Effectiveness of mindfulness-based stress reduction for improving quality of life in patients with cardiovascular disease: a randomised controlled trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON55428

Source
ToetsingOnline

Brief title
Mind Our Heart Study

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerotic vascular disease, Cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Innovatiesubsidie Hartstichting;Chronisch Zorgnet

Intervention

Keyword: Active control group, Cardiovascular disease, Mindfulness, Quality of life

Outcome measures

Primary outcome

Quality of life measured with SF-12 questionnaire over the twelf month study

period.

Secondary outcome

- Stress (PSS-10)

- Depression (PHQ-9)

- Anxiety (GAD-7)

- Wellbeing (WHO-5)

- Self-efficacy (GSES)

- Fysical activity (EVS)

- Nutrition (MEDAS)

- Smoking (ja/nee)

- Alcohol use (AUDIT-C)

- Sleep (SQS)

- Fatigue (VVV)

- Body Mass Index (lichaamsgewicht- en lengte)

- Medication adherence (SMAQ)

- Cost-effectiveness (EQ-5D-5L)

Study description

Background summary

A cardiovascular disease can hinder patients in their daily life. About 1 in 5 people with cardiovascular disease suffer from stress and feelings of sadness and anxiety. This has a major impact on quality of life and can worsen the outcomes of regular treatment. Furthermore, many cardiovascular patients are urged to adopt a healthier lifestyle, since cardiovascular diseases are often the result of an unhealthy lifestyle. Mindfulness seems to be a promising way to get started with stress reduction and lifestyle change.
Mindfulness programs such as the 8-week mindfulness-based stress reduction program (MBSR) have been used successfully for years in people with stress, pain, psychological complaints (such as depression) and various chronic diseases. In this study, mindfulness training is also aimed at developing and maintaining a healthy lifestyle.

Study objective

In the Happy Hart study we investigate whether adding this mindfulness program to the standard treatment of people with cardiovascular diseases leads to a better quality of life, better mental health and a healthier lifestyle compared to the standard treatment alone. If this program proves to be beneficial, the study may help make it available as standard of care for this patient population.

Study design

2-group, single-blind, randomized, pragmatic study consisting of an intervention interval of 8 weeks and a follow-up period of 10 months.
Patients are randomly assigned to the 8-week mindfulness program as an adjunct to usual treatment (intervention group n = 120) or to usual care (control group n = 120). Patients in the intervention group can attend the mindfulness training live online or in person, depending on their preference and the corona measures in place.

Intervention

8-week mindfulness program

Study burden and risks

Participation in this study is not associated with any risks or side effects.
It does take time to participate in the 8-week (online/live) meetings (8x2.5 hours), to practice at home (30 min per day for 8 weeks), and to complete the questionnaires (3x30 min).

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

a. Adult (18 years and older);
b. Established atherosclerotic cardiovascular disease (i.e. coronary artery disease, ischemic heart failure, peripheral artery disease).

Exclusion criteria

a. Current acute cardiovascular event (myocardial infarction, major stroke, acute limb ischemia in prior 2 weeks)
b. Critical limb ischemia
c. Terminal illness
d. History of psychosis
e. Current severe psychiatric disorder
f. Current psychotherapy
g. Non-Dutch speaking
h. Cognitive impairment
i. Behavioural problems that distort group meetings
j. Active mindfulness/meditation or yoga practice within the past year
k. Current participation in another clinical trial that possibly interferes with the study intervention or primary outcome

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	240
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-11-2018

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-09-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL66291.100.18