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Understanding delivery of a new home rehabilitation programme for people with heart failure and their caregivers in Scotland

Submission date
15/07/2020

Recruitment status
No longer recruiting

Registration date
16/07/2020

Overall study status
Completed

Last Edited
03/02/2023

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Heart failure is a serious condition that affects nearly one million people in the UK. Heart failure means that the heart is unable to pump blood around the body properly, and often results in fatigue, breathlessness and potentially dangerous accumulation of fluid in bodily tissues, effects which can have a very negative impact on quality of life. Existing research shows that cardiac rehabilitation (e.g. specially tailored exercise programmes) is highly effective, cost-effective, and integral to comprehensive care of people with heart failure. Despite national guidelines recommending that everyone with heart failure should receive cardiac rehabilitation (CR), currently only a small proportion are offered or participate in it. Most of what is offered is hospital-based, which has been found to be a barrier to participation. Home-based CR can provide an accessible alternative.
We have co-developed an evidence and theory-based home CR programme: Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF). A clinical trial found the addition of REACH-HF to usual medical care had a positive impact on participants living with heart failure.

The SCOT:REACH-HF study seeks to understand what shapes delivery of the REACH-HF programme in a real-world setting. To do so we will implement REACH-HF across six NHS Scotland health board areas. We will collect before and after data from people with heart failure and their nominated 'caregiver' (family member or friend), to find out whether results in the 'real world' resemble those from the previously conducted trial. We will also conduct interviews with heath professionals involved in delivery, to understand what helps or hinders delivery of the programme. Lastly we will assess some audio recordings of facilitator-patient sessions, to see how closely what is delivered resembles what was planned.

Who can participate?
Anyone currently being seen at participating heart failure services can participate, if they are over 18, have been diagnosed heart failure within the past five years, have had no worsening of symptoms in the last 2 weeks, and are deemed suitable by their care team.
Health professionals involved in delivery of REACH-HF in any of the participating health boards will be invited to take part in an interview.

What does the study involve?
Participants with heart failure will be involved with the study for about four months. They will have an initial assessment to check they are suitable to participate in the study and, if so, they will be asked to complete a questionnaire and undertake a walking test. Once this assessment is completed, participants will then be contacted by the clinical team to start you on the 12-weeks of REACH-HF programme. After that 12-weeks, the research team will contact participants again to repeat the questionnaires and walking test. If participants wish to nominate a 'caregiver' (family member/friend), the caregiver will also complete before and after questionnaires, and be asked to support the person with heart failure in the programme.

We will also conduct interviews with health professionals involved in delivering REACH-HF, and review audio recordings of HF patient-facilitator sessions.

What are the possible benefits and risks of participating?
We don’t expect participants 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 participants might initially experience muscle soreness. The facilitator will make sure that the starting level of exercise is appropriate. The facilitators involved in the study are professionally trained and will work with patients sensitively. If needed, facilitators can refer participants to the heart failure nursing service or their GP for further support.

We hope that participation in the REACH-HF programme will improve how people with heart failure feel and how they are able to manage their 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-based rehabilitation available for people with heart failure.

Where is the study run from?
The study is being conducted by a research team from the University of Glasgow. This includes chief investigator Prof Rod Taylor. The Glasgow team are working with four NHS ‘beacon sites’ across Scotland, based in NHS Ayrshire and Arran, Lanarkshire, Forth Valley, and Highland /Orkney/Shetland (who have teamed up due to smaller patient numbers).

When is the study starting and how long is it expected to run for?
The study initially started in February 2020 but was paused due to the Covid-19 pandemic. We aim to restart (and begin recruitment) in September 2020 and, unless Covid-19 causes further delays, to finish data collection by September 2021 (updated 05/05/2021, previously: March 2021)

Who is the study funded by?
SCOT:REACH-HF is funded by Heart Research UK.

Who is the main contact?
The main contact for the study is Prof Rod Taylor, rod.taylor@glasgow.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
276172

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 276172

Study information

Scientific Title
Implementation of an evidence-based home cardiac rehabilitation programme for heart failure patients and their caregivers in Scotland

Acronym
SCOT:REACH-HF

Study objectives
Aim: To study the real-world implementation of an evidence- and home-based cardiac rehabilitation programme (REACH-HF) for people with heart failure and their caregivers in Scotland.
Specific research questions that this project will assess are:
• What are the service level facilitators and barriers to the implementation of a home-based cardiac rehabilitation programme (REACH-HF) for people with heart failure and their caregivers across four NHS Health Boards in Scotland?
• Can the improvement in patient outcomes following participation in a 12-week home-based programme seen in the REACH-HF randomised controlled trial (RCT) be replicated in a 'real world' setting?

• What is the economic (health and social costs) impact of implementing a home-based programme of cardiac rehabilitation (REACH-HF) for people with heart failure and their caregivers across four NHS Boards in Scotland?

Hypothesis: Introduction of REACH-HF will increase access to cardiac rehabilitation and quality of life of people with heart failure in Scotland.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/03/2020, West of Scotland Research Ethics Committee 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140213; WoSREC5@ggc.scot.nhs.uk), ref: 20/WS/0038

Study design
A mixed-method implementation study comprising a multi-centre prospective cohort study and nested process and economic evaluations

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart failure (reduced ejection fraction)

Interventions
140 people with heart failure and their caregivers, recruited from 4 Beacon Sites across Scotland, participate in REACH-HF 12-week home cardiac rehabilitation programme, overseen by trained facilitators (typically heart failure nurses or physiotherapists). Sites will assess patient outcomes before and after administering the 12-week intervention/programme with 35 people with heart failure (140 total). Members of the HF team at each site will be interviewed. Detailed information of the costs and utilisation of the provision of the REACH-HF programme will be collected.

Intervention Type
Behavioural

Primary outcome(s)
1. Effect of heart failure on life measured using the Minnesota Living with Heart Failure Questionnaire (baseline and 4 month follow up)

Key secondary outcome(s))
At baseline and 4 month follow up:
Patient outcomes:
1. Generic quality of life (EQ-5D-5L)
2. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS)
3. Patient-reported outcome measure for cardiac rehab (PROM-CR)
4. Exercise capacity (incremental shuttle walk test)

5. Hospitalisations and primary care contacts (number, reason, duration)
6. Adverse events (e.g. skeletomuscular injury)
7. Health literacy (Health Literacy Questionnaire (HLQ))
Caregiver outcomes:
8. Generic quality of life (EQ-5D-5L)
9. Psychological wellbeing (HADS)
10. Family Caregiver Quality of Life Scale questionnaire (FamQol)
11. Caregiver Burden Questionnaire HF (CBQ-HF)
12. Caregiver Contribution to Self-care of HF Index questionnaire (CC-SCHFI)

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Confirmed diagnosis of systolic (reduced ejection fraction) heart failure within the past five years
3. Have experienced no deterioration of HF symptoms in the preceding two weeks resulting in hospitalisation or alteration of HF medication
4. Deemed suitable for CR by their local clinical team
5. For caregivers: must be a caregiver to the person with heart failure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
182

Key exclusion criteria
1. Undertaken CR in the preceding 12 months
2. Has medical contraindications to exercise testing or training
3. Is in a long-term care establishment, or unwilling/unable to travel to research assessments or accommodate home visits
4. Is unable to understand the study information or unable to complete the outcome questionnaires

Date of first enrolment
04/01/2021

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University Hospital Crosshouse
NHS Ayrshire and Arran
Kilmarnock Rd
Crosshouse
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
Forth Valley Royal Hospital
NHS Forth Valley
Stirling Rd
Larbert
United Kingdom
FK5 4WR

Study participating centre
University Hospital Wishaw
NHS Lanarkshire
50 Netherton Street
Wishaw
United Kingdom
ML2 0DP

Study participating centre
Raigmore Hospital
NHS Highland
Old Perth Rd
Inverness

United Kingdom
IV2 3UJ

Study participating centre
Gilbert Bain Hospital
South Road
Lerwick
United Kingdom
ZE1 0TB

Study participating centre
Balfour Hospital
Foreland Road
Kirkwall
United Kingdom
KW15 1BH

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Heart Research UK

Alternative Name(s)
HRUK

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 03/02/2023:
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Participant-level data will be/is available upon request from Prof Rod Taylor, rod.taylor@glasgow.ac.uk. The type of data that will be shared is outcome data and all data will be anonymised. These data will be available within 3 months of the request. Whether consent from participants was required and obtained.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	primary and secondary outcome results	06/01/2023	11/01/2023	Yes	No
Protocol article	protocol	04/12/2020	07/12/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Poster results	Graphical abstract of results		03/02/2023	No	No
Statistical Analysis Plan	version 1.0	16/01/2021	01/02/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes