Occupational Health Guideline for Preventing Weight Gain among Employees

Lisanne Verweij

Body @ Work

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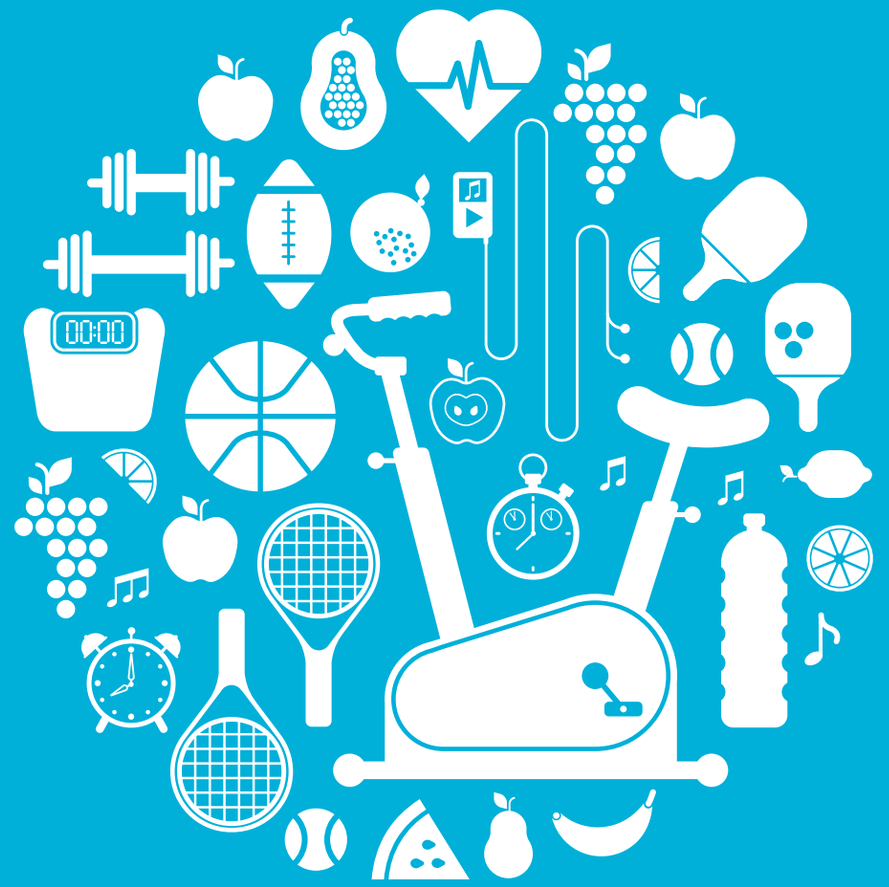
a (cost-) effectiveness study



Lisanne Verweij

TNO
eMGO+ Institute for Health and Care Research
BODY@WORK

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a (cost-) effectiveness study

The study presented in this thesis was conducted within the EMGO+ Institute for Health and Care Research, Department of Public and Occupational Health of the VU University Medical Center (www.emgo.nl). The EMGO+ Institute participates in the Netherlands School of Primary Care Research (CaRe) which was acknowledged in 2005 by the Royal Netherlands Academy of Arts and Sciences (KNAW). The EMGO+ Institute participates in Body@Work, Research Center on Physical Activity, Work and Health, which is a joint initiative of VU University Medical Center (Department of Public and Occupational Health, EMGO Institute for Health and Care Research), VU University Amsterdam, and TNO.

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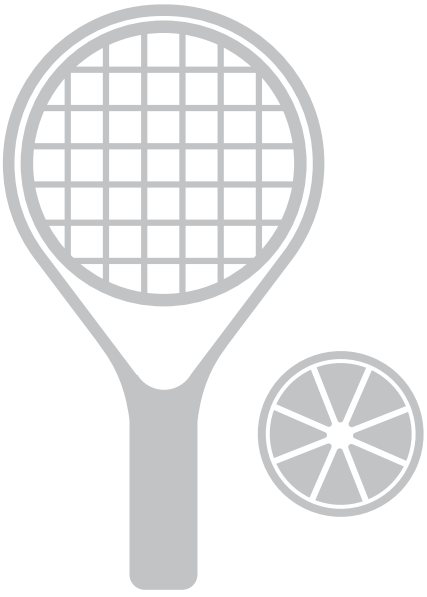
Chapter 1

General Introduction



Case description

The vast amount of publicity on health and economic consequences of overweight and obesity triggers a large company to inquire their occupational physician (OP) about the possibility of a health promotion campaign among their workforce. The OP reflects that the health status of the employees is largely unknown. Together with the employer, he decides to perform a pilot study to assess the current health status of employees. From the voluntary health risk appraisal the OP finds that few employees comply to the Dutch public health norms for a healthy body weight, physical activity and nutrition. Among employees, some respond positive and ask the OP for follow-up advice on how to improve their lifestyle. Others do not appreciate further interference with their lifestyle. The employer asks the OP what he can do to improve employees' lifestyle, against what costs and what outcomes. The OP turns to the Netherlands Society of Occupational Medicine (NVAB) to inform what is known about preventing weight gain, but is informed that specific evidence-based methods, strategies and tools for OPs are lacking. The main question of the OP, the employer, and the employee that will be addressed in this thesis is: how can weight gain be successfully prevented by a workplace health promotion program, in order to reach and maintain a healthy workforce?

Over the last years, attention for preventing weight gain and for treating obesity has increased substantially. Today, numerous studies are published on preventing weight gain, public health initiatives arise and more occupational health services are providing workplace health promotion programs [1-3]. Despite this increased attention, preventing weight gain in occupational health is still relatively new [4]. Like most innovations, weight gain prevention programs will not automatically succeed or be adopted rapidly, unless they have proven efficacy and are tailored to the needs of all stakeholders [5]. Fulfilling the promise of weight gain prevention requires a systematic program, that is evaluated on successes and that identifies and overcomes barriers, and which will facilitate widespread diffusion and adoption of knowledge, skills and tools. This introduction describes the problem of overweight and obesity, and provides the rationale and barriers for preventing weight gain viewed from relevant stakeholders as mentioned in the case; employers, employees, and OPs.

Epidemiology of overweight and obesity

The worldwide increasing prevalence of overweight and obesity is a well recorded, growing problem [6]. The most recent population estimates for the Netherlands show that 35% of the adults is overweight and 12% is obese [7]. Among the working population, over 30% is overweight and around 6% is obese [8]. The percentage of overweight adults seems to have stabilized during the last years. The percentage of obese adults however, continues to increase [7].

Overweight and obesity are defined as conditions of abnormal or excess body fat accumulation in adipose tissue, to the extent that health may be impaired [6]. Numerous epidemiological studies have shown a relationship between excess weight, abdominal fatness and the risk of a wide range of illnesses, including type II diabetes, cardiovascular diseases,

and various cancers [9,10]. Moreover, overweight and obesity have been associated with musculoskeletal disorders, psychosocial problems, and depression [11]. As a result of the increasing overweight-related morbidity and mortality, health care costs have increased. For the Netherlands, annual costs attributable to obesity amount up to 887 billion Euros, a relative economic burden of 0.2% of the national gross domestic product [12].
Although treating obesity is associated with improvements in obesity-related comorbidities, the long-term success of obesity treatment is limited, mainly due to biological and behavioral stimuli to regain weight. Since overweight and obesity, as well as their related morbidity and mortality, are for most part preventable, interventions aimed at preventing weight gain seem the logical choice [6].
The increased prevalence of overweight and obesity over the past decades is caused by a combination of societal, environmental, and genetic influences. The primary cause for this epidemic is thought to be changes in our daily physical (in)activity and nutrition behavior, as a result of urbanization and wealth [13]. The increased availability of cheaper food, large portion sizes and the influence of commercials increased our energy intake, while at the same time work-related activity declined and leisure-time inactivity (dominated by television viewing and computer usage) increased over recent decades in industrialized countries [14]. These changes led to a so-called 'obesogenic environment', characterizing an environment that promotes unhealthy food choices and discourages physical activity [15]. One of the major challenges of this century seems to be creating environments that are supportive for making the healthy choices at several levels, such as agriculture, food services, education, transportation, and urban planning, but also changes within homes, individual behavior, and workplaces [3].

Rationale for preventing weight gain at the workplace
The workplace presents a useful setting for preventing weight gain as a major part of the adult population can be reached, in groups as well as individually [16,17]. The workplace allows for relatively straightforward communication and information exchange, and provides social and organizational support structures that can help guide certain behaviors and discourage others [17]. Support for such programs have been reported among employees, employers, and occupational health service providers for several reasons.
Employers increasingly recognize that they can serve their own (economic) interests by engaging in workplace health promotion. Several reports have shown that employees with poor modifiable lifestyle habits such as physical inactivity, poor diet or obesity are less productive, are more likely to be absent, and have higher disability rates [18-20]. In addition, workers in poor health have higher medical costs, workers' compensation expenses, and higher employee turnover [17]. Workplace health promotion can improve workers health, employee satisfaction, organizational atmosphere, and may even reduce sickness absence [16], presenteism [21], and total organizational costs [22]. In light of the challenges employers face for the future, such as retirement at higher age, a rapidly aging workforce, a growing number of employees with chronic diseases, and fewer young people who enter the workforce, improving employees lifestyle is considered a potentially effective tool to

maintain a productive workforce, and prolong or sustain healthy employability of workers for the future [23]. Moreover, promoting employees health may provide an essential advantage for recruitment and retention of talented young employees in a competitive labor market [24]. Thus, employers may not just perceive investing in workers health as the cost of doing business, but as an investment in their human capital.
Employees, as a targeted population, also recognize that they can benefit from workplace health promotion programs. Reasons to participate in lifestyle interventions by employees are for example improving or maintaining health, preventing complaints, and providing direct benefits to the employer or the greater good [25].
A key role in preventing weight gain can be provided by occupational health professionals. In the Netherlands, employers can contract certified multidisciplinary occupational health services or individual occupational physicians to assist them with occupational health and safety, and with sickness absence management. This occupational health care is aimed at: 1 providing safe working conditions for employees, 2. preventing work-related diseases; 3. facilitating participation of employees with and without limitations and 4. improving functioning at work. Over the last years, a shift from sickness absence management to prevention has been seen due to substantially reduced sickness absence and disability rates. Moreover, due to competition in the occupational health market more employers and OPs recognize the need, and are willing, to intervene on the growing population of employees at risk for illness due to overweight and obesity. This shift now provides OPs with opportunities to conduct preventive activities [2].

Barriers to preventing weight gain
Despite the mutually beneficial goal - improving employees' health - initiatives are performed by a small part of employers [17] and occupational health professionals [26]. Several reasons have been stated by employers, employees and OPs that may explain this.
First, many employers are not convinced that such programs can prevent weight gain, improve health or achieve a positive financial return on investment. There is indeed some evidence that health promotion interventions have limited use in general populations [27]. In addition, some employers do not feel responsible for their employees health, do not want to interfere with employees personal lifestyles, or do not see a business purpose [28]. Even among employers who support workplace health promotion initiatives, there is often some reluctance to initiate such programs because financial gains may only be achieved after a number of years.
Among employees, the question arises why it is necessary for them to change their lifestyle, as reflected in their low participation rates. Frequently reported reasons for non-participation among employees are that they feel healthy, already adopted a healthy lifestyle, have other pressing health problems, or lack confidence that they can change their behavior [29,30]. On the other hand, several studies have shown that (especially overweight and obese) employees may not accurately perceive their weight and health risks, and do not recognize advantages of improving health [31]. Finally, some employees simply question the intention of the employer [28] or mistrust the independent position of the OP [26].

Among OPs, main barriers to implement weight gain prevention interventions are the lack of knowledge and evidence-based methods and strategies [4]. Today, the majority (75%) of OPs still perform tasks concerning sickness absence management and return to work, and only 4% of the OPs time is spent on preventive activities concerning lifestyle and vitality [26]. Furthermore, of the few OPs who perform lifestyle interventions via occupational health care, the strategies vary, and are not based on the latest evidence [4]. Nevertheless, 70% of the OPs want more opportunities to conduct preventive activities concerning employees lifestyle [26]. To meet this need, ways have been sought to support OPs to play a more active - key - intervening role with regard to preventing weight gain.

Guideline on preventing weight gain

Since 1999, the Netherlands Society of Occupational Medicine (NVAB) has been developing and disseminating evidence-based practice guidelines, which are one of the most promising and effective tools for improving the quality of occupational health care [32]. Practice guidelines are "documents with recommendations to assist practitioners and care users, aimed at improvement of quality of care, based on a systematic review of evidence and an assessment of the benefits and harms of alternative care options, and supplemented with expertise and experiences of practitioners and care users" [33]. Guidelines generally describe optimal situations, rather than formulating recommendations for existing situations. Thereby, guidelines can improve the quality of health care by enhancing professionalization, transparency, and efficiency as well.

Practice guidelines are particularly useful if they contain new evidence with an important impact on health management; if there is a large variation in current practice; and if they affect many individuals at high risk or involve such high costs that even small changes in practice could have major impact on health outcomes or resources. An occupational health guideline aimed at the prevention of weight gain may therefore be important because 1) there is a need to address overweight on a larger scale in the Netherlands, as overweight is associated with an enormous public health impact as well an economic burden, 2) it enhances the professional quality of OPs and 3) it provides OPs with a practical guideline on how to advice on preventing weight gain.

Promising practices for the guideline

In order to successfully prevent weight gain of employees, all important stakeholders need to collaborate. Although the objective may be clear, the "how to" often remains difficult. Information on the effectiveness and feasibility of implementing primary prevention lifestyle interventions for OPs was summarized in a previous review [4]. Moreover, key principles of successful worksite health promotion programs have been summarized by Sparling (2010) [34]. Their results described positive effects of (worksite) physical activity interventions on physical activity levels, as well as on some relevant health-related outcomes (e.g. body fat percentage). Positive effects were also concluded for dietary interventions on the intake of fruit, vegetables, and fat. As to the prevention of weight gain, interventions that incorporated both physical activity and diet were particularly effective. The majority of the

effective interventions included tailored, stage-based counseling, education, incentives and management commitment. Further, most successful interventions consisted of for example systematic health assessments, tailored feedback, and regular follow-up in order to help employees initiate or sustain healthy behavior. Also, interventions striving for sustained environmental and policy changes that can support healthy behavior of all employees were described as potentially most effective. An advantage of programs that are open to all employees is that they could reach large populations that would not normally be exposed to organized health improvement initiatives.

Evaluation of the guideline

Despite these insights in promising practices, employers and occupational health professionals often lack the knowledge and experience to design, implement, and evaluate a guideline that may achieve desired outcomes [35]. Moreover, although guidelines contain best evidence and practice recommendations, it is not clear whether such recommendations will enhance the quality of care, i.e. lead to improvements on employee health, adoption of the guideline by occupational health professionals, and to improvements on employer relevant outcomes such as productivity, sickness absence and costs. Systematic evaluation of the guideline on effects, process, and success or fail factors can thus provide relevant insights in the potential of the guideline on these outcomes, and for translation into occupational health practice.

Objectives

The central aim of this thesis is to contribute to improving employee health via occupational health care according to an evidence-based guideline aimed at preventing weight gain among employees in the Netherlands. First, we developed the draft guideline in 2008 from literature, interviews with relevant stakeholders, and consensus among a guideline working group consisting of practitioners and experts. Second, we evaluated the (cost-) effectiveness of the guideline on behavior-related outcomes (physical activity, sedentary behavior and nutrition), body weight-related outcomes (waist circumference, body weight and BMI), health-related outcomes (blood pressure, cholesterol and quality of life), and work-related outcomes (sick leave and productivity) during 18 months follow-up. In a randomized controlled trial, we compared the effects of working according to the guideline by OPs during a 6-months intervention period to usual care, which generally consisted of a health risk appraisal with anthropometric measurements and a subsequent health advice. Third, this thesis focused on the quality of the process of occupational health care, and identified barriers and facilitators to implementation and continuation of the guideline. Based on this thesis, the Netherlands Society of Occupational Medicine will decide on adjusting and (after authorization) publishing the guideline together with several implementation aids.

Outline of this thesis

Chapter 2 describes a meta-analytic review that was conducted to examine the effectiveness of workplace interventions targeting physical activity and dietary behavior on body weight-related outcomes. In chapter 3, the development of the draft occupational health guideline is presented, as well as the design for evaluation and implementation of the guideline. Chapter 4 presents the process evaluation, that examines how the intervention was administered. The short-term results on behavior-related outcomes (physical activity, sedentary behavior and nutrition) and body weight-related outcomes (waist circumference, body weight and BMI) are described in chapter 5. The long-term results on body weight-related outcomes, CVD-risk factors (blood pressure, cholesterol) and quality of life are presented in chapter 6. In chapter 7, the results are presented of an economic evaluation performed alongside the trial. Chapter 8 presents the results of interviews among OPs and employers on barriers and facilitators to implementation and continuation of the guideline. In chapter 9, we aimed to clarify the magnitude of measurement error of waist circumference, as well as what constitutes a clinically relevant change, as the consequences of errors in measuring waist circumference are unclear for clinical practice. The thesis concludes with a general discussion in chapter 10. Finally, this thesis contains a summary in English and Dutch.

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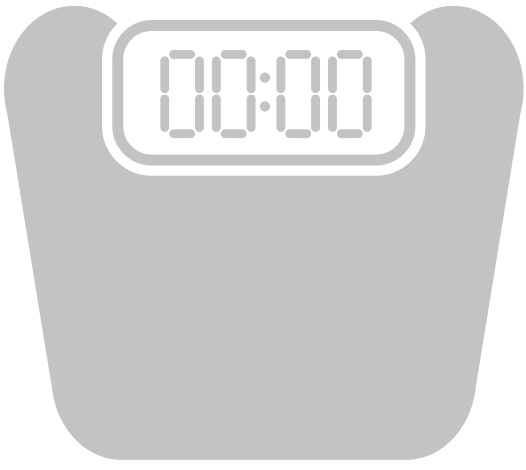
Chapter 2

Meta-analyses of workplace physical activity and dietary behavior interventions on weight outcomes



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Abstract

This meta-analytic review critically examines the effectiveness of workplace interventions targeting physical activity, dietary behavior, or both on weight outcomes. Data could be extracted from 22 studies published between 1980 and November 2009 for meta-analyses. The GRADE approach was used to determine the level of evidence for each pooled outcome measure. Results show moderate quality of evidence that workplace physical activity and dietary behavior interventions significantly reduce body weight (9 studies; Mean Difference -1.19 kg [95% Confidence Interval -1.64 to -0.74]), BMI (11 studies; MD -0.34 kg/m2 [95% CI -0.46 to -0.22]), and body fat percentage calculated from sum of skin-folds (3 studies; MD -1.12% [95% CI -1.86 to -0.38]). There is low quality of evidence that workplace physical activity interventions significantly reduce body weight and BMI. Effects on percentage body fat calculated from bioelectrical impedance or hydrostatic weighing, waist circumference, sum of skin-folds and waist-hip ratio could not be investigated properly due to a lack of studies. Subgroup analyses showed a greater reduction in body weight of physical activity and diet interventions containing an environmental component. As the clinical relevance of the pooled effects may be substantial on a population level, we recommend workplace physical activity and dietary behavior interventions, including an environment component, in order to prevent weight gain.

Introduction

The worldwide increasing prevalence of overweight and obesity is a cause for concern as the overweight-related morbidity, mortality and health care costs concurrently increase (1). According to US data, more than 37% of the workers is currently overweight (BMI≥25 kg m^{-2}) and at least 29% is obese (BMI≥30 kg m^{-2}) (2). The burden of disease attributable to overweight includes effects on chronic diseases such as cardiovascular diseases and type II diabetes, musculoskeletal disorders and a lower quality of life (1;3). Additionally, overweight and obesity are related to increased absenteeism rates and productivity-loss, and thus influence overweight-related costs (4-6).

Efforts to prevent weight gain by targeting physical activity, dietary behavior, or both via the workplace have been numerous over the last decades. Several systematic reviews have been conducted that found favorable effects on physical activity, dietary behavior or both (7-10) and on weight outcomes (7;8;10-12). However, a rigorous quantification of the effects is lacking. Summarising these effects in a meta-analyses has the advantage of a higher power to detect an effect, thus providing better estimates of an effect. Recently, a meta-analysis was published that found modest evidence for an effect of worksite physical activity and nutrition interventions in favor of the intervention group with a decrease of -1.3 kg (9 studies; [95% CI -2.1 to -0.45]) and -0.5 kg/m^2 (6 studies; [95% CI -0.8 to -0.2]) compared to controls at 6 or 12 months follow-up (13). Nevertheless, these results were limited to studies published up until 2005 and included studies aimed at weight loss only. In this rapidly growing research area, our meta-analytic review adds to the current body of evidence by providing an up-to-date meta-analyses excluding studies that focused on weight loss, and studies among only overweight or obese populations. Although the central aim of most included studies was not improving physical activity and dietary behavior or preventing weight gain, but for example reducing cardiovascular disease risk, a focus on primary and secondary prevention is important as population-based prevention of weight gain may prove to be more efficient in tackling the obesity epidemic than individual treatment of overweight subjects. The aim of this study is to critically examine the effectiveness of workplace interventions targeting physical activity, dietary behavior, or both on weight outcomes.

Methods

Inclusion criteria

Studies were eligible for inclusion if they were English-written randomized controlled trials (RCT), targeting physical activity and/or dietary behavior of employees, and reported any weight-related outcome measure (e.g. body weigh, body mass index, body fat percentage, waist circumference, waist-hip ratio and sum of skin-folds) (table 1). No limitations were set as to the subject and worksite characteristics (e.g. gender, age, occupation, number of employees), intervention content (e.g. exercise, counselling), follow-up measurements (e.g. short-term, long-term), or control group (e.g. health risk appraisal, waiting list, no intervention). As our focus is to assess possibilities for prevention, interventions aimed solely at overweight subjects (BMI≥25 kg m^{-2}) were excluded, as well as treatment and weight loss programs. Interventions targeting participants with an identified risk factors for

chronic conditions (e.g. such as elevated blood lipids, cholesterol, or systolic blood pressure) were included. Studies targeting only participants with chronic conditions (e.g. diabetes, hypertension) were excluded.

Table 1. Search strategy.

