

# SPRING-study: Efficacy of paramedical use of software-guided cardiovascular prevention programs in a first-line general practitioner setting, comparison of care provided via telemonitoring or within general practice setting.

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Which is the best way for cardiovascular prevention according to the Dutch general practitioner's guidelines, in a general practitioner's office? a. By a nurse practitioner, supervised by the general practitioner, while the frequency and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Coronary artery disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30952

### Source

ToetsingOnline

### Brief title

SPRING study

### Condition

- Coronary artery disorders
- Vascular disorders NEC

### Synonym

moderate cardiovascular risk

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** ZON-MW, de Gavere fonds; Friesland

## Intervention

**Keyword:** cardiovascular, prevention, software-guided, telemonitoring

## Outcome measures

### Primary outcome

Change in SCORE-score after one year of treatment.

### Secondary outcome

- Change in specific risk factors (blood pressure, cholesterol, physical activity, weight, waist circumference, smoking habits)
- Psychological wellness
- Patient satisfaction
- Cost effectiveness
- AGE

## Study description

### Background summary

In patients with a moderately elevated cardiovascular risk (SCORE-score  $\geq 5\%$ ), the effects of treatments are investigated. These treatments are losing weight, stopping smoking, increase of physical activity and treatment of hypertension and cholesterol by a nurse practitioner. These treatments conform established Dutch general practitioner's guidelines. We will compare intensive feedback based on home monitoring, with usual care.

### Study objective

2 - SPRING-study: Efficacy of paramedical use of software-guided cardiovascular prev ... 9-05-2025

Which is the best way for cardiovascular prevention according to the Dutch general practitioner's guidelines, in a general practitioner's office?

- a. By a nurse practitioner, supervised by the general practitioner, while the frequency and intensity of the control visits are as usual.
- b. By a nurse practitioner, supervised by the general practitioner, with the help of home monitoring devices by the patient himself and telemonitoring by the nurse practitioner.

## **Study design**

randomised controlled trial

## **Intervention**

Participants receive medication and lifestyle advice from a nurse practitioner over the year. With the intervention group this is accompanied by intensive feedback based on and home monitoring devices.

## **Study burden and risks**

Risks: No risks, this study involves a standard treatment according to the guidelines; treatment with the help of home monitoring will be compared with treatment as usual.

Burden: regular 20 minute visits to the general practitioner's office, three time venipuncture, questionnaire, normal physical examination, lifestyle interventions including diet and a program to stop smoking.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- men 50-75 yr, females 55-75 yr
- BMI  $\geq 25$  or smokers or low physical activity
- SCORE-score  $\geq 5\%$
- able to use simple home monitoring devices

### Exclusion criteria

- not motivated for lifestyle intervention
- known cardiovascular disease
- known diabetes
- thyroid function abnormality
- life expectancy  $< 2$  yr

## Study design

### Design

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

Primary purpose: Prevention

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-11-2007  
Enrollment: 400  
Type: Anticipated

## Ethics review

Approved WMO  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL19465.042.07