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A randomised controlled trial of a self-management programme for people with heart failure and their family carers

Submission date 06/10/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/11/2005	**Overall study status** Completed	
Last Edited 17/02/2014	**Condition category** 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

Acronym
SEMAPHFOR (Self-management of heart failure for people with heart failure open randomisation)

Study objectives
The primary objective is to assess the clinical effectiveness of the newly developed nurse facilitated, cognitive behavioural self-management programme in helping patients and their carers better manage the medical and psychological aspects of living with heart failure. To do this we will test the hypothesis that, patients using a cognitive behavioural self-management programme facilitated by a nurse will have fewer admissions to hospital, better self-management and an improved health related quality of life compared to patients receiving usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Huntingdon Research Ethics Committee, approved on 20/09/2005, ref: 05/Q0104/107

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart Failure

Interventions
Participants will be randomised to either the nurse facilitated cognitive behavioural self-management programme or usual care from the heart failure nurse, with the same manual of information produced by the British Heart Foundation (BHF).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome is patient re-admission/admission to hospital within 12 months of randomisation.

Key secondary outcome(s))

1. Patient-related measures:
1.1. Minnesota Living with Heart Failure
1.2. EQ5D
1.3. Hospital Anxiety and Depression scale
1.4. European self-care form
1.5. Cardiac beliefs questionnaire
1.6. Patient satisfaction

2. Carer-related measures:
2.1. Caregiving Demands Scale
2.2. EQ5D

Completion date
03/07/2007

Eligibility

Key inclusion criteria
Patients who have a definitive diagnosis of symptomatic heart failure (left ventricular systolic dysfunction [LVSD]) as defined by ECHO, clinical diagnosis or coronary angiography within the past 24 months.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. There is written case record of cognitive deficits
2. They are unable to make decisions about their own care
3. They are unable to give informed consent
4. They are unable to read English
5. They are living in nursing homes
6. If the patient has a life-threatening concomitant condition

Date of first enrolment
03/01/2006

Date of final enrolment
03/07/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK) (ref: PG/03/098/15811)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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	01/09/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes