Effects of a nurse coordinated program of lifestyle interventions aimed at reducing the risk of recurrent events in patients who have suffered a heart attack.

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A comprehensive multisiciplinary lifestyle intervention program reduces the risk of recurrent cardiovascular events in patients who have suffered an acute coronary syndrome.

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

Samenvatting

ID

NL-OMON20582

Bron
NTR

Verkorte titel
RESPONSE 2

Aandoening

secondary intervention, nurse coordinated care, acute coronary syndrome

Secondaire interventie, verpleegkundig gecoördineerd spreekuur, acuut coronair syndroom

Ondersteuning

Primaire sponsor: Department of cardiology
Overige ondersteuning: Stichting Möller Foundation Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The following parameters are compared between the intervention group and the control group at 12 months:
1. Smoking status (binary, non-smoking is defined as urinary cotinine < 200 ng/ml);
2. Body Mass Index (kg/m2);
3. 6 Minute walking distance (meters).

Treatment success in an individual patient is defined as a significant improvement in at least one of the suboptimal lifestyle factors, without deterioration in any of the other two.

Toelichting onderzoek

Achtergrond van het onderzoek

A previous trial, RESPONSE 1, demonstrated that a practice oriented, hospital-based nurse coordinated prevention program on top of usual care leads to an important reduction in the risk of recurrent events in patients who have been hospitalised for an acute coronary syndrome. This improvement was achieved by better control of targets for drug treatment, including blood pressure and serum lipids. Lifestyle improvements were not achieved, however particularly regarding smoking cessation, physical exercise or weight loss.

The RESPONSE 2 trial will focus on lifestyle improvements by offering existing commercial programs regarding the lifestyles mentioned above. The study design consists of a multicenter randomised controlled trial, in at least 10 participating centres in the Netherlands The primary outcome of RESPONSE 2 is the achievement of successful management of lifestyle related risk factors in the intervention group compared to the control group after 12 months follow-up.

5-nov-2014: "The following lifestyle-related CAD risk factor combinations are possible at the individual level at baseline:
1. Smoking only
2. BMI >27 kg/m2 only
3. Physical inactivity only
4. Smoking and BMI >27 kg/m2
5. Smoking and physical inactivity
6. BMI >27 kg/m2 and physical inactivity
7. Smoking, BMI >27 kg/m2 and physical inactivity

At 12 month follow-up treatment success is defined as achieving the target for at least one of the three lifestyle-related risk factors, without deterioration in any of the other. Note that if smoking cessation is accomplished, an increase of ≤ 2.5% in the BMI or BMI remaining < 25 kg/m2 will be classified as no deterioration.

An increase of >2.5% in the BMI or BMI remaining < 25 kg/m2 in case of significantly improved level for physical activity is also classified as no deterioration, because of the possibility that exercise may increase muscle mass."

Doel van het onderzoek

A comprehensive multisiciplinary lifestyle intervention program reduces the risk of recurrent cardiovascular events in patients who have suffered an acute coronary syndrome.

Onderzoeksopzet

After 12 months each patient will be invited for 12 month follow-up.

In this research there will be specific visits for measurements:

Five nurse led visits will be offered, including the baseline visit and the 12 months follow-up visit. During each visit the cardiovascular risk profile will be evaluated including of lifestyle related risk factors.

During a year patients in the intervention group have the opportunity to attend the offered commercial programs in order to improve their lifestyles, with their partner where appropriate.

Full study measurements will be performed at baseline and at 12 months follow-up.

Onderzoeksproduct en/of interventie

On top of usual care, the intervention group will receive a comprehensive, modular, tailored lifestyle intervention, involving the partner where appropriate, using e-health support and referral to up to three existing commercial programs for weight reduction (Weight Watchers®), physical exercise (DirectLife®, Philips) and smoking cessation (Luchtsignaal®). Each intervention program lasts at least 3 months.
Weight Watchers and DirectLife can be offered for a longer period than 3 months if

necessary.
Weight Watchers offers a program aimed at reducing weight and at improving awareness of healthy foods.
DirectLife offers a commercial activity program, to improve more awareness of the daily physical activity. This program consists of an accelerometer and a personal coach in a web based system.
Luchtsignaal offers personal telephone based coaching during 3 months, including drug intervention where appropriate.
The control group will receive care as usual; patients randomized in this group will not be offered a commercial program in order to improve their lifestyle. As per current guidelines, they will be advised by their nurse (practitioner) to improve their lifestyle. If necessary, patients may be referred to existing smoking cessation programs. Patients with a HADS > 14 will be included in a separate registry.They will not participate in the randomization and their results will not contribute to the primary outcome of the study.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients aged 18-80 years who have been hospitalized for an acute coronary syndrome less

than 4 weeks before inclusion and who have at least one of the following lifestyle related risk factors:

1. Smoking (including smoking of any tobacco product in the 6 months preceding hospitalisation);

2. BMI≥27 kg/m2;

3. Physical activity below recommended levels (self reported, 5 times 30 minutes/week)

10-jul-2014: Inclusion criterium changed into: "Patients aged 18years and older who have been hospitalized for an acute coronary syndrome or patients who have recently undergone coronary artery bypass surgery or a percutaneous coronary intervention less than 8 (instead of 4) weeks before inclusion and who have at least one of the following lifestyle related risk factors:"

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients are ineligible if they meet any of the following exclusion criteria:

1. Visits to the prevention programs not feasible;

2. Not available for follow-up;

3. Coronary arterial bypass graft surgery expected within 8 weeks after inclusion;

4. Limited life expectancy (≤2 years);

5. New York Heart Association class III or IV heart failure;

6. Patients with a HADS (Hospital Anxiety Depression Scale) score ≥ 14 will also be excluded from randomisation, but they will be included in a separate registry and invited for follow-up measurements after 12 months.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	1000
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-04-2013
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	NL3751
NTR-old	NTR3937

Register	ID
Ander register	METC / CCMO : 2012_272 / NL41645.018.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A