer to your home.
- **A community setting** with cardiac rehabilitation run by the NHS or an independent health service provider commissioned by the NHS.

Depending on where you go for your cardiac rehabilitation, you may be able to choose to do the exercise sessions at home, in clinic, or you could do some at home and some in clinic. If you choose to do your exercise sessions at home, you will be telephoned each week to see how you are getting on and discuss any problems you may be having.

10. What will happen at cardiac rehabilitation?

Cardiac rehabilitation includes a first appointment, exercise sessions and a final appointment. You may also receive advice and information as part of your cardiac rehabilitation. Your care team can provide further details and let you know what to expect.

- **First appointment:** During this appointment, you will be assessed by a specialist cardiac rehabilitation team. You will be asked to complete an exercise test and a questionnaire.
- **Exercise sessions:** You will then complete the exercise part of the programme, with sessions happening once or twice a week for around 8 weeks. The exercise sessions will be tailored to your fitness level and you will be closely monitored throughout. As part of the study, you may be asked to complete a record of the exercises you complete during these sessions. The cardiac rehabilitation team can help you with this. As detailed in Section 9, it may be possible to do the exercise sessions at home, in clinic, or a mixture of both.
- **Final appointment:** During this appointment you will be asked to repeat the exercise test and complete a questionnaire.

11. Is there anything different about the cardiac rehabilitation?

The content and structure of the cardiac rehabilitation programme is the same as it would be if you were not taking part in the study. The content is also the same for whichever treatment group you are in. The only thing that is different between the two treatment groups is the timings (i.e. the number of weeks after you have been discharged from hospital before starting the cardiac rehabilitation—see Section 7).

12. How and when will I be asked to complete questionnaires?

You will be asked to complete your first questionnaire while on the hospital ward after your operation. You will then be asked to complete further questionnaires at your first and final cardiac rehabilitation appointments (Section 10) and at the 6 month 'extra' appointment (Section 13). The final questionnaire that you will be asked to complete will be at 12 months. This questionnaire may be emailed or posted to you, or the study team can call you to complete the questionnaire by telephone. You will be asked to choose your preferred method. Questionnaires will take between 20-30 minutes to complete.

13. Are there any 'extra' appointments?

Around 6 months after your operation, you will be asked to attend an extra outpatient appointment. This appointment is not part of usual care. At this appointment you will undergo another clinical assessment. You will also be asked to do a final exercise test and complete a questionnaire.

14. What is the total time commitment?

Your time commitment for your outpatient appointment and cardiac rehabilitation will be the same as it would be even if you choose not to take part in the study.

'Extra' time commitment if you take part in the study:

- Recording exercises completed in cardiac rehabilitation exercise sessions (see Section 10).
- Questionnaire completion (see Section 12).
- An extra outpatient appointment at around 6 months after your operation (see Section 13).

15. Will it cost me money to be involved?

Your outpatient appointment and cardiac rehabilitation sessions are all part of usual care, and therefore you should not have any extra costs for attending these. You will be asked to attend one extra outpatient appointment, at around 6 months after your operation, which is not usual care. For attending this appointment, you will be reimbursed £10 to cover travel costs.

16. Are there any risks or burdens involved?

You are about to have a major operation which is not without risks and these will have been discussed with you by your care team. In order to minimise risks in taking part in this study, you will be closely monitored providing the opportunity to find any complications early on.

Potential risks involved in taking part in this study are due to starting physical exercise earlier after your operation. This could interfere with healing of breastbone, which could cause severe wound pain and/or a click in the breast bone. The feasibility study 'FARSTER' did not find that starting physical exercise earlier increased such problems. Should you experience such problems you will be seen urgently by the surgical staff, examined, investigated and treated appropriately.

All participants in the study will experience some extra burden due to the time commitment required (see Section 14). We have designed the study to reduce the burden on participants by making the questionnaires as short as possible. Also, the study uses information from clinical assessments that are part of usual care, reducing the extra clinical assessments needed.

17. Are there any benefits to taking part?

If you do take part, you will be contributing to our knowledge about when it is best for people to have an outpatient appointment and start cardiac rehabilitation after having a heart operation. We cannot promise the study will benefit your recovery; but the information we get from this study will help to show whether an earlier outpatient appointment and cardiac rehabilitation after having a heart operation are better or not.

18. Who is organising the research?

The study is being organised by Professor Dumbor L Ngaage from Hull University Teaching Hospitals NHS Trust.

