Randomized controlled trial of mindfulness training as complementary therapy in adults with structural heart disease

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Objective of this study is to determine (1) whether mindfulness training has an additional clinical and psychological effect to standard care, and (2) whether offering mindfulness training is a cost-effective intervention, in adult patients with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON38306

Source
ToetsingOnline

Brief title
Mindfulness training as complementary therapy

Condition

- Myocardial disorders
- Cardiac and vascular disorders congenital

Synonym
structural heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: complementary therapy, mindfulness training, structural heart disease

Outcome measures

Primary outcome

Primary outcome:

* exercise tolerance

Secondary outcome

Key secondary outcome:

* quality-of-life (SF36), using the mental- and physical composite outcome

scales

Other secondary outcomes:

* heart rate (a marker of cardiac fitness)

* NTproBNP (a biomarker for heart failure)

* composite endpoint (all-cause mortality, heart failure, arrythmia, cardiac

surgery,

percutaneous cardiac intervention, electrical cardioversion)

* psychological well-being (anxiety and depression)

* Social support (Blumenthal PSSS12)

* preference values (societal EuroQol EQ-5D-5L values, and the patients values

though the VAS rating scale)

* health care costs

* related non-health care costs (Tic-P)

Study description

Background summary

There is increasing evidence suggesting that mindfulness training (also know as mindfulness-based stress reduction or mindfulness meditation) has a beneficial effect in patients with cardiovascular disease. Objective of this study is to determine whether mindfulness training has beneficial clinical and psychological effects, and whether offering the training is effective and cost-effective, in adult paitents with structural heart disease.

Evidence is accumulating that mindfulness training and related therapies can be used as effective and safe adjuncts to medical treatment for a number of common clinical conditions including depression, insomnia, anxiety, post-traumatic stress, irritable bowel syndrome, nausea, pain, diabetes, hypertension and cardiovascular disease.
Some studies suggest that mindfulness training may have a beneficial clinical effect in patients with cardiovascular disease or those at increased cardiovascular risk.

In addition, psychological problems and symproms of depression and anxiety appear to be amenable to mindfulness meditation.

Study objective

Objective of this study is to determine
(1) whether mindfulness training has an additional clinical and psychological effect to standard care, and
(2) whether offering mindfulness training is a cost-effective intervention, in adult patients with structural heart disease (congenital heart disease and cardiomyopathy)

Study design

Randomized controlled trial

Intervention

Intervention:
The intervention is a mindfulness training and consists of a structured

standardized online program, which has been used extensively in the normal population (http://www.psychologiemagazine.nl/web/Trainingen/Online-training-mindfulness.htm). Every 3 days the patient receives an email message with a link to a website where they are offered text explanations, video clips, sound tracks with mindfulness exercises, assignments that need to be filled out, and practice suggestions for the coming few days. The program is further supported by emails and intermittent text messages on the patient*s cell phone. The duration of the training will be 100 days. Various materials are offered for continuing practice thereafter. The low cost of the online programme (¤ 30,-) gives the program the potential of being a cost effective intervention. Adherence to the intervention will be monitored by including additional questions and by recording login time.
In addition, all patients will receive usual care.

Study burden and risks

Nature and extent of the burden and risks associated with participation:
Patients in the
active intervention arm will be offered online mindfulness training for the duration of 100 days.
At 5 points in time over the course of 2 years all patients will undergo exercise tolerance
testing, ECG, and NTproBNP measurement and they will be asked to fill out questionnaires
concerning quality-of-life, preference values, psychological well-being, medical resource use,
and non-health care costs

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3065 CE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3065 CE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adults 18 to 65 years old known to have structural heart disease (congenital heart disease and cardiomyopathy)

Exclusion criteria

planned operation or percutaneous intervention
inability or unwillingness to give informed consent
inability to understand Dutch, inability to read or write Dutch
no internet acess or no email or no cell phone

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2012
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO Date:	11-05-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL36710.078.11