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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

Submission date
13/11/2014

Recruitment status
No longer recruiting

Registration date
13/11/2014

Overall study status
Completed

Last Edited
10/02/2023

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

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

Secondary outcome measures
N/A

Overall study start date
05/01/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 324; UK Sample Size: 324; Description: The trial aims to recruit 216 patients with systolic heart failure. The intervention is designed to benefit caregivers also, and so caregive

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
England

United Kingdom

Study participating centre
Peninsula Medical School
Exeter
United Kingdom
EX2 4SG

Sponsor information

Organisation
Royal Cornwall Hospitals NHS Trust (UK)

Sponsor details
Treliske
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England
United Kingdom
TR1 3LJ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/026xdcm93

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	23/12/2015		Yes	No
Results article	results	10/10/2018	29/01/2019	Yes	No
Results article	results	06/07/2020	08/07/2020	Yes	No
Other publications	Secondary analysis	09/02/2023	10/02/2023	Yes	No
HRA research summary			28/06/2023	No	No