

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

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>22/01/2007   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>22/01/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>26/02/2021       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data   |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms I F Groeneveld

**Contact details**  
VU University Medical Center  
EMGO-Institute  
Van der Boechorststraat 7  
Amsterdam  
Netherlands  
1081 BT  
+31 (0)20 444 6496  
[iris.groeneveld@vumc.nl](mailto:iris.groeneveld@vumc.nl)

## Additional identifiers

## Study information

Scientific Title

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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

- 1. BMI (kg/ m<sup>2</sup>)
- 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

### **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<sup>2</sup>
  - 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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

Male

**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)

**ROR**

<https://ror.org/00q6h8f30>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Arbouw Foundation (Stichting Arbouw) (The Netherlands)

# Results and Publications

## 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? |
|----------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results       | 01/12/2009   | 26/02/2021 | Yes            | No              |
| <a href="#">Results article</a>  | results       | 31/10/2011   | 26/02/2021 | Yes            | No              |
| <a href="#">Protocol article</a> | protocol      | 03/01/2008   |            | Yes            | No              |
| <a href="#">Study website</a>    | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |