

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/02/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.cardiacrehabilitation.org.uk/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

03/01/2006

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

Age group

Adult

Sex

Both

Target number of participants

720

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

England

United Kingdom

Study participating centre

University of York

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

University of York (UK)

Sponsor details

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Sponsor type
University/education

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

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?
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[Results article](#)

results

01/09/2014

Yes

No