REACH-HF

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Information Sheet for Participants

(Online Version)

Study title

D:REACH-HF: Acceptability

Chief Investigator: Dr Hasnain Dalal

Invitation and brief summary

Thank you for taking the time to read this information sheet. You are receiving this because your clinical care team deems you to be eligible and potentially interested in this research study. This research study is about testing a digitally adapted version of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) home-based cardiac rehabilitation programme for people with heart failure. Taking part in the study is entirely up to you. So, before you decide, it is important for you to understand why the research is being done and what it will involve. 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 shown to be effective in improving the health-related quality of life of those with heart failure and reducing hospitalisation.

We are developing a digital intervention to help patients with heart failure and their caregivers to access cardiac rehabilitation from the comfort of their own home. We are

undertaking this study to make sure that the content and format of the intervention is suitable to, and appropriate for, the people it is intended to help.
We already have an effective cardiac rehabilitation intervention that is delivered in the home, using printed materials and with facilitation from a healthcare professional. In this particular study, we would like to focus on whether a digital version facilitated by a healthcare professional is acceptable and relevant to people with heart failure and their caregivers.

What would taking part involve?

We are looking for individuals who have been diagnosed with heart failure and health care professionals working in cardiac rehabilitation. Additionally, access to a computer and the internet is required for study participation.
Once participants have given informed consent (approximately 15 minutes), taking part in the study will involve being asked to complete a demographic (sample characteristic) questionnaire (approximately 15 minutes), before starting a home-based cardiac rehabilitation programme that is delivered through an online platform along with facilitation from a REACH-HF trained health or allied healthcare professional over a 12-week period. 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. After the first few weeks of getting to grips with the programme, you will be asked to take part in a remote (via a video platform called Zoom or by telephone) semi-structured interview with the researcher about your initial thoughts and experiences with the REACH-HF programme (40-60 minutes). After this interview, you will be asked to continue with the rest of the programme. We will then get in touch with you again closer to the end of your programme to ask you to take part in a second remote interview (approximately 40-60 minutes) and a platform usability questionnaire (approximately 30 minutes).

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. Offering a digitally adapted home-based programme could increase access to cardiac rehabilitation and help patients and their caregivers better manage their health, particularly for groups who may struggle to access centre-based cardiac rehabilitation. The digital platform provides access to REACH-HF content which comes from the paper-based version of the intervention. This paper-based version, with support from a trained facilitator, has been shown to be effective in increasing quality of life for patients with heart failure. Thus, taking part in this study, through access to that very same content, but via different means (web-platform instead of paper manuals), you

may find that it helps you to understand and access information to help you manage your heart failure better.

What are the possible disadvantages and risks of taking part?

The main risk involved in this study surround data security. The data entered on the platform is stored on secure UK servers owned by Health and Care Innovations (HCI -see below for more detail on the processing of data). Another possible risk relates to the home-based exercises. Your cardiac rehabilitation team will be conducting assessments as part of their routine services to see if you are suitable to take part in home-based exercise programmes. If you have been offered REACH-HF, your team has deemed you eligible and capable to do so. REACH-HF facilitators and the intervention materials help guide safe engagement in exercise. Ethical issues arise from the burden that we might be placing on your time by requiring participation in the semi-structured interviews, which lasts roughly 40-60 minutes. To try to minimise this burden, we would happily schedule interviews at a time that is most convenient for you. The interviews will be done remotely via Zoom video conferencing or telephone (depending on your preference), which means you can be interviewed from the comfort of your own home, without the need for travel. We would also like to offer you a £10 shopping voucher, as a thank you for participation in the two interviews.

Do I have to take part?

Please remember that participation in this study is entirely voluntary. It is up to you to decide whether you would like to take part or not. If you do decide to participate in this study, you will be asked to complete an electronic consent form before you start. This is accessible via the digital platform and will involve confirming your agreement or consent to a number of statements regarding involvement in the digital REACH-HF programme. You will be sent a copy of the consent statements and how you have responded to these. We will also ask you to keep this information sheet for your own records as it contains information about the study, what we do with the data collected, and important contact information.

Right to withdraw

Your participation in the study is voluntary and you are free to withdraw at any time without giving any reason. You have the right to request that researchers remove your data if you make an explicit request for this to be done. However, your rights to access, to 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

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, Senior Research Governance Officer (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 your information will be protected and cannot be identified outside of the research team. Any personally identifiable information will be stored separately and securely from information obtained from the research, it will only be kept for a limited time (up to five 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 (on 31.03.2021 or 31.03.2026 if optional consent is given).

Participant data entered and stored on the D:REACH-HF platform, which include, name, email, telephone number, weight, step count and free text notes, will be accessible to their REACH-HF facilitator via the facilitator dashboard. This dashboard is only accessible to the healthcare professionals at your own cardiac rehabilitation service as each NHS site will have their own site-specific dashboard. This means that there will be no sharing of patient data across the sites who have access to D:REACH-HF. For the purpose of this project, the research team will also have access to some of your data. More specifically, the researchers will be able to access your email address (to help them contact you for interviews and to send questionnaires), platform usage statistics (the pages on the D:REACH-HF platform you view and interact with and how long you spend on them), and data that you might enter in the Progress Tracker. Data that is accessible to the research team is linked to your unique participant ID code. The researcher will export your platform use data from the servers. Data from your interviews will initially be stored as audio-recordings until they are transcribed into text files. These will be stored as Word documents. All files will be encrypted, password secured, and stored on the University of Exeter's secure storage drives, to which only the REACH-HF researchers will have access using their Staff IT account details.

Transcriptions may be performed by an external company, with a confidentiality agreement in place, or by the researcher. The recordings will be deleted after transcripts have been checked for accuracy. The transcripts will be pseudonymised using unique participant ID codes. This will ensure the information provided in the interview will be protected and cannot be identified by anyone else. There will be no paper data (such as researcher interview notes). Any notes taken by the researcher during interviews will be digital notes on the study laptop (University of Exeter owned). These notes will be pseudonymised through the use of unique participant ID codes. In the event that notes have to be taken down on paper, the researcher will transfer these to an encrypted password-protected file and destroy the paper copy. Any personally identifiable information (such as contact details required to be able to schedule and conduct the interviews), will be stored separately and securely from information obtained from the interviews or D:REACH-HF platform. These contact details will be destroyed following the study, unless you provide separate optional consent to allow the research team to approach you for future related projects. The key linking identifiable information to the other data in the study, will be securely deleted at the end of the study.

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

The interview transcripts and interviewer fieldnotes will be fully anonymised, this means that all unique participant ID codes will be removed. They will be preserved for 5 years following

publication of the study results and will be archived securely, on the University of Exeter's Open Research Exeter storage drive.

The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do 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 the University of Exeter Sponsor Representative, Ms Pam Baxter, Research Governance Manager, 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 will be presented at conferences in the UK or abroad. We may wish to use quotes (data) from the interviews to illustrate our findings, this may be used in reports, articles, websites, training materials, the digital tool itself 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: 300423) and HRA and Health and Care Research Wales (HCRW) (REC Reference: 21/EM/0273) on 09.12.2021. The study will seek local approval before the study commences.

Funder

The British Heart Foundation, Hope For Hearts Fund grant funds innovative patient-centric programs to deliver better heart failure care and services for the Heart Failure Community. Research funded through this grant focuses on transforming the way the millions of people affected by heart failure are cared for so that they can live a fuller, more engaged lifestyle, supporting patients in taking more ownership of their healthcare, and enhancing the education of patients including topics on transition, adherence, and navigating new environments. The funder 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 study advertisements and written materials explaining its findings.

What if there is a problem?

If you have any concerns or complaints relating to taking part in this study, please contact the Project Manager: Dr Samantha van Beurden.

If you would prefer to speak to someone in the University who is independent of the study, you can contact the Sponsor Representative, Ms Pam Baxter, who assists with any concerns or complaints of people taking part in research run by the University of Exeter.

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.

Researcher: **Dr Rosina Cross** University of Exeter Primary Care Research Group, Smeall Building, Medical School, College of Medicine and Health, St Luke's Campus, Magdalen Road, Exeter, Devon, UK, EX1 2LU Tel: 01392 726189 Email: r.cross2@exeter.ac.uk	Project Manager: **Dr Samantha Van Beurden** University of Exeter Primary Care Research Group, Smeall Building, Medical School, College of Medicine and Health, St Luke's Campus, Magdalen Road, Exeter, Devon, UK, EX1 2LU Tel: 01392 726440 Email: S.B.vanBeurden@exeter.ac.uk,
Principal Investigator: **Dr Hasnain Dalal** Honorary Clinical Associate Professor University of Exeter Primary Care Research Group, Smeall Building St Luke's Campus Heavitree Road Tel: 07974818345 H.Dalal@exeter.ac.uk	Sponsor Representative: **Ms Pam Baxter** Research Governance Manager University of Exeter Research Ethics and Governance Office Lafrowda House, St Germans Road Exeter EX4 6TL Tel: 01392 723588 Email: P.R.Baxter2@exeter.ac.uk

Thank you for your interest in the study