

# Rehabilitation Enablement in Chronic Heart Failure (REACH HF). A multicentre parallel group randomised controlled trial with parallel economic and process evaluation to assess the clinical effectiveness and cost-effectiveness of the REACH HF manual for patients and caregivers

<b>Submission date</b> 13/11/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/11/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/02/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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# Additional identifiers

## Protocol serial number

17779

# Study information

## Scientific Title

Rehabilitation Enablement in Chronic Heart Failure (REACH HF). A multicentre parallel group randomised controlled trial with parallel economic and process evaluation to assess the clinical effectiveness and cost-effectiveness of the REACH HF manual for patients and caregivers

## Acronym

REACH HF - Main trial

## Study objectives

The overarching aim of the REACH HF programme is to develop and evaluate a nurse facilitated, homebased heart failure (HF) Manual to enhance the quality of life and self-management of people with heart failure (and their caregivers).

This trial will assess how effective the HF Manual is as a self-help manual for patients with systolic heart failure as well as usual care, compared to usual care alone. This study will also enable the research team to see whether the HF Manual is good value for money and to ensure the manual is delivered consistently.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

14/NW/1351; First MREC approval date 06/11/2014

## Study design

Randomised; Interventional; Design type: Treatment

## Primary study design

Interventional

## Study type(s)

Treatment

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

Topic: Primary Care; Subtopic: Cardiovascular disease, Primary care; Disease: All Diseases

## Interventions

REACH HF Manual: A self-help home-based manual designed to be delivered by a specially trained facilitator; Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

## Intervention Type

Other

**Phase**

Phase III

**Primary outcome(s)**

Minnesota living with Heart Failure® Questionnaire (MLHFQ); Timepoint(s): Baseline, +4, +6 and +12 months

**Key secondary outcome(s)**

N/A

**Completion date**

31/12/2015

**Eligibility****Key inclusion criteria**

1. Provision of informed consent to participate
2. Adults (aged ≥18 years)
3. Patients who have a confirmed diagnosis of systolic HF on echocardiography (i.e. left ventricular ejection fraction <45%) within the last 5 years
4. Patients who have experienced no deterioration of HF symptoms in the past 2 weeks resulting in hospitalisation or alteration of HF medication

Patients caregivers who are aged 18 years or older may participate if they meet the following definition and provide informed consent to take part:

1. Someone who provides unpaid support to family or friends who could not manage without this help. This could be caring for a relative, partner or friend.
2. Unpaid support includes providing emotional support, prompting with taking medications, observing for signs and symptoms of heart failure, getting prescriptions, encouraging participation in social events, physical activity, helping with household tasks as well as providing physical care.

A patient may still participate in the study if s/he does not have an identified caregiver, or if the patients caregiver is not willing to participate. The caregiver component of the HF manual will not be applicable for such patients in the intervention group.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

## **Key exclusion criteria**

1. Patients who have undertaken cardiac rehabilitation (CR) within the last 12 months
2. Patients who have received an intracardiac defibrillator (ICD), cardiac resynchronisation therapy (CRT), or combined CRT/ICD device implanted in the last 6 months
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 lifethreatening 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 35 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. New onset atrial fibrillation/atrial flutter
4. Patients who are in a long term care establishment or who are unwilling or unable to travel to research assessments or accommodate home visits
5. Patients who are unable to understand the study information or unable to complete the outcome questionnaires
6. Patients judged to be unable to participate in the study for any other reason (e.g. psychiatric disorder, diagnosis of dementia, life threatening comorbidity)
7. Patients participating in concurrent interventional research which may overburden the patient or confound data collection

## **Date of first enrolment**

05/01/2015

## **Date of final enrolment**

31/12/2015

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**Peninsula Medical School**

Exeter

United Kingdom

EX2 4SG

# Sponsor information

## Organisation

Royal Cornwall Hospitals NHS Trust (UK)

## ROR

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

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research (UK)

## 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

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	10/10/2018	29/01/2019	Yes	No

<a href="#">Results article</a>	results	06/07/2020	08/07/2020	Yes	No
<a href="#">Protocol article</a>	protocol	23/12/2015		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Secondary analysis	09/02/2023	10/02/2023	Yes	No