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

Submission date
22/01/2007

Recruitment status
No longer recruiting

Registration date
22/01/2007

Overall study status
Completed

Last Edited
26/02/2021

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.bouwenaangezondheid.nl

Contact information

Type(s)
Scientific

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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
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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?
Protocol article	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