

# SPRING: Self monitoring and Prevention of Risk factors by Nurse practitioners in the region of Groningen. A randomised controlled trial about prevention of cardiovascular disease in general practice.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28544

### Source

Nationaal Trial Register

### Brief title

SPRING

### Health condition

cardiovascular prevention, general practice, nurse practitioners  
cardiovasculaire preventie, huisartsgeneeskunde,  
praktijkondersteuners/praktijkverpleegkundigen

## Sponsors and support

**Primary sponsor:** - University Medical Center Groningen (UMCG), the Netherlands  
- Stichting Hypertensiedient Groningen

**Source(s) of monetary or material Support:** - Van Gaverefonds

## Intervention

### Outcome measures

#### Primary outcome

SCORE 10-year risk of fatal cardiovascular disease.

#### Secondary outcome

1. Determinants of SCORE: smoking, blood pressure (which will be measured twice during the examination), fasting serum lipids;
2. Other cardiovascular risk factors: weight and BMI, waist circumference, fasting serum glucose en serum creatinine, physical activity (SQUASH questionnaire), food intake (FFQ, food frequency questionnaire), standardised questionnaire about motivation to change lifestyle;
3. Health related quality of life (RAND 36 questionnaire);
4. Medication use.

## Study description

### Background summary

Cardiovascular diseases are one of the leading causes of death. The aim of the SPRING study is to investigate the effects of lifestyle counselling and medication on patients with a moderately elevated cardiovascular risk (SCORE  $\geq 5\%$ ). The treatment is based on Dutch General Practitioner's Guidelines (which are based on the European guideline that was published in 2003) and is carried out by specially trained nurse practitioners working in general practice. From 20 practices, middle aged men and women, with no history of cardiovascular disease, diabetes or thyroid dysfunction, were invited to establish their risk. People were included if they had a moderately elevated cardiovascular risk (SCORE  $\geq 5\%$ ) and at least one of the following risk factors: smoking, overweight or physical inactivity. Screening started during spring 2008 and finished during spring 2009, from 218 participants informed consent was obtained. The participants were randomly divided into 2 groups and for each participant an individual advice was composed based on the risk profile that was obtained during screening. One group received usual care based on the guidelines, the other group received the same care with additional intensive feedback based on home monitoring from home blood pressure measurement, pedometers etc. After one year follow-up, the effect on the SCORE risk profile and the separate risk factors will be investigated.

## Study objective

We expect that the effect on the cardiovascular risk profile will be higher in people receiving intensive feedback based on home monitoring compared to people receiving usual care.

## Study design

Baseline and one year follow up: interview (including general characteristics), physical examination, blood tests and standardised questionnaires (as mentioned above).

## Intervention

All participants had a moderately elevated cardiovascular risk profile (SCORE  $\geq 5\%$ ) and received 1 year of life style counseling and medication according to Dutch General Practitioner's Guidelines (which are based on the European guideline that was published in 2003), by specially trained nurse practitioners. One group received usual care based on these guidelines, the other group received the same care with additional intensive feedback based on home monitoring from home blood pressure measurement, pedometers etc.

## Contacts

### Public

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### Scientific

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The Netherlands

## Eligibility criteria

### Inclusion criteria

1. Men aged 50-75y and women aged 55-75y;
2. BMI  $\geq 25$  kg/m<sup>2</sup> or smoking or physical inactivity;
3. SCORE 10-year risk of fatal cardiovascular disease  $\geq 5\%$ .

## Exclusion criteria

1. History of cardiovascular disease;
2. Diabetes;
3. Thyroid dysfunction;
4. Severe or terminal illness/severely diminished life expectancy.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2008
Enrollment:	200
Type:	Actual

## Ethics review

Positive opinion	
Date:	25-01-2010
Application type:	First submission

## 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
NTR-new	NL2071
NTR-old	NTR2188
Other	METC Groningen : 2007/232 (formerly 2005/053)
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A