Hull University Teaching Hospitals NHS Trust is the sponsor for this study, based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. On behalf of Hull University Teaching Hospitals NHS Trust, the University of York will keep identifiable information about you for 10 years after the study has finished.

This study is funded by the National Institute for Health and Care Research (NIHR) 'Health Technology Assessment Programme' (reference: NIHR152069). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. This study has been reviewed and given a favourable opinion by North West - Liverpool Central Research Ethics Committee (REC reference: 24/NW/0036)

If you would like to be informed of the study results, please indicate this on the consent form and a summary of the results will be sent you.

To contact the Hull University Teaching Hospitals NHS Trust about this study, please use the following contact details:

Telephone: 01482 461662; Email: hyp-tr.farstercare.rct@nhs.net.

19. Confidentiality

- **Where and how your information be stored**

Information collected about you may be stored at your hospital trust and at the University of York, who are organising the research on behalf of Hull University Teaching Hospitals NHS Trust, or at an alternative secure facility. All information will be kept strictly confidential and will be stored in accordance with the with the UK General Data Protection Regulations (GDPR) and the UK Data Protection Act 2018.

Information collected about you during the research and from your medical records will be held securely on paper or electronically, either under lock and key or via encrypted and password protected computers at your hospital trust or the University of York . A secure 'cloud' hosted server known as 'Research Electronic Data Capture' (REDCap) which has been designed to collect and store research data will be used to collect and store information for this study.

- **Who will know about your involvement in the study**

The research team and your care team at the hospital will be aware of your involvement in the study. We will need to inform your GP of your involvement in the study. We will keep all information about you safe and secure, and we will write our reports so that no-one else outside of the research team will know that you have taken part in the study. We will not share your information with any other organisation or party outside of the research team and/or relevant NHS Trusts.

- **What information will be stored and how it will be used**

Your name, NHS number, address, email and telephone number will be stored securely at the University of York and your hospital trust to allow them to contact you and access your information from medical and other health records. You will be assigned a participant number so that no information collected can be linked to you directly. All documents will be identified by your participant number (and not by any of your personal identifiable information) and kept securely. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

- **What will happen to your information at the end of the study**

At the end of the study, any personal identifiable information collected from you will be securely archived for at least 10 years. Any identifiable information will be kept strictly confidential and access will be limited to the original study team. Confidential and secure destruction will then be arranged.

Study results that do not include your personal identifiable information may be stored indefinitely. Researchers analysing the data in the future will be unable to identify you.

- **How your hospital will use your information**

Your hospital trust will collect information from you and your medical records for this research study in accordance with our instructions.

Your hospital trust will keep your name, contact details and date of birth confidential and will not pass this information to Hull University Teaching Hospitals NHS Trust. Your hospital trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Hull University Teaching Hospitals NHS Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Hull University Teaching Hospitals NHS Trust will only receive information without any identifying information.

Your hospital trust will keep identifiable information about you from this study for 10 years after the study has finished.

- **Your choices about how your information is used**

Copies of your signed consent form will be kept and you will be given a copy. By signing the consent form, you give permission for the above to occur.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

- **To find out more about how we use your information**

- <https://www.hra.nhs.uk/information-about-patients/>
- <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/> and
- Contact a member of the research team (see Section 22 for contact details)

20. Your rights

Your participation in this study is entirely voluntary and declining will not affect any other medical treatment. You may, without reason, decline to take part in the study at any point, and this will not, in any way, affect your continuing treatment.

21. What if there is a problem?

If you have any medical problems or concerns relating to your chest, please contact your care team. If the event of you requiring urgent care, you should contact the usual emergency services.

If you have a problem about any aspect related to your participation in this study, please phone the researcher. Their details are at the end of this information sheet.

While we anticipate no harm or distress to anyone as a result of this study it is important to state that there are no special compensation arrangements. In the unlikely event that you suffer from injury or illness as a result of participation in this study, indemnity cover will be provided by the Hull University Teaching Hospitals NHS Trust.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints processes are available to you. You can also contact the study sponsor (Hull University Teaching Hospitals NHS Trust) to complain using the contact details in Section 18.

22. How to contact us

If you have any questions about this study, please contact your care team (at participating hospitals only).

If you would like independent advice about whether or not to take part, please contact your hospital's Patient Advice and Liaison Service (PALS). Contact details can be found online or by asking your care team.



**Thank you for taking the time to read this information leaflet.
If you decide to take part, please retain this leaflet for your future reference.**