Enhancing quality of life in patients with chronic heart failure: A feasibility study of a mindfulness-based psychological intervention

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1. To evaluate the feasibility of a mindfulness-based intervention in patients with chronic heart failure.2. To have a preliminary test of the effectiveness of the mindfulness-based intervention in patients with chronic heart failure regarding...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON29818

Source
ToetsingOnline

Brief title
Enhancing quality of life in patients with chronic heart failure

Condition

- Heart failures

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic heart failure, intervention, psychological, quality of life

Outcome measures

Primary outcome

The outcomes will be measured before and after the intervention by means of validated questionnaires. These measure the extent of psychological distress (including symptoms of anxiety and depression), positive and negative affect, fatigue, and quality of life. In addition, an evaluation form will be used to determine the practical feasibility of the study in this group.

Secondary outcome

Not applicable.

Study description

Background summary

Patients with chronic heart failure often report psychological distress (including symptoms of anxiety and depression) and a poor quality of life. In addition, these symptoms are associated with a poor prognosis in these patients. An effective method to reduce these complaints would be welcome. A new method to reduce distress and to enhance quality of life is based on training in open, nonjudgmental and mindful attention to whatever happens in each successive moment (mindfulness). In various patient groups, positive results have been obtained: reduced symptoms of distress and elevated quality of life. However, in patients with chronic heart failure this intervention has not been applied yet.

Study objective

1. To evaluate the feasibility of a mindfulness-based intervention in patients with chronic heart failure.
2. To have a preliminary test of the effectiveness of the mindfulness-based intervention in patients with chronic heart failure regarding stress reduction

and enhancement of quality of life.

Study design

A pilot intevention study in patients with chronic heart failure, who report substantial complaints of distress. They will be divided into two groups: an intervention and a control group that will be matched regarding important characteristics. Measurements will be done along a pre-post-test design.

Intervention

The intervention consists of weekly group sessions of two hours and thirty minutes during which participants will practice in mindfulness: mindful breathing, mindful slow movement, mindful sitting, etc. In addition, a half-day of practice is included in the sixth week and participants are requested to practice at home as well.

Study burden and risks

The intervention is a mild psychological training aiming at stress reduction and enhancement of quality of life and therefore does not hold any risk for the patients. The participants are expected to invest a substantial amount of time (24 hours of meetings plus homework). It is expected that this investment will pay off in stress reduction and enhancement of well-being.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Systolic heart failure
- LVEF < 40%
- stable regarding medication during last month
- functional NYHA-class I-III
- sufficient understanding of Dutch
- self-reported psychological stress

Exclusion criteria

- age > 80 years
- hospitalisation or medical invasive interventions within a month before inclusion
- cognitive impairment
- treatment for a psychological disorder

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2006
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	24-05-2006
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL11971.008.06