# Risk Education: Effect on Acceptance of Cardiovascular risk lowering Treatment In Primary care.

Published: 28-11-2006
Last updated: 10-08-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30463

**Source**
ToetsingOnline

**Brief title**
REACT IP

### Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
cardiovascular diseases

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** antihypertensives and statins, cardiovascular risk, patient education, risk reduction

## Outcome measures

### Primary outcome

Usual care of cardiovascular education of patients with increased

cardiovascular risk.

Patients' knowledge about cardiovascular risk after education

Patients' willingness to start cardiovascular risk lowering medication

### Secondary outcome

Not applicable.

# Study description

### Background summary

Treatment of hypertension and increased cholesterol level reduces cardiovascular risk. There are several education strategies to explain cardiovascular risk and benefits of riskreducing treatment.

### Study objective

In this trial, current usual care concerning cardiovascular education is described. Second aim is to study what is understood of this education by the patient. Last aim is to study what effect training of GP's on this subject will have on the patients' cardiovascular knowledge and their decision to start risk lowering medication.

### Study design

Interventional study

### Intervention

The study consists of two parts.
Part 1: observation by GP's in vocational training during their first year (aios).
If a patient fulfills the criteria of high risk, the aios observes with the aid of structured observation lists, which strategy the GP uses to educate his patient about his cardiovascular risk.
Part 2: interviews by GP's in vocational training during their third year.
If patients fulfil the criteria of high risk, the aios interviews them with the aid of a structured interview list. Aim is to register what patients understand of the cardiovascular education they received and to study if patients are willing to start with cardiovascular lowering medication. After this, GP's will be trained on cardiovascular education to improve the quality of cardiovascular education. Then again, (other) patients will be interviewed after their cardiovascular education.

**Study burden and risks**

The burden of the patients exists of one interview of 10 minutes after a visit to his GP. There is no risk associated with this interview.

# 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

Systolick Bloodpressure > 140 mmHg
Total cholesterol > 6,5 mmol/l
Smoking men > 50 years
Smoking women > 55 years

## Exclusion criteria

Not have mastered the Dutch language

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 26-03-2008 |
| Enrollment: | 254 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 28-11-2006 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 23-10-2007 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL12179.041.06 |