The (cost-) effectiveness of a lifestyle intervention for male workers at risk for cardiovascular disease in the construction industry in The Netherlands.

Published: 03-04-2007
Last updated: 14-05-2024

The main objective of the study is to evaluate the effectiveness of an individually- based lifestyle intervention for male workers with an elevated CVD risk in the construction industry in The Netherlands.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON30635

Source
ToetsingOnline

Brief title
Health under Construction

Condition

- Cardiac disorders, signs and symptoms NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Elevated risk for cardiovascular disease.

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Arbouw

Intervention

Keyword: Cardiovascular disease, Construction workers, Intervention, Lifestyle

Outcome measures

Primary outcome

Lifestyle factors:

Physical activity: Frequency, duration and intensity of PA in leisure time.

Fulfilling Dutch PA norms (NNGB and Fitnorm)

Diet: Intake of fruit, vegetables, fish

Intake of sodas, snacks, alcohol, sugar,

Amount of bread, number of portions

Smoking: yes/ no

Secondary outcome

Biomedical variables:

BMI (kg/m2)

Total cholesterol (mmol/l),

HDL-cholesterol (mmol/l)

Systolic blood pressure (mmHg),

Diastolic blood pressure mmHg),

HbA1c (%)

Other factors:

Fitness (deduced from resting heart rate, BMI, age and self reported PA)

Stage of change

Perceived general health

Absenteeism

Cost-effectiveness

Study description

Background summary

In The Netherlands, cardiovascular diseases (CVD) are responsible for 33% of total mortality each year. Among those working in the construction industry, many suffer from one or more risk factors for CVD; in 2005 > 60% had overweight, >33% was a smoker, 40% did not meet any of the Dutch Guidelines for physical activity. Improving lifestyle has been proven an effective strategy for lowering the risk for CVD.

Study objective

The main objective of the study is to evaluate the effectiveness of an individually- based lifestyle intervention for male workers with an elevated CVD risk in the construction industry in The Netherlands.

Study design

The study is a randomized controlled trial. 700 participants will be included, of whom 350 are allocated to the intervention group and 350 to the control group. After the baseline meaurement (Periodical Occupational Health Check; PAGO) workers will be invited to partipate and receive a questionnaire. The inflow is continuous. Duration of the intervention is six months. The control group receives usual care. Six and twelve months after the start of the intervention, health measurements (comparable to the PAGO) will take place at the Health Service and all participants will be asked to fill in a questionnaire.

Intervention

For each participant, the intervention comprises three face to face contacts at the arbodienst (45 - 60 minutes each) and four telephone conversations (15-30 minutes each).

The individual counseling will be carried out by a professional health counselor employed at the Health Service (occupational physician or occupational nurse).

Counseling will be in the style of Motivational Interviewing. Benefits and barriers for change will be discussed. The stage of change of the participant will be taken into account. If desired, oral advice about changing lifestyle will be given.

Furthermore, written information about healthy lifestyle will be provided, e.g. from the Dutch Heart Foundation and the Dutch Nutrition Centre.

Study burden and risks

Benefit for the participant is improving lifestyle and reducing CVD risk.
This will be achieved by

- Support in changing lifestyle by e.g. discussing barriers and benefits;
- Advice about healthy lifestyle, oral as well as on paper.

It takes about 6 hours to complete the whole intervention (counselling, measurements and filling out forms). If the participant does not want to visit the Health Service for the face to face contact, a home visit can be arranged withthe counsellor.

The participant has to visit the Health Service twice (T= 6 months and T=12 months) for an extra health check. Some may not regard this as a burden but as a benefit; by this means all participants, also the ones in the control group, will be informed about their health.

During the health checks, blood pressure and resting heart rate will be measured and blood will be drawn from the participant. This will be done following the same procedure as in the PAGO; thus this is a familiar to the participant.

Contacts

Public
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
1081 BT Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
1081 BT Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male, aged 18-55, working in construction industry

Signed an informed consent form
Elevated risk of cardiovascular disease based on:
The Framingham Risk Score AND one or more of the following:
BMI >< = 30 kg/m2; HbA1c > 6.5%; Alcohol abstinence or > 35 consumptions per week; Psychological complaints, Cardiovascular complaints; Not fulfilling both Dutch physical activity norms (NNGB and Fitnorm). Also see section 4.1, page 13-14 in the protocol.

Exclusion criteria

Inable to be physically active;
Not sufficiently capable of using the Dutch language;
Not having signed an informed consent form

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	865
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-04-2007
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
CCMO	NL15734.029.06