ISRCTN88363287 https://doi.org/10.1186/ISRCTN88363287

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

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(s)
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)

Key secondary outcome(s)

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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting), University Hospital Maastricht

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	01/11/2010		Yes	No
Protocol article	protocol	20/07/2006		Yes	No