Study design	Participants	Intervention	Outcome
Randomised controlled trial	Worker* Employee* Adult Occupational health Workplace*	Physical activity Exercise* Diet* Nutrition* Health promotion Health education Obesity prevention and control Weight gain prevention	Body weight Body fat Body mass index Waist circumference Sum of skinfolds Waist-hip ratio

This search strategy is from MEDLINE (MeSH) with search terms expanded. Keyword searches were further performed in EMBASE, PsycINFO, Cochrane Library, SportDiscus and Current Controlled Trials.
* terms expanded

Literature search

The search strategy was conducted following recommendations of Lipsey and Wilson for a comprehensive literature search (14). First, a computer search was performed in six electronic databases (MEDLINE, EMBASE, PsycINFO, Cochrane Library, SportDiscus and Current Controlled Trials) for studies published between 1980 and November 2009. Key articles were checked in MEDLINE to assess if relevant publications were missed. Second, references in relevant systematic reviews, narrative reviews and identified RCTs were screened. Third, personal databases were hand-searched for additional relevant publications. Identified studies were imported into the electronic bibliographic management package Reference Manager 11 (15).

Study selection

Two reviewers (LV and JC) independently applied the inclusion criteria to select potentially relevant studies from the titles, abstracts and keywords of the references retrieved from the literature search. The inclusion criteria were pilot tested by both reviewers on ten articles that were not included in this review, in order to resolve initial disagreement. Abstracts were scored as positive if all inclusion criteria were met, negative when one or more inclusion criteria was not met or unclear if there was insufficient information for a decision. Full text articles were retrieved for the studies that were scored as positive or unclear, as well as articles for which disagreement between the reviewers existed. All full text articles were read and subsequently checked to assess if inclusion was justified. Articles for which disagreement existed between the two reviewers were discussed with a third reviewer (KP).

Data extraction

Data were independently extracted by two authors (LV and JC) using a pre-designed data extraction form. Each study was summarized with regard to characteristics of participants, interventions, follow-up duration, outcome measures, and results. The data extraction form was pilot tested on three articles that were not included in this review. Disagreement between the reviewers about the data extraction was resolved by the third reviewer (KP). Missing data necessary for pooling was calculated according to the Cochrane Handbook for Systematic Reviews of Interventions (16-18). If articles did not contain sufficient information on the outcome measures, authors were contacted for the missing data.

Methodological quality assessment

The methodological quality of studies was independently assessed by two authors (LV and JC) following a predefined checklist based on recommendations of the Cochrane Handbook for Systematic Reviews of Interventions (table 2) (19). The checklist was pilot tested on three articles that were not included in this review. The checklist was slightly adapted for use in this review (20;21). A criterion regarding blinding of intervention providers was not used because this item is not applicable in lifestyle interventions. Regarding detection bias, items G, H, and I were added. This resulted in twelve criteria for internal validity that are related to selection bias (A, B), performance bias (C1, D1, D2), attrition bias (E, F) and detection bias (C2, G, H, I, J). Per article, criteria were scored as positive if the criterion was met, negative if the criterion was not met or unclear if insufficient information was provided for judgement. In case of disagreement, the third reviewer (KP) was consulted for a final decision. For articles that did not contain sufficient information, the authors were contacted. If authors could not be contacted or did not respond, the item was scored as unclear. Finally, each article received a quality judgement based on the number of positively scored criteria: excellent (10-12), good (7-9), fair (5-6) and poor (0-5).

Data synthesis and the GRADE approach

Data were analyzed of those studies that provided sufficient information for meta-analysis. For each continuous weight outcome measure, results were pooled per target behavior (physical activity, dietary behavior, or both) using the number of participants per group, mean differences (MD) and corresponding standard deviations (SD). Although included studies were all RCTs and none reported significant baseline differences for weight outcome measures, substantial differences between intervention and control groups were observed in several studies (22;23). To dissolve this bias, only change-from-baseline scores were included in our meta-analysis. Studies which provided final measurements and sufficient information to calculate change scores, were converted according to the Cochrane Handbook for Systematic Reviews of Interventions (16;17).

The measurement scales per outcome measure were comparable, allowing for the calculation of weighted mean differences using the random-effects model. A study was considered to have a positive effect in case of statistically significant results or a relevant effect size (i.e. >20% difference between study groups) (24). Heterogeneity was examined using the I^2 test,

with moderate heterogeneity assigned at 30–60% (17). To determine whether publication bias among included studies was present, the symmetry of the funnel plots was examined. Additional sensitivity analyses were conducted to explore subgroups. All meta-analyses were conducted using Review Manager 5.0 software (25).

Table 2. Methodological quality in included randomized controlled trials.

	Criterion	**Definition**
A	Randomisation Procedure	Positive if there was a clear description of the randomisation procedure *and* if randomisation was adequately performed: treatment allocation was concealed, i.e. by random aselect numbers or by a computer generated list (not by birthdate, entry order).
B	Similarity of study groups	Positive if the study groups were similar at the beginning of the study with regard to age and at least one of the relevant weight outcome measures ($p<0.05$). If differences existed between the groups, an adjusted analysis had to be performed.
C1	Blinding of participants	Positive if the participant was unaware of being assigned to the intervention group or the control group.
C2	Blinding of outcome assessor	Positive if the person performing the assessments was blinded as to the assignment of subjects to the groups. If questionnaires only were used, a negative score is given.
D1	Compliance	Positive if participants attended the intervention satisfactory according to the opinion of the reviewers. If compliance was not described, the author was contacted to provide the compliance data.
D2	Co-intervention	Positive if co-intervention was not present, such as following a program by a dietician or medication use.
E	Loss-to-follow-up	Positive if the percentage of dropouts during the study period did not exceed 20% for short term follow up (≤ 3 months) or 30% for long term follow up (>3 months).
F	Intention-to-treat	Positive if an intention-to-treat analysis was performed for at least one of the relevant weight outcome measures. Intention to treat was defined as analyzing participants in the group they were randomized to.
G	Timing of outcome assessments	Positive if the timing of the outcome measurement was identical for the intervention and control group
H	Data analyses	Positive if data analysis was adequate: if confounders were accounted for in at least one of the relevant outcome measures, if 95% CI were presented and analysis stratified where necessary.
I	Data collection methods	Positive if data collection methods were adequate: measurements done by trained personnel by means of standardized protocols. A negative score was given when data was self-reported.
J	Follow up	Positive if follow up was 6 months or longer, from the moment of randomization to the combined duration of intervention and (passive) follow up.

The overall quality of the evidence for each pooled weight outcome measure was assessed using GRADE, as recommended by the Cochrane Handbook for Systematic Reviews of Interventions (19). GRADE describes the confidence reviewers have in the estimated effect. The GRADE system provides information on 1) limitations of the included studies (methodological quality), 2) consistency of results, 3) directness (generalizability), 4) precision (sufficient data), and 5) publication bias. The overall quality of evidence was considered to be high if multiple RCTs with a low risk of bias provided consistent and generalizable findings, based on sufficient data with narrow SDs and no known or suspected publication bias. From this starting point, the quality of evidence was downgraded one level per factor that was not met. Thus, the GRADE approach results in four levels of evidence: high, moderate, low and very low. GRADEprofiler software (version 3.2.2) was used (26).

Results

Description of included studies

The literature search identified 1032 studies. After reading titles and abstracts, 43 randomized controlled trials were identified that met the inclusion criteria. Twenty-two of these studies provided sufficient information to be included in the meta-analyses (Figure 1). The description of the study characteristics is outlined in table 3. Twenty-six studies focused on improving physical activity and dietary behavior, 14 studies on physical activity only and 3 studies on dietary behavior only. The number of randomized participants ranged from 33 to 18,210. The age of the study populations ranged from 18 to 67 years. Seven studies included men only, four studies included women only, and the remaining 32 studies included both men and women. Based on the description of characteristics, 16 studies were performed among white collar workers, 9 among blue collar workers, and 18 studies did not describe this. Nine studies included participants with an elevated cardiovascular disease risk. Seventeen studies aimed at cardiovascular disease risk reduction, cholesterol reduction or chronic disease prevention. Sixteen studies aimed to improve physical fitness or physical activity, eight stated to focus on health promotion or healthy lifestyles, and two were aimed at obesity prevention or weight control. The interventions generally consisted of a health risk appraisal, an educational/informational component, a behavioural component, an exercise program or an environmental component. In 23 studies the control group received a health risk appraisal, 3 studies provided an educational/informational component, 3 provided a behavioral component, and 14 control groups received no intervention or were a wait list control group. The length of the intervention varied from 4 weeks to 3 years. Follow-up measurements were conducted at the short-term (< 6 months) in 11 studies, and long term (≥ 6 months) in 32 studies.

Table 3. Characteristics of trials (n=43) included in this review targeting physical activity and diet, physical activity only, or diet only.

1st Author year (ref) Country	Quality score	Study aim	Population	Intervention and control conditions	Compo-nents	Follow-up	Outcome measure	Result in mean difference
Target: PA and Diet								
Aldana 2005 (27) USA	8 (good)	Chronic disease prevention	145 Medical personnel and staff. I: 62 (T1); 61 (T2) C: 79 (T1); 76 (T2)	I: 4 weeks, 4x per week 2 hour group meetings by dieticians and medical professionals to improve understanding of importance of health risks and lifestyle changes + workbook and assignments + access to shopping tours and cooking demonstrations. C: Waiting list	I: b, c C: f	T1: 6 weeks T2 :6 months	1. Body weight (kg) 2. BMI (kg/m^2) 3. Body fat (%)	Significant decrease in I vs. C: 1. -2.9 vs. -0.4 **(T1); -4.4 vs. -1.0 **(T2) 2. -1.1 vs. -0.2 **(T1); -1.6 vs. -0.03 **(T2) 3. -1.1 vs. -0.3 *(T1); -2.4 vs. -0.4 **(T2)
Atlantis 2006 (30) Australia	7 (good)	Physical fitness	73 sedentary, healthy casino employees. I: 19 (T1) C: 23 (T1)	I: 24 weeks, 20 min 3x per week supervised aerobic exercise and 30 min 2-3x per week strength exercise + dietary/health education via 5 group seminars, one-on-one counselling, worksite manual +HRA C: Waiting list + HRA	I: a, b, c, d C: a	T1: 24 weeks	1. Body weight (kg) 2. BMI (kg/m^2) 3. WC (cm)	No significant difference in I vs. C: 1. +0.1 vs. +0.5 2. 0.0 vs. +0.1 Significant decrease in I vs. C: 3. -4.3 vs. -1.1**
Bruno 1983 (33) USA	0 (poor)	Cholesterol reduction	145 employees (selected on cholest, glusceos, age, weight, blood pressure, no heart disease) Ia + Ib: 47 (T1) C: 28 (T1)	Ia: 8 week cholesterol reduction program by health educator during lunch hours on food behavior change techniques: nutrition education, PA planning and self-management skills + HRA. Ib: Same as Ia, but different presentation in education materials C: HRA	Ia: a, b, c Ib: a, b, c C: a	T1: 3 months	1. Ideal body weight (%)	Significant decrease in Ia+Ib vs. C: 1. -2.4 vs. 1.1**
Cockcroft 1994 (34) England	5 (fair)	Health promotion	297 hospital staff I: 40 (T2) C: 43 (T2)	I: HRA + personal advice + leaflets + individual targets for change in 6 months C: HRA	I: a, b, c C: a	T1: 6 months	1. BMI (kg/m^2)	Significant decrease in I vs. C: 1. -0.54 vs. +0.01*
Connell 1995 (35) USA	3 (poor)	Health promotion	801 office workers, nurses and instructional staff, aged 19-67 years Ia: 142 Ib:248 Ic:253 C:158	1-year program with 4 arms. Ia: Health promotion + HRA booklet Ib: Health promotion Ic: HRA booklet C: HRA Health promotion: 1x per month optional individual counselling and feedback by health educator, optional classes and self-help materials. HRA booklet: personalized booklet based on HRA containing feedback, info, advice, space for an action plan and target dates.	Ia: a, b, c Ib: a, b, c Ic: a, b, c C: a	T1: 1 year	1. BMI (kg/m^2)	Significant decrease in Ia, Ib, Ic vs C: 1. ß: -0.05**, ß: -.0.05**, ß:-0.04* vs. ß:0

