

PSYchological factors and Cardiovascular, Hormonal and Emotional responses to stress in patients with established coronary artery disease (PSYCHE)

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The current research proposal therefore aims to examine the relation between a range of psychological risk factors and several mental stress-induced physiological responses in a large sample of PCI patients.

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

Summary

ID

NL-OMON40395

Source

ToetsingOnline

Brief title

PSYCHE

Condition

- Coronary artery disorders

Synonym

acute coronary syndrome, atherosclerosis

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: NWO Aspasia beurs N Kupper

Intervention

Keyword: mood, personality, physiological stress reactivity, stress

Outcome measures

Primary outcome

Predictors: Psychological risk factors (depression, anxiety, Type D

personality, mindfulness);

Outcome variables: hormonal (cortisol), hemodynamic (blood pressure, cardiac

output), and myocardial (pre-ejection period, heart rate variability, heart

rate) stress reactivity.

Secondary outcome

complications, events and death at 1 year after PCI

Study description

Background summary

Psychological risk factors such as depression, anxiety and Type D personality have a negative impact on prognosis in cardiac patients. However, to date it is still unclear through which mechanisms psychological risk factors exert this effect, and whether the same mechanisms apply for all or that there are differential mechanisms at play.

Study objective

The current research proposal therefore aims to examine the relation between a range of psychological risk factors and several mental stress-induced

physiological responses in a large sample of PCI patients.

Study design

Prospective experimental study in which patients will be asked to fill out a questionnaire, and to participate in the Trier Social Stress Test, including a public speech task and a mental arithmetic task, while their physiological response to this stressor is assessed.

Study burden and risks

The risk associated with the current study is low. For this mechanistic study, investigators will ask patients to fill out a psychological survey, including among others questions on personality, mood, anxiety, mindfulness, illness perception, work stress, and satisfaction with life. Also, participation in a mental stress test is requested, during which participants are subjected to mild psychological stress.

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

Elective percutaneous coronary intervention 3-4 months ago, stable, without complaints related to this PCI, or acute percutaneous coronary intervention 6 months ago, stable, without complaints related to this PCI; Not on beta-blocker medication or willing to discontinue beta-blocker medication for 48 hours preceding the stress test (when agreed upon by treating intervention cardiologist); Aged ≥ 18 ; Fluent in Dutch

Exclusion criteria

Life threatening comorbidity (e.g. cancer) or psychiatric disorder (except mood disorders)
Unstable at 3 months post-elective PCI, with complaints, or unstable at 6 months post-acute PCI, with complaints.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 12-12-2013

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 28-10-2013

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 18-12-2014

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	NL46111.028.13