Older people with heart failure may have difficulty in doing everyday things. Current health services aren't always able to meet their needs. Our research study is testing a new treatment programme to try to improve care.

We are inviting you to take part in our study because a doctor at your local hospital thought it may be suitable for you based on information in your medical records.

What information do I have about the research?

Before you decide if you want to take part, please look through all the information in this **document**.

This will explain why we are doing the research and what taking part would involve for you. It contains everything you might need to know before you make your decision.

You can find some optional extra information in **the additional information leaflet and on the webpage** https://ctru.leeds.ac.uk/chart/. **You don't have to look at any of that extra information before making your decision, if you don't want to.** But you might find it useful if you still have any questions, either now or in the future.

Patients like you have helped put all these resources together.

Please take the time to read this **document** and as much of the **additional information** as you want to. Discuss it with others, if you like. Ask the researcher if you still have questions, or if you would like more information.

We may update this information during the research, for example if we learn something new about the treatment programme. We will tell you about any important updates, and give you the chance to choose if you still want to take part or not.

Once you have read the information, your researcher will talk to you about the research again and you can ask any questions you like.

Who can I contact if I have more questions?

If you have any questions about this research, please talk to:

<<Enter PI, nurse name >>

at

<< Contact details for site>>

What is this research about and why are we doing it?

What is the purpose of the research?

Older people with heart failure can experience challenges doing everyday things. Our research is testing a new treatment programme to try to improve the care for these people. The new treatment programme involves a full health assessment with a doctor or nurse in an outpatient clinic, and a physiotherapist visiting you at home.

Our research will work out if the new treatment programme in addition to usual care helps people maintain their independence.

What is usual care?

This is the care that is provided by your GP, hospital care team and community and social services in your area as standard. If you have questions about what the usual care is near you, you can talk to your doctor.

What is the new treatment programme?

The new treatment programme involves a full health assessment with:

- A doctor or nurse. This may happen at a clinic or at your home. They will discuss what is important to you and come up with a plan for your care. They will speak with you again

at least one more time to see how the plan is working. These appointments will last for about 30 minutes each.

- A physiotherapist. They will visit you at home for an initial assessment which could last up to 90 minutes and then contact you by phone or visit you at home weekly for about three months. They will introduce a **home-based programme**, tailored to you, including activities to improve your strength and balance and increase your confidence, as appropriate. They will help you to set personal goals to work towards.

Who is doing this research?

This research is being run by the Academic Unit for Ageing and Stroke Research, Bradford Institute for Health Research, the University of Exeter and the Clinical Trials Research Unit at the University of Leeds. The research team includes people with lived experience of heart failure.

Your hospital is helping us to find people who could take part in the research.

Bradford Teaching Hospital NHS Foundation Trust is also involved and has overall responsibility for how the research is run.

The research is funded by National Institute for Health and Care Research (NIHR).

You can read more about who is involved in the **additional information**, as well as who is responsible for approving and checking the research.

What would I have to do if I take part?

Finding out if the research is suitable for you

Although your care team thinks the research might be suitable for you, our researchers will need to carry out an assessment and ask you some questions to make sure.

Who will decide what treatment I get?

If you decide to take part in this research, your doctor or the researcher will not decide what treatment you get. Instead, you will get one of the treatments **by chance** (randomly). We do this so that we can do a fair test of which treatment is best.

There is a higher chance that you will receive the new treatment programme than not. You should only agree to take part if you are happy with this. We will write to you to tell you which treatment you will get. You will receive the letter shortly after you agreed to take part.

Will I get back any travel or other costs?

You may be asked to see a doctor/nurse for a clinic appointment to agree a plan for your care. You will be able to

claim for travel expenses. Your hospital will provide further details on how to claim for this money.

What else will I need to do?

You will fill in a questionnaire with a researcher at the start. You will then be asked to fill in similar questionnaires 6 months and 12 months after you started. You can receive the questionnaires to your email address or get a paper copy in the post. Or you may complete them over the phone or in your home with a researcher. The questionnaires will take no more than one hour to complete. At 12 months we will send you a £10 voucher as a thank you for taking part.

You will receive **reminders** to complete **questionnaires** by post, email and/or phone. If you do not want to receive reminders at any point you can let us know and we will stop them.

If you agree, a qualified researcher will access relevant parts of your **medical and care records** so that we can find out about the treatment and services being provided to you. We will also collect further health and treatment information held in central NHS databases. You won't need to do anything else for this to happen. To do this we will send your name, date of birth, NHS number, gender and postcode to electronic health registries, such as NHS England, using secure processes.

This saves time for you and your hospital, as it means you don't need to have as many appointments for the research. We would only access information that is needed for the research. We would also like to access this information to see how you are doing in a few years' time. You do not have to agree to this if you do not wish to.

We will continue to collect this information about you in this way if you stop taking part in other parts of the research, unless you tell us you want us to stop. This helps make the research results reliable. But you can say you want this to stop at any time.

Staying in touch

We will need to contact you sometimes while you're taking part in the research. Please do let your researcher know if you change your address, email address or phone number during the research, so they don't lose touch with you. You can also let them know if you want to change the main way they contact you.

If we lose contact with you when we're expecting to hear from you, one of our researchers may contact your GP to try to get your current details.

We are not expecting this to happen, but if during the study your clinical care team determine that you are unable to make your own decisions, we would stop collecting information about

you. However, any information collected up until this point will remain on file and will be included in the study analysis.

Recordings and Interviews (Optional)

Your care provider may ask to **audio record** your assessment and rehabilitation appointments. The recordings will be shared with the trial researcher, but they won't be able to identify you from the recording.

Members of the research team may ask to contact you to see if you would like to take part in an **interview** about your experiences in the study. It would take place at a location and time convenient to you and take about an hour. We will send you a £20 voucher as a thank you for taking part in an interview.

These parts of the research are optional. You can still take part in the research without doing these.

What are the potential benefits and risks?

What are the possible benefits of taking part?

Although we don't know if our new treatment programme helps people with heart failure, you might find it useful to you. You may have more frequent contact with a care team, which you may find helpful. You will also be contributing to important research that may benefit patients in future.

What are the potential risks of taking part?

We do not expect there to be many risks to taking part. Agreeing to take part in the study means that if you receive the new treatment programme you will need to attend additional appointments and allow member(s) of the physiotherapy team to visit you at home.

As the treatment involves activities you may experience muscle soreness. The physiotherapy team member will make sure that the exercise is appropriate for you.

You will give up some of your time to complete questionnaires. We will ask you some questions about your health and wellbeing. You don't have to answer any questions you don't wish to.

What will happen to me at the end of the research?

Your care team will monitor your health during the study as they normally would. After the three- month treatment period, participants receiving the new treatment programme will no longer have study-specific appointments with the study healthcare team. Your routine care appointments will continue.

What will happen to the results of the research?

We will make sure you have a chance to find out the results of the research, if you would like them. You will still be able to have a copy of the research results if you stop taking part before the end.

When the research is complete the results will be published in a medical journal and a public registry. We will provide updates on our website: https://ctru.leeds.ac.uk/chart/

No individual participants will be identified in the results.

Research like this can take a while to complete. The results will not be ready for **a few years.** You can stay in touch with our progress by checking the CHART website and by contacting your researcher**.**

Who will see information about me if I take part?

- Your **GP, and the other doctors involved in your healthcare, will be kept informed** of your participation in this research.
- We may also **need to contact your GP and other doctors** to check you are still OK to take part in the research.
- Your **medical notes may be looked at** by people from the research team at the University of Leeds, the University of Exeter and Bradford Teaching Hospitals NHS Foundation Trust, the regulatory authorities or other authorised bodies.

  These checks are to make sure the research is being carried out correctly. This will only be done in line with your hospital's rules about making sure your records are secure. This could happen at any point during the research. But if you tell us you no longer agree to this, then it won't happen after that.
- We would like to **collect a copy of your completed consent form**, if you agree to take part in the research. This is so that we can check you have definitely agreed to take part.
- If you agree for a researcher to contact you about taking part in an optional interview, CHART researchers will

access your contact details to provide you with more information.

How will my information be used?

If you decide to take part in this research, we will collect some information about you and your health.

What will the information be used for? We will use your information to run the research, produce the research results, and to help keep you and other participants safe. We will keep all your information secure at all times.

