

Effects of a mindfulness based stress reduction program on psychological and physiological measures in cardiac patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26707

Source

NTR

Brief title

MindfulHeart

Health condition

cardiac patients undergoing a percutaneous coronary intervention; psychological stress, anxiety and depression; quality of life; elevated blood pressure

Sponsors and support

Primary sponsor: Tilburg University and St. Catharina Hospital Eindhoven

Source(s) of monetary or material Support: Tilburg University and St. Catharina Hospital Eindhoven

Intervention

Outcome measures

Primary outcome

Psychological distress (symptoms of perceived stress, anxiety and depression) at post-intervention.

Secondary outcome

1. Vitality;
2. Quality of life, blood pressure;
- 3 Heart rate variability;
4. C-reactive protein at post-intervention;
5. Psychological distress (symptoms of perceived stress, anxiety and depression) at post-intervention at 1-year follow-up.

Study description

Background summary

N/A

Study objective

Compared to a control group, the mindfulness group intervention is expected to result in:

1. A decrease in symptoms of psychological distress;
2. An increase in quality of life;
3. An increase in heart rate variability;
4. A decrease in blood pressure in those with elevated blood pressure;
5. Decrease in low-grade inflammation.

Study design

1. Pre-intervention (T1);

2. Post-intervention (T2);

3. 1-year follow-up (T3).

The following measures are taken at all time points:

Perceived Stress Scale (PSS); Symptoms of Anxiety and Depression (SAD-4); WHOQoL-Bref and Seattle Angina Questionnaire (for quality of life); Global Mood Scale (GMS); Freiburg Mindfulness Inventory-short (FMI-s); Balanced Index of Psychological Mindedness.

The following measures are taken at T1 and T2: Systolic and diastolic blood pressure (means of 3 measurements); heart rate variability; C-reactive protein.

Intervention

The applied group (6-8 patients) intervention is a mindfulness training, which is loosely based on the Mindfulness-Based Stress Reduction (MBSR) program, as developed by Kabat-Zinn (1990). The adjusted program in this study is less intensive, including only three weekly 90 to 120 minutes meetings and an additional evaluation session two weeks later.

The control group is an active control group: A self-help intervention consisting of a booklet based on the group training and written by the same clinical psychologist. The psychoeducation and exercises are identical to the information given in the group intervention. The participants who receive the self-help booklet are asked to read the theory and to practice the exercises daily as indicated.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients who had a percutaneous coronary intervention in the previous month;
2. Age 18-70.

Exclusion criteria

1. Serious medical co-morbidity (e.g., heart failure; cancer);
2. Serious psychiatric co-morbidity (e.g., suicidal ideation; psychoticism);
3. Past or present brain-damage;
4. Inadequate knowledge of the Dutch language;
5. Acute infection in past two weeks;
6. Use of anti-inflammatory drugs, except aspirin.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 01-02-2008
Enrollment: 128
Type: Actual

Ethics review

Positive opinion
Date: 13-04-2012
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32039
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3245
NTR-old	NTR3397
CCMO	NL19795.060.07
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32039

Study results

Summary results

N/A