

Effects of a nurse coordinated program of lifestyle improvement aimed at reducing the risk of recurrent cardiovascular events in patients who have suffered an acute coronary syndrome.;RESPONSE2: (Randomised Evaluation of Secondary Prevention by Outpatient Nurse SpEcialists 2)

Published: 22-03-2013

Last updated: 26-04-2024

Primary Objective: To determine the effectiveness of a comprehensive lifestyle intervention program aimed at reducing the risk of recurrent cardiovascular events in patients who have suffered an acute coronary syndrome.Secondary Objective:...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON37248

Source

ToetsingOnline

Brief title

RESPONSE 2

Condition

- Coronary artery disorders
- Lifestyle issues

Synonym

atherosclerosis, cardiovascular diseases

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Philips Consumer Lifestyle DirectLife, Stichting Möller Foundation; Weight Watchers; Philips, Weight Watchers International Inc.

Intervention

Keyword: cardiovascular disease, lifestyle, nurse coordinated care, secondary prevention

Outcome measures**Primary outcome**

The following parameters are compared between the intervention group and the control group at 12 months:

- * Smoking status (binary, non-smoking is defined as urinary cotinine < 200 ng/ml)

- * Body Mass Index (kg/m²)

- * 6 Minute Walking Distance (meters)

Secondary outcome

Comparison between baseline and 12 months of:

- * Smoking status (urinary cotinine < 200 ng/ml)

- * Body Mass Index (kg/m²)

- * Waist circumference (cm)

- * 6 Minute Walking Distance (meters)

2. The following parameters are compared between the intervention group and the

control group at 12 months:

- * fasting serum LDL levels (mmol/L)
- * systolic blood pressure (mmHg)
- * incidence of newly diagnosed diabetes mellitus
- * control of existing diabetes mellitus (fasting blood glucose and plasma HbA1c levels)
- * body composition (fat and muscle mass by impedance scales)
- * hospital readmission rates
- * signs of depression (Beck's Depression Inventory)

Study description

Background summary

The RESPONSE 1 trial 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. Most of this improvement was achieved by better control of targets for drug treatment, including blood pressure and serum lipids. In contrast, lifestyle changes were not achieved, particularly smoking cessation, increases in physical exercise or weight loss.

Study objective

Primary Objective: To determine the effectiveness of a comprehensive lifestyle intervention program aimed at reducing the risk of recurrent cardiovascular events in patients who have suffered an acute coronary syndrome.

Secondary Objective: improvement in blood pressure, cholesterol and glucose levels, reduction in hospitalization, newly diagnosed diabetes mellitus

Study design

Multicenter, prospective randomised controlled trial

Intervention

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 existing commercial programs for weight reduction (Weight Watchers®), physical exercise (DirectLife®, Philips) and smoking cessation (local facilities).

Study burden and risks

no experimental treatments are performed during the study

Main burdes are time investment and discomfort in taking of blood samples, blood pressure, weight, length, waist hip ratio.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

age 18-80 years

hospitalized for an acute coronary syndrome less than 8 weeks before inclusion ,
at least one of the following lifestyle related risk factors:

- Smoking (including smoking of any tobacco product in the 6 months preceding hospitalisation).
- BMI*27 kg/m²
- Physical activity below recommended levels (5 times 30 minutes/week)

Exclusion criteria

- visits to the prevention programs not feasible
- not available for follow-up
- surgery, percutaneous coronary intervention or other interventions expected within 8 weeks after inclusion
- limited life expectancy (*2 years)
- New York Heart Association class III or IV heart failure
- Beck's Depression Inventory (BDI) score of *10

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:	Will not start
Enrollment:	1000
Type:	Anticipated

Ethics review

Approved WMO

Date: 22-03-2013

Application type: First submission

Review commission: METC Amsterdam UMC

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
ClinicalTrials.gov	NCTTC=1290
CCMO	NL41645.018.12