Balance@Work: the (cost)-effectiveness of an occupational health guideline to improve physical activity and dietary behaviour among workers in order to prevent weight gain

Submission date	Recruitment status	Prospectively registered		
27/07/2009	No longer recruiting	<pre>Protocol</pre>		
Registration date	Overall study status	Statistical analysis plan		
02/09/2009	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
12/05/2014	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.balanceatwork.org

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR1190

Study information

Scientific Title

The (cost)-effectiveness of an occupational health guideline to improve physical activity and dietary behaviour among workers in order to prevent weight gain: a randomised, controlled, parallel group, single blinded trial

Acronym

Balance@Work

Study objectives

The intervention group, receiving a lifestyle intervention, is expected to significantly improve their daily physical activity and dietary behaviour, and thus prevent weight gain compared to the control group at the short (6 months) and the longer term (12 months).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the VU University Medical Centre ('Medisch Ethische Toetseingscommissie VU medisch centrum') approved on the 7th May 2009 (ref: 2009/002).

Study design

Randomised controlled parallel group single blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Obesity prevention

Interventions

The intervention is aimed at physical activity and dietary behaviour (both sides of the energy balance) in order to prevent weight gain. Using social ecological models and implementation intentions, respondents receive a tailored intervention by means of counselling based on motivational interviewing by occpational physicians. The control group receives care as usual.

Treatment in the intervention group is 6 months. Follow-up measurements in both groups take place at 6, 12, and 18 months after baseline.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Physical activity, measured with the Squash questionnaire at baseline, 6, 12, and 18 months
- 2. Dietary behaviour, measured with the Short Fruit and Vegetable questionnaire and the Fat list at baseline, 6, 12, and 18 months
- 3. Waist circumference, measured with the Seca 201 waist circumference measure at baseline, 6, 12, and 18 months
- 4. Body weight at baseline, 6, 12, and 18 months

Secondary outcome measures

- 1. General health status (sedentary behaviour measured with the International Physical Activity Questionnaire [IPAQ], anthropometrics [body weight, body height, blood pressure and cholesterol] measured retrospectively) at baseline, 6, 12, and 18 months
- 2. Quality of life, measured with the EQ-5D questionnaire at baseline, 6, 12, and 18 months
- 3. Cardiovascular disease risk profile, calculated following SCORE at baseline, 6, 12, and 18 months
- 4. Sick leave, measured with the HPQ questionnaire at 3, 6, 9, 12, 15, and 18 months
- 5. Cost-effectiveness, measured with EQ-5D and HPQ data at 3, 6, 9, 12, 15, and 18 months

Overall study start date

01/06/2009

Completion date

01/06/2011

Eligibility

Key inclusion criteria

- 1. Workers who do not comply to Dutch physical activity and nutrition guidelines, and/or workers who are overweight
- 2. Aged 18 55 years, either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

600

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
- 4. Sick leave for the last 3 weeks

Date of first enrolment

01/06/2009

Date of final enrolment

01/06/2011

Locations

Countries of recruitment

Netherlands

Study participating centre Vrije University Medical Center

Amsterdam Netherlands 1081 BT

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (Netherlands)

Sponsor details

EMGO+ Institute Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT +31 (0)20 444 9681 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

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) (ref: 120510007)

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?
Results article	results	14/12/2009		Yes	No
Results article	results	01/07/2012		Yes	No
Results article	results	01/05/2013		Yes	No
Other publications	economic evaluation	01/09/2013		Yes	No