# Nurse- and web based intervention to improve medication adherence in high risk cardiovascular patients

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Arteriosclerosis, stenosis, vascular insufficiency and necrosis |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36683

**Source**
ToetsingOnline

**Brief title**
intervention to improve medication adherence in cardiovascular patients.

### Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
adherence, compliance

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** Adherence, Cardiovascular, Intervention, Nurses

## Outcome measures

### Primary outcome

The number of non-adherent patients with improvement of adherence after specific intervention.The results of the refill records of computerized pharmacy systems evaluation will be used as gold standerd for medication adherence.

### Secondary outcome

Determination of best applicable method for current adherence and risk of non-adherence in usual cardiovascular preventive care by comparing the results of the MMS and the BMQ with refill records of computerized pharmacy systems.

Determination of most effective and best applicable intervention to improve adherence or prevent decline in adherence in cardiovascular patients, by evaluation combinations of regular care, web based visualization and support and/or nurse-based intervention with refill records of computerized pharmacy systems.

# Study description

### Background summary

Poor adherence to medicines is one of the limitations in the treatment of cardiovascular disease.
According to WHO takes only 50% of patients with a chronic illness takes its medication as prescribed. Approximately 25-50% of patients stops taking their

medication within one year after starting treatment. The consequences are an increased risk of premature death, hospital admissions and related costs. The dedection of a poor adherence is of great importance to provide adequate interventions in time.In this study the adherence data of all patients within the hospital-wide cardiovascular prevention project, will be requested at their pharmacy. The effect of a structured communication intervention by a nurse and an intervention by the interactive website vascular care (iVAZ) in the therapy of statins, will be explored in a randomized study.

**Study objective**

Primary objective of this study is to improve medication adherence by introduction of adequate screening methods and an additional specific nurse based intervention (structural informative consulting and motivational counseling) in combination with personalized visualization of cardiovascular risk levels (website) in cardiovascular patients.

Secondary objectives are:
1) Evaluation of best applicable screening method for current adherence and risk of non-adherence (combinations of health status, motivation to change, prescribed therapy, and/or BMQ, MMS and refill records results) in usual cardiovascular preventive care.

2) Evaluation of most effective and best applicable intervention (combinations of regular care, web based visualisation and support and/or nurse-based intervention) to improve adherence or prevent decline in adherence in cardiovascular patients

**Study design**

It is a prospective, randomized study comparing the effect of an intervention by a communication nurse and the effect of an intervention by the interactive patient portal. These will be compared to the usual care. Patients will be randomly randomized (1:1:1) in either a group with regular care (group I) or a group with regular care including access to website (iVAZ) to be informed about their cardiovascular risk (group II) or a group with access to the website (iVAZ) and referring to nurse-based interventions to improve adherence (group III) on top of regular care.
During a period of 6 months, 600 successive patients visiting the outpatient clinic for secondary prevention will be randomized for this study. All patients will be regularly screened according to the hospital screening program including an automated lifestyle questionnaire, which will include the MMS and BMQ, regular medication use will be recorded. As part of the screening, blood lipid levels (total cholesterol, triglycerides, HDL-C and LDL-C) will be determined. The screening also includes: Blood pressure, waist circumference (wc), BMI, blood level of glucose and a family history for cardiovascular

diseases.
After 12 months from baseline a regular evaluation of the cardiovascular risk profile, including the automated lifestyle questionnaire and the MMS and the BMQ will be performed to all three groups.

Simultaneously, data of refill records of the pharmacys of all patients will be collected by a computerized system to adequately register changes in adherence.

**Intervention**

Group II + III will get access to web portal (iVAZ) to see their cardiovascular risk level. On 12 weeks and 10 months for the groups II+III their lipid level, blood pressure, BMI and waist circumference will be determined and made visual on iVAZ. Group III will also have group- and individual consultation on 9 and 12 weeks and 10 months.
The group- and individual consultation is a structured communication intervention carried out by a nurse, consisting a group consultation and three one-on-one contacts between nurse and patient. Communication strategies in these consultations by means of a literature study and observation of other practices in the UMC St.Radboud already proved successful (eg approach smoking, obesity) will be explored. These are strategies such as
- Positive reward strategies,
- Enabling the network of the patient,
- Discussion group / consultation with peers,
- Use of specific interview techniques by the nurse (in understandable language, consistent with the level and knowledge of the patient)

After 12 months all patients (usual care):
re-determination of their cholesterol, blood pressure, BMI and medication .

**Study burden and risks**

1) Intervention
Both intervention groups will have to go to the hospital three to four times.
The interventiongroup (viualization of cholesterollevels in a risk meter) will have to come three times to the hospital.The cholesterol will be determined through a vein punction.
The intervention group + will also recieve1x60 minutes (group consultation) and 3x 20 minutes consultation with a nurse at the hospital.

There is no risk associated with participation

# 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

Cardiovascular patients with indication for secundary cardiovascular prevention, best medical treatment

## Exclusion criteria

Pregnancy
Age below age of 18years
No Dutch speaking

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Health services research

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-10-2011 |
| Enrollment: | 600 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 25-05-2011 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL34338.091.11 |