ISRCTN25032672 https://doi.org/10.1186/ISRCTN25032672

# Rehabilitation EnAblement in Chronic Heart Failure (REACH-HF)

**Submission date**
13/03/2014

**Recruitment status**
No longer recruiting

**Registration date**
13/03/2014

**Overall study status**
Completed

**Last Edited**
21/08/2020

**Condition category**
Circulatory System

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

## Plain English summary of protocol

Background and study aims
This study forms one part of a wider research project led by a research team based in Cornwall (UK), who are interested in improving the care provided to people with heart failure. The overall aim of this study project is to develop and test a new self-help manual (the HF manual) for people with heart failure and for the caregivers that help them to manage the condition.

Who can participate?
People with heart failure who have not participated in a cardiac rehabilitation programme before.

What does the study involve?
You will be involved with the study for about 17 weeks, starting with a clinic visit to see the researcher, followed by a 12-week period in which you will receive the HF manual, and then a final clinic visit with the researcher. At the first clinic, a member of the research team will answer any questions you (and your caregiver) may have about the study and check that you are suitable to take part. If you are happy to take part, both you and your caregiver (if you have one) will be asked to sign a consent form. At both clinics, the researcher will ask questions about your health and you will be asked to fill in a questionnaire booklet to find out about your heart failure and how it affects your day-to-day life. One of the questionnaires includes potentially sensitive questions about your levels of anxiety and depression. This is a standard questionnaire used in most hospitals but you should think about how willing you are to answer such questions when deciding whether to take part in the study. The questionnaire booklets will take about 30 minutes to complete at each of the two clinics. In addition, the researcher will collect a small sample of blood from you (about a teaspoons worth) which will be transferred to the Royal Cornwall Hospitals NHS Trust laboratory and tested, then destroyed. You will also be asked to complete an exercise test called a shuttle walk test, which involves walking between two markers (about ten metres apart) in time to a beeping device. The walking pace will be slow at first but will increase as the test proceeds. You will be asked to walk for as long as you can until you are either too breathless or can no longer keep up with the beeps at which time the test will end and the researcher will record the results. At the end of each of the two clinic visits, an accelerometer will be attached to you, and will need to stay on your wrist for seven days. This accelerometer (which looks like a wristwatch) will record your activity levels over the 7-day

period. At the end of the 7 days, we will ask you to return the device to a member of the research team in a stamped addressed package which will be provided (you wont have to pay any postage). The 12-week home-based treatment period will begin soon after the first research clinic. The person you care for will be contacted by your local facilitator who will have been told by the researcher that you have both joined the study. Your facilitator will arrange to visit you and the person you care for at their home to explain the HF manual, making sure that you are introduced to the sections most suitable to your individual needs. S/he will set some specific behavioural objectives for the person you care for and discuss with you how you can use the caregiver resource to support the person you care for with their objectives. Over the next 12 weeks, the facilitator will visit you both at the home of the person your care for at least three times, and will also call you both on the telephone regularly to see how you are getting on. S/he will help you both develop skills for managing heart failure and to make plans about how to improve the current situation. The facilitator will also help you monitor your progress over time and to adapt your strategies for managing heart failure if necessary. The actual number of home visits and telephone calls will be determined by your facilitator depending on the individual needs of the person you care for. Note that the HF Manual is an addition to the usual care the person you care for already receives, so all the other aspects of their care and the support you currently receive will be exactly the same as if you had decided not to be involved in the study. If you are already visited at home by care providers as part of the usual care for the person you care for, you may experience more home visits than usual throughout the 12-week period.

What are the possible benefits and risks of participating?
Although at this stage we dont know if the HF Manual will be effective, you will be one of the first patients to receive it. More importantly perhaps, you will be helping us to evaluate and improve the manual so that it is suitable for use by heart failure patients, their caregivers, and the facilitator delivering the manual in future. We cannot promise that the study will help you personally, but the information we get from your participation in the study may help to improve the rehabilitation of patients with heart failure in the future. We dont expect you to be harmed in any way by taking part in our study. Whilst working through some of the sections of the HF Manual with the facilitator, and during the interviews with members of the research team, you may be asked questions about your experiences with caring for someone with heart failure and its impact on your day-to-day life which might be upsetting. The facilitators, nurses and researchers involved in the study are professionally trained and will ask questions sensitively. You do not have to answer any questions which cause you to feel upset. If you do get upset, your facilitator or local researcher can refer you to the heart failure nursing service or your GP.

Where is the study run from?
Four centres in the UK - Truro, Birmingham, South Glamorgan and York.

When is the study starting and how long is it expected to run for?
March 2014 to October 2014

Who is funding the study?
The National Institute for Health Research (UK)

Who is the main contact?
Prof. Rod Taylor
r.taylor@exeter.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Prof Rod Taylor

### Contact details
University of Exeter Medical School
Veysey Building
Salmon Pool Lane
Exeter
United Kingdom
EX2 4SG
-
r.taylor@exeter.ac.uk

## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
15915

## Study information

### Scientific Title
Rehabilitation enablement in chronic heart failure: a feasibility study

### Acronym
REACH-HF

### Study objectives
This feasibility study is a single component of the ongoing REACH-HF Programme Grant for Applied Research awarded by the NIHR. The overarching aim of the study is to develop and evaluate a nurse facilitated, home-based heart failure (HF) manual to enhance quality of life and self-management of people with heart failure and their caregivers. This feasibility study is conducted in preparation for a fully powered randomised controlled trial assessing the clinical and cost effectiveness of the HF Manual plus usual care vs. usual care alone in patients with systolic HF (HF with reduced ejection fraction) and a separate single centre pilot trial in patients with HF with preserved ejection fraction. Both of these subsequent trials will be the subject of separate protocols and separate REC applications and registration.
The specific aims of this feasibility study are:
1. To assess the feasibility and acceptability of the REACH HF Manual for patients, caregivers and intervention nurses
2. To assess the fidelity of HF Manual delivery by intervention nurses
3. Evaluate the components of the main trial: outcome data collection processes, outcome

burden, outcome completion rates and attrition
4. To finalise the content and format of HF Manual
5. To finalise the delivery of training to intervention nurses as required
6. To finalise the training materials

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
First MREC approval date 22/01/2014, ref: 13/SC/0640

## Study design
Multicentre single-arm feasibility study with parallel process evaluation

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Cardiovascular; Subtopic: Not Assigned, Cardiovascular (all Subtopics); Disease: All Diseases, Heart Failure

## Interventions
REACH HF Manual: The HF manual comprises a self-help manual which patients will work through with facilitation by the REACH-HF intervention facilitator. The manual includes information and interactive elements relating to a wide range of topics relating to living with /adapting to living with heart failure, and covers three core elements:
1. An exercise training programme based on a walking programme or a chair-based exercise DVD, or a combination of the two (the patients choice)
2. Stress management
3. Medication management

Follow Up Length: 3 month(s); Study Entry : Registration only

## Intervention Type
Other

## Phase
Not Applicable

### Primary outcome measure
Feasibility and acceptability of intervention delivery and proposed outcomes battery. Methods for data collection will include qualitative methods e.g. interviews with patients, carers and intervention faciltators, recording of intervention nurse and patient interactions and qualitative outcomes e.g. recruitment and attrition rate, patient and carer satisfaction questionnaires. These outcomes will be assessed over the 3 months of the study.

### Secondary outcome measures
The following health-related outcomes will be collected at clinic visits at baseline (prior to intervention) at 3 months following baseline:
1. Disease-specific health-related quality of life (HRQoL) measured using the MLHFQW [patients]
2. Composite outcome of death or hospital admission related to HF or not related to HF [patients]
3. Blood natriuretic peptide levels [patients]
4. Exercise capacity (incremental shuttle walking test) [patients]
5. Psychological wellbeing (Hospital Anxiety and Depression Scale, HADS) [patients & caregivers]
6. Physical activity level (accelerometry over a 7-day period) [patients]
7. Eneric health-related quality of life (EQ-5D) [patients]
8. Disease-specific quality of life (HeartQoL) [patients]
9. Self-care of Heart Failure Index (SCHFI) [caregivers]
10. Caregiver Burden Questionnaire  Heart Failure (CBQ-HF) [caregivers]
11. Caregiver Contribution to Self-care of Heart Failure Index (CC-SCHFI) [caregivers]
12. Family Caregiver-Specific Quality of Life Scale (FAMQOL) [caregivers]
13. Healthcare utilisation (primary and secondary care contacts, social care contacts and medication usage) [patients]
14. Safety outcomes (worsening HF event, musculoskeletal injuries, dropout due to adverse events) [patients]

### Overall study start date
04/03/2014

### Completion date
04/10/2014

## Eligibility

### Key inclusion criteria
1. Adults (aged ≥18 years)
2. Patients who have a confirmed diagnosis of systolic HF on echocardiography (i.e. left ventricular ejection fraction <45%) within the last 5 years.
3. Patients who have been clinically stable for at least 2 weeks and in receipt of medical treatment for HF.
4. Patients deemed suitable for exercise, and who do not have a contraindication to exercise, as adjudged by the site Principal Investigator in collaboration with the local clinical team (with reference to the Amercian Heart Association 2013 guidelines).
5. Provision of informed consent to participate.

Patient's caregivers aged 18 years or older may participate if the meet the following definition: Someone who provides unpaid support to a family member or friend with heart failure who is enrolled in the study'.

Intervention nurses will only participate following completion of the HF Manual training course and the provision of informed consent to provide study data.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 16-24; UK Sample Size: 16-24

### Key exclusion criteria
1. Patients who have undertaken cardiac rehabilitation (CR) within the last 12 months
2. Patients who have received an ICD or CRT or combined CRT/ICD device implanted in the last 6 months.
3. Patients who are in a long-term care establishment or who are unwilling or unable to travel to research assessments or accommodate home visits.
4. Patients who are unable to read English.
5. 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

### Date of first enrolment
04/03/2014

### Date of final enrolment
04/10/2014

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of Exeter Medical School**
Exeter
United Kingdom
EX2 4SG

# Sponsor information

### Organisation
Royal Cornwall Hospitals NHS Trust (UK)

### Sponsor details
Treliske
Truro
England
United Kingdom
TR1 3LJ

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/026xdcm93

# Funder(s)

### Funder type
Government

### Funder Name
NIHR Programme Grants for Applied Research; Grant Codes: RP-PG-1210-12004

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 02/08/2016 | | Yes | No |

| | | | | | |
|---|---|---|---|---|---|
| Other publications | process evaluation | 02/08/2019 | 21/08/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |