CHART
CompreHensive Assessment for older people with hearT failure and frailty

Participant Information Sheet Additional Information

A large-print version of this sheet is available on request.

More information and frequently asked questions

You don't have to read any of this information before making your decision about taking part, if you don't want to. But you might find it answers questions you may have now or later.

Contents

1. More about the research

Older people with heart failure can experience challenges doing everyday things and may not receive the right sort of care they need. Our research is testing a new approach to care. This approach uses an assessment and rehabilitation programme that involves older people as well as their families, carers and healthcare professionals.

The assessment will identify and help manage health problems and prevent new ones arising. Similar assessments are offered to older people already, but are not always offered in all areas of the UK or to people with heart failure. Rehabilitation helps people to do what is important to them and is a key aspect of care.

Will I need to have any extra appointments?
If you get allocated to receive the new treatment programme, you will need to see a healthcare professional such as a doctor or nurse in clinic or at your home for at least two appointments. For the home rehabilitation part of the treatment programme, a therapist will visit you at home and call you weekly (up to 12 times) during the 3 months.

Will I get back any travel or other costs?

If you need to travel to see the doctor/nurse for a study clinic appointment, you will be able to get your travel costs reimbursed.

If I want to, will I definitely be able to take part?
The CHART researcher will discuss the study with you and ask you some questions to see if the study is suitable for you. The study treatment programme has been designed to target people's specific needs. If you do not have the same needs the study may not be a good fit for you.

2. Who has organised, reviewed and funded the research. Who will be supervising?

The study is being organised and supervised by:

- Bradford Teaching Hospitals NHS Foundation Trust: https://www.bradfordhospitals.nhs.uk/
- alongside the Clinical Trials Research Unit (CTRU), University of Leeds https://ctru.leeds.ac.uk/chart/
- University of Exeter https://www.exeter.ac.uk/

It is funded by the National Institute for Health and Care Research (NIHR) https://www.nihr.ac.uk/about-us/who-we-are/ .

A group of patients with a diagnosis of heart failure helped in the design of the study. All research is looked at by an independent group of people called a Research Ethics Committee, to protect the safety, rights, wellbeing, and dignity of those taking part. The study has been reviewed and

approved by a Research Ethics Committee: Yorkshire & The Humber - Leeds East Research Ethics Committee. You can read more about the role of a Research Ethics Committee here: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committees-overview/ .

3. More about how your information will be used

We know that some people want to know more than others about how their information is used.

The information here goes into some more detail about how your information will be used if you take part. It may help address particular questions or concerns you may have.

If you would like more detailed explanations about anything, including why we need to do things in a certain way, you can find it in our comprehensive guide. This is available anytime at https://ctru.leeds.ac.uk/ctru-comprehensive-privacy-guide/ or you can ask for a printed copy from your researcher. This can also be made available in large print or other formats, if you need them.

You can find more general information from the NHS about how people's information is used in research at www.hra.nhs.uk/patientdataandresearch. (Please feel free to ask for a printed copy of this if you cannot access this online version.)

a. What information will be collected, and what will it be used for?

If you agree to take part in this research, we will need to collect and use some information about you and your health. We will only use what we need to run the research, to produce the results of the research and to make sure you and other people taking part in the research are safe.

This research is in the public interest, which means our results will be used to improve the healthcare of patients in the future. Because of this, if you agree to take part in the research, we will be able to use information about you, including sensitive information about your health.

Specifically, the ways we will use information about you are:

- We will use information from you and your medical notes to run the research, to produce the research results and to confirm it is safe and appropriate for you to join the research. We will also collect information about your health from your research doctor or nurse and your medical notes to help make sure you and others are safe.
- We will collect a copy of your signed consent form so that we can be sure you have agreed to take part in the research.
- We will collect information about you and your health directly from you on research questionnaires. We will use this information to produce the research results.

- We will collect information about you held in NHS databases managed by **NHS England.** To do this, we will securely send **your initials, your date of birth, your NHS number** to **NHS England** and they will return the information about you that we need for the research. We do this because it means we can do the research while taking up less of your time, and less of your hospital's time.
- Sometimes we need to ask doctors who work with us to give us advice on specific medical situations. To help the doctors do this, we might need to collect copies or scans of parts of your medical notes. These will have any details that could identify you removed before they are sent to us.
- If you join this research, we would like to send you **study questionnaires, reminders to complete study questionnaires and occasional newsletters or updates.** To do this, we will need to collect your **postal address and phone number. If you prefer to receive questionnaires by email, we will also collect your email address.** You can choose which details to provide and we will only use it for the purposes mentioned here. If you provide a mobile number, we may also send you reminders via **SMS**.