Edye 1989 (36) Australia	5 (fair)	CVD risk reduction	2489 white collar government workers, elevated cvd risk. I: 861 (T1) C: 1076 (T1)	I: HRA + 20 min counselling by physician on outcomes, attitude, and motivation. Tailored follow-up program during 3 months 3x 20 min counselling by nurse for reinforcement and measurements. C: HRA	I: a, b, c C: a	T1: 3 years	1. Body weight (kg)	No significant difference in I vs. C: 1. -1.00 vs. -1.25.
Elliot 2004 (37) USA	5 (fair)	Healthy lifestyle	33 fire fighters (3 fire stations) Ia: 12 (T1) Ib: 10 (T1) C: 11 (T1)	Ia: team-based curriculum with 10x 45 min peer taught sessions + workbooks, video, quiz, guide, goals + HRA Ib: 4x (+ 4.5 optional hours) individual counselling based on motivational interviewing + 1 physician visit + guide + HRA C: HRA	Ia: a, b, c Ib: a, b, c C: a	T1: 6 months	1. BMI (kg/m^2) 2. Body fat (%)	No significant difference in Ia, Ib vs. C: 1. -0.6; 0 vs. -0.3 2. -1.6, -0.9 vs. -0.4
Elliot 2007 (22) USA	3 (poor)	Healthy lifestyle	599 fire fighters (5 departments), aged 20-60. Ia: 186 Ib: 165 C: 129	Ia: team-based curriculum with 11x 45 min peer taught sessions + workbooks, video, quiz, guide, goals + HRA Ib: 4x (+ 5 optional hours) individual counselling based on motivational interviewing + guide + HRA C: HRA	Ia: a, b, c Ib: a, b, c C: a	T1: 1 year	1. Body weight (kg) 2. BMI (kg/m^2)	Significant less increase in Ia, Ib vs. C: 1. +0.4, -0.5 vs. +1.5 * 2. +0.1, +0.2 vs. +0.5 *
Erfurt 1991 (38) USA	5 (fair)	Health promotion	4 plants (500-600 workers per site)	Ia: HRA + Health education Ib: HRA + Health education + follow-up counselling Ic: HRA + Health education + follow-up counselling + organisation C: HRA Health education: classes, use of media, guided self-help, individual counselling, mini-groups. Organisation: health network, peer support group, environmental interventions	Ia: a, b Ib: a, b, c Ic: a, b, c, e C: a	T1: 3 years	1. Body weight (kg)	Significant decrease in Ia, Ib, Ic vs. C: 1. +0.6, -1.2, -4.7 vs. +3.1*
Gemson 1995 (41) USA	4 (poor)	Health promotion	161 white collar workers, aged ≥ 30. I: 42 (T1) C: 48 (T1)	I: HRA + take-home report + 1x counselling by physician C: HRA	I: a, c C: a	T1: 6 months	1. Body weight (kg)	No significant difference in I vs. C: 1. -2.0 vs -0.7
Goetzel 2009 (44) USA	3 (poor)	Obesity prevention	10282 Dow Chemical employees Ia + Ib: 1583 (T1) C: 417 (T1)	Ia+Ib: health education materials (newsletters, intranet), PA and weight management programs. Ia: HRA + Moderate environmental changes using prompts and point-of-choice messages Ib: HRA + Ia+ Intensive environmental changes using adapted business goals and management commitment, and rewards for employees C:HRA	Ia: a, b, e Ib: a, b, e C: a	T1: 1 year	1. Body weight (kg) 2. BMI (kg/m^2)	Significant difference in Ia+Ib vs. C: 1. -1.0 vs +1.4 ** 2. +0.1 vs +0.3**

Gomel 1993 (45) Australia	4 (poor)	CVD risk reduction	431 ambulance workers Used for analyses: I + C: 403 (T1), 369 (T2), 364 (T3)	Ia: C+ 20 min standard advice, educational manual and information video Ib: Ia + 10 weeks, 6x 50 min behaviour counselling + self-help manual Ic: Ic + goal setting + incentives C: HRA	Ia: a, b Ib: a, b, c Ic: a, b, c C: a	T1: 3 months T2: 6 months T3: 12 months	1. BMI (kg/m^2) 2. Body fat (%)	1. Significant difference between groups, change unknown. 2. No significant difference between groups, change unknown.
Hanlon 1995 (47) England	6 (fair)	CVD risk reduction	1632 employees at two worksites, aged 20-65. Ia: 247 (T1) Ib: 250 (T1) Ic: 241 (T1) Id: 219 (T1) Ie: 200 (T1) C: 246 (T1)	Ia: Health education without feedback Ib: Health education with feedback on cholesterol Ic: Health education with feedback on risk score Id: Health education with feedback on cholesterol and risk score Ie: No intervention (internal control group, intervention delayed) C: No intervention (external control group, intervention delayed)	Ia: b Ib: b, c Ic: b, c Id: b, c Ie: f C: f	T1: 5 months	1. BMI (kg/m^2)	No significant difference in I vs. C: 1.+0.11 vs. +0.02 (Id vs. Ie); +0.11 vs. +0.11 (Id vs. C)
Harrell 1996 (48) USA	2 (poor)	Physical fitness	1504 police trainees at 25 sites. I: unknown C: unknown	I: 4 hours lectures on health, nutrition and fitness + 12 hours fitness testing + 27 hours supervised aerobic and strength training by peers. C: Usual physical training.	I: b, c, d C: f	T1: 10 weeks	1. Body fat (%)	No significant difference in I vs C: 1. change unknown
Jeffery 1993 (49) USA	8 (good)	Weight control	Employees at 32 worksites participated in weight control program. I: 2041 C: unknown	I: during 2 years, 4x 11 bi-weekly health education classes (smoking cessation + weight loss) led by health educators + payroll-based incentives C: No treatment	I: b, c C: f	T1: 2 years	1. BMI (kg/m^2)	No significant difference in I vs. C: 1. -0.02 vs. +0.08
Kamioka 2009 (51) Japan	7 (good)	Healthy lifestyle	43 male white collar employees I: 22 (T1) C: 21 (T1)	I: during 24 weeks, every 2 weeks 2-hour health education by professionals and hot spa bathing and every week individualized program. C: general health guidance	I: b, c, d C: b	T1: 1 year	1. Body weight (kg) 2. BMI (kg/m^2) 3. WC (cm) 4. Body fat (%)	No significant difference in I vs. C: 1. -0.5 vs. -0.6 2.-0.2 vs. -0.3 3. +0.1 vs. 0 4. -2.4 vs. -2.3
Makrides 2008 (54) Canada	4 (poor)	CVD risk reduction	566 employees, aged 19-66, ≥2 cvd risk factors. I: 282(T1), 178(T2) C: 284(T1), 219(T2)	I: 12 week health promotion program by professionals in exercise (individual + classes), education seminars, nutrition analysis, counselling + telephone follow up C: Waiting list	I: b, c, d C: f	T1: 3 months T2: 6 months	1. BMI (kg/m^2) 2. WH ratio	Significant difference in I vs C: 1. -0.57**(T2) No significant difference in I vs. C: 2. -0.007 (T2)
Muto 2001 (55) Japan	4 (poor)	CVD risk reduction	326 male workers at a building company, ≥1 abnormality in cvd risk factors. I: 152 (T2) C: 150 (T2)	I: 4 days education by professionals, counselling, group sessions + goals + during 1 year 4x self-evaluation with feedback from counsellor and family + HRA. C: Mailed advice after HRA	I: a, b, c, d, e C: a	T1: 6 months T2: 18 months	1. Body weight (kg) 2. BMI (kg/m^2)	Significant difference in I vs C: 1. -1.6 vs +0.1 ** (T1), -1.0 vs +0.5 ** (T2). 2. -0.5 vs 0.0** (T1), -0.3 vs +0.2**(T2).

Nilsson 2001 (56) Sweden	3 (poor)	CVD risk reduction	128 workers, elevated cvd risk. I: 44 (T1), 48 (T2) C: 43 (T1), 46 (T2)	I: HRA + during 1 year 16 group sessions with lectures, discussions, video, outdoor activities + individual counselling by a nurse C: HRA	I: a, b, c C: a	T1: 12 months T2: 18 months	1.BMI (kg/m^2) 2. WH ratio	Significant difference in I vs C: 1. -0.7 vs +0.1 (T1), -0.5 vs 0.0* (T2) No significant difference in I vs. C: 2. +0.01 vs. 0 (T1); 0 vs. -0.01 (T2)
Nisbeth 2000 (57) Denmark	5 (fair)	CVD risk reduction	85 male white collar workers, aged 25-45 years. I: 34 (T1) C: 36 (T1)	I: 15 min counselling by exercise physiologist at baseline and 5 months on health information and education, and choice of goals (exercise, diet, smoking cessation, no change/ motivation) C: No intervention	I: b, c, d C: f	T1: 1 year	1. Body weight (kg) 2. BMI (kg/m^2)	Significant difference in I vs C: 1. -0.2 vs +1.4 * 2. -0.06 vs +0.42*
Okayama 2004 (59) Japan	7 (good)	CVD risk reduction	197 chemical company workers aged 30-64 with cholesterol ≥200 mg/dl. I: 96 (T1) C: 92 (T1)	I: HRA + blood tests every 2 months + education by health professional + personal action plan + feedback C: HRA + blood tests every 2 months	I: a, b, c C: a	T1: 6 months	1. Body weight (kg)	Significant difference in I vs C: 1. -0.8 vs -0.3*
Prochaska 2008 (61) USA	5 (fair)	Health promotion	1400 medical university workers. Ia: 464 Ib: 433 C: 503	Ia: C + 3 counselling sessions based on motivational interviewing during 6 months Ib: C+ Online tailored feedback program during 6 months C: HRA with feedback according to stage of change	Ia: a, c Ib: a, c C: a, c	T1: 6 months	1. BMI (kg/m2)	No significant difference in I vs. C: 1. change unknown
Proper 2003 (62) Netherlands	9 (good)	Physical fitness and health	299 white collar civil servants. I: 75 (T1) C: 117 (T1)	I: during 9 months, 7x 20 min counselling by professionals according to stages of change + standard information C: Standard information	I: b, c C: b	T1: 9 months	1. BMI (kg/m^2) 2. Peripheral body fat (%)	No significant difference in I vs. C: 1. -0.08 vs. 0.13 Significant difference in I vs C: 2. -1.4 vs -0.6*
Racette 2009 (63) USA	8 (good)	CVD risk reduction	151 medical centre employees, 80% overweight I: 68 (T1) C: 55 (T1)	I: HRA + 1 year interventions by dietician/ exercise specialists; pedometers, weight watchers, group meetings, exercise program seminars, walking maps, team competitions, and rewards C: HRA	I: a, b, c, e C: a	T1: 1 year	1. Body weight (kg) 2. BMI (kg/m^2)	Significant difference in I vs C: 1. -0.8 vs. +0.6* 2. -0.4 vs. +0.1*
Rose 1980 (64) England	3 (poor)	CVD risk reduction	18210 male industry workers, aged 40-59. I: unknown C: unknown	I: C+ 4 extra OP visits + booklet + food records diary C: Letters + Poster + meeting + OP visit	I: a, b, c C: a, c	T1: 2 years T2: 4 years T3: 6 years	1. Body weight (kg)	No significant difference in I vs. C: 1. 0 between I and C (T3)
Veverka 2003 (66) USA	4 (poor)	Physical fitness	39 US air force men, aged 30-44. I: 20 (T1) C: 19 (T1)	I: during 6 months 1x per month tailored information via internet according to stage of change C: No intervention	I: b, c C: f	T1: 6 months	1. Body weight (kg) 2. BMI (kg/m^2) 3. Body fat (%) 4. WH ratio	Significant difference in I vs C: 1. -2.2 vs -1.0**. 2. change unknown. 3. change unknown. 4. change unknown.

Target: PA								
Anshel 2009 (29) USA	7 (good)	*Physical fitness*	65 unfit, healthy university faculty and staff, aged 24-61. I: 29 (T1) C:36 (T1)	I: 8 week exercise, 3x per week aerobic and strength exercise, weekly coach visit, and weekly self monitoring exercise checklist C: 3x per week aerobic and strength exercise, weekly coach visit, but no checklist.	I: c, d C: c, d	T1: 8 weeks	1. Sum of skinfolds (mm)	No significant difference in I vs C: 1. -0.03 vs. -0.02
Fukahori 1999 (39) Japan	3 (poor)	*Physical fitness*	108 male blue and white collar workers, ≥2 cvd risk factors. I: 49 (T1) C: 52 (T1)	I: HRA + 6 months, 3x per week 20 min walking on treadmill at 70-75% heart rate + walk test 1x per month + notebook C: HRA	I: a, c, d C: a	T1: 3 months T2: 6 months	1. BMI (kg/m^2) 2. WH ratio	No significant difference in I vs C: 1. -0.3 vs. +0.2 (T2) 2. -0.06 vs. -0.01 (T2)
Garber 1992 (40) USA	1 (poor)	*Physical fitness*	60 university employees, aged 24-48. Ia: 14 (T1) Ib: 11 (T1) C: 10 (T1)	Ia: 8 weeks, 3x per week 50 min aerobic dance program. Ib: 8 weeks, 3x per week 50 min walk-jog program C: no intervention	Ia: d Ib: d C: f	T1: 8 weeks	1. Body weight (kg)	No significant difference Ia, Ib vs. C: 1. -1.0, -2.0 vs. +1.0
Gerdle 1995 (42) Sweden	6 (fair)	*Physical fitness*	97 female home care service workers I: 46 (T1) 32 (T2) C: 49 (T1) 45 (T2)	I: HRA + 1 year, 2x per week 1-hour aerobic exercise program by fitness instructor C: HRA	I: a, d C: a	T1: 1 year	1. Body weight (kg)	No significant difference in I vs. C: 1. -1.0 vs 0
Gilson 2007 (43) England	4 (poor)	*Physical activity*	70 academic and administrative university employees. Ia: 21 (T1) Ib: 21 (T1) C: 22 (T1)	Ia: Increasing steps per day by walking routes during 10 weeks15 min per day. Ib: Increasing steps per day during normal tasks during 10 weeks C: No intervention	Ia: b, c Ib: b, c C: f	T1: 10 weeks	1. Body fat (%) 2. WC (cm)	No significant difference in I vs. C: 1. +0.6 vs +0.9 2. +1.0 vs. +1.8
Grandjean 1996 (46) USA	1 (poor)	*CVD risk reduction*	37 female blue collar employees I: 20 (T1) C: 17 (T1)	I: 24 weeks, 3x per week 20-60 min aerobic training of increasing intensity + logbook. C: No intervention	I: c, d C: f	T1: 24 weeks	1. Body weight (kg) 2. Body fat (%)	Significant difference in I vs. C: 1. -2.0 vs +0.7 * No significant difference in I vs. C: 2. -4.1 vs. -2.1
Junea 1987 (50) USA	5 (fair)	*Physical fitness*	120 sedentary employees, aged 40-60. I: 60 (T1) 57 (T2) C: 60 (T1) 56 (T2)	I: HRA + 1x counselling + video + during 6 months, self-monitored home based exercise at moderate intensity C: HRA	I: a, b, c C: a	T1: 12 weeks T2: 24 weeks	1. Body weight (kg) 2. Body fat (%)	No significant difference in I vs. C: 1. -1.0 vs -0.2 (T2) 2. -1.5 vs. -1.7 (T2)
Keele-Smith 2003 (52) USA	3 (poor)	*Physical fitness*	149 faculty, students and staff. I: unknown C: unknown	I: during 5 weeks, education + monitoring by research assistant + brochure about exercise + individual written exercise prescription C: Monitoring only by telephone	I: b, c, d C: c	T1: 5 weeks	1. Body weight (kg) 2. Body fat (%)	No significant difference in I vs. C: 1. -0.6 vs. -0.3 2. -0.5 vs. +0.3

Lee 1997 (53) Australia	6 (fair)	*Physical fitness*	37 female university employees, aged 40-61. I: 16 (T1), 14 (T3) C: 16 (T1), 11 (T3)	I: during 12 weeks, weekly aerobic exercise class at 60% HR by fitness instructors + self-help exercise booklet C: Waiting list	I: c, d C: f	T1: 12 weeks T2: 24 weeks T3: 48 weeks	1.BMI (kg/m^2) 2. WC (cm) 3. Sum of skinfolds (mm)	No significant difference in I vs. C: 1. +0.8 vs. +1.1 (T3) 2. -1.7 vs. -0.2 (T3) 3. 18.3 vs. 18.9 (T3)
Murphy 2006 (23) England	6 (fair)	*CVD risk reduction*	37 civil service workers, aged ≤65. I: 21 (T1) C: 12 (T1)	I: 8 weeks, 2 days per week 45 min self-paced walking + diary. C: No intervention	I: c, d C: f	T1: 8 weeks	1. Body weight (kg) 2. Body fat (%) 3. WC (cm)	No significant difference in I vs. C: 1.+0.4 vs. +1.2 2. -0.1 vs. +1.8 3. -0.8 vs. +0.2
Oden 1989 (58) USA	2 (poor)	*Physical fitness*	45 sedentary workers, aged 18-49. I: unknown (T1) C: unknown (T1)	I: during 24 weeks individual exercise prescription (3x per week aerobic training at increasing heart rate) + weekly exercise logs, feedback and friendship. C: Normal daily routine.	I: c, d C: f	T1: 6 months	1. Body fat (%)	Significant difference in I vs. C: 1. change unknown.
Pedersen 2009 (60) Denmark	7 (good)	*Physical fitness*	549 public administration workers from 9 offices Ia: 106 (T1) Ib: 107 (T1) C: 106 (T1)	Ia: during 1 year 2-3x per week 20 min supervised resistance training + diary Ib: during 1 year all-round physical exercise using step counters, Cd, 1-4x per month instructor, information, contract, environmental campaign C: during 1 year self-supporting groups, presentations, no worksite changes.	Ia: c, d Ib: b, c, d, e C: c	T1: 1 year	1. Body weight (kg) 2. BMI (kg/m^2) 3. Body fat (%)	No significant difference in I vs. C: 1, 2, 3. change unknown
Spittaels 2007 (65) Belgium	10 (excellent)	*Physical activity*	526 healthy adults at 6 worksites, aged 25-55, no cvd history Ia: 14 (T1) Ib: 22 (T1) C: 21 (T1)	Ia: Online tailored PA advice + stage based reinforcement e-mails. Ib: Online tailored PA advice C: Online non-tailored PA advice	Ia: b, c Ib: b, c C: b	T1: 6 months	1. BMI (kg/m^2) 2. Body fat (%)	No significant difference in I vs. C: 1. Ia:-0.3, Ib:0.0 vs C:-0.3 Significant difference in Ia vs Ib,C: 2. Ia:-2.1* vs Ib:+0.1, C:-0.9
Von Thiele Schwarz 2008 (67) Sweden	9 (good)	*Physical activity and fitness*	195 women in dentistry at 6 worksites. Ia: 58 (T2) Ib: 43 (T2) C: 64 (T2)	Ia: on 2 days 1-2.5 hours medium-high intensity mandatory self chosen activity + diary. Ib: 1-2.5 hours reduction in working hours. C: No intervention.	Ia: c, d Ib: f C: f	T1: 6 months T2: 12 months	1. WH ratio	No significant difference in Ia vs C, significant increase in Ib vs C: 1. Ia:+0.03, +0.05** vs. C: -0.01 (T2)

Target: Diet								
Anderson 1999 (28) USA	3 (poor)	*CVD risk reduction*	502 blue collar workers at 8 worksites, aged 18-64, cholesterol ≥200 mg/dl. Ia: 50 (T1); 35 (T2) Ib: 41 (T1); 35 (T2) C: 276 (T1); 61 (T2)	Intervention participants could choose Ia or Ib. Ia: 4 group nutrition education classes for skill building on risk factors and food issues + HRA. Ib: 4 step individual nutrition education program (same content as Ia) for skill building + HRA. C: usual care: 20 min HRA counselling session with nurse + results + printed materials	Ia: a, c Ib: a, b C: a, b	T1: 6 months T2 :12 months	1. Body weight (kg) 2. BMI (kg/m^2)	No significant difference in Ia, Ib vs C: 1. +1.7, -2.4 vs. -0.1 (T2) 2. -0.1, -0.8 vs. +0.1 (T2)
Barratt 1994 (31) Australia	2 (poor)	*Cholesterol reduction*	683 workers at 6 hospitals, cholesterol ≥200 mg/dl. Used for analyses: 417 (T1); 430 (T2)	Ia: HRA + self-help package: educational workbook and behavior change aids (quizzes, shopping guidelines, recipes, 3-min video, monitoring sheet). Ib: HRA + nutrition course: 5x 1 hour group sessions by a dietician with opportunities to discuss fat, fiber, labelling, and barriers + taste sessions + workbook. C: HRA	Ia: a, b, c Ib: a, c C: a	T1: 3 months T2: 6 months	1. Body weight (kg)	Significant decrease in Ib vs. C: 1. - 0.35 vs. unknown* at (T2)
Braekman 1999 (32) Belgium	8 (good)	*Cholesterol reduction*	770 male blue-collar employees at 4 worksites, aged 35-59. I: 272 (T1) C: 366 (T1)	I: HRA with tailored feedback + 3 month education program to lower fat and cholesterol intake via 2-hour group sessions by a dietician on knowledge and skills, video and mass media activities (posters and leaflets). C: HRA	I: a, c, e C: a	T1: 3 months	1. BMI (kg/m^2)2. WH ratio	Significant *increase* in I vs. C: 1. + 0.1 vs. -0.2** No significant difference in I vs. C: 2. -0.005 vs. -0.002

a. Health risk appraisal (HRA); b. Educational/ informational; c. Behavioral; d. Exercise; e. Environmental; f. Wait list/no intervention. BMI: body mass index; WC: waist circumference; WH ratio; waist-hip ratio. * $p<0.05$; ** $p<0.01$.

