

# Value of Intermediate endpoints for Treatment in outPatient cLinic: Nurse-led multi-factorial risk counselling intervention to improve adherence to lipid lowering medication and lipid levels versus routine clinical care in patients with an increased cardiovascular risk

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<b>Registration date</b> 02/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/05/2015	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Reducing high blood levels of LDL cholesterol decreases the chances of getting a heart attack and other cardiovascular events both in people who have had previous heart attacks (secondary prevention) and in people who have risk factors but have not yet had a heart attack (primary prevention). Statins are drugs that treat high blood cholesterol levels. Many studies show that statins are effective in the primary and secondary prevention of heart attacks and other cardiovascular events. People need to take their statins as prescribed and not to miss doses for the drugs to work properly. Taking drugs as prescribed and not missing doses is called adherence. Many people find it hard to be adherent with their medications all the time. The aim of this study was to investigate if a nurse counselling people about their personal cardiovascular risk factors, including their actual cholesterol levels in the blood, and their personal risk of getting a cardiovascular event would improve adherence to statins without making people anxious.

### Who can participate?

People aged 18 or older who are prescribed statins for prevention of cardiovascular disease.

### What does the study involve?

Participants are randomly allocated to receive either medical care as usual or to receive additional counselling from a nurse about their personal cardiovascular risk factors.

### What are the possible benefits and risks of participating?

The possible benefit of the additional counselling is that it may improve the participants' adherence with statin treatment and thereby lower (improve) the participants' blood cholesterol

levels. The possible risk of receiving the additional counselling is that receiving information about personal cardiovascular risk factors could make someone anxious about his or her risk of getting a cardiovascular event.

Where is the study run from?

Academic Medical Center and Slotervaart Hospital, Netherlands.

When is the study starting and how long is it expected to run for?

The study started in May 2002 and ended in May 2004.

Who is funding the study?

Pfizer, Netherlands.

Who is the main contact?

Prof. Erik Stroes

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## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Erik Stroes

**Contact details**

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## Additional identifiers

**Protocol serial number**

N/A

## Study information

**Scientific Title**

Nurse-led multi-factorial risk counselling intervention to improve adherence to lipid lowering medication and lipid levels versus routine clinical care in patients with an increased cardiovascular risk: a randomised non-blinded two-centre controlled trial

**Acronym**

VITAL

**Study objectives**

Nurse-led multi-factorial risk counselling will result in improved adherence to lipid lowering medication and lipid levels compared with routine clinical care in patients with an increased cardiovascular risk.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Medical Ethics Review Academic Medical Center Amsterdam, MECnr 01/156, approved the study on 20/03/2002 for the Academic Medical Center, Amsterdam, and on 27/06/2002 for the Slotervaart Hospital, Amsterdam.

### **Study design**

Randomised non-blinded two-centre controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Cardiovascular disease

### **Interventions**

Patients were randomly assigned to receive routine care or extended care at baseline and at months 3, 9 and 18. Patients in the extended care group received a personalized risk factor passport, showing modifiable and un-modifiable individual risk factors and a graphical presentation of their calculated absolute 10-year cardiovascular disease risk as well as the target risk that could be reached if all modifiable risk factors were optimally treated.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

1. Lipid levels: total cholesterol, triglycerides, higher-density-lipid cholesterol, and lower-density-lipid cholesterol
2. Adherence to lipid lowering medication in the past week (scale from 1 to 5), and in the past month (scale from 1 to 9)
3. Anxiety, assessed by the Hospital Anxiety and Depression Scale  
Assessed at baseline and at months 3, 9 and 18.

### **Key secondary outcome(s)**

1. Carotid intima-media thickness
2. Flow-mediated dilatation
3. Body Mass Index
4. Quality of Life (SF-12)
5. Symptoms (symptom checklist EORTC)
6. Beliefs about Medication Questionnaire (BMQ)
7. Risk perception (scale from 1 to 9)

8. Self-reported smoking status (yes/no)
9. Blood pressure, systolic and diastolic.

Carotid intima-media thickness and flow-mediated dilatation are assessed at baseline and at month 18. The other secondary outcomes are assessed at baseline and at months 3, 9 and 18.

**Completion date**

31/05/2004

## Eligibility

**Key inclusion criteria**

1. Indication for statin therapy
2. Age >18 years
3. Written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Use of statin therapy > 3 months
2. Diabetes mellitus type II: fasting glucose >7,0 mmol/L
3. Fasting total cholesterol > 9,0 mmol/L
4. Fasting Triglycerides > 4,0 mmol/L
5. Liver function disturbances (ASAT/ALAT >2 times reference values)
6. Creatinine kinase (CK) elevations (>3 times reference values)
7. Drug and/or alcohol abuse
8. Pregnancy and breastfeeding
9. Life expectancy <2 years
10. Inability to fill out a Dutch questionnaire, because of problems with Dutch language

**Date of first enrolment**

01/05/2002

**Date of final enrolment**

31/05/2004

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**Academic Medical Center**

Amsterdam

Netherlands

1105 AZ

## Sponsor information

**Organisation**

Academic Medical Center (Netherlands)

**ROR**

<https://ror.org/03t4gr691>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Pfizer Ltd (Netherlands)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration