Prevention of obesity at work

| Submission date | Recruitment status | Prospectively registered |
|-------------------|-----------------------------------|--|
| 19/08/2013 | No longer recruiting | ∐ Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 14/10/2013 | Completed | Results |
| Last Edited | Condition category | Individual participant data |
| 14/10/2013 | Nutritional, Metabolic, Endocrine | Record updated in last year |

Plain English summary of protocol

Background and study aims

Obesity is a major problem in the Netherlands. Overweight people are 15% more likely to get sick and are more absent from work than people of normal weight. They also have an increased risk of diabetes and heart disease. It is important that the employer plays an active role in promoting a healthy lifestyle and prevention of obesity in the workplace. To date, few studies have addressed this problem at work and this is the aim of this study. Employees learn skills which they can use to develop a healthier diet. To support the application of the newly learned skills we create an environment where the healthy choice was an easier choice. Employees are encouraged to improve their diet via two different approaches: a self-management course and an environmental intervention. The aim of this study is to find out whether these two approaches can improve healthy eating.

Who can participate?

Companies in the Netherlands were approached through an occupational health service, or they received an email/letter with research information, asking them to participate in research promoting healthy eating. Any company in the Netherlands that employs enough employees to form course groups could participate.

What does the study involve?

After companies agreed to participate in the research, they were first allocated to a condition in which unhealthy foods in the canteen were made less accessible or not. Employees were invited to join by email or by messages on the intranet. They were randomly assigned to the self-management course group or environmental intervention, a group receiving one two-hour group session only. In the self-management course, called Healthy Eating at Work, people learn to set small concrete goals, recognize conditions for and barriers to goal achievement, come up with problem solving strategies in specific challenging situations, formulate action plans and evaluate their progress. In the environmental intervention minor adjustments were made to the presentation of unhealthy foods in the canteen. Unhealthy foods in the canteen were made less accessible by placing them about 40 cm further behind the counter.

What are the possible benefits and risks of participating? Participants could benefit by improving their diet. Specifically, participants in the selfmanagement course could improve their skills in identifying the difficulties they may encounter when pursuing their goals. These skills can be implemented in many areas. No risks of participation in the study have been identified.

Where is the study run from? The study was run from various companies in the Netherlands.

When is the study starting and how long is it expected to run for? The study started early 2009 and was completed by early 2013.

Who is funding the study? The study is funded by Stichting Instituut GAK, Netherlands.

Who is the main contact? Mrs Josje Maas j.maas@uu.nl

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 N/A

Study information

Scientific Title

Prevention of obesity at work: a prospective randomized controlled trial

Study objectives

Aim of this study is to evaluate the effectiveness of a brief self-management intervention for employees apart and on top of an environmental intervention.

Hypotheses are that the self-management intervention will help participants:

- 1. To increase healthy diet and maintain weight or, if appropriate (for overweight individuals who want to lose weight), promote weight loss.
- 2. To improve their self-regulatory skills.

Ethics approval required

Old ethics approval format

Ethics approval(s)

In this intervention participants were taught a skill that they can implement as they wish. No behavioural guidelines were imposed on participants nor were they subjected to any kind of medical treatment. Naturally, participation in any part of the study or course was completely voluntary, and participants were well informed of all aspects of the study.

Study design

Prospective randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

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

Interventions

Four study arms: 2 (self-management intervention or active control) x 2 (either or not environmental intervention) design with three points of measurement (baseline, and 2 follow-up)

- 1. Self-management course Healthy Eating at Work, aimed at improving self-regulatory competence.
- 2. Environmental intervention: restaurant adjustments: minor adjustments were made to the presentation of unhealthy foods in the company restaurants. Unhealthy foods in the company restaurant were made less accessible by increasing distance.

The total duration of the course is approximately 2 months. The first follow-up measure is after the course is completed (3 months after the baseline questionnaire), the second follow-up measure is taken 9 months after course completion.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Proactive coping competence: assessed using the Utrecht Proactive Coping Competence questionnaire (UPCC). The UPCC contains 21 items answered on a 4-point scale from 1 (not at all able) to 4 (very able).
- 2. Food intake (healthy and unhealthy): participants filled in a food diary on seven consecutive days. On each day, participants indicated for 26 food categories (e.g., fruit) whether they had eaten a product from that category. Number of meals was also assessed.
- 3. Snack habits: measured using the Self-Report Habit Index (SRHI). Responses on the twelve items range from 1 (completely agree) to 5 (completely disagree).
- 4. Body Mass Index: Participants weight was measured. Body Mass Index (BMI) was computed by dividing weight by the square of self-report height
- 5. Waist circumference: Participants waist circumference was measured following the Dutch Nutrition Center guidelines

Measured at baseline and first follow-up, 3 months after the baseline questionnaire and the second follow-up, 9 months after course completion.

Secondary outcome measures

- 1. Self-regulation strategies: self-rgulation strategies was assessed using the Tempest Self-Regulation Questionnaire for Eating (TESQ-E). The scale contains 24 items assessing how often they employ a regulation strategy, answered on a 7-point scale 1 (never) to 7 (always).
- 2. Self-efficacy: Self-efficacy was assessed using the Eating during Socially Acceptable Circumstances subscale of the Eating Self-Efficacy Scale. Responses on the ten items range from 1 (not difficult) to 7 (very difficult).

Measured at baseline and first follow-up, 3 months after the baseline questionnaire and the second follow-up, 9 months after course completion.

Overall study start date

01/03/2009

Completion date

01/07/2012

Eligibility

Key inclusion criteria

- 1. Both men and women of all ages could participate in the study. Since we focused on a working population age is between 18 and 65 years.
- 2. Any company in the Netherlands that employs enough employees to form course groups

could participate. Employees could participate if they were employed by a participating company and hold a motivation to actively work on healthy eating behavior. No other restrictions applied.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

440

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/03/2009

Date of final enrolment

01/07/2012

Locations

Countries of recruitment

Netherlands

Study participating centre Heidelberglaan 1

Utrecht Netherlands 3584 CS

Sponsor information

Organisation

Utrecht University (Netherlands)

Sponsor details

c/o Denise de Ridder Heidelberglaan 1 Utrecht Netherlands 3584 CS

Sponsor type

University/education

Website

http://www.uu.nl

ROR

https://ror.org/04pp8hn57

Funder(s)

Funder type

Research council

Funder Name

Stichting Instituut GAK (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