A randomised controlled trial of exercise rehabilitation in addition to specialist heart failure nurse intervention

Submission date Recruitment status [X] Prospectively registered 08/04/2004 No longer recruiting [X] Protocol Statistical analysis plan Registration date Overall study status 10/06/2004 Completed [X] Results [] Individual participant data Last Edited Condition category 05/07/2018 Circulatory System

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

N/A

Study information

Scientific Title

A randomised controlled trial of exercise rehabilitation in addition to specialist heart failure nurse intervention

Acronym

BRUM-CHF

Study objectives

The primary research question seeks to evaluate whether there are additional benefits from exercise rehabilitation over specialist heart failure nurse management and to establish the cost-effectiveness and patient acceptability of a predominantly home-based programme of exercise rehabilitation. In addition, the study will investigate the patient experience of heart failure and rehabilitation whilst attaining information about effectiveness, uptake and compliance of patients in a predominantly home-based setting.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval was obtained from Sandwell and West Birmingham Local Research Ethics Committee (ref: 03/10/708).

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Heart failure

Interventions

Intervention group: Six month structured exercise programme, predominantly home-based plus specialist heart failure nurse care.

Usual care group: Specialist heart failure nurse care.

Follow-up by postal questionnaire and clinical assessment occurs at 6 months and by postal questionnaire at 1 year.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary outcome measure is the Minnesota Living with Heart Failure Questionnaire (MLwHF) Questionnaire.

Key secondary outcome(s))

Secondary outcome measures at six months are:

- 1. Composite of death or admission with heart failure or myocardial infarction
- 2. Admission with heart failure
- 3. Mortality (all-cause and vascular)
- 4. EuroQol questionnaire
- 5. Hamilton Anxiety and Depression Score (HADS)
- 6. Blood pressure
- 7. Self-reported physical activity
- 8. Distance walked on the Incremental Shuttle Walk Test (ISWT)

At 12 months the ISWT and blood pressure measurements are omitted.

Completion date

01/11/2007

Eligibility

Key inclusion criteria

Patients referred to the specialist heart failure services, who have been admitted with heart failure or been New York Heart Association (NYHA) III within the previous year, with an ejection fraction of less than 40%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

No exclusion criteria provided

Date of first enrolment

01/11/2004

Date of final enrolment

01/11/2007

Locations

Countries of recruitment

United Kingdom

Study participating centre
Department of Public Health & Epidemiology
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation

Department of Health (UK)

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

Department of Health (DH/BHF Heart Failure research Initiative) (UK)

Results and Publications

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	01/02/2009		Yes	No
Protocol article	protocol	07/03/2007		Yes	No