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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
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/07/2018	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Kate Jolly

Contact details
Department of Public Health & Epidemiology
Public Health Building
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
-
C.B.Jolly@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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.

Overall study start date
01/11/2004

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

Age group
Not Specified

Sex

Not Specified

Target number of participants
169

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
c/o Dr Clare Croft-White
Research & Development Division
Department of Health
Skipton House
80 London Road
London
United Kingdom
SE1 6LH

Sponsor type
Government

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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