Quality of included studies

The methodological quality of the 43 included studies is outlined in table 3 (second column). The two reviewers disagreed on 74 of the 516 items (14%). Disagreement was mainly due to differences in interpretation of the methodological quality items and due to reading errors. Of the 21 authors that were contacted, 10 authors provided us with additional information on methodological quality.

Many studies failed to report information on methodological quality. Therefore, the majority of the studies was of fair (11/43) or poor quality (20/43). Eleven studies were of good quality and one of excellent quality. Recurrent methodological limitations were an inadequate or unclear description of the randomization procedure and treatment allocation concealment (31/43), inadequate or an unclear description of blinding of participants and outcome assessors (40/43), unclear whether co-intervention was present (39/43), and inadequate or an unclear description as to the performance of an intention-to-treat analysis (31/43).

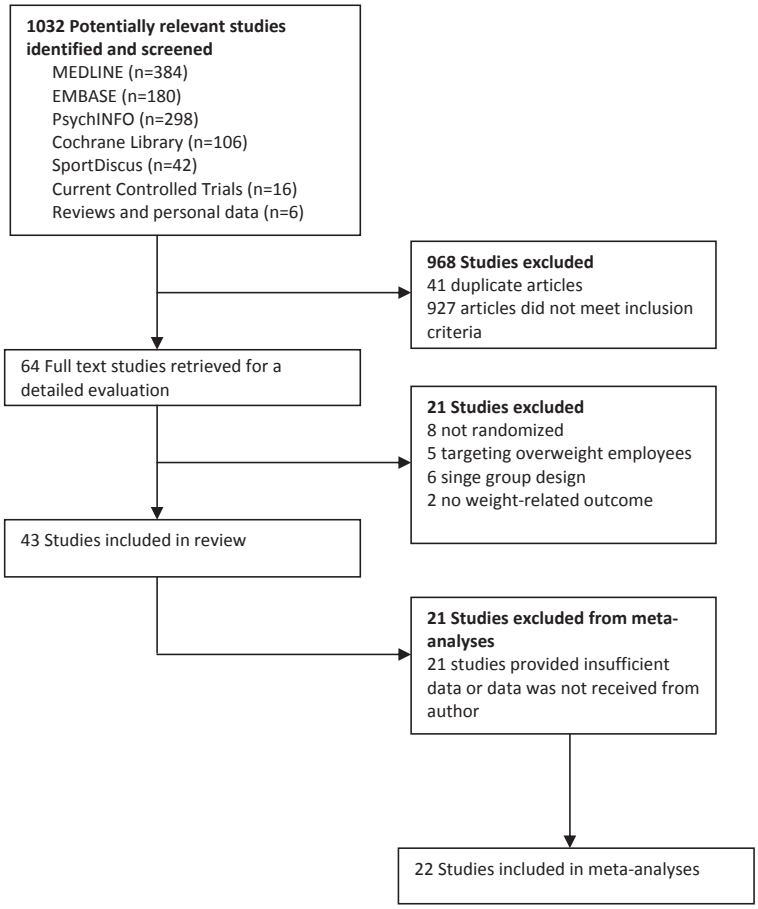

Figure 1. Flow chart for inclusion of studies.

Effectiveness of interventions

Twenty-two studies provided sufficient information to calculate mean differences and standard deviations for body weight (fourteen studies), body mass index (fourteen studies), percentage body fat (seven studies), waist circumference (four studies), waist-hip ratio (four studies), and sum of skin-folds (two studies) (figure 2-7). Eight authors were contacted for additional information on data, but none responded. All studies that provided weight data as final measurements could be converted into change scores. For all analyses, the random-effects model was used as mild heterogeneity was present. Sensitivity analyses using the fixed-effects model did not change the results. Funnel plots were examined for publication bias (data not shown). The distribution of point estimates were symmetrically distributed across the horizontal axis, indicating limited association between study precision and effect size.

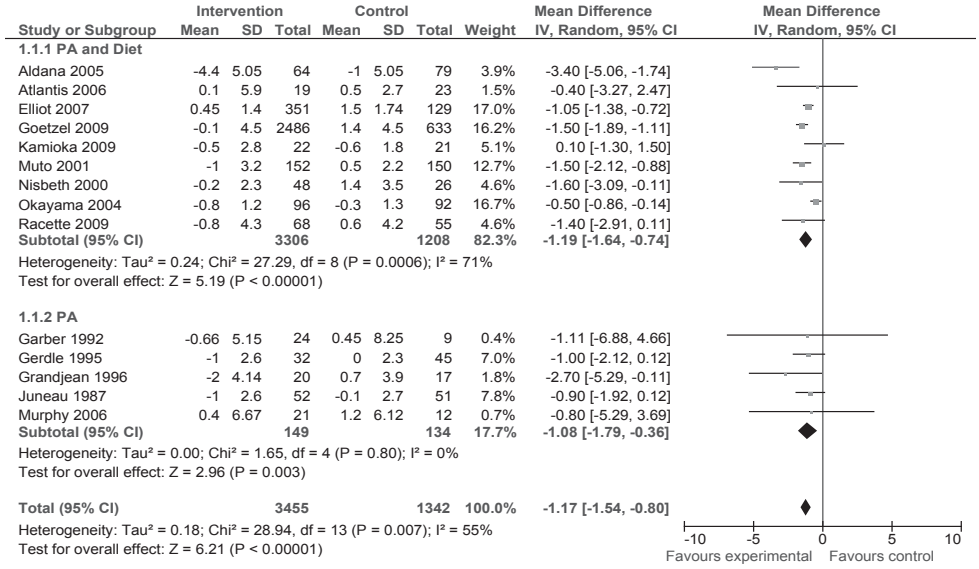

Figure 2. Comparison: Physical activity and dietary behavior interventions (1.1.1), physical activity interventions (1.1.2) versus control– Outcome: Body weight (kg).

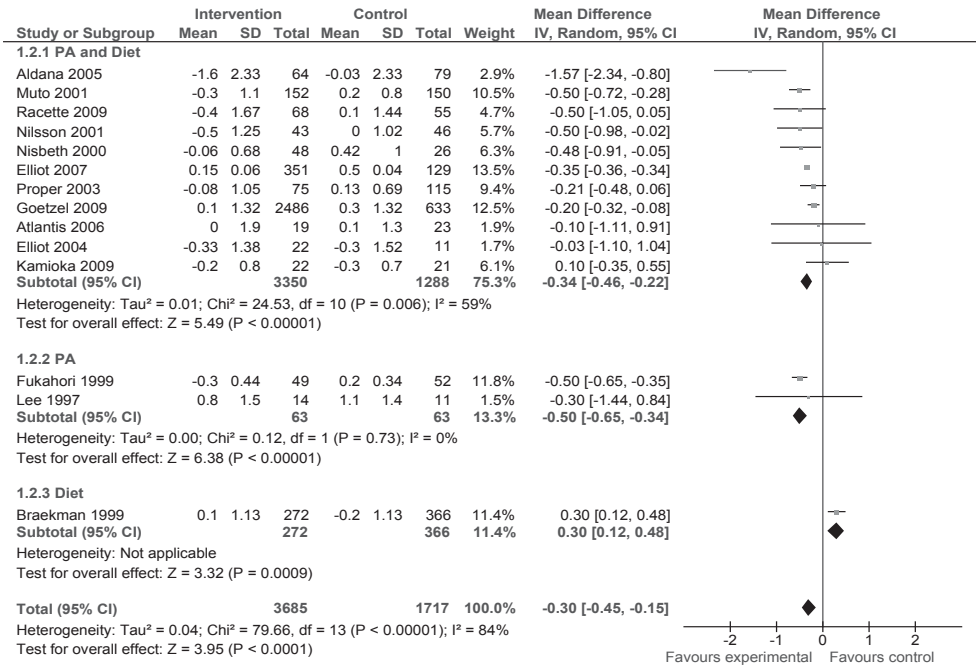

Figure 3. Comparison: Physical activity and dietary behavior interventions (1.2.1), physical activity interventions (1.2.2), dietary behavior interventions (1.2.3) versus control – Outcome: Body Mass Index.

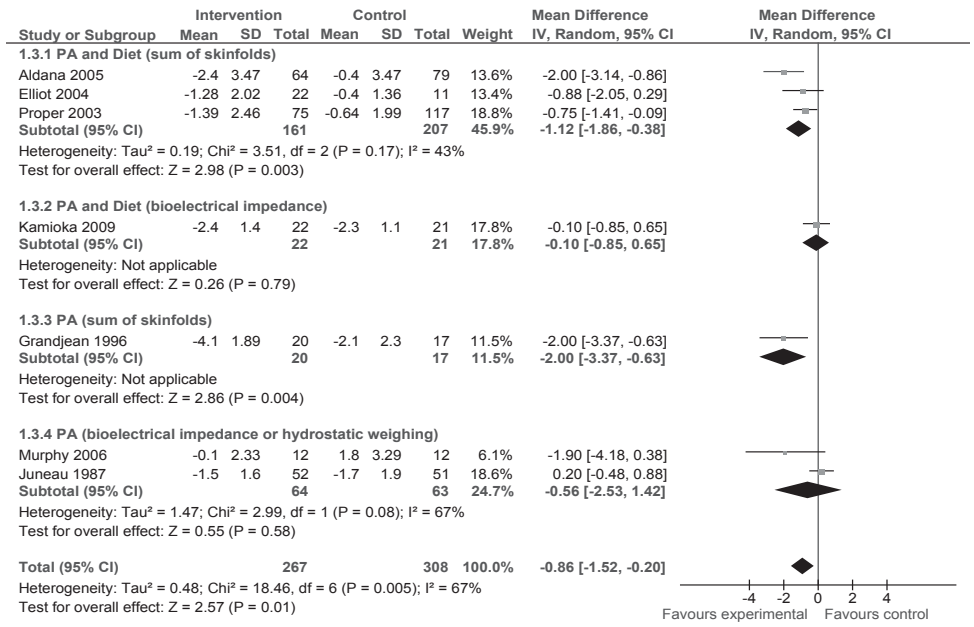

Figure 4. Comparison: Physical activity and dietary behavior interventions calculated from sum of skinfolds (1.3.1) or bioelectrical impedance (1.3.2), physical activity interventions calculated from sum of skinfolds (1.3.3) or bioelectrical impedance (1.3.4) versus control – Outcome: Body fat (%).

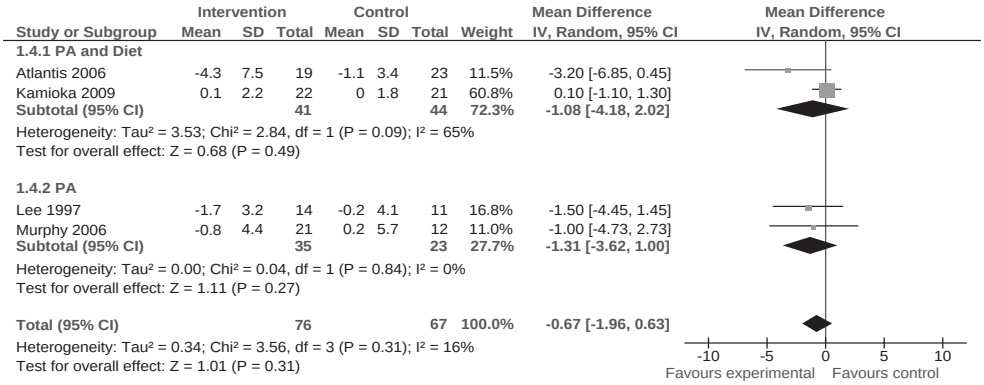

Figure 5. Comparison: Physical activity and dietary behavior interventions (1.4.1), physical activity interventions (1.4.2) versus control – Outcome: Waist circumference (cm).

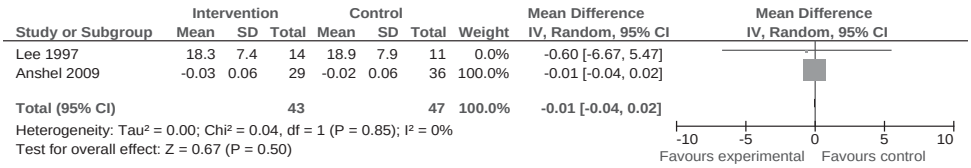

Figure 6. Comparison: Physical activity interventions versus control – Outcome: Sum of skinfolds (mm).

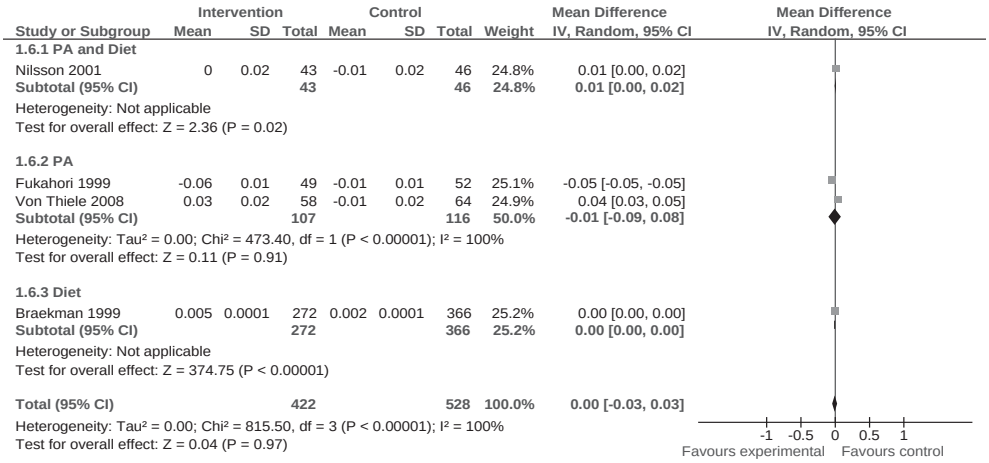

Figure 7. Comparison: Physical activity and dietary behavior interventions (1.6.1), physical activity interventions (1.6.2), dietary behavior interventions (1.6.3) versus control – Outcome: Waist-hip ratio.

Body weight

Nine studies that focused on improving physical activity and dietary behavior, and five studies that focused on improving physical activity, provided sufficient information to calculate mean differences for body weight. No studies were available for pooling that focused on improving diet only. Of the studies targeting physical activity and dietary behavior, five were of good quality, one of fair quality and three of poor quality. Two of the good quality studies found significant decreases in weight of -3.4 kg and -0.5 kg at 6 months respectively, by comparing a 4-week group sessions program provided by health professionals to wait list controls (27) and a 6-month education program by professionals, including an action plan and feedback to HRA controls (59). The other three good quality studies found non-significant differences by comparing an exercise program combined with education and counselling during 24-weeks (30), or combined with group meetings and team competitions during 1 year (63) to HRA controls, or counselling to general information during one year (51). The fair quality study found a significant effect of -1.6 kg by comparing counselling and goal setting to no intervention (57). The three poor quality studies found significant effects by comparing counselling sessions, group sessions, feedback and goals (-1.5 kg) (55), an informational and environmental intervention (-1.5 kg) (44), or team-based sessions and motivational interviewing (-1.1 kg) (22) to a HRA control group. Of the interventions targeting physical activity, three were of fair quality and two of low quality. The three fair quality interventions compared an 8-week self-paced walking program to no intervention (23), an aerobic exercise program during 1 year (42), or counselling sessions combined with 24-weeks of self-monitored home-based exercise (50) to HRA controls. The two poor quality, small studies compared a 24-week and 8-week exercise program to no intervention, but only the 24-week program found a significant effect of -2.7 kg (42;46).

According to the GRADE guidelines, the level of evidence for interventions targeting physical activity and dietary behavior was downgraded by one level due to statistical heterogeneity (-1 for item: inconsistency because I^2=71%) (Table 4). The level of evidence for interventions targeting physical activity was downgraded by two levels because less than 50% of the studies scored good on methodological quality (-1 for item: limitations) and the small number of participants (-1 for item: imprecision). **There is moderate quality of evidence from 9 studies (n=4514) that workplace interventions targeting physical activity and dietary behavior significantly reduce body weight (MD -1.19 kg [95% CI -1.64 to -0.74]). There is low quality of evidence from 5 studies (n=283) that workplace interventions targeting physical activity significantly reduce body weight (MD -1.08 kg [95% CI -1.79 to -0.36]). No studies were available targeting dietary behavior.**

Table 4. GRADE: overall judgement of quality of evidence.

Quality assessment							Summary of findings			
							No of patients		Effect	
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention versus control (change from baseline)	control	Absolute*	Quality
Body weight (kg) (PA and Diet; follow-up 6-18 months)										
9	randomized trials	no serious limitations	serious[†]	no serious indirectness	no serious imprecision	none	3306	1208	MD -1.19 (-1.64 to -0.74) ‡	MODERATE
Body weight (kg) (PA; follow-up 2-12 months)										
5	randomized trials	Serious[§]	no serious inconsistency	no serious indirectness	Serious[¶]	none	149	134	MD -1.08 (-1.79 to -0.36) ‡	LOW
BMI (kg/m^2) (PA and Diet; follow-up 6-18 months)										
11	randomized trials	Serious[§]	no serious inconsistency	no serious indirectness	no serious imprecision	none	3350	1288	MD -0.34 (-0.46 to -0.22) ‡	MODERATE
BMI (kg/m^2) (PA; follow-up 6-12 months)										
2	randomized trials	Serious[§]	no serious inconsistency	no serious indirectness	Serious[¶]	none	63	63	MD -0.50 (-0.65 to -0.34) ‡	LOW
BMI (kg/m^2) (Diet; follow-up 3 months)										
1	-	-	-	-	-	-	272	366	MD +0.3 (+0.12 to +0.48) ‡	VERY LOW[**]
Body fat (%) (PA and Diet; calculated from sum of skinfolds; follow-up 6-9 months)										
3	randomized trials	no serious limitations	no serious inconsistency	no serious indirectness	Serious[¶]	none	161	207	MD -1.12 (-1.86 to -0.38) ‡	MODERATE
Body fat (%) (PA and Diet; calculated from bioelectrical impedance; follow-up 1 year)										
1	-	-	-	-	-	-	22	21	MD -0.10 (-1.85 to -0.65) ‡	VERY LOW[**]
Body fat (%) (PA; calculated from sum of skinfolds follow-up 24 weeks)										
1	-	-	-	-	-	-	20	17	MD -2.00 (-3.37 to -0.63) ‡	VERY LOW[**]
Body fat (%) (PA; calculated from hydrostatic weighing or bioelectrical impedance; follow-up 8-24 weeks)										
2	randomized trials	Serious[§]	Serious[††]	no serious indirectness	Serious[¶]	none	64	63	MD -0.56 (-2.53 to +1.42)	VERY LOW

Waist circumference (cm) (PA and Diet; follow-up 24 weeks-1 year)										
2	randomized trials	no serious limitations	Serious‡‡	no serious indirectness	Serious¶	none	41	44	MD -1.08 (-4.18 to +2.02)	LOW
Waist circumference (cm) (PA; follow-up 8-48 weeks)										
2	randomized trials	Serious§	no serious inconsistency	no serious indirectness	Serious¶	none	35	23	MD -1.31 (-3.62 to +1.00)	LOW
Sum of skinfolds (mm) (PA; follow-up 8-48 weeks)										
2	randomized trials	no serious limitations	no serious inconsistency	Serious§§	Serious¶	none	43	47	MD -0.01 (-0.04 to +0.02)	LOW
Waist-Hip ratio (cm) (PA and Diet; follow-up 3-18 months)										
1	-	-	-	-	-	-	43	46	MD +0.01 (0 to +0.02)	VERY LOW**
Waist-Hip ratio (cm) (PA; follow-up 3-18 months)										
2	randomized trials	no serious limitations	Serious¶¶	no serious indirectness	Serious¶	none	107	116	MD 0 (-0.03 to +0.03)	LOW
Waist-Hip ratio (cm) (Diet; follow-up 3-18 months)										
1	-	-	-	-	-	-	272	366	MD 0 (-0.03 to +0.03)	VERY LOW**

The basis for the *assumed risk* (e.g. the median control group risk across studies) is provided in footnotes. The *corresponding risk* (and its 95% confidence interval) is based on the assumed risk in the comparison group and the *relative effect* of the intervention (and its 95% CI).
CI: Confidence interval; MD: Mean Difference; PA: Physical activity.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

*Better indicated by lower values.
† Statistical heterogeneity was present (I^2=71%).
‡ Significant at p<0.05.
§ less than 50% of the studies scored above 7 (good or excellent) on methodological quality.
¶ Small number of participants (<400) and wide 95% CI that could either support or refute the effectiveness of the workplace intervention.
** Only one study available.
†† Statistical heterogeneity was present (I^2=67%).
‡‡ Statistical heterogeneity was present (I^2=65%).
§§ Controls (29) are not comparable to those defined in inclusion criteria.
¶¶ Statistical heterogeneity was present (I^2=100%).

Body mass index

Eleven studies that focused on improving physical activity and dietary behavior, two studies that focused on improving physical activity and one study that focused on improving dietary behavior provided sufficient information on body mass index for pooling. Five of the studies that targeted physical activity and dietary behavior were of good quality, two were of fair quality and four were of poor quality. Of the good quality studies, only Aldana *et al* found a significant effect of -1.6 kg/m² at 6 months for the 4-week group sessions intervention program provided by health professionals compared to wait list controls (27). Racette *et al* compared exercise combined with group meetings and team competitions during 1 year compared to HRA controls (63). Two studies compared counselling to general information (51;62), and one study compared a short-term exercise program combined with education and counselling during 24-weeks to HRA controls (30). The two fair quality, small, long-term studies favored the intervention group. Elliot *et al* did not find a significant effect by comparing team-based sessions and motivational interviewing sessions to a HRA control group (37). Nisbeth *et al* found a significant difference (-0.5 kg/m²) by comparing counselling and goal setting during 5 months to no intervention (57). The four poor quality, long-term studies targeting physical activity and diet were all compared to a HRA control group, and found significant effects of -0.2 to -0.5 kg/m² in favor of the intervention group. The interventions varied from counselling sessions, group sessions, feedback and goals (22;55;56) to an informational and environmental intervention (44). Of the two studies that focused on improving physical activity, the fair quality study of Lee *et al* did not find a significant effect by comparing a self-help booklet during 12-weeks to a wait list control group (53). The poor quality study of Fukahori *et al* found a significant effect (-0.50 kg/m²) of an exercise intervention compared to a HRA control group (39). Remarkably, the high quality study that focused on improving dietary behavior significantly favored the intervention group (+0.30 kg/m²) via an education program and the environment during 3 months (32).

