The Heart Inside Out: emotions and mood as mediators of cardiac symptoms in microvascular dysfunction*

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Primary objective 1: To determine whether expressed emotions, current mood and perceived stress are associated with the presence of cardiac symptoms in patients with coronary microvascular disease.Hypothesis: Expressed emotions, current mood, and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43239

Source
ToetsingOnline

Brief title
The heart inside out.

Condition

- Coronary artery disorders

Synonym
Coronary microvascular disease; oxygen deficiency of small coronary vessels of the heart.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac symptoms, emotions, microvascular dysfunction, quality of life

Outcome measures

Primary outcome

parameters primary research question 1:

Cardiac symptoms: Reported during stress MPI: chest pain, dyspnea or other (e.g. flushing, nausea, pain in neck/jaw), and intensity of symptoms on a 0-10 VAS scale.

Groups: Three groups will be created, based on presence or absence of myocardial ischemia as detected with the MPI, and presence or absence of clinically significant CAD (at least one coronary lesion > 50%, or history of PCI/CABG) based on hospital records:

(Suspect) Coronary microvascular disease (CMD) = presence of ischemia and nonobstructive CAD

Reference group = absence of ischemia

CAD group = presence of ischemia and obstructive CAD.

Expressed emotions: Prevalence and intensity of 6 key emotions: happy, sad, angry, surprised, scared, disgusted, or neutral as measured by recordings of the face during rest and stress, and analysed using Noldus FaceReader software.

Mood and stress: Short form of the profile of mood states (POMS). Perceived stress, and current emotions on a 0-10 VAS scale, as have been studied before.

Endpoint parameter primary research question 2:

Quality of life: Questionnaires on quality of life and health status will be filled-out by the participants at 12 months.

Hospital records: At 12 months we aim to collect health care utilization from hospital records at the Elisabeth-TweeSteden Hospital on: number and date of (emergency dept) visits using invasive/noninvasive testing or procedures.

Secondary outcome

Hemodynamics: Heart rate, blood pressure and ECG at rest and stress are recorded as part of the routine MPI procedure.

Distress and sociodemographic factors: Questions on sociodemographic variables, and validated questionnaires on psychosocial factors will be filled out by the participants.

Study description

Background summary

Patients with cardiac symptoms undergo testing to determine the presence or absence of clinically significant CAD. In the Netherlands, over 54,000 coronary angiographies are performed annually. An estimated 50-80% of women and 30-60% of have nonobstructive CAD, and are being treated conservatively. However, myocardial ischemia in the absence of clinically significant CAD is not without cardiovascular risk. Our TweeSteden Mild Stenosis (TWIST) study, has also shown that 44% of these patients continue to report chest pain 3 months later, and chest pain is related to psychological distress and Type D personality.This group is hypothesized to be at (increased) risk for poor quality of life, recurrent diagnostic testing, hospitalization and long-term major adverse cardiac events.

In the present study we look at the role of emotions and mood in cardiac symptoms and myocardial ischemia .

Coronary Microvascular Dysfunction (CMD) is the presence of ischemia in the absence of obstructive coronary artery disease. CMD is believed to be caused by stenotic , or endothelial dysfunction of small coronary arteries. CMD can be determined on the basis of a myocardial perfusion scan for the presence of ischemia, and additional information about the presence or absence of obstructive coronary artery disease.
It is necessary to investigate the role of psychological symptoms, in view of the prevalence of anxiety associated with recurrent chest pain .

Previous studies have shown that acute mental stress is associated with increased sympathetic activation and (nor)adrenaline release affecting vasoconstriction. In line with this evidence studies have shown that mental stress can induce myocardial ischemia. Moreover,emotions such as fear have been associated with higher cardiovascular reactivity. Heart rate and blood pressure provide additional cues on the activated or inhibitory pathway of distress and fear, which are routinely being assessed during myocardial perfusion imaging.

Study objective

Primary objective 1: To determine whether expressed emotions, current mood and perceived stress are associated with the presence of cardiac symptoms in patients with coronary microvascular disease.
Hypothesis: Expressed emotions, current mood, and perceived stress mediate the association between CMD and cardiac symptoms.

Primary objective 2: To establish whether patients with CMD, compared to the reference and CAD group, are significantly more likely to experience poor quality of life and recurrent health care utilization at 12 months follow-up, and whether is this association is affected by psychological distress.
Hypothesis: CMD is significantly associated with poor quality of life, cardiac symptoms and recurrent health care utilization when compared to the reference group, and CAD group. The presence of psychological distress as measured by anxiety, depressive symptoms or Type D personality is expected to mediate this association in each patient group.

Study design

Study design: Quasi experimental longitudinal design of three groups with follow-up assessments of quality of life and health care utilization.

Study burden and risks

The proposed study incurs no extra risk to patients, as they receive no additional treatment na/ or tests nor will any treatment be withheld from them compared to patients who choose not to participate or are excluded on the basis

of the exclusion criteria. No extra venapuncture will take place.The only burden to patients is the time that it will take to complete a set of psychological questionnaires on site, which is estimated to take 1 hour. Another set of questionnaires can be filled-out at home and returned by pre-stamped envelope.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients referred to the Verbeeten Institute Tillburg who are eligible for adenosine or exercise induced single-photon emission computed tomography rest-stress test (myocardial imaging), older than 18 years of age and capable of answering questionnaires.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: age < 18 years, a life-threatening disease, and inability to fill out questionnaires.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2017
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-10-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	21-11-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-01-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL56707.028.16