

Cost-effectiveness of a lifestyle intervention on health and sustainable employability among workers of 40 years and older with high physical work demands: a randomized controlled trial

Published: 04-12-2012

Last updated: 26-04-2024

- to evaluate (cost-) effectiveness of a personalized health intervention among workers of 40 years and older with high physical work demands to contribute to a reduction in CVD and sustainable employability.

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

Summary

ID

NL-OMON39881

Source

ToetsingOnline

Brief title

Cost-effectiveness of a lifestyle intervention.

Condition

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

Synonym

cardiovascular disease; heart and vessel disease

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: cardiovascular disease., Cost-effectiveness, general health, lifestyle intervention

Outcome measures

Primary outcome

Primary outcome measure: general health from the SF-36.

Secondary outcome

Secondary outcome measures: work ability (workability index), productivity

(WorkLimitations Questionnaire), working conditions (profession), CVD risk

score (QRISK2 and SCORE), physical activity (SQUASH), quality of life (EuroQol

and physical functioning and vitality from the SF-36), total cost, lifestyle

factors, energy measurements (MET's) just for users of the

"activemeter"-program

Study description

Background summary

Introduction:

In an aging Dutch society, where the frequency of unhealthy lifestyles rarely decreases, is the sustainable employability and well-being of workers under increasing pressure. In addition to primary aging, major risk factors for general well-being are secondary aging processes, such as physical inactivity, unhealthy diet, smoking and stress. The disorders which are associated with these lifestyle behaviors are cardiovascular disease (CVD), pulmonary disease and diabetes, and are often chronic in nature and thus press heavily on the (company) healthcare.

Study objective

- to evaluate (cost-) effectiveness of a personalized health intervention among workers of 40 years and older with high physical work demands to contribute to a reduction in CVD and sustainable employability.

Study design

Cluster randomized controlled trial. A webbased randomisation program will be used.

Intervention

Intervention A: Control-group. Access to a standard web-based health intervention customized for the organization and usual care by the occupational health physician.

Intervention B: Intervention-group. Access to a comprehensive web-based health intervention customized for the organization, i.e., including computer-tailored advice and motivational interviewing is given.

Study burden and risks

Not applicable.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age 40 years and older and If at least one of the following risk factors are present:
 - a. BMI > 30 kg/m² and / or waist circumference ≥ 102 cm (men), ≥ 88 cm (women)
 - b. hypertension (diastolic value > 90 mm Hg or a systolic value > 140 mmHg);
 - c. use of antihypertensive drugs;
 - d. self-reported diabetes mellitus or random glucose ≥ 11.1 mmol / l;
 - e. dyslipidemia (total cholesterol, LDL cholesterol ≥ 2.5 mmol; triglycerides: ≥ 1.7, mmol / l, HDL-cholesterol: ≤ 1.0 mmol / l;
 - f. angina or myocardial infarction in first degree relatives;
 - g. physical activity less than 30 minutes daily for 5 days per week or comparable effort;
 - h. smoking.

Exclusion criteria

- a. manifest CVD (history of myocardial infarction, heart failure, or cerebrovascular accident);
- b. terminal illness;
- c. a history of psychosis.
- b. not wanting to be informed about a finding by chance

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2013
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO	
Date:	04-12-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	11-06-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	30-01-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	06-06-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL38802.078.12