Optimizing patient experience during cardiac stress testing

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Primary objective: To determine whether adding information and coaching support to the standard diagnostic testing environment for the inducibility of myocardial ischemia improves patient psychological wellbeing.The role of the testing environment...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON51832

Source
ToetsingOnline

Brief title
OPTIMIZE

Condition

- Myocardial disorders

Synonym
Myocardial ischemia. Oxygen deficiency of the heart muscle.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Instituut Verbeeten

Intervention

Keyword: Cardiac symptoms, Emotion, Myocardial ischemia, Patient experience

Outcome measures

Primary outcome

Primary outcome measure: Psychological wellbeing will be assessed using self-report measures of emotional states (anxiety, stress and uncertainty) and facial expression of emotions based on video recordings during the diagnostic testing procedure. Facial expressions will be analyzed (valence and intensity; e.g., anxiety) using FaceReader software as in our prior METC-approved research projects at Institute Verbeeten. These measures of psychological wellbeing will be compared between the four groups and associations with the secondary outcomes will be investigated (cardiac symptoms, patient satisfaction and stress-related autonomic nervous system measures).

Secondary outcome

Cardiac symptoms: Type and intensity of cardiac symptoms and other common symptoms during MPI SPECT (e.g., headache, dizziness, fatigue, nausea) will be assessed using self-report measures.

Patient experience/satisfaction: Patient experience and satisfaction of the clinic visit, cardiac tests and coaching will be assessed using a validated questionnaire.

Physiological measures: During the cardiac stress-test, heart rate and blood pressure are routinely collected. These data will be used as physiological measures that are relevant to emotional experiences, cardiac symptoms and inducibility of myocardial ischemia.

Ambulatory ECG monitoring: A 24-hour Holter-ECG will be used to assess heart rate variability and other ECG parameters during everyday life activities. These assessments are obtained out-of-clinic during the days between the resting and stress MPI SPECT assessment and will reveal ambulatory data related to heart rate and heart rate variability.
SPECT images: As part of patients clinical care, single-photon emission computed tomography will be used to obtain myocardial perfusion images on the rest and cardiac stress test days. The presence or absence of ischemia can be evaluated based on these images.

During the myocardial perfusion stress-test, blood pressure and heart rate are being collected routinely. We ask patients for permission to collect these data for the present study. Blood pressure and heart rate provide additional relevant information about emotion-related physiological responses relevant to cardiac symptoms and myocardial ischemia.

Study description

Background summary

Cardiovascular disease is one of the main causes of death worldwide (Khan, 2020). One of the precursors of serious heart problems such as a heart attack is myocardial ischemia which occurs when blood flow to the heart is reduced, preventing enough oxygen supply to the heart muscle. Myocardial ischemia is often caused by partial or complete blockage of the coronary arteries (coronary artery disease: CAD). Resulting persistent cardiac symptoms, such as chest pain, are a substantial burden to patients and society. Optimal and efficient diagnosis of myocardial ischemia is therefore paramount. The present study focusses on the effects of testing environment on emotion and mood states, cardiac symptoms and patient satisfaction during cardiac stress testing in

patients that are referred to the Verbeeten Institute for SPECT MPI.

Study objective

Primary objective: To determine whether adding information and coaching support to the standard diagnostic testing environment for the inducibility of myocardial ischemia improves patient psychological wellbeing.
The role of the testing environment on psychological measures will be assessed by comparing four approaches during the diagnostic project: care-as-usual (CAU), providing information support using video clips, providing supportive coaching by a coach, and a combination of information support and supportive coaching. It is hypothesized that both interventions will additively improve psychological wellbeing during the diagnostic process (i.e., emotional states and mood).

Secondary Objectives
2.1. To determine whether adding information and coaching support to the standard diagnostic testing environment for the inducibility of myocardial ischemia reduces cardiac and other physical symptoms during the testing procedure.
Previous studies have already shown a relation between negative emotions such as anxiety with cardiac and other physical symptoms. It is therefore hypothesized that both information and supportive coaching interventions will additively reduce cardiac and other physical symptoms during the diagnostic testing procedure.

2.2. To determine whether adding information and coaching support to the standard diagnostic testing environment for the inducibility of myocardial ischemia will improve patient satisfaction with the clinic visit.
It is hypothesized that information support and supportive coaching improves patient satisfaction by improving psychological wellbeing (i.e., reducing anxiety, uncertainty and distress) and reducing cardiac and other physical symptoms during the diagnostic testing procedure.

2.3 To establish the association between patient wellbeing experiences during the diagnostic testing procedure for inducibility of myocardial ischemia with autonomic nervous system activity.
It is hypothesized that higher levels of psychological wellbeing are associated with a shift towards reduced sympathetic and increased parasympathetic autonomic nervous system activity as indexed by lower heart rate and blood pressure responses during cardiac testing and higher levels of heart rate variability during ambulatory ECG monitoring.

Study design

Experimental 2x2 factorial design with four groups: CAU, CAU + Information, CAU

+ Coach, CAU + Information + Coach. Outcome measures: psychological wellbeing (primary outcome: emotional states self-report and FaceReader assessments), and symptoms during the diagnostic testing procedure, patient satisfaction and autonomic nervous system activity (secondary outcome measures).

Intervention

To improve the patient experiences during cardiac stress testing and MPI, we will compare four approaches while patients visit the Institute Verbeeten: Care as usual, information support, emotional support by a coach and a combination of information and emotional support. This type of intervention is intended as quality of care evaluation. As per study protocol, participating patients will be randomly assigned into four groups before their first clinic visit at Institute Verbeeten.
Group 1: Care as usual (CAU) = Patients in this group will not receive any additional information materials or support on top of care as usual, but information videos will be made available after completion of the MPI procedures.
Group 2: CAU + Information support = patients in this group will primarily receive additional information on the diagnostic process that they will go through with the use of video materials as well as answers to questions. Emotional support by additional coaching will not be provided in this group.
Group 3: CAU + Supportive coaching = Patients in this group will receive emotional support throughout their clinic visit. The coach is available for questions as well as specific support for each patient. Additional information using video materials will not be supplied to the patients during the diagnostic process, but will be made available after completion of the MPI procedures.
Group 4: CAU + Information + Coaching = Patients in this group will receive both additional information as well as supportive coaching during their visit of the clinic.

Study burden and risks

- Filling out one questionnaire on psychological factors, which takes approximately 25 minutes.
- Filling out a second questionnaire on demographic and psychosocial factors in a take-home questionnaire, and returning them by postal mail. Estimated time 25 minutes.
- Receiving two short (<5 min each) information video clips or interacting with a coach who provides emotional support (<10 minutes total)
- Filling out a third brief questionnaire on patient experience and satisfaction using an online questionnaire taking approximately 25 minutes.
- Use of a Holter monitor over the 24 hours after the hospital visit.
- Consent to have video recordings taken of the patient during the bicycle or adenosine myocardial perfusion stress task. These recordings will be used to

detect facial expressions using specialized software (FaceReader) at Tilburg University. See protocol for details. Reporting (cardiac) symptoms during the second day of cardiac stress testing; which is part of routine clinical practice, expanded by a scale to measure intensity of the symptoms for the present study
- Consent to collect additional collection of data from hospital records at the Verbeeten Institute (including blood pressure and heart rate monitoring) and the Elisabeth-Tweesteden hospital cardiology unit.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: All patients who are referred to the Verbeeten Institute Tilburg who are eligible for adenosine-exercise SPECT MPI, older than

18 years of age, capable of answering questionnaires and receiving information and coaching in Dutch.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2022
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2022
Application type:	First submission
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	NL81600.028.22