

# The impact of a first cardiac event in middle-aged patients on cognitive functioning, mood and fatigue.

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Our interest is to gain a better understanding about cognitive complaints, mood and fatigue in relation to cognitive deficit in adults 30 to 60 years of age after a first cardiac event.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Cardiac disorders, signs and symptoms NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON43851

### Source

ToetsingOnline

### Brief title

cognitive functioning, mood and fatigue in middle-aged cardiac patients

### Condition

- Cardiac disorders, signs and symptoms NEC
- Cognitive and attention disorders and disturbances

### Synonym

attention and concentration, problems in memory

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Deventer Ziekenhuis

**Source(s) of monetary or material Support:** Deventer Ziekenhuis;  
wetenschapscommissie

## Intervention

**Keyword:** cognitive functioning, fatigue, heart disease, middle age

## Outcome measures

### Primary outcome

Determination Test for complex information processing (number of correct items). Vienna Test System.

### Secondary outcome

Presence of cognitive disorder as measured through these cognitive subdomains:

1) Speed of information processing:

Determination Test, Reaction Time Tests 1, 2, 3 (Vienna Test System), Trailmakingtest A, Stroop color card and Stroop word card.

2) Executive function:

Zoo-map (BADS), Trailmakingtest B, Controlled Oral Word Association Test (COWAT), Stroop color-word card, Trailmakingtest B.

3) Memory:

Rey Auditory Verbal Learning Test (RAVLT), digit span (WAIS II), category fluency (GIT-2).

Presence of potential causal factors:

1) anxiety and depression: Hospital Anxiety and Depression Scale (HADS)

2) fatigue: The Fatigue Severity Scale (FSS)

3) cognitive complaints: The Cognitive Failure Questionnaire (CFQ)

# Study description

## Background summary

In recent studies the connection between heart disease and cognitive disorder has become increasingly important in understanding patient complaints, symptoms and rehabilitation to daily routines. Cognitive deficit, as well as mood disorders and fatigue, may hinder disease management in cardiac patients. Although this has been studied extensively in the elderly, this area is less well researched for the group of middle-age patients. Consequently, some cardiac patients may not be able to benefit sufficiently from cardiac rehabilitation, as the current program requires normal cognitive function. Middle-aged patients have many major responsibilities to return to after a cardiac event. There is a need for a better understanding of cognitive deficits in heart disease due to the implications of these deficits for disease management, rate of dependence for daily activities and return to work.

## Study objective

Our interest is to gain a better understanding about cognitive complaints, mood and fatigue in relation to cognitive deficit in adults 30 to 60 years of age after a first cardiac event.

## Study design

The study proposed is cross-sectional in nature, using a matched-control design. Quantitative data will be collected through neuropsychological tests, self-report questionnaires and from medical files.

## Study burden and risks

There are no serious health threats associated with participation in this study.

1. Participation may lead to fatigue, as considerable attention and concentration is required for the cognitive tasks.
2. Participation may prove to be confrontational as some tasks go well, while others do not. Confrontation with performance may be frustrating for some individuals.

Benefits include objective measure of cognitive functioning, fatigue, depression and anxiety, which are reported back to participants. This extra care and attention may contribute positively to the rehabilitation process.

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- a) First cardiac event requiring in hospital medical intervention, 30-60 years of age.
- b) Elective knee surgery, 30- 60 years of age.

### Exclusion criteria

- a) psychiatric disorder (history of bipolar disorder or actual psychosis)
- b) current use of anti-psychotics
- c) chronic pain syndrome,
- d) history of contusio cerebri,
- e) history of cerebral stroke

## 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):	29-02-2016
Enrollment:	40
Type:	Actual

## Ethics review

Approved WMO	
Date:	18-01-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

## 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	NL51448.075.15