

Self-management and congestive heart failure: a randomized controlled trial to improve health-behavior and health-related quality of life by increasing self-efficacy expectancies in congestive heart failure patients

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/09/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NHS, number 2002B005; NTR467

Study information

Scientific Title

Self-management and congestive heart failure: a randomized controlled trial to improve health-behavior and health-related quality of life by increasing self-efficacy expectancies in congestive heart failure patients

Study objectives

1. Self-efficacy expectancies may increase by the 'Chronic Disease Self-Management Program' in congestive heart failure intervention patients as compared to controls
2. These higher levels of self-efficacy expectancies contribute to health behavior, and will decrease demoralization (depressive symptoms, feelings of anxiety) and functional disability and increase levels of quality of life

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Congestive heart failure

Interventions

1. Patients in the intervention group attend a protocolled self-management group course (6 weekly sessions of 2.5 hours per session)
2. Patients assigned to the control group received usual care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Self-efficacy expectancies:
 - a. General expectancies: General Self-Efficacy Scale (GSES)
 - b. Cardiac expectancies by scale Sullivan et al. (1998)
2. Perceived control/mastery by Mastery scale (Pearlin & Schooler 1978)

Secondary outcome measures

1. Quality of life:
 - a. General: RAND/SF-36
 - b. CHF-specific: Kansas City Cardiomyopathy Questionnaire (KCCQ)
 - c. Symptoms of anxiety/depression: Hospital Anxiety & Depression Scale (HADS)
2. Health behavior:
 - a. Lifestyle
 - b. Physical activity level
 - c. Self-care behavior (European Heart Failure Self-Care Behavior Scale)
3. Health care utilization (number of consultations of cardiologist/nurse specialist, hospitalization days, etc.)

In addition, the following variables are assessed with respect to the process evaluation: performance according to protocol, attendance, overall adherence per course session /adherence with regard to home work assignments, opinions about the intervention (participants + course leaders), etc.

Overall study start date

15/12/2003

Completion date

15/12/2007

Eligibility

Key inclusion criteria

1. Extent of congestive heart failure (CHF): systolic CHF; LVEF <40% (NYHA 2-3) or diastolic CHF (NYHA 2-3 + additional hospital admission Decompensatio Cordis after being diagnosed with CHF)
2. Diagnosis of CHF at least 3 months ago to include only stable patients (an additional 3 months before the start of the intervention sums up to 6 months)
3. Ability to understand/write/speak Dutch

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

318

Key exclusion criteria

Participation in other scientific research

Date of first enrolment

15/12/2003

Date of final enrolment

15/12/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Maastricht

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

CAPHRI, The Research Institute of the University Maastricht (The Netherlands)

Sponsor details

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Sponsor type

Not defined

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Heart Foundation (Nederlandse Hartstichting), University Hospital Maastricht

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	20/07/2006		Yes	No
Results article	results	01/11/2010		Yes	No