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

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29087

Bron
NTR

Verkorte titel
Bouwen aan Gezondheid

Aandoening

Intervention group (receiving: see below) and control group, receiving usual care.

Ondersteuning

Primaire sponsor: Stichting Arbouw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Dietary intake:
a. Fruits, vegetables and fish;
b. Sweet and salty snacks, soda, alcohol and sugar 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.

Toelichting onderzoek

Achtergrond van het onderzoek

In The Netherlands, cardiovascular diseases 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. Improving lifestyle is considered as an appropriate strategy to improve the risk profile. The aim of this project is to develop, implement and evaluate a lifestyle intervention aimed at male construction workers who are at risk for CVD. The diagnose ‘at risk’ will be established by an Occupational Health practitioner during the Periodical Medical Screening, according to a screening instrument that is based on the Framingham risk score, and suffering from one or more other risk factors: i.e., psychological complaints, heart complaints, alcohol use, Body Mass Index, HbA1c and fulfilling the physical activity norms). In this randomised controlled trial we aim to include 700 participants, of whom 350 in the intervention group and 350 in the control group. The intervention group will receive an individually-based lifestyle intervention. According to the participants’ risk profile and his own wishes, he will try to improve diet & physical activity (the energy balance) or quit smoking. The participant will be contacted each month by an Occupational Health Service counsellor. Four face-to-face sessions and three telephone calls will take place. The counselling will be done in the form of Motivational Interviewing, with the transtheoretical model as a basis. Short- and long term goals will be defined by the participant. Furthermore, participants will receive general written information as to diet, physical activity and smoking. The control group will receive usual care.
Data from physical measurements and standardized questionnaires will be collected at baseline (T=0), directly after the intervention (T=6 months) and at the longer term (T=12 months). Outcome measures are lifestyle (e.g. frequency, duration and intensity of physical activity; fruit and vegetable intake, intake of sodas and snacks, smoking) and separate biomedical CVD risk factors (ie., total and HDL-cholesterol, systolic and diastolic blood pressure, BMI, and HbA1c). Finally, the cost-effectiveness of the intervention will be determined.
The project has started in April 2006; the intervention will start around April 2007; first results will be available in 2008.

Doel van het onderzoek

Participants in the intervention group, receiving an individual lifestyle intervention, will improve lifestyle and CVD-risk related biomedical outcome values at the short (6 months) and the longer (12 months) term, whereas in the control group these variables will remain the same as at baseline.

Onderzoeksproduct en/of interventie

Intervention: Individual counseling about improving the energy balance (diet & physical activity) or smoking cessation, in the form of Motivational Interviewing, with the stages of change as a basis. Duration is 6 months, in which 3 face to face contacts at the Occupational Health Service and 4 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.

Contactpersonen

Publiek

VU University Medical Center, EMGO-Institute,
Van der Boechorststraat 7
I.F. Groeneveld
Amsterdam 1081 BT
The Netherlands
+31 (0)20 4446496

Wetenschappelijk

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Van der Boechorststraat 7
I.F. Groeneveld
Amsterdam 1081 BT
The Netherlands
+31 (0)20 4446496

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Gender: Male;

2. Age: 18-55 years;
3. Availability: Available for the study for the following 12 months;
4. Permission: Signed an informed consent form;
5. Health status: at risk for CVD, according to the screening instrument;
6. At risk for CVD according to the Framingham risk score, AND one or more of the following other risk factors:
Insufficiently active;
Fulfilling none of the Dutch PA standards (NNGB and Fitnorm);
Alcohol use;
No alcohol at all or > 35 glasses of alcohol per week;
HbA1c > 6.5%;
BMI >30 kg/m2;
Psychological complaints;
Tiredness or stress and/or treated for psychological disorders and/or low motivation to recover;
Heart complaints: 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2007
Aantal proefpersonen:	700

Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL834
NTR-old	NTR847
Ander register	: N/A
ISRCTN	ISRCTN60545588

Resultaten

Samenvatting resultaten
N/A