

Predictors of effects of a mindfulness based psychological treatment on psychological well-being in cardiac rehabilitation patients.

No registrations found.

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

Summary

ID

NL-OMON20355

Source

NTR

Brief title

MindfulHeart II

Health condition

coronary artery disease; emotional problems (anxiety and depression);

Sponsors and support

Primary sponsor: Tilburg University

St. Catharina Hospital Eindhoven

Source(s) of monetary or material Support: Tilburg University

St. Catharina Hospital Eindhoven

Intervention

Outcome measures

Primary outcome

Psychological well-being (anxiety, depression, psychological stress).

Secondary outcome

1. Quality of life;
2. Self-esteem.

Study description

Background summary

This study investigates predictors of effects on psychological well-being and quality of life of a mindfulness based intervention in cardiac rehabilitation patients.

It is hypothesized that the mindfulness based intervention will be associated with a reduction in psychological symptoms and increase in quality of life. In addition, it is hypothesized that patients scoring high on psychological mindedness at baseline will show larger benefits compared to those low in psychological mindedness.

Study objective

It is hypothesized that the mindfulness based intervention will be associated with a reduction in psychological symptoms and increase in quality of life. In addition, it is hypothesized that patients scoring high on psychological mindedness at baseline will show larger benefits compared to those low in psychological mindedness. No effects of attention deficits or hyperactivity are anticipated.

Study design

T1: Before intervention. All variables will be measured: anxiety and depression (Hospital Anxiety and Depression Scale), stress (Perceived Stress Scale), Quality of Life (QLMI), self-esteem (Rosenberg Self-Esteem Scale), psychological mindedness (BIPM), symptoms of ADHD.

Also at T2 (after the intervention) and T3 (one year after the intervention) all these questionnaires will be completed.

Intervention

Mindfulness-based stress reduction versus treatment as usual (TAU).

The applied mindfulness-based stress reduction is a group (6-8 patients) intervention, 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 treatment-as-usual (TAU) group consists of those cardiac rehabilitation patients who do not sign up for the intervention. They will be matched with the treatment group regarding age, sex, education, and level of baseline psychological well-being.

Contacts

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Eligibility criteria

Inclusion criteria

1. Participants in cardiac rehabilitation of St. Catharina Hospital Eindhoven;
2. Age between 18-80 years.

Exclusion criteria

1. Severe psychiatric (e.g., suicidal ideation; psychoticism) or somatic (e.g., heart failure; cancer) comorbidity;
2. Insufficient mastery of Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion	
Date:	27-04-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39938

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3266
NTR-old	NTR3419
CCMO	NL34522.060.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39938

Study results

Summary results

N/A