

Mindfulness-based cognitive therapy in female patients with microvascular coronary disease

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To evaluate the efficacy of MBCT in comparison with treatment as usual (TAU) in women with MCD in terms of: reduction of psychological distress such as anxiety, depression and QOL, reduction of anginal symptoms, and improvement of vascular function

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON40779

Source

ToetsingOnline

Brief title

Mind MCD study

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym

microvascular coronary disease (microvascular angina pectoris)

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: subsidieaanvraag loopt nog

Intervention

Keyword: microvascular coronary disease (MCD), Mindfulness, Women

Outcome measures

Primary outcome

Subjective and objective improvement in women with MCD. This will be measured by questionnaires, which the subjects will fill out themselves, and two vascular measures.

Secondary outcome

not applicable

Study description

Background summary

The prognosis of women with persistent chest pain with non-obstructive CAD have a worse prognosis when compared with asymptomatic women. Recent research had revealed that particularly in this group of women, microvascular coronary dysfunction (MCD), involving endothelial and nonendothelial pathways, are important determinants for ischemia. Psychosocial factors such as anxiety disorders are more often present in patients with MCD. Almost 50% of patients with atypical chest pains have psychiatric co-morbidity. The prognosis of women with angina pectoris due to non-obstructive CAD and MCD has been shown to be less beneficial than previously considered.

Study objective

To evaluate the efficacy of MBCT in comparison with treatment as usual (TAU) in women with MCD in terms of: reduction of psychological distress such as anxiety, depression and QOL, reduction of anginal symptoms, and improvement of vascular function

Study design

Exploratory pilot study in which we will randomize 40 female outpatients to either MBCT or usual care

Intervention

Mindfulness-based cognitive therapy.

Study burden and risks

The intervention and the cardiovascular measures are low risk.

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

Women 45-65 years old with recurrent angina pectoris for at least 3 months, in the absence of obstructive CAD (as assessed by CAG or CCTA <1 year ago), who are normotensive

(with/without medication) and have no structural heart disease (as detected by echocardiogram)

Exclusion criteria

Women outside of the age range, who are hypertensive and/or have a structural heart disease.

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:	Recruitment stopped
Start date (anticipated):	27-07-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO	
Date:	23-05-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL48476.091.14