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.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28544

Bron
Nationaal Trial Register

Verkorte titel
SPRING

Aandoening

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

Ondersteuning

Primaire sponsor: - University Medical Center Groningen (UMCG), the Neteherlands

- Stichting Hypertensiedient Groningen
Overige ondersteuning: - Van Gaverefonds
- ZON-MW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

SCORE 10-year risk of fatal cardiovascular disease.

Toelichting onderzoek

Achtergrond van het onderzoek

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 >/= 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 >/= 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

All participants had a moderately elevated cardiovascular risk profile (SCORE >/= 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Men aged 50-75y and women aged 55-75y;

2. BMI >/= 25 kg/m2 or smoking or physical inactivity;

3. SCORE 10-year risk of fatal cardiovascular disease >/= 5%.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of cardiovascular disease;

2. Diabetes;

3. Thyroid dysfunction;

4. Severe or terminal illness/severely diminished life expectancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-01-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2071
NTR-old	NTR2188
Ander register	METC Groningen : 2007/232 (formerly 2005/053)
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A