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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	[_] Prospectively registered [X] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 14/09/2017	**Condition category** Circulatory System	[_] 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
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Sponsor information

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

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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