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Trial of a facilitated home-based rehabilitation intervention in patients with heart failure

Submission date 21/07/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/07/2021	**Overall study status** Ongoing	
Last Edited 04/06/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
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, the trial team 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, they 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. They now wish to carry out a study to assess that REACH-HF also works for people with heart failure with preserved ejection fraction ('HFpEF').

Who can participate?
Adults aged 18 years or over with HFpEF and their caregivers.

What does the study involve?
Participants who consent to take part will be involved with the study for about twelve months. They will firstly be invited by their local cardiology/heart failure research team to take part in an initial assessment to check that they are suitable to participate in the study and, if so, to complete some questionnaires. If this is a face-to-face meeting, they will also be asked to undertake a walking test and provide a sample of blood. Once the initial assessment is completed, they will then be allocated at random (like tossing a coin) to either the REACH-HF programme plus usual care or usual care only.

For participants assigned to the REACH-HF programme plus usual care group:
They 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 participants on the 12-week REACH-HF programme.

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

A small group of participants and their caregivers who participate in the REACH-HF programme will be asked to take part in an interview at 4 and 12 months to talk about their experience in receiving the intervention and ways in which it can be improved.

For participants assigned to the usual care group:
They will continue to receive usual care for their heart failure as per their local and national guidelines.

All participants will be asked to repeat the walking test, questionnaires and provide a blood sample at the 4 and 12 months visits.

As part of the study, participants will be asked to wear an activity monitor. This is a wrist-worn 'watch' which records all their movements throughout the day as well as their sleep patterns; participants will be asked 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 it to be removed. Participants will receive instructions on how and where to attach the monitor. All participants will be asked to do this at the start of the study then again at 4 and 12 months. The monitor cannot be used to locate anyone and does not transmit any live data while wearing it. All the movement data is stored on the watch.

What are the possible benefits and risks of participating?
It is hoped that participation in REACH-HF will improve how participants feel and how they are able to manage their heart failure. The information provided from this study will help the research team to understand how to best make home cardiac rehabilitation available for people with heart failure.

It is not expected for participants to be harmed in any way by taking part in this study. Cardiac rehabilitation for people with heart failure has been shown to be safe. As Cardiac rehabilitation involves exercise, there is always a risk that participants might initially have muscle soreness. The facilitator will make sure that the starting level of exercise is appropriate for the participant. Whilst working through some of the sections of the REACH-HF Manual with the facilitator, participants may be asked questions about their experiences with heart failure and its impact on day-to-day life which might be upsetting. The facilitators are trained health professionals and will ask questions sensitively, and participants don't have to answer any questions which cause them to feel upset. The facilitator can refer participants to their heart failure and cardiology service or GP for further support.

Where is the study run from?
University of Glasgow (UK)

When is the study starting and how long is it expected to run for?
March 2021 to May 2026

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (UK).

Who is the main contact?
The REACH-HFpEF project management team, based at the Glasgow Clinical Trials Unit can be contacted at: REACH-HFpEFproject@glasgowctu.org

Study website
https://www.reach-hfpef.co.uk

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
298247

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 298247, GN19CA434, NIHR130487

Study information

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

Acronym
REACH-HFpEF

Study objectives
Is REACH-HF plus usual care superior to usual care alone in terms of improving health-related quality of life of patients with HFpEF?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/09/2021, West of Scotland Research Ethics Committee 3 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 3140213; WoSREC3@ggc.scot.nhs.uk), ref: 21-WS-0085

Study design
Multicentre parallel two group randomised superiority trial with nested process and health economic evaluations and internal pilot phase

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)

Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Exercise-based cardiac rehabilitation in patients with heart failure with preserved ejection fraction (HFpEF).

Interventions
Randomisation will be done via the study web portal and participants will be randomly allocated in a 1:1 ratio to either intervention (REACH-HF plus usual care) or control (usual care only) groups. Usual care will be determined by local NHS policies. Randomisation will be stratified by investigator site and minimised on sex, baseline pro-brain-natriuretic peptide (NT-proBNP) levels (≤2000 vs. >2000 pg/mL), and ejection fraction (45-55% vs. >55%). The research team will be blinded to the treatment allocation. Only the rehab team will receive the allocation details.

REACH-HF is a home-based cardiac rehabilitation programme providing comprehensive self-care support to the patient and their caregiver (http://sites.exeter.ac.uk/reach-hf/). This comprehensive intervention includes four core elements:
1. REACH-HF Manual for patients with a choice of two structured exercise programs: a chair-based exercise and a progressive walking training program. Patients are advised to exercise ≥3 times per week, starting from their own personal level and gradually building up over 2-3 months in time/distance/walking pace.
2. Patient 'Progress Tracker' – an interactive booklet designed to facilitate learning from experience to record symptoms, physical activity, and other actions related to self-care. Patient's record: (1) how long/far they plan to walk, (2) whether they have done it, (3) how it felt to identify whether they should be moving up or down in efforts next time and (4) their weekly steps per minute (pace).
3. 'Family and Friends Resource' – a manual for use by caregivers aimed to increase their understanding of HF and caregiver physical and mental wellbeing.
4. Facilitation by healthcare staff (e.g., nurse, physiotherapist, exercise specialist) experienced in cardiac rehabilitation/heart failure management.

Participating patients and caregivers will work through the self-help manual over a 12-week period with facilitation involving contact by a specially trained intervention facilitator (typically a cardiac rehabilitation nurse, physiotherapist or exercise specialist) who will help to assess patient needs and concerns, build the patient's and caregiver's understanding of how best to manage HFpEF and provide individually-tailored support based on each patient's identified needs and concerns.

Intervention Type
Behavioural

Primary outcome measure
Change in Minnesota Living with Heart Failure Questionnaire (MLWHF) score from baseline to 12 months.

Secondary outcome measures
Patients:
1. Exercise capacity measured using the Incremental Shuttle Walk Test (ISWT), performed if

COVID-19 restrictions permit participants to attend clinic visits, measured at baseline, 4, and 12 months
2. Psychological wellbeing measured using Hospital Depression and Anxiety Scale (HADS) at baseline, 4, and 12 months
3. Level of physical activity measured using accelerometry (GENEActive device) at baseline, 4, and 12 months
4. Generic health-related quality of life measured using the EQ-5D-5L and Short-Form-12 at baseline, 4, and 12 months
5. Self-management measured using the Self-care of Heart Failure Index (SCHFI) & Self-efficacy for key-behaviours questionnaire at baseline, 4, and 12 months
6. Frailty measured using the Clinical Frailty Scale at baseline, 4, and 12 months
7. Prognostic biomarker measured from NT-proBNP at baseline, 4, and 12 months
8. Clinical Events measured by all-cause and heart failure-specific deaths and hospital admissions at baseline, 4, and 12 months
9. Adverse Events and Serious Adverse events recorded at baseline, 4, and 12 months

Caregivers:
1. Health-related quality of life measured using EQ-5D-5L and Family Caregiver Quality of Life Scale questionnaire (FAMQoL) at baseline, 4, and 12 months
2. Psychological Wellbeing measured using Hospital Depression and Anxiety Scale (HADS) at baseline, 4, and 12 months
3. Self-management measured using Caregiver Contribution to Self-care of HF Index questionnaire (CC-SCHFI)at baseline, 4, and 12 months
4. Burden measured using Caregiver Burden for HF Questionnaire (CBQ-HF) at baseline, 4, and 12 months

Overall study start date
01/03/2021

Completion date
31/05/2026

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 03/04/2024:
Patients:
1. Women or men aged ≥18 years
2. Currently symptomatic HF (NYHA Class II-IV)
3. Prescribed loop diuretics and the need for intermittent loop diuretics for the management of symptoms or signs of congestion
4. Left ventricular ejection fraction (LVEF) (within 3 years by echocardiography or MRI) ≥45% prior to randomisation. If Simpsons LVEF is missing, please use the qualitative eyeball assessment and assign a quantitative value as previously described for the BIOSTAT-CHF validation cohort [62]:
4.1. Severe: 25%
4.2. Moderate to severe: 30%
4.3. Moderate: 35%
4.4. Mild to moderate: 40%
4.5. Mild: 44%
4.6. Normal: 55%

Patients defined as a 'normal' LVEF would therefore meet this inclusion criteria.
5. At least one of the following risk factors:
5.1. Hospital admission in last 3 years for which HF was a major contributor
5.2. N-terminal proBNP >300 pg/ml for patients with sinus rhythm in last 3 years
5.3. N-terminal proBNP >900 pg/ml for patients in atrial fibrillation in last 3 years
B-type natriuretic peptide (BNP) and N-terminal prohormone B-type natriuretic peptide (NT-proBNP) levels differ in their values. Guided by the latest ESC 2021 guideline [63] values for BNP and NT-proBNP in the diagnosis of HFpEF and the conversion factor based on these values, the BNP cut offs for the REACH-HFpEF trial are as below:
5.4. 100 pg/ml (If in sinus rhythm)
5.5. 300 pg/ml (if in atrial fibrillation)
6. Informed consent to participate.

Caregivers:
1. Women or men aged ≥18 years
2. Providing unpaid support to patients

Cardiac rehabilitation facilitators:
1. Health care professionals facilitating and trained in the REACH-HF intervention delivery.
2. Health care professionals delivering the REACH-HF intervention to participants in the REACH-HFpEF trial.

