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Rehabilitation enablement in chronic heart failure

Submission date
07/07/2015

Recruitment status
No longer recruiting

Registration date
07/08/2015

Overall study status
Completed

Last Edited
18/09/2024

Condition category
Circulatory System

[_] Prospectively registered
[X] 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, 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

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s))

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

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Male or female aged ≥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) ≥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

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 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
United Kingdom

Scotland

Study participating centre
NHS Tayside
United Kingdom
DD1 9SY

Sponsor information

Organisation

Royal Cornwall Hospitals NHS Trust

ROR
https://ror.org/026xdcm93

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

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). 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?
Results article	results	09/04/2018	29/01/2019	Yes	No

Results article		01/02/2021	18/09/2024	Yes	No
Protocol article	protocol	25/10/2016		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	process evaluation	06/01/2021	12/01/2021	Yes	No
Other publications	Secondary analysis	09/02/2023	10/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes