Mindfulness training for patients with structural heart disease.

Gepubliceerd: 22-05-2012 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26153

Bron
Nationaal Trial Register

Aandoening

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

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

Ondersteuning

Primaire sponsor: Board of Directors, Erasmus Medical Center Rotterdam.
Overige ondersteuning: Board of Directors, Erasmus Medical Center Rotterdam.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	04-06-2012
Aantal proefpersonen:	330
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3306
NTR-old	NTR3453
Ander register	METC ErasmusMC : MEC2012-002
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A