Evaluation Program *Coaching patients On Achieving Cardiovascular Health* (Hartcoach)

Published: 03-11-2011
Last updated: 27-04-2024

Primary objective: The primary purpose of the study is to investigate the effect of the Heart Coach program (in addition to usual care) on the individual risk factors body mass index, waist circumference, blood pressure, cholesterol, physical...

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

Summary

ID

NL-OMON38260

Source
ToetsingOnline

Brief title
Hartcoach

Condition

- Coronary artery disorders

Synonym
Acute coronary syndrome, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Achmea Zorg
Source(s) of monetary or material Support: Achmea Zorg

Intervention

Keyword: coaching, coronary heart disease, life-style, risk factors

Outcome measures

Primary outcome

-BMI

-waist size

-Physical activity

-Food intake

- Blood Pressure

-Cholesterol (total, HDL and LDL)

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Secondary outcome

Secundary outcomes

- Bloodglucose

- HbA1c

- Smoking

- Medication adherence

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Study description

Background summary

Patients who have coronary heart disease lead a high probability of future clinical events. To prevent this, it is important that patients are aware of the risk factors for cardiovascular event and of the potential for better control through adapting their lifestyle. However, current treatments are not

sufficiently successful in facilitating a lifestyle change so that the risk of coronary heart disease decreases. Therefore, there is a need for effective lifestyle management interventions. A program that stimulates peoples* self-awareness of their personal risk factors and values they should pursue is: Coaching Patients On Achieving Cardiovascular Health (Heartcoach). In this program, a trained professional coaches patients achieving targets of the influential risk factors, while focusing on lifestyle factors and drug use. In Australia good results have been achieved with Heartcoach. Heartcoach is also expected to have a beneficial effect on the health of patients with coronary artery disease in the Netherlands.
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Study objective

Primary objective: The primary purpose of the study is to investigate the effect of the Heart Coach program (in addition to usual care) on the individual risk factors body mass index, waist circumference, blood pressure, cholesterol, physical activity and diet in patients with a coronary event (ACS or stable angina which PCI and / or CABG).

Secondary goal: Secondary purpose of this study is to see to what extent the Heart Coach program, compared to usual care, affects glucose, HbA1c, smoking, compliance, self-management, anxiety, depression and quality of life.

The effect of the Heart Coach program on the cardiovascular risk profile of the patient is also evaluated using two risk scores, calculated from several individual risk factors. For this, the SCORE (gender, age, smoking, cholesterol, (systolic) blood pressure, Conroy et al, 2003) and the Framingham coronary risk score (age, smoking, cholesterol, (systolic) blood pressure, treatment for hypertension, and diabetes status; D'Agostino et al, 2008) is used.

Study design

A randomized controlled clinical trial. The experimental group (Heartcoach + usual care) is compared with a control group (delayed heartcoach + usual care). In total, 400 patients with coronary disease are included, 200 in each group. These patients are recruited through the participating hospitals. During the study, we will try to find additional funding for a measurement at 12 months. This will provide a follow-up measurement and will change the study design into a cross-over design.

Intervention

The experimental group receives the Heartcoach program in addition to usual care (that is: care that all patients with coronary artery disease receive from

the hospital, doctor, physiotherapist etc. and possibly a rehabilitation phase). The control group recieves usual care.

Study burden and risks

The measurements of height and weight, blood pressure (by sphygmomanometer), cholesterol and blood glucose (by taking blood) are performed once at week 0 and once after 6 monthsin the treating hospital . For physical activity, smoking, diet, disease perception, self-management, quality of life, depression and adherence a questionnaire completed by the participants in the same week . In principle, patients fill in these questionnaire themselves, but if necessary, the research assistant can help the participants to fill in the questionnaires by telephone. Participation in research takes time from patients, but little additional effort or discomfort.
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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

1. The patient was admitted to one of the participating hospitals because of an acute coronary syndrome (STEMI, NSTEMI, IAP) or stable angina pectoris. The patients were treated with a corinary artery bypass (CABG), percutaneous coronary intervention (PCI) or with medication.

Exclusion criteria

1. have no telephone
2. do not speak the Dutch language
3. are, according to their doctors to ill to participate in the programme ((NYHA 3 or 4, prognosis of death < 2 year)
4. participate in another, comparable programme
5. refuse to sign the informed consent
6. are incapable to attend the 6 months measurement

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):	08-12-2011
Enrollment:	400

Type:	Actual

Ethics review

Approved WMO Date:	01-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2012
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
CCMO	NL32896.018.11