# 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.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON29524

**Source**
Nationaal Trial Register

**Brief title**
N/A

**Health condition**

Congestive heart failure

### Sponsors and support

**Primary sponsor:** CAPHRI, The Research Institute of the University Maastricht
**Source(s) of monetary or material Support:** Netherlands Heart Foundation, University Hospital Maastricht (Profileringsfonds, Administrative Board)

### Intervention

## Outcome measures

### Primary outcome

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

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. Life style;

b. Physical activity level;

c. Self-care behavior (European Heart Failure Self-Care Behavior Scale);

3. Health care utilization (number 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.

# Study description

### Background summary

This study comprises both an effect and a process evaluation of the into Dutch translated "Chronic Disease Self-Management Program" among congestive heart failure patients. The self-management course, developed by Lorig and colleagues (Stanford University), has been broadly evaluated and implemented in the USA. In the present study the course is led by 2 trained course leaders (nurse specialist + congestive heart failure patient). Effectiveness of the Dutch version among congestive heart failure patients is assessed in a RCT-design with 1-year follow-up.

### Study objective

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.

### Study design

N/A

### Intervention

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.

## Contacts

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# Eligibility criteria

## 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 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.

## Exclusion criteria

Participation in other scientific research.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-12-2003 |
| Enrollment: | 360 |

| | |
|---|---|
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 21-10-2005 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL427 |
| NTR-old | NTR467 |
| Other | : NHS, nr. 2002B005 |
| ISRCTN | ISRCTN88363287 |

## Study results

**Summary results**

N/A