Previous participant inclusion criteria:
Patient:
1. Women or men aged ≥18 years
2. Currently symptomatic HF (NYHA Class II-IV)
3. Prescribed loop diuretics and the need for intermittent loop diuretics for the management of symptoms or signs of congestion
4. Left ventricular ejection fraction (by echocardiography) ≥45% within 12 months prior to randomisation
5. At least one of the following risk factors:
5.1. Hospital admission in last 12 months for which HF was a major contributor
5.2. N-terminal proBNP >300 pg/ml for patients with sinus rhythm
5.3. N-terminal proBNP >900 pg/ml for patients in atrial fibrillation
6. Informed consent to participate

Caregivers:
1. Women or men aged ≥18 years
2. Providing unpaid support to patients

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
520 patients and their caregivers

Key exclusion criteria
Current participant exclusion criteria as of 03/04/2024:
1. Patients who have undertaken CR within the last 12 months
2. Patients who have any contraindications to exercise training (according to local cardiac rehabilitation guidelines)
3. Probable alternative diagnoses that in the opinion of the investigator could account for the patient's HF symptoms (i.e. dyspneoa, fatigue), such as significant pulmonary disease (including primary pulmonary hypertension), anaemia, or obesity. Specifically, patients with the following should be excluded:
3.1. Severe pulmonary disease including COPD (i.e. requiring home oxygen, chronic nebulizer therapy, or chronic oral steroid therapy or hospitalised for pulmonary decompensation within 12 months)
3.2. Haemoglobin <10 g/dll
3.3. BMI >40 kg/m²;
4. Patients with prior ejection fraction <45%.
5. Patients located in a long-term care home/support setting who are considered to be too frail to engage with the intervention or who are unwilling to travel to research assessments or accommodate home visits.
6. Patients who are unable to understand the study information or unable to complete the outcome questionnaires.
7. Patients judged to be unable to participate in the study for any other reason (e.g. psychiatric disorder, diagnosis of dementia, life-threatening co-morbidity).

Previous participant exclusion criteria:
1. Patients who have undertaken CR within the last 12 months
2. Patients who have any contraindications to exercise training
3. Patients who have alternative reasons for shortness of breath such as significant pulmonary disease or severe COPD, haemoglobin <10 g/dl, or body mass index (BMI) >40 kg/m²
4. Patients with prior ejection fraction <45%
5. eGFR <30 ml/min

Date of first enrolment
25/05/2022

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Ninewells Hospital and Medical School
NHS Tayside
Department of Cardiology
Dundee
United Kingdom
DD1 9SY

Study participating centre
Glasgow Royal Infirmary
NHS Greater Glasgow and Clyde
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Lister Centre
NHS Ayrshire and Arran
University Hospital Crosshouse
Kilmarnock
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KA2 0BE

Study participating centre
Aintree University Hospital
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Study participating centre
Darlington Memorial Hospital
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DL3 6HX

Study participating centre
St Thomas' Hospital
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Westminster Bridge Road
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SE1 7EH

Study participating centre
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Denmark Hill
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SE5 9RS

Study participating centre
Glenfield Hospital
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LE39 9QP

Study participating centre
Manchester Royal Infirmary
Manchester Heart Centre
Manchester University NHS Foundation Trust
Oxford Road
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United Kingdom
M13 9WL

Study participating centre
University Hospital of North Tees
North Tees and Hartlepool NHS Foundation Trust
Hardwick Road
Stockton on Tees
United Kingdom
TS19 8PE

Study participating centre

Royal Devon and Exeter Hospital
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EX2 5DW

Study participating centre
Russell's Hall Hospital
The Dudley Group NHS Foundation Trust
Pensnett Road
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DY1 2HQ

Study participating centre
West Suffolk Hospital
The Cardiac Centre
West Suffolk NHS Foundation Trust
Hardwick Lane
Bury Saint Edmunds
United Kingdom
IP33 2QZ

Study participating centre
St Catherine's Health Centre
Wirral Community Health and Care NHS Foundation Trust
Derby Road
Tranmere
Wirral
Merseyside
United Kingdom
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Study participating centre
Wycombe Hospital
Cardiology Research
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Buckinghamshire Healthcare NHS Trust
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Study participating centre
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Study participating centre
Royal Gwent Hospital
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NP20 2UB

Study participating centre
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John Radcliffe Hospital
Headley Way
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Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
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CB2 0QQ

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
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United Kingdom
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details
Research and Innovation
Ward 11 Dykebar Hospital
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+44 (0)141 314 4012
Maureen.Travers@ggc.scot.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 11/11/2024:
Study results will be published in open-access publications in high-impact peer-reviewed journals, including an end-of-trial NIHR monograph, and will be presented at national and international conferences. The study will be featured at a stakeholder dissemination workshop (with patients, clinicians, commissioners, academics, and key groups such as the British Heart Foundation, the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) and Pumping Marvellous). Direct feedback will be given to trial participants and information will be digitally publicised on the REACH-HF website and relevant profiles on social media platforms.

Previous publication and dissemination plan:
Planned open access publications in high-impact peer-reviewed journals including end of trial NIHR monograph.

Intention to publish date

01/12/2026

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	15/12/2021	13/06/2022	No	Yes
Participant information sheet	version 5.0	19/02/2025	07/05/2025	No	Yes
Protocol article		27/05/2025	04/06/2025	Yes	No