

# Rehabilitation enablement in chronic heart failure

<b>Submission date</b> 07/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/09/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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, who are interested in improving the care provided to people with heart failure. The overall aim of the 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. The HF Manual has been designed for patients with a type of heart failure referred to as 'heart failure with reduced ejection fraction'. In this type of heart failure, the heart muscle does not contract effectively and less blood is pumped out to the body. It is hoped that the HF Manual will also be appropriate for patients with another type of heart failure referred to as 'heart failure with preserved ejection fraction (HFpEF)'. In this type of heart failure, the heart muscle contracts normally but does not relax as it should after contraction. The purpose of this study is to see if a larger study is feasible in patients with HFpEF. This study will assess the suitability of the HF Manual for HFpEF patients, and test the procedures for collecting research data in preparation for a larger study in the future.

### Who can participate?

Patients aged 18 or over with HFpEF

### What does the study involve?

Participants are randomly allocated to one of two groups: participants in the control group continue to receive their usual care, while patients in the intervention group receive the new HF Manual in addition to their usual care. It is not known whether the new manual is effective or not but this can be found out by comparing information collected from people in both groups. It is known that heart failure affects the lives not just of the people with the condition, but can also impact those family members and friends who help to support them. If patients have a family member or friend who provides unpaid support to help them manage the condition, they are also invited to take part in the study as a caregiver.

### What are the possible benefits and risks of participating?

Participants will be helping to evaluate the effectiveness of the HF Manual. Although participants may not benefit personally, the information gathered from their participation in the study may help to improve the rehabilitation of patients with heart failure in the future.

Participants are not expected to be harmed in any way by taking part in this study. When blood samples are taken, participants may feel some discomfort at the puncture site, although this is usually short lived. A total of about 8 ml (less than one tablespoon) of blood will be collected over the study period. Blood sampling can occasionally lead to localised bruising and discomfort and (rarely) infection at the site where the blood was taken. If participants are in the intervention group and receive the HF Manual, they may be asked questions about their experiences with heart failure and its impact on their day-to-day life which might be upsetting. This may be whilst working through some of the sections of the HF Manual with the facilitator and during the interviews with members of the research team if they choose to take part. The facilitators and researchers involved in the study are professionally trained and will ask questions sensitively. Participants do not have to answer any questions which cause them to feel upset. If participants do get upset, the facilitators and local researchers can refer patients to the heart failure nursing service or their GP. Attendance at research clinics may incur an expense to participants in the first instance. However, any travel expenses for taking part in this study, including those incurred through use of their own vehicle, will be reimbursed at public transport rates.

Where is the study run from?  
NHS Tayside (UK)

When is the study starting and how long is it expected to run for?  
June 2015 to October 2016

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

Who is the main contact?  
Prof. Rod Taylor

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Rod Taylor

**ORCID ID**  
<http://orcid.org/0000-0002-6538-5760>

**Contact details**  
University of Exeter  
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EX1 2LU

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

2012/004\_3

## **Study information**

### **Scientific Title**

A single-centre randomised controlled pilot trial to assess the feasibility of a definitive trial of the clinical effectiveness and cost effectiveness of the HF Manual in patients with heart failure with preserved ejection fraction and their caregivers (REACH-HFpEF)

### **Acronym**

REACH HFpEF

### **Study objectives**

To assess the feasibility of a definitive trial of the effectiveness of the HF Manual in patients with heart failure with preserved ejection fraction.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

East of Scotland Research Ethics Service, 26/03/2015, ref: 15/ES/0036

### **Study design**

Parallel two-group randomised controlled pilot trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Heart failure

## **Interventions**

1:1 individual participant allocation to either:

1. REACH-HF Manual plus usual care (intervention group) or
2. Usual care alone (control group)

## **Intervention Type**

Other

## **Primary outcome measure**

1. Recruitment rate for participants (patients and caregivers)
2. Attrition and loss to follow up at 4 and 6 months
3. Completion and completeness of main trial outcome measures

## **Secondary outcome measures**

1. Fidelity of HF manual delivery by intervention facilitators
2. Acceptability of the intervention to HFpEF patients, their caregivers and facilitators
3. Acceptability of study participation to participants

## **Overall study start date**

01/06/2015

## **Completion date**

31/12/2016

# **Eligibility**

## **Key inclusion criteria**

1. Male or female aged  $\geq 18$  years
2. Patients with heart failure, defined by the presence of at least one of the following symptoms at the time of screening:
  - 2.1. Paroxysmal nocturnal dyspnoea
  - 2.2. Orthopnoea
  - 2.3. Dyspnoea on mild or moderate exertion
- AND at least one of the following signs prior to study entry:
  - 2.4. Basal crepitations
  - 2.5. Elevated jugular venous pressure
  - 2.6. Lower extremity oedema
  - 2.7. Chest radiograph demonstrating pleural effusion, pulmonary congestion or cardiomegaly
3. Patients with left ventricular ejection fraction (EF)  $\geq 45\%$  obtained within 6 months prior to randomization and after any myocardial infarction (MI) or other event that would affect EF (ideally obtained by echocardiography, although radionuclide ventriculography and angiography are acceptable)
4. Provision of informed consent to participate.

## **Participant type(s)**

Patient

## **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50

**Key exclusion criteria**

1. Patients who have undertaken cardiac rehabilitation (CR) within the last six months
2. Patients with severe chronic pulmonary disease defined as requiring home oxygen or hospitalization for exacerbation within 12 months, or significant chronic pulmonary disease in the opinion of the investigator
3. Patients who have any of the following contraindications to exercise testing or exercise training (adapted from ESC HF guidelines) documented in their medical notes:
  - 3.1. Early phase after acute coronary syndrome (up to 2 days)
  - 3.2. Untreated life-threatening cardiac arrhythmias
  - 3.3. Acute heart failure (during the initial period of haemodynamic instability)
  - 3.4. Uncontrolled hypertension (SBP >200 and/or DBP >100)
  - 3.5. Advanced atrioventricular block
  - 3.6. Acute myocarditis and pericarditis
  - 3.7. Symptomatic aortic stenosis
  - 3.8. Severe hypertrophic obstructive cardiomyopathy
  - 3.9. Acute systemic illness
  - 3.10. Intracardiac thrombus
  - 3.11. Progressive worsening of exercise tolerance or dyspnoea at rest over previous 3–5 days
  - 3.12. Significant ischaemia during low-intensity exercise (<2 METs, <50 W)
  - 3.13. Uncontrolled diabetes (blood glucose >16 mmol/l or HbA1C >9% or equivalent unit)
  - 3.14. Recent embolism
  - 3.15. Thrombophlebitis
  - 3.16. Recent-onset atrial fibrillation/atrial flutter (in the last 4 weeks)
4. Patients who are unable to understand the study information or unable to complete study procedures
5. Patients who are in a long-term care establishment or who are unwilling or unable to travel to research assessments or accommodate home visits
6. 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
7. Patients participating in concurrent interventional research which may over-burden the patient or confound data collection

**Date of first enrolment**

30/06/2015

**Date of final enrolment**

30/06/2016

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**NHS Tayside**

United Kingdom

DD1 9SY

## **Sponsor information**

**Organisation**

Royal Cornwall Hospitals NHS Trust

**Sponsor details**

Royal Cornwall Hospital

Gloweth

Truro

England

United Kingdom

TR1 3LJ

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/026xdc93>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research (RP-PG-1210-12004)

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

**Publication and dissemination plan**

The authors are planning open access publication of the study results in Q4 2017/Q1 2018 in a peer reviewed journal.

**Intention to publish date**  
01/03/2018

**Individual participant data (IPD) sharing plan**

The authors confirm that all data underlying the findings will be made fully available without restriction. The authors will make the clinical and economic dataset available through the University of Exeter’s Institutional Repository – Open Research Exeter (see <https://ore.exeter.ac.uk>). Access to these data is permitted but controlled through requests made via the repository to the chief investigator (Professor Taylor: [r.taylor@exeter.ac.uk](mailto:r.taylor@exeter.ac.uk)). Although use is permitted, this will be on the basis that the source of the data is acknowledged (including the funder) and it includes reference to the data set ‘handle’. It is expected that this will be made available open access from Q2 2018.

**IPD sharing plan summary**  
Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	25/10/2016		Yes	No
<a href="#">Results article</a>	results	09/04/2018	29/01/2019	Yes	No
<a href="#">Other publications</a>	process evaluation	06/01/2021	12/01/2021	Yes	No
<a href="#">Other publications</a>	Secondary analysis	09/02/2023	10/02/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		01/02/2021	18/09/2024	Yes	No