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

Published: 26-11-2018 Last updated: 12-04-2024

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...

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)

# **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**

#### **Public**

Catharina-ziekenhuis

Michelangelolaan 2 Eindhoven 5623EJ NL

Scientific

Catharina-ziekenhuis

Michelangelolaan 2 Eindhoven 5623EJ NL

## **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