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

Circulatory System

Plain English summary of protocol

Not provided at time of registration

Study website

26/02/2021

http://www.bouwenaangezondheid.nl

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

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

Study objectives

Participants in the intervention group, receiving an individual lifestyle intervention, will improve lifestyle and Cardiovascular Disease (CVD)-risk related biomedical outcome values at the short (six months) and the longer (12 months) term, whereas in the control group these variables will remain the same as at baseline.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethics Committee of the VU Medical Centre ('Medisch Ethische Toetseingscommissie VU medisch centrum') on 3rd April 2007 (ref: 2006/291).

Study design

Randomised, controlled, parallel group, single blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

Intervention:

Individual counselling about improving the energy balance (diet and physical activity) or smoking cessation, in the form of Motivational Interviewing, with the stages of change as a basis.

Duration is six months, in which three face to face contacts at the Occupational Health Service and four telephone contacts with a professional health counsellor (OP or nurse) will take place. Additional written information about a healthy lifestyle will also be provided.

Control:

Care as usual.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Dietary intake:
- a. fruits, vegetables and fish
- b. snacks, soda, and alcohol intake
- c. slices of bread, plates for dinner
- 2. Physical activity:
- a. fulfilling the NNGB and the Fitnorm
- b. frequency, duration and intensity of habitual PA in leisure time
- 3. smoking status: smoker/ non-smoker

Secondary outcome measures

- 1. BMI (kg/m^2)
- 2. Systolic and diastolic blood pressure (mmHg)
- 3. High Density Lipoprotein (HDL)-cholesterol and total cholesterol (mmol/litre)
- 4. HbA1C (%)
- 5. Cardio-respiratory fitness
- 6. Stage of change
- 7. Behaviour determinants
- 8. Perceived general health
- 9. Absenteeism
- 10. Cost-effectiveness

Overall study start date

01/04/2007

Completion date

01/10/2008

Eligibility

Key inclusion criteria

- 1. Male
- 2. 18 to 55 years
- 3. Available for the study for the following 12 months

- 4. Signed an informed consent form
- 5. At risk for CVD according to the Framingham risk score, and one or more of the following other risk factors:
- a. fulfilling none of the Dutch Physical Activity (PA) standards (Nederlandse Norm Gezond Bewegen [NNGB] and Fitnorm)
- c. alcohol use: more than 35 glasses of alcohol per week
- d. HbA1c more than 6.5%
- e. Body Mass Index (BMI) more than 30 kg/m^2
- f. tiredness or stress and/or treated for psychological disorders and/or low motivation to recover h. shortness of breath and/or suffering from chest pain and/or diagnosed with or treated for CVD or its predictors (e.g. high blood pressure)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

700

Key exclusion criteria

- 1. Unable to be physically active
- 2. Not sufficiently capable of using the Dutch language
- 3. Not having signed an informed consent form

Date of first enrolment

01/04/2007

Date of final enrolment

01/10/2008

Locations

Countries of recruitment

Netherlands

Study participating centre VU University Medical Center

Amsterdam Netherlands 1081 BT

Sponsor information

Organisation

VU University Medical Centre (The Netherlands)

Sponsor details

EMGO-Institute Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT +31 (0)20 444 8180 emgo@vumc.nl

Sponsor type

Hospital/treatment centre

Website

http://www.vumc.nl/english/

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type

Research organisation

Funder Name

Arbouw Foundation (Stichting Arbouw) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	03/01/2008		Yes	No
Results article	results	01/12/2009	26/02/2021	Yes	No
Results article	results	31/10/2011	26/02/2021	Yes	No