Who will be responsible for how my information is used? Bradford Teaching Hospitals NHS Foundation Trust and the University of Leeds will have overall responsibility for how your information is used in this research.

Will my information be shared or used for other reasons? We may use the information we collect for this research for other research projects within Bradford Teaching Hospitals NHS Foundation Trust, the University of Leeds and the University of Exeter. We may also share it with others outside the University for other research projects. Anyone outside the original research team will not be able to identify you.

We will only do this for worthwhile research projects with all appropriate approvals. If you ask us to collect no more information about you, the information we share for other

research will still include information we have collected up to that point.

We will sometimes need to share your information outside Bradford Teaching Hospitals NHS Foundation Trust and the University of Leeds for other reasons, including to run the research, to keep you and others safe and to comply with laws and other rules around research. The information we share will not identify you.

We will never sell your information, or pass it on to people who will sell it. Information that we share will never be used to make decisions about future services available to you, such as insurance.

What are my rights? We will use your information to do this research in the public interest. Research like this is protected in the law. So some of your usual rights about how your information is used are limited. We might not be able to delete your information once we had already collected it, for example.

How long will my information be kept for? We will need to keep your identifiable information until at least 10 years after the research has finished.

What if I change my mind?

If you agree to take part, you can change your mind at any time and stop all or just some parts of the research. Your usual care won't be affected if you stop or change how much you take part.

You won't have to explain to anyone why you want to stop. However, if you do feel able to tell us about your experience in the research it can help the research team learn and improve what we do.

It can really help the research to keep collecting information from any research visits or routine healthcare appointments you have, if they are useful to the research. So we will keep doing this until you say you want us to stop. You don't need to do anything extra to help the research in this way. You can say you want to stop at any time. There is some further detail about this in the **additional information**.

Please contact your researcher if you are finding it hard to take part. They may be able to help you.

What if something goes wrong?

Raising a concern:

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Experience team on email: [insert contact email]. Details are available on the Trust's website at [insert website link].

Claims for compensation

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action against the Trust but you may have to pay your legal costs. The normal National Health Service Complaints mechanisms does not make provision for payment of compensation although modest ex-gratia payments (goodwill payments) may be considered in certain circumstances.

Participant ID *Site Code* | *Trial No*	Initials:
Date of Birth:	NHS/CHI/Hospital Number:
ISRCTN: 22229432	Principal Investigator:

CHART

PARTICIPANT CONSENT FORM

Please initial each box

1. I confirm that I have read through the information about this research and have had the opportunity to ask questions. ☐

2. I understand that my participation in this research is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. ☐

3. I understand that my healthcare records may be looked at by authorised individuals from the research team, regulatory bodies or Sponsor to check that the research is being carried out correctly. ☐

4. I agree for my details (which will include my name, date of birth, NHS number, gender and postcode) to be submitted to the NHS registers such as the Office for National Statistics and Hospital Episodes Statistics via NHS England ☐

5. I agree to a copy of this Consent Form being securely sent to the Leeds Clinical Trials Research Unit (CTRU). I understand that this will show my name and signature. ☐

6. I agree that my GP, or any other doctor treating me, will be notified of my participation in this research and may be contacted if the study team are unable to reach me during the study. ☐

7. I agree to complete questionnaires for this research. I understand that my address and/or email address will be passed to the Leeds CTRU so questionnaires can be sent to me. ☐

8. I understand that information collected about me in this research may be used later for other research in the public interest. Information would only be shared outside the original research team in a way that means I could not be identified. ☐

9. I agree to take part in the research ☐

The following points are OPTIONAL.

Even if you agree to take part in this research, you do not have to agree to this section.

	Please tick ✓ Yes	No
1. I give permission to be contacted over the study period by researchers from the study team to discuss taking part in an interview to talk about my experiences in the study.	☐	☐
2. I give permission for my care appointments to be audio-recorded.	☐	☐
3. I agree for my details to be submitted to the Office for National Statistics and Hospital Episodes Statistics via NHS England after the initial two years of my involvement.	☐	☐

Participant:

Signature……

Name (block capitals)……

Date……

Investigator:

I have explained the research to the above-named patient and they have indicated their willingness to participate.

Signature……

Name (block capitals)……

Date……

(1 copy for participant; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)