Mindfulness training for patients with structural heart disease.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26153

Source
Nationaal Trial Register

Health condition

English:
Patients with known structural heart disease (congenital heart disease and cardiomyopathy)

Dutch:
Patienten bekend met een structurele hartaandoening (aangeboren hartafwijking of cardiomyopathie)

Sponsors and support

Primary sponsor: Board of Directors, Erasmus Medical Center Rotterdam.
Source(s) of monetary or material Support: Board of Directors, Erasmus Medical Center Rotterdam.

Intervention

Outcome measures

Primary outcome

The 6 minute walk test has been chosen as primary outcome since it is a measure of cardiac and overall physical fitness.

Secondary outcome

Key secondary outcome:

1. Quality-of-life (SF36), using the mental- and physical composite outcome scales.

Other secondary outcomes:

1. Heart rate, blood pressure, resting respiratory rate (markers of cardiac fitness);

2. NTproBNP (a biomarker for heart failure);

3. Cumulative cortisol in 2 cm of hair taken from the scalp (cumulative measure of stress);

4. Composite endpoint (all-cause mortality, heart failure, arrythmia, cardiac surgery, percutaneous cardiac intervention, electrical cardioversion);

5. Psychological well-being (Hospital Anxiety Depression questionnaire);

6. Preference values (societal EuroQol EQ-5D-5L values, societal SF-6D values obtained from the SF-36, VAS rating scale [Philip Moons version]);

7. Social support (perceived social support scale 12 Blumenthal PSSS12);

8. Medical consumption of health-care use;

9. Health care costs;

10. Related non-health care costs (Tic-P).

Study description

Background summary

Pragmatic randomized controlled single-blind trial of mindfulness training as complementary therapy in adults with structural heart disease (congenital and cardiomyopathie), conducted in the Erasmus medical center Rotterdam, the Netherlands.
Objective of this study is to determine whether mindfulness training has beneficial clinical and psychological effects when provided as adjunct to usual care, and whether offering the training is effective and cost-effective, in adult patients with structural heart disease (congenital heart disease or cardiomyopathy). Adults 18 years and older known to have structural heart disease. Exclusion criteria: patients in whom an operation or percutaneous

intervention is planned, patients unable or unwilling to give informed consent, those without internet access, those unable to read or write Dutch.

To demonstrate an improvement of 5% in the active intervention group vs 1% in the control group in exercise tolerance requires 330 patients.
The intervention is mindfulness-training complementary to usual care. The mindfulness training consists of online sessions with assignments and practice supplemented with intermittent supportive email and text messages. The control group will receive usual care which includes lifestyle advice.

Primary outcome will be differences between the active intervention and control groups in the mean improvement, compared to baseline, of age- and sex expected exercise tolerance (6 minute walk test). The intention-to-treat analysis will address the question whether offering the training is effective. The as-treated analysis will evaluate the treatment effect depending on the degree of adherence. Secondary outcomes will be heart rate, blood pressure, and resting respiratory rate (markers of cardiac fitness), NTproBNP (a biomarker for heart failure), cumulative cortisol in hair taken from the scalp (cumulative measure of stress), a composite endpoint (all-cause mortality, heart failure, arrythmia, myocardial infarction, cardiac surgery, percutaneous cardiac intervention, electrical cardioversion), quality-of-life, psychological well-being, preference values, health care costs, and non-health care costs
All patients will be given usual care which includes lifestyle advice. Patients in the active intervention group will be offered an online training for the duration of 12 weeks with email messages and assignments 1-3 times per week, followed by reminder messages once every 2-4 weeks for another 40 weeks. At baseline, 3-months, and 1 year all patients will undergo a 6 minute walk test and blood tests, one scalp hair will be taken, and they will be asked to fill out quality-of-life, psychological well-being, medical resource use and cost questionnaires.

Study objective

Evidence is accumulating that mind-body therapies can be used as effective and safe adjuncts to medical treatment for a number of common clinical conditions. Some studies suggest that mindfulness training (also known as mindfulness-based stress reduction or mindfulness meditation) may have a beneficial clinical effect in patients with cardiovascular disease or those at increased cardiovascular risk. In addition, psychological problems and symptoms of depression and anxiety appear to be amenable to mindfulness meditation. Adult patients with structural heart disease have a high incidence of both physical (cardiac) and psychological problems and may therefore benefit from mindfulness training.

Study design

The primary outcome and all secondary outcomes will be measured at: baseline, 3 months and 1 year.

Intervention

Intervention:

The intervention is a mindfulness training and consists of a structured standardized online program, which has been provided to clients in the general 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, breathing exercises, assignments that need to be filled out, and practice suggestions for the coming few days. The online program is further supported by emails and intermittent text messages on the patient's cell phone. The online training is currently 8 weeks. It will be extended to 12 weeks followed by reminder emails, sms-messages, and suggestions for continuing practice every 2-4 weeks thereafter until a year after the beginning. The low cost of the online programme (€ 30,-) gives the program the potential of being a cost effective intervention. Patients will not be charged for the online program. They will receive a personal code from Psychologie Magazine to start the online mindfulness training. Adherence to the intervention will be monitored by documenting whether the questions have been filled out.
In addition, all patients will receive usual care just like patients in the control group.

Control:

The control group will receive usual care which consists of regular outpatient visits, lifestyle advice regarding healthy nutrition, smoking cessation, physical activity, and stress reduction, and medical therapy and procedures if indicated.

Contacts

Public
Dept. of Cardiology and Dept. of Epidemiology
P.O. Box 2040
J.O. Younge
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033989
Scientific
Dept. of Cardiology and Dept. of Epidemiology
P.O. Box 2040
J.O. Younge
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033989

Eligibility criteria

Inclusion criteria

Adults 18 to 65 years old known to have structural heart disease, including congenital heart disease and cardiomyopathy.

Exclusion criteria

1. Planned operation or percutaneous intervention;

2. Inability or unwillingness to give informed consent;

3. Inability to understand Dutch, inability to read or write Dutch;

4. No internet access or no email or no cell phone;

5. Patients who do not fill out their baseline questionnaires or do not show up for the scheduled baseline tests.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-06-2012
Enrollment:	330
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-05-2012
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	NL3306
NTR-old	NTR3453
Other	METC ErasmusMC : MEC2012-002
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A