Randomised controlled trial of a facilitated home-based rehabilitation intervention in patients with heart failure with preserved ejection fraction and their caregivers (REACH-HFpEF Trial)

PARTICIPANT INFORMATION SHEET - PATIENT

You are being invited to take part in a research study called the REACH-HFpEF trial. Before you decide, it is important that you understand why the research is being done, and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that you find unclear or if you want more information.

What is the purpose of this study?

We know that **cardiac rehabilitation (CR)** is a highly effective and cost-effective treatment for people with heart failure and is the recommended NHS treatment. It improves quality of life and may reduce risk of a hospital admission. However, at present less than one in 20 people in the UK discharged from hospital with diagnosis of heart failure participate in CR. A key reason for this is that people with heart failure find it difficult to get to hospital, and some dislike group formats. With the COVID-19 pandemic, the barrier to accessing hospital based cardiac rehabilitation programmes has become much greater.

Between 2012-18, we co-developed and tested (with people with heart failure, clinicians, and National Health Service (NHS) managers) a home-based CR programme called '**Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF)**'. Through a clinical trial, we were able to confirm that participation in REACH-HF improves quality of life of people with heart failure with reduced ejection fraction ('HFrEF'), and that it is affordable for the NHS. We now wish carry out a study to assess that REACH-HF also works for people with heart failure with preserved ejection fraction ('HFpEF').

Why have I been invited to take part?

You have been invited to take part in this trial because you have HFpEF and could potentially benefit from the REACH-HF programme, and because you have shown an interest in participation. A total of 520 people with HFpEF and their caregivers will be included in the study from sites across twenty NHS Health Boards in the UK. Your Health Board/Clinical Commissioning Group is participating in the study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Taking part in medical research in the UK is voluntary and you should feel under no pressure to agree if you don't think it is right for you. A member of the study team (usually a research nurse or doctor) will discuss the study with you. You can then decide whether or not you wish to take part.

You are free to stop taking part at any time without giving a reason. If you decide not to take part, or change your mind at any time, this won't affect your current or future NHS care.

What will happen to me if I decide to take part?

If you agree to take part in this study, you will be given this information sheet to keep, and be asked to sign and date a consent form.

You will be involved with the study for about twelve months. You will firstly be invited by your local cardiology/heart failure research team to take part in an initial assessment to check that you are suitable to participate in the study. If this is a face-to-face meeting, you will also be asked to undertake a walking test and provide a sample of blood. Once the initial assessment is completed, you will then be allocated at random (like tossing a coin) to either the REACH-HF programme plus usual care or usual care only.

You will be asked to complete some questionnaires online (there will be the option to complete the questionnaires on paper for those who are unable to use the online method).

If you are assigned to the REACH-HF programme plus usual care group:

You will be contacted by one of the clinical team (usually a CR nurse, HF specialist nurse, physiotherapist) to set up a phone call, online appointment, or home visit (if available) to start you on the 12-week REACH-HF programme. After the 12-week programme, the research team will contact you again to invite you to repeat the questionnaires, perform the walking test and provide a sample of blood, if applicable. This is usually about 4 months after you started. You will then be asked to complete this again at 12 months.

The REACH-HF programme uses a manual that is designed for people with heart failure and their caregivers (friends/family). The manual includes three core elements; 1) walking or chair-based exercise training (using a DVD or via an internet link); 2) self-management of stress and 3) medication management.

You will meet with a REACH-HF 'facilitator' by phone or online (or face-to-face at your home or in the hospital, if this is permitted under local COVID-19 guidelines). Your facilitator will be a heart failure or CR specialist nurse, or physiotherapist. They will talk with you and your caregiver to introduce the programme. Over a 12-week period you will then typically have four to five phone calls with your facilitator, to check that you are progressing with the programme and whether you are having any problems. In order to assess the delivery of the intervention we will select a sample of participants to take part in our fidelity assessment. If you agree, some of these sessions with your facilitator will be audio recorded, so that one of the research team can listen back and assess how closely the sessions matched what was intended in the REACH-HF programme.

The facilitator will help you to: develop skills for managing heart failure; make plans about how to improve your current situation; monitor your progress over time; and adapt your heart failure management strategies if necessary. More details are available on the REACH-HF website (http://sites.exeter.ac.uk/reach-hf/).

We would also like to interview a small group of patients who participate in the REACH-HF programme (at 4 and 12 months) to ask about your experience in receiving the intervention and ways in which we can improve it. If you have a caregiver participating in this study, interviews may also include them. If you agree, the interview will be audio recorded so that one of the research team can listen back and assess participant experiences.

If you are assigned to the usual care group:

You will continue to receive usual care for your heart failure as per your local hospital and national guidelines. You will be contacted by one of the cardiology/heart failure research team to set up a phone call or online appointment to start you on completing the questionnaires online (there will be the option to complete the questionnaires on paper for those who are unable to use the online method), arrange for you have to a walking test and provide a blood sample (if it is possible with local COVID-19 guidelines for you to visit the clinic). After 4 months, the research team will contact you again to invite you to repeat the questionnaires either on paper or online (depending on your preference), perform the walking test and provide a sample of blood, if applicable. You will be asked to complete this again at 12 months.

What will happen to any blood samples I give during the trial?

The blood samples you give during the study will be sent to the laboratory at NHS Tayside, Dundee where they will be tested to check your blood for biological markers of your heart failure.

What will happen to any additional blood samples I may agree to provide?

You will be given the option to provide additional blood samples at recruitment into the study and then again after 4 and 12 months for storage for future, ethically approved research (you can still continue with the main study if you don't want to be involved in this part). This is to help us to understand how levels of different substances in the blood are linked with different outcomes for heart failure patients. These samples will be held securely and analysed at NHS Tayside, Dundee. These samples may also be analysed at other organisations both in and outside the UK, but only when de-identified; none of your personal data will be shared. This is to get the maximum benefit from the samples collected.

No extra study visits are required for this. At each time point approximately 4-5mls (a small syringe) of extra blood will be taken at the same time as the blood is taken for your other blood tests.

Do I have to wear an activity monitor?

As part of the study, we would like you to wear a monitor. This is a wrist worn 'watch' which records all your movements throughout the day as well as your sleep patterns; we would like you to wear it for 24 hours a day, for 9 consecutive days. The monitor is waterproof and can be worn at all times; therefore, there should be no need for you to remove it. We will send you instructions on how and where to attach your monitor. We will ask you to do this at the start of the study then again at 12 months.

The monitor cannot be used to locate you and does not transmit any live data while you are wearing it. All the movement data is stored on the watch.

What are the possible disadvantages and risks of taking part?

We don't expect you to be harmed in any way by taking part in our study. CR for people with heart failure has been shown to be safe. As CR involves exercise, there is always a risk that you might initially have muscle soreness. Your facilitator will make sure that the starting level of exercise is appropriate for you. Whilst working through some of the sections of the REACH-HF Manual with the facilitator, you may be asked questions about your experiences with heart failure and its impact on your day-to-day life which might be upsetting. The facilitators are trained health professionals and will ask questions sensitively, and you don't have to answer any questions which cause you to

feel upset. Your facilitator can refer you to your heart failure and cardiology service or GP for further support.

What are the possible benefits of taking part?

We hope that participation in REACH-HF will improve how you feel and how you are able to manage your heart failure, but we can't guarantee this. The information we get from this study will help us to understand how we best make home CR available for people with heart failure.

What happens when the research study ends?

Your involvement with the study will end following the 12-month assessment. If you were in the REACH-HF treatment group, when you speak with your facilitator at the end of the 12 week period (by phone/online), they will talk to you about your ongoing use of the REACH-HF manual. Everyone in the study will continue to receive any usual care required.

If you give us permission, we would like to follow-up on your progress through centralised electronic NHS and Government health records for a period of up to ten years after the study has finished (subject to additional funding and ethical approval).

Will my taking part in this study be kept confidential?

Yes. All information about your participation in the study will be kept confidential. The information will be held securely and anonymously in electronic format under the provisions of the Data Protection Act 2018 and the General Data Protection Regulation. Your data will be stored in a secure database held in the University of Glasgow where it will be used for both statistical and health economic analyses and as part of a process evaluation to explore your experiences of participation in the intervention. Your data will be accessed by members of the research teams involved in these analyses at the Universities of Glasgow, Birmingham and Exeter.

Your participation in this trial will be noted in your medical records and, if you consent, your GP will also be informed. The research team will not share any information collected about you with your caregiver without your permission.

If we need to send out the anonymous questionnaires by post, we will require your name, postal and email address in order to this. These personal details will be stored securely in a separate database within the University of Glasgow. We may want to contact you again at a later date about potentially completing an additional follow-up questionnaire (to assess whether REACH-HF has helped you in the longer term). If you agree to this, we will keep your contact details for 12 months after the end of the study. If you do not agree, your contact details will be destroyed at the end of the study unless you have consented to your progress being followed up through centralised electronic databases. We will obtain this information by linking records held by the Government (e.g. Registrar General) or NHS (e.g. health records). If you agree to this, we will retain your NHS/CHI number, date of birth and address for a period of up to ten years after the study has finished (subject to additional funding and ethical approval).

If you agree to take part in REACH-HFpEF, approved members of the study team (health professionals from your local NHS service) will be able to access your medical records. It is a requirement that relevant sections of your medical notes and research data may be looked at by responsible individuals from the research team, research regulatory authorities, the NHS or monitors appointed by the trial sponsor (NHS Greater Glasgow and Clyde), to check that the research is properly conducted and the interests of those taking part are adequately protected.

The blood samples you give will be transferred to the laboratory at NHS Tayside, Dundee where they will be held securely and analysed. The results of the blood tests will be sent to University of Glasgow, via a secure online process, to be held with the rest of your study data.

The GENEActiv monitor will be sent to you by members of the research team at the University of Exeter. In order to facilitate this process they will need to have access to your contact details. Your details will be held securely and will not be shared outside of the research team. The study team at University of Exeter will download the data from the monitor for analysis before sending it the University of Glasgow to be held with the rest of your study data. This will be done using a secure online process.

If you agree to the session with your facilitator being recorded, these audio recordings will be held securely at the University of Exeter and University of Birmingham. There is a possibility that you may be identified in the recording, e.g. your name is mentioned during the session. All recordings will be treated as confidential with access only given to members of the research team involved in their analysis.

If you agree to participate in the REACH-HF interview the research team at the University of Birmingham and University of Exeter will need to have access to your contact details. Your details will be held securely and will not be shared outside of the research team. The interviews will be recorded and your audio recording will be held securely by the University of Birmingham and University of Exeter where it will be listened to and analysed by members of the research team.

If you agree, your audio recordings from the intervention delivery that represent good practice may be used for training and education purposes. All recordings will be anonymised and no data that could potentially identify you will be shared.

Since it is important that we make the most of medical research data, we may in future share data from the trial with other researchers, both in the UK and in other countries. Anonymous data from the study will be deposited in a secure archive called the UK Data Service for this purpose. No data that could personally identify you will be shared.

No participants will be named or identified in any way in any study reports. You will be given an option to receive a summary of the study results.

Will my expenses be reimbursed?

Dependent on COVID-19 circulation and hospitalisation rates, you may or may not have to visit your heart failure clinic at your local hospital as part of your participation in the REACH-HFpEF study. If you do, reasonable travel costs, such as bus fares, mileage, or parking will be paid for clinic visits required for the study.

What will happen to the results of the research study?

The results of the study will be written up in a report for the funder, and may be presented at national and international conferences and published in medical journals. You won't be identified in any information included in any of these presentations or publications. You will be given an option to receive a lay summary of these results.

Who is organising and funding the research?

The study is being run by Professor Rod Taylor (University of Glasgow) and Professor Chim Lang (University of Dundee/NHS Tayside) and is taking place in twenty hospital centres across the UK. The Principal Investigator (PI) at this site is *<NAME>*

The sponsor for this study is NHS Greater Glasgow and Clyde.

The research is funded by the National Institute for Health Research Health Technology Assessment programme.

What if something goes wrong?

We do not anticipate that anything will go wrong. In the event that something does go wrong, there are no special compensation arrangements. The trial sponsor (NHS Greater Glasgow and Clyde) is a member of the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) which covers the Sponsor's legal liability in relation to clinical trials; this includes clinical negligence. Clinical negligence is also covered by the participating sites' own insurance schemes. Harm from study design is covered by the University of Glasgow's clinical trial insurance. If you are harmed due to someone's negligence, or your participation in the study you may have grounds for legal action for compensation, but you may have to pay your legal costs.

If you have a concern about any aspect of this study, you should ask to speak to your study doctor who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Chief Investigators, Professor Rod Taylor (Rod.Taylor@glasgow.ac.uk) or Professor Chim Lang (C.C.Lang@dundee.ac.uk).

The normal National Health Service complaints mechanisms are available if you wish to complain or have any concerns [insert local hospital complaints phone number].

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This is done to protect your safety, rights, wellbeing and dignity. The study, this Participant Information Sheet, Informed Consent Form and other study documents have been reviewed and given a favourable opinion by the West of Scotland Research Ethics Service (reference number 21/WS/0085).

The study is registered on the ISRCTN trial registry (reference ISRCTN47894539).

If I wish to discuss the study further, who can I contact for additional information?

You are encouraged to ask any questions that you may have before, during or after treatment. If you have any specific queries about any aspect of this study, please ask to speak to the researchers who will do their best to address any questions or concerns. Your local research contact is:

<Name of local contact> <Telephone number and email address>

Please keep this information sheet for your own records. Thank you for taking the time to read this information sheet and for considering taking part in this study.

The NHS Greater Glasgow and Clyde is the sponsor for this study based in the United Kingdom. We will be using information from you and/or 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. The University of Glasgow and NHS Greater Glasgow and Clyde will keep identifiable information about you for the duration of the trial.

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. You can find out more about how we use your information by contacting the Data Protection Team at https://www.nhsggc.org.uk/patients-and-visitors/faqs/data-protection-privacy