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: 24-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON53161

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 en Philips Consumer Lifestyle Nederland,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 (Hospital Anxiety and Depression score)

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 Luchtsignaal®.

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age *18 years
hospitalized for an acute coronary syndrome less than 8 weeks before inclusion or patients who have recently undergone coronary artery bypass surgery or a (first) percutaneous coronary intervention less than 8 weeks before inclusion and 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 (coronary arterial bypass graft) expected within 8 weeks after inclusion
- limited life expectancy (-2 years)
- New York Heart Association class III or IV heart failure
- Hospital Anxiety and Depression score of -14 or greater

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:	Recruitment stopped
Start date (anticipated):	22-04-2013
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2014
Application type:	Amendment
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	NL43133.018.12