



The REACH-HF Digital Training Study:

Information Sheet for Participants - Patients

Invitation and brief summary

Thank you for taking the time to read this information sheet. You are receiving this because you have been referred for cardiac rehabilitation and have been offered the Rehabilitation Enablement in Chronic Heart Failure REACH-HF home based cardiac rehabilitation programme. This research study is about testing our new digital training course for providers of the REACH-HF cardiac rehabilitation programme. Taking part in the study is entirely up to you. So, before you decide, please take the time to read the following information. You can also discuss it with other people or the researcher, to decide whether you wish to take part or not.

Why are we doing this research study?

We believe that all people with heart failure should have access to cardiac rehabilitation. Cardiac rehabilitation has been shown to be effective in improving health-related quality of life and reducing hospitalisation in patients with heart failure. The Rehabilitation Enablement for Chronic Heart Failure (REACH-HF) programme is a theory and evidence-based cardiac rehabilitation programme, co-developed with patients, caregivers, and health care professionals. Trial evidence shows that REACH-HF produces clinically significant improvements in heart-failure related quality of life and is cost-effective.

To build on this success, we now wish to scale up implementation across the UK, by training staff in a large proportion of NHS cardiac rehabilitation centres to deliver REACH-HF. However, the current three-day face-to-face training programme is time-consuming and relatively expensive. Offering training online would allow busy NHS staff to access the training when it is convenient to them and be more cost-efficient. This study aims to develop and evaluate the digital /online training.

What would taking part involve?

Taking part in this study will involve receiving the 12 week REACH-HF home-based cardiac rehabilitation programme. This will be delivered by a REACH-HF facilitator who has been trained using our new digital/online REACH-HF training platform. If you have a family, friend,

or someone else who supports you in managing your condition we may ask you to consider extending an invite for this person to take part as well. Taking part in the study does not change the REACH-HF programme that you receive in any way. What is different is the way in which the facilitator was trained - using the REACH-HF digital training platform, instead of using a two or three day “live” training course. To check that the training has worked well, we will evaluate the quality of delivery of the REACH-HF programme using audio recordings of the intervention sessions delivered to you. This means that the REACH-HF facilitator will bring a digital audio recorder with them to their sessions with you and (with your permission) record the conversations that you have about managing your condition. In addition, at the start of the study we will collect demographic data (e.g. age, gender etc) from you over the phone.

What are the possible benefits of taking part?

Cardiac rehabilitation programmes are beneficial for people with heart failure but very few patients with heart failure access these programmes. To increase access to cardiac rehabilitation we need to scale up training of REACH-HF facilitators while maintaining the quality of the training and delivery of the programme itself. The current three-day face-to-face training programme is time-consuming and relatively expensive. Offering training online would allow busy NHS staff to access the training when it is convenient to them and be more cost-efficient. This study aims to develop and evaluate the digital /online training.

What are the possible disadvantages or risks of taking part?

There are no significant disadvantages or risks for you taking part in this study. It will take up some of your time to have a phone call with the researcher and complete a consent form at the start of the study. In addition, your home-based sessions with the REACH-HF facilitator will be recorded so we can assess the way in which they deliver the programme.

Do I have to take part?

Participation in this study is entirely voluntary. If you do decide to take part, you will be asked to sign a consent form before you start. You will be given a copy of the consent form and we'll ask you to keep this information sheet for your own records.

Should you wish to withdraw, you can do so at any time without having to give a reason (although we would like to know if you are willing to tell us). All data can be destroyed on request. However, this request is time-limited. Once data has been used in the analysis or published, it will no longer be possible to remove it from the study.

Right to withdraw

Should you wish to withdraw, you can do so at any time without having to give a reason. Your rights to access, or change 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.

Should you wish to withdraw, you can do so at any time without having to give a reason. All data can be destroyed or securely deleted on request. However, for some data, this request is time limited. Once data has been fully anonymised and used in the analysis or published, it will no longer be possible to remove this from the study as we will be unable to identify what data relates to you.

How the University of Exeter is complying with Data Protection Act 2018 and the UK GDPR

In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a 'UK-only' version) and the DPA 2018 still applies.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the 'public interest'. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be collected, processed, stored and destroyed. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the link;
<https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/>

If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative: Pam Baxter, University of Exeter (Contact details at the end of the information sheet).

Will my data be confidential?

All information collected in this study will be kept strictly confidential and stored either on an encrypted password protected computer, or in a locked cabinet in a secure office at the University of Exeter, which can only be accessed by the research team. You will be allocated a unique participant number to ensure that your information will be protected and cannot be identified outside of the research team. Any personally identifiable information will be stored securely and separately from information obtained from the research, it will only be kept for a limited time (up to 12 months or an additional five years if optional consent is given for personally identifiable information to be retained for an extra five years) and securely destroyed (31.01.2024 or 31.01.2029 if optional consent to retain the data for 5 years is given). It will be kept on the University of Exeter's secure storage drives, to which only the researchers will have access. Any personally identifiable information (such as contact details), will be stored separately and securely and will be destroyed following the study, unless you tick the optional box on the consent to allow us to retain this data and allow the research team to approach you for future related projects. The data collected during the study may be shared amongst individuals from the University of Exeter, University of Birmingham or from regulatory authorities, where it is relevant to you taking part in this research.

What happens to my data at the end of the study?

The data collected during the study will be anonymised and preserved for 5 years following publication of the study results and will be archived with password protection, on the University of Exeter storage drive.

If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection.

If you have any concerns about how the data is controlled and managed for this study then you can also contact Pamela Baxter, the University of Exeter Sponsor Representative whose details are at the end of this information sheet.

What will happen to the results of this study?

The results of this study will be published in research journals and presented at conferences in the UK or abroad. Your data may be used in reports, articles, websites, and training materials or presentations by the research team. The data presented will always remain anonymous and no real names will appear on any results.

Who has reviewed this study?

All research activity at the University of Exeter is examined and approved by an ethics committee to protect your interests. This study has been approved by the NHS Research Ethics Committee (IRAS ID: 305835) on received approval on 29.03.2022.

Funder

The funder (National Institute for Health Research) has had no role in the design of the study and will play no role in the conduct and write-up of the research other than supporting wider dissemination of its findings.

What if there is a problem?

If you have any complaints relating to taking part in this study, please contact the Research Lead: Dr Samantha van Beurden using the contact details below.

If you would prefer to speak to someone in the University who is independent of the study, you can contact the Sponsor Representative, Pam Baxter.

Contacts for further information

If you would like more information or if you have any further questions about the study please contact the investigators using the details below. **If you wish to take part, please let us know within the next 7-10 days, as we will need to communicate about this with your cardiac rehabilitation team.**

<p>Researcher:</p> <p>Dr Rosina Cross</p> <p>University of Exeter</p> <p>Primary Care Research Group, Smeall Building, Medical School, College of Medicine and Health, St Luke's Campus, Magdalen Road, Exeter, Devon, UK, EX1 2LU</p> <p>Tel: 01392 726189</p> <p>Email: r.cross2@exeter.ac.uk</p>	<p>PM:</p> <p>Dr Samantha Van Beurden</p> <p>University of Exeter</p> <p>Primary Care Research Group, Smeall Building, Medical School, College of Medicine and Health, St Luke's Campus, Magdalen Road, Exeter, Devon, UK, EX1 2LU</p> <p>Tel: 01392 726440</p> <p>Email: S.B.vanBeurden@exeter.ac.uk,</p>
	<p>Sponsor Representative</p> <p>Ms Pam Baxter</p> <p>Research Governance Manager</p> <p>University of Exeter</p> <p>Research Ethics and Governance Office</p> <p>Lafrowda House</p> <p>St Germans Road</p> <p>Exeter</p> <p>Devon</p> <p>EX4 6TL</p> <p>Email: _</p> <p>Tel: 01392 723588</p> <p>Mobile: 07485042117</p>