Effect of lifestyle intervention on cardiovascular riskfactors in 1000 participants in Maastrichts Mooiste (Happy Trip) 2007.

Published: 04-06-2007
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To decrease the PROCAM risk score by participation in a lifestyle-intervention.

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

Summary

ID

NL-OMON30703

Source
ToetsingOnline

Brief title
HAPPY 2007

Condition

- Coronary artery disorders

Synonym
arteriosclerosis, atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac biomarkers, cardiovascular risk, exercise

Outcome measures

Primary outcome

Primary study parameters are the decrease in PROCAM risk score due to lifestyle intervention.

Secondary outcome

Secundaire study parameter is the decrease in concentration of CRP, MPO en PAPP-A.

As described in the amendment:

Identification of the circulating forms of cardiac Troponin and its fragments present after the run.

Study description

Background summary

In modern western world cardiovascular disease is frequently seen. Lack of exercise and an unhealthy diet are factors that increase the chance of cardiovascular disease. Knowledge of the cardiovascular risk score and awareness of lifestyle will help to prevent cardiovascular disaese. This is the aim of the HAPPY program wich is the acronym for Heart Attack Prevention Program for You.

As described in the amendment:
Identifying the circulating forms of cTnT or cTnI allows us to acquire knowledge on their release mechanism from the cardiomyocyte, e.g. in the intact form or degraded. We aim to identify the circulating forms of cTnT and cTnI after running 5 or 15 km in the Maastrichts Mooiste trip, using a highly sensitive immunoprecipitation assay combined with western blotting. This knowledge will provide new information for physicists on how to interpret the

minor troponin elevations seen after exercise, i.e. is this reversible cardiac damage or irreversible damage?

Study objective

To decrease the PROCAM risk score by participation in a lifestyle-intervention.

Study design

In june Maastrichts Mooiste run will be organised. The aim of this event is to get people to exercise more and live healthier.
In this study 1000 participants at Maastrichts Mooiste will be included. In preperation of the run there will be two "healthchecks". In the period of 3 months between these checks, the participants will be offered a number of voluntary exercise clinics and diet advise.
Before the inventions the first healthcheck takes place in wich blood is drawn from the participants. From certain blood parameters the PROCAM riskscore will be determined. In addition a number of novel cardiovascular biomarkers will be assessed. Moreover the length, weight, bellycontour and bloodpressure will be meassured.
Hereafter the participants will be participate in a voluntary lifestyle, which includes exercise clinics and diet advise.
Three monds later there will be a second healthcheck, which is similar to the first healthcheck. The calculated PROCAM riskscore will be communicated to the participants by mail and will be accompanied by an appropriate advise.

As described in the amendment:
Serum samples from participants participating in Maastrichts Mooiste (5 or 15 km) will be analyzed for cTnT and cTnI with the currently available troponin immunoassays.

Study burden and risks

All participants will undergo venapunction, the risk are minimal.
The excercise clinics are voluntary.

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

Participants in the Maastrichts Mooiste
Age above 18 years

Exclusion criteria

age under 18 years
no signed informed consent
incapable of participate in exercise clinics

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2007
Enrollment:	1000
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	04-06-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL16250.068.07