If you want to find out more about any of these, please refer to the University of Leeds' **comprehensive guide** to how your information is used.

b. Who is collecting my information?

Your information will be collected by the **Clinical Trials Research Unit** within the **Leeds Institute of Clinical Trials Research**, **University of Leeds**. You can find out more about our work at https://ctru.leeds.ac.uk/. If you consent to contact by a researcher to participate in interviews, the University of Exeter and/or Bradford Teaching Hospitals NHS Foundation Trust will be responsible for recording and transcribing your data. They will do so confidentially and securely. If you are allocated to receive the CHART trial treatment, the University of Exeter and University of Leeds will collect information on your care.

University of Leeds and **Bradford Teaching Hospitals NHS Foundation Trust** which is the 'sponsor' of the research, jointly have responsibility for what information is collected, how it is collected, and making sure people's information is used securely and correctly. If you want to contact someone within the **Bradford Teaching Hospitals NHS Foundation Trust** about how your information has been or will be used, you can see section 3, below. **The University of Exeter** and **Bradford Teaching Hospitals NHS Foundation Trust** will be jointly responsible for data collected as part of any care recordings or interviews that you take part in.

We will make sure we follow the principles of data protection in everything we do. This means we will keep your information secure, keep it only for as long as we need it, only use the minimum information we need for specific, necessary purposes, and we will be open, transparent and fair with you about how we use your information. You can find out more

about how the University of Leeds follow the principles of data protection in the **comprehensive guide.** You can also read more about how Bradford Teaching Hospitals NHS Foundation Trust collect, use, retain and disclose personal information here: https://www.bradfordhospitals.nhs.uk/privacy-statement/

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c. Will my information be kept secure?

We will take all necessary measures to ensure that information about you is sent and stored securely by us or by anyone acting on our behalf.

Most of your information that we need for the research will be sent to us by post. Research forms only show your initials, date of birth and your unique research identification number. Your completed consent form will also be sent to us so that we can be sure you have agreed to take part in the research. This will be sent separately to rest of the research forms.

Study researchers will enter some of the information needed for the research directly into our secure research database.

Sometimes we will also get information about you by email. Emails will never contain your name, only your trial identifying number and sometimes your initials and date of birth.

Finally, some particularly sensitive documents, such as **your consent form** will be sent to us via a 'secure file transfer'. This means information is sent by the internet in a very secure way.

Information stored in our databases or other electronic storage locations is held very securely, in a way that would make it very difficult for any unauthorised people to access it.

d. Who will see my information in the research team?

We will make sure that the only people at the University of Leeds, Bradford Teaching Hospitals NHS Foundation Trust or the University of Exeter who can see your information are people who need to run or analyse the research, or check how the research has been run.

e. Who else will see my information?

There are some specific situations where we need to share information with other people or other organisations. We will always do this carefully and only when it is really necessary. We will avoid sharing information that could identify you whenever possible. We will never sell your information, or pass it on to people who will sell it. We will only share information when it is necessary for the research, necessary to protect your safety or the safety of others, or in

the public interest. Information we share will not be used to make decisions about future services available to you, such as insurance.

We will share your information for the following reasons. You can find out more about these in the University of Leeds' **comprehensive guide.**

- To run and analyse parts of the research, we need to share your information with collaborators (such as doctors, statisticians or other experts) outside the University of Leeds, Bradford Teaching Hospitals NHS Foundation Trust and the University of Exeter.
- To obtain additional information from your **NHS** medical records, we need to share your information with **NHS England** or other information providers. They will send us information about you that we need for the research. This is an important way we can do the research while saving time and money for you and for the NHS.
- To keep you and other people safe, we will need to share some information about health-related events you may have with authorised organisations. None of these organisations will be able to identify you from this information.
- To report to authorised people about the progress of the research, we will need to share some basic information with some authorised organisations, including the Research Ethics Committee that has approved this research. None of these organisations will be able to identify you from this information.
- To allow other researchers to carry out future research in the public interest. We will only share your information for worthwhile research with all appropriate approvals. We will only share your information in such a way that researchers outside the University of Leeds will not be able to identify you.
- We may also use research information for additional research projects within the University of Leeds, Bradford Teaching Hospitals NHS Trust or the University of Exeter. We will only agree to do this for worthwhile projects with all appropriate approvals, and we will not share any clearly identifiable information with researchers outside the original research team.
- Due to storage space limitations, we will store information securely away from the University of Leeds for a period after the main part of the research is over. The archiving companies we use to do this for us will only store your information and will not access it or see your details.

f. Can I see my information, or ask you to correct it?

Usually, when an organisation or a company has information about you, you can ask to have access to that information at any time, or ask them to correct it if it needs correcting. However, this does not apply in the same way to information used for research in the public interest, because allowing people to access or change their information could harm the quality of the research. You therefore cannot ask to access or correct information we have about you. You should speak to your researcher, research doctor and nurse if you would like more information about care you have received.

If you have provided us with contact details for use in the research such as your **address, email address, phone number** it is important that we find out about any changes to these. Please let your researcher know about any changes so that they can let us know. Otherwise, we might lose contact with you or send messages for you to your previous contact details.

g. How long will my information be stored for?

If you agree to take part in this research, we will need to keep your information for at least **ten years** after the end of the research. We need to do this in order to comply with laws and other rules about research, which say it must be possible to check the results of the research for a period of time after it has finished.

We will keep your information secure during all this time. For practical reasons, we may ask reputable archiving companies to store information securely on our behalf, away from the University of Leeds and Bradford Teaching Hospitals NHS Foundation Trust.

At the end of this period, we will securely destroy your information.

h. What will happen if I stop taking part in the trial?

If you decide you would like to stop taking part in the research for any reason, we will need to keep the information we have about you to make sure the results of the research are reliable.

Usually, when an organisation or a company has information about you, you can ask them to delete it, or not use it for a certain purpose. However, this does not apply in the same way to information used for research done in the public interest, because it would harm the quality of the research if people could delete or remove their information.

We also need to comply with laws and other rules about research that say we need to keep all information used in research for a period of time after the research finishes.

If you agree to take part in this research, it will therefore not be possible for us to remove or delete your information later on, although you can ask us to collect no further information after a given time.

Some other things you should know about what will happen to your information if you stop taking part:

- In this research we will get some information from your electronic medical records held in NHS databases by **NHS England**. If you ask to stop your research visits, we will continue doing this. Again, this means we can make sure the results of the research are reliable, without you having to give any more of your time. However, you can tell your study researcher at any time that you would like us to stop doing this, and they will make sure your wishes are respected.
- If you stop attending your research visits without telling anyone in your care team, or you change your contact details or move house and do not tell your hospital, they will

lose contact with you. If this happens, we may ask your researcher to contact your GP to check if you are OK and still happy to take part in the research.

If you want to know more about what might happen to your information if you stop taking part in the research, including *why* we need to use your information in the ways we do, please see the University of Leeds' **comprehensive guide.**

i. What if I have concerns about how my information is being used?

Your study researcher should be your first contact for any questions about your participation in this research.

If you still have questions that they cannot answer, and which are not answered by any of this information, you can contact the Bradford Teaching Hospitals NHS Foundation Trust Data Protection Officer, (the Trust's main contact for anything to do with how your information is used).

You can do this using any of the details below. If you do contact them, please mention the name of this research **CHART Study**.

- Email: dataprotectionofficer@bthft.nhs.uk

You can also contact the Information Governance team:

- Email: Information.Governance@bthft.nhs.uk

If you are not happy with the response to any queries or complaints, or believe your information is being used incorrectly or unlawfully, you should contact the Information Commissioner's Office:

- General website: ico.org.uk
- ICO contact webpage: ico.org.uk/global/contact-us
- Telephone number: 0303 123 1113
- Postal address: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

You can also find out more about how we use your information by contacting the trial manager (details below) The research team would be happy to forward any further queries you may have on to the Data Protection Officer.

- CHART Trial Manager
- Clinical Trials Research Unit
  Leeds Institute of Clinical Trials Research
  University of Leeds
  Leeds
  LS2 9JT
- 0113 343 2653

4. Stopping or changing your level of participation

a. Can I stop taking part in some parts of the research while still carrying on with others?

Yes. For example, you might stop completing questionnaires but keep having study appointments with your care team. Or you might stop questionnaires, but still allow information about you to be collected from any routine health visits you make.

It helps the research for you to continue making some sort of contribution for as long as you can. The more of the planned information we collect for the research, the more reliable the research results can be.

b. Can I stop taking part for a while, then start taking part again?

In some cases, yes, if you want to. We understand that sometimes life might get in the way of continuing in research. You might just need a break from the research. If things change and you want to start taking part again, please get in touch with your researcher to discuss what is possible.

c. Can I keep receiving the new treatment programme but stop all other parts of the research?

The CHART treatment programme is not currently available outside of this research. This means you can only keep getting it while you are taking part in the research.

You are able to keep receiving the new CHART treatment programme but stop getting the study questionnaires. However, we would still need to collect some information about you from your CHART care appointments and your health records. If you prefer for this not to happen, you would need to withdraw from the CHART treatment programme as well.

d. What should I expect to happen if I say I want to stop taking part?

It can be helpful for you and for the research if you can **discuss your involvement** with your study researcher. They can explain what your options are, and you can tell them exactly what you want to do.

Your study researcher may be able to help with the things that are making you want to stop taking part. With their support, you may find that you can carry on in the research after all. But it is fine if you do want to stop. Your researcher or nurse will confirm what will happen next.

You **will not have to complete any forms** or sign anything to stop taking part. Just saying what you want to do is enough.

Your researcher **will make clear what will happen next** about your treatment and care. Ask for more information on this if you need to.

Feel free to ask if you need more **support** while you leave the research. It should be made clear who your main contact will be about your **health and care** especially if it won't be someone who works on the research.

If you agreed before for your GP to find out about you taking part in the research, your researcher **may inform your GP** that you have stopped.

Your researcher may ask you whether you want to get **updates about the study in future**. For example, you might want information about the research results at the end.

Your researcher may ask you if you'd be **willing to say why you want to stop** taking part. It's fine if you would prefer not to say why. See below for more information: 'Why is it useful to know my reasons if I stop taking part?'

e. Why is it useful to know my reasons if I stop taking part?

You don't have to give any information about why you are stopping if you don't feel comfortable about saying.

However, it can be useful to know if you have any feedback on your experience in the research. This can help the research team improve patients' experiences in this research and improve how other research is planned and run in the future.

It can also be helpful if you are willing to give a reason why you want to stop taking part. This can help the research team understand the results of the research better.

Knowing people's reasons for stopping can help the research team understand if people who stopped taking part might have done better or less well (in terms of their health) than people who carried on in the research.

It is especially helpful to know if stopping has anything to do with changes in your health. We would not need to know any more detail than that for it to be useful information. Any information you give to us will be treated sensitively and confidentially.

f. Why can my information not be deleted if I stop taking part?

Usually, when an organisation has information about you, you can ask them to delete it, or only use it in certain ways. However, this does not apply to the information used for research like this. It would harm the quality of the research if people could remove their information. This is important because patients in future are affected by the results of research.

We also need to comply with rules about research that say we need to keep all the information for a while after the research finishes. This allows authorities who oversee research to check that the research has been carried out correctly. This is important because the results of research often impact on the treatment patients receive.

If you stop taking part, we will therefore keep the information we already have about you. We will still include it in the research results. We will make sure we keep information about you secure and confidential. No one will be able to see who you are from the research results.

Research done in the public interest has special protection under the General Data Protection Regulation (GDPR). You can read more about this on the Information Commissioner's Office website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/the-research-provisions/

g. What should I do if I want no more information about me to be collected for the research?

All you have to do is contact your researcher and tell them you want this. We will make sure no more information about you will be collected from after that point.

Your usual care will not be affected if you decide you want no more information to be collected.

If you stop a part of the research (for example, receiving the research treatment), your researcher will check if you are still OK for information being collected about you for the research.

If you do not say anything about wanting the information collection to stop, we would assume you are still OK with it carrying on. You can still say you want the information collection to stop at any time. We would remind you that we were still planning to collect information about you at the time you stop taking part in the other parts of the research.

For as long as we do keep collecting information about you, we will only collect information that is useful to this research. We will only do it in line with the consent you have given.

h. Can I still stay in touch with the research if I stop taking part?

Yes. Just because you stop taking part, it doesn't mean that you can't get updates about the research, if you still want to have them.

If you stop taking part, your researcher should ask if you want to have any further contact about the research.

5. Finding out the research results and other information at the end of the study

a. How and when will I be able to find out 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.

6. What if something goes wrong?

a. 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].

b. 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.

7. Useful links

a. For more information on the CHART study, including copies of this information, see: https://ctru.leeds.ac.uk/chart/

b. You can read more about data and why it is important for research. The organisation Use My Data is made up of patients and carers in the UK. Their work is focused on the use of patient data. You may find some of their resources interesting or helpful: https://www.usemydata.org/