The evidence for studies targeting physical activity and dietary behavior, and physical activity only was downgraded by one level because less than 50% of the studies scored good on methodological quality (-1 for item: limitations). The evidence for studies targeting physical activity only was additionally downgraded due to the small number of participants (-1 for item: imprecision). The evidence for studies targeting diet was directly downgraded to very low because only one study was available. **There is moderate quality of evidence from 11 studies (n=4638) that workplace interventions targeting <u>physical activity and dietary behavior</u> significantly reduce body mass index (MD -0.34 kg/m² [95% CI -0.46 to -0.22]). There is low quality of evidence from 2 studies (n=126) that workplace interventions targeting <u>physical activity</u> significantly reduce body mass index (MD -0.50 kg/m² [95% CI -0.65 to -0.34]). No conclusion is provided for workplace interventions targeting <u>dietary behavior</u> because only one study was available.**

Body fat percentage

Four studies focused on improving physical activity and dietary behavior, and three studies focused on improving physical activity reported sufficient information on body fat percentage for pooling. However, because different measurement methods were used that do not correlate well (68), analysis were separated for studies that calculated percent body fat based on sum of skin-folds versus studies that used bioelectrical impedance or hydrostatic weighing. Three of the studies targeting physical activity and diet calculated body fat percentage from sum of skin-folds. Two were of high quality and found a significant decrease of -2.0% and -0.8% by comparing an intensive group session to a wait list control at 6 months, and individual counselling to standard information at 9 months respectively (27;62). The other study was of fair quality study and favored the intervention group by comparing team-based sessions and motivational interviewing to a HRA control group (37). One small, fair quality study focused on improving physical activity and diet, that calculated body fat percentage from bioelectrical impedance, found a non-significant effect after one year in favor of the intervention group receiving individual and group health education including hot spa bathing, compared to general health guidance (51). One small, low quality study focused on improving physical activity, that calculated body fat percentage from sum of skin-folds, found a 24-week aerobic training intervention significantly decreased body fat percentage with -2.0% at 24 weeks compared to no intervention (46). Finally, two studies focused on improving physical activity, that calculated body fat percentage from bioelectrical impedance or hydrostatic weighing, found non-significant effects on body fat percentage by comparing an 8-week self-paced walking program to no intervention (23) or one counselling session and self-monitored home-based exercise during 6 months to a HRA control group (50).

The evidence for studies targeting physical activity and dietary behavior, and physical activity only was downgraded by one level due to the small number of participants (-1 for item: imprecision). The evidence for studies targeting physical activity was additionally downgraded because less than 50% of the studies scored good on methodological quality (-1 for item: limitations) and due to statistical heterogeneity (-1 for item: inconsistency because I^2=67%). Because only one study was available, the evidence was directly downgraded to very low for the study that focused on improving physical activity and dietary behavior which calculated body fat percentage from sum of skin-folds, and the study that focused on improving physical activity which calculated body fat percentage from bioelectrical impedance or hydrostatic weighing.

There is moderate quality of evidence from 3 studies (n=368) that workplace interventions targeting <u>physical activity and dietary behavior</u> significantly reduce percent body fat calculated from sum of skin-folds (MD -1.12 % [95% CI -1.86 to -0.38]). No conclusion is provided for percent body fat calculated from bioelectrical impedance because only one study was available. There is very low quality of evidence from 2 studies (n=127) that workplace interventions targeting <u>physical activity</u> reduce percent body fat calculated from bioelectrical impedance or hydrostatic weighing (MD -0.56 % [95% CI -2.53 to 1.42]). No conclusion is provided for percent body fat calculated from sum of skin-folds because only one study was available. No studies were available targeting <u>dietary behavior</u>.

Waist circumference

Two small, good quality studies focusing on improving physical activity and dietary behavior (30;51) and two small, fair quality studies focusing on improving physical activity (23;53) provided sufficient information on waist circumference for pooling. Atlantis *et al* and Kamioka *et al* found non-significant effects from an exercise program combined with education and counselling during 24 weeks, or an individual and group health education including hot spa bathing after one year compared to general health guidance (30;51). Lee *et al* and Murphy *et al* found non-significant effects from a self-help booklet for 12-weeks, or a diary during 8-weeks, compared to no intervention (23;53).

The evidence was downgraded for both groups due to the small number of participants (-1 for item: imprecision). The evidence was additionally downgraded for interventions targeting physical activity and dietary behavior due to statistical heterogeneity (-1 for item: inconsistency because I^2=67%) and for interventions targeting physical activity because less than 50% of the studies scored good on methodological quality (-1 for item: limitations).

There is low quality of evidence from 2 studies (n=85) that workplace interventions targeting physical activity and dietary behavior reduce waist circumference (MD -1.08 cm [95% CI -4.18 to +2.02]). There is low quality of evidence from 2 studies (n=58) that workplace interventions targeting physical activity reduce waist circumference (MD -1.31 cm [95% CI -3.62 to +1.00]). No studies were available targeting dietary behavior.

Sum of skin-folds

Two small studies that focused on improving physical activity only provided sufficient data on sum of skin-folds for pooling. Lee *et al* found a non-significant effect in favor of a 12-week aerobic exercise class at 60% heart rate compared to wait list controls (53). Anshel *et al* found a non-significant effect in favor of an 8-week exercise intervention combined with weekly coach visits and a self-monitoring checklist, compared to the same program but without the self-monitoring checklist (29).

The evidence was downgraded to low quality because the controls of Anshel *et al* were not comparable to those in the inclusion criteria (-1 for item: indirectness), and due to the small number of participants (-1 for item: imprecision).

There is low quality of evidence from 2 studies (n=90) that workplace interventions targeting physical activity reduce sum of skin-folds (MD -0.01 mm [95% CI -0.04 to +0.02]). No studies were available targeting physical activity and dietary behavior, or dietary behavior.

Waist-hip ratio

Four studies that measured waist-hip ratio provided sufficient information for pooling. One study focused on improving physical activity and diet found a small difference in favor of the control group compared to individual counselling by a nurse combined with 16 groups sessions (56). Two studies focused on improving physical activity found small significant effects from a walking intervention versus a health risk appraisal control group (-0.05) (39) and a medium intensity mandatory self-chosen activity on 2 days per week during six

months compared to no intervention (+0.04) (67). One study focused on improving diet via an education program and the environment during 3 months found no effects compared to a HRA control group (32).
The evidence of studies targeting physical activity was downgraded by two levels based on statistical heterogeneity (-1 for item: inconsistency because I^2=100%) and the small number of participants (-1 for item: imprecision). The evidence for studies targeting physical activity and diet, and diet only was directly downgraded to very low because only one study was available.
There is low quality of evidence from 2 studies (n=223) that workplace interventions targeting physical activity do not reduce waist-hip ratio (MD 0 [95% CI -0.03 to 0.03]). No conclusion is provided for studies targeting physical activity and dietary behavior, or dietary behavior because only one study was available.

Subgroup analyses
A sufficient number of participants for subgroup analyses was only available for workplace interventions targeting physical activity and dietary behavior for outcome measures body weight and body mass index. Subgroup analyses could be performed for follow-up duration (6 months or >6 months (none had <6 months follow-up)), intervention content (educational, behavioural, exercise or environmental), and methodological quality (good quality versus fair or poor quality). Analyses could not be performed for gender, age or blue versus white collar workers, because this could not be determined in the majority of the studies. Analyses could neither be performed for a health risk appraisal versus waiting list/ no intervention control group due to statistical heterogeneity.
Analysis by follow-up duration did not show a relevant change (>20%) in pooled body weight estimates. Analysis by intervention content showed that the pooled reduction on body weight of interventions targeting physical activity and dietary behavior, providing an environmental component was larger (3 studies; -1.50 kg [95% CI -1.82 to -1.17]) (44;55;63) than the pooled effect of interventions without an environmental component (6 studies; -1.01 kg [95% CI -1.63 to -0.38]). Analysis by methodological quality showed that the pooled reduction of weight for high quality interventions targeting physical activity and dietary behavior was smaller and non-significant (5 studies; -1.07 kg [95% CI -2.15 to 0.00]) (27;30;51;59;63) than the pooled effect of fair or poor quality interventions (4 studies; -1.30 kg [95% CI -1.58 to -1.03]). Analyses by follow-up duration, intervention content or methodological quality did not show a relevant change (>20%) in pooled body mass index estimates.

Discussion
This meta-analyses of twenty-two studies showed there is moderate quality of evidence that workplace physical activity and dietary behavior interventions significantly reduce body weight, body mass index, and body fat percentage calculated from sum of skin-folds. Additionally, there is low quality of evidence that workplace physical activity interventions significantly reduce body weight and body mass index. No evidence was found from workplace interventions focusing on dietary behavior only due to a lack of studies. Moreover, effects

on percentage body fat calculated from bioelectrical impedance or hydrostatic weighing, waist circumference, sum of skin-folds and waist-hip ratio could also not be investigated properly due to a lack of studies.

Our findings are consistent with a previous review, that demonstrated a similar modest weight loss of -1.3 kg (9 studies; [95% CI -2.1 to -0.45]) and -0.5 kg/m^2 (6 studies; [95% CI -0.8 to -0.2]) among studies up until 2005 (13). Six of the studies found by Anderson et al. that measured body weight, and five that measured BMI, were also included in this review. Thus, in our study we were able to include eight and nine additional studies with regard to body weight and body mass index, respectively. In total, eight studies were included that were published after 2005. Moreover, this review presents pooled results for body fat, waist circumference, waist-hip ratio and sum of skin-folds. These findings emphasize the ongoing interest for research in this area and the rationale for this review.

Subgroup analyses showed that studies targeting physical activity and dietary behavior, with an environmental component were more effective in reducing body weight than studies without an environmental component. The environmental component varied from walking maps and team competitions (63) to family involvement (55) and prompts, point-of-choice messages, walking routes, business goals and management commitment (44). This finding implicates that even though these environmental components differ, future studies should seriously consider environmental components besides personal components. Although this has been suggested previously (69), our study is the first to quantify the importance of environmental components. Subgroup analyses further showed that effects of good quality studies on body mass index (change>20%; also on body weight but change<20%) were smaller and non-significant, than for fair or poor quality studies. Thus, based on the current evidence the conclusion that there is moderate evidence ('future research may change the estimate') for effects of physical activity and dietary behavior interventions body mass index remains the best conclusion. Future research may find that the addition of one or more good quality studies may strengthen the effect, and change the quality of evidence judgement from 'moderate' to 'high'.

Moderate evidence was also assigned to the effect of studies targeting physical activity and dietary behavior on body weight. Although the evidence was downgraded based on the significant random-effect meta-analysis and I^2 larger than 50%, all studies were in the direction of benefit. It is therefore safe to conclude that the intervention is beneficial, even though the amount of benefit is uncertain (70). Finally, evidence was downgraded to moderate for effects of three physical activity and dietary behavior interventions on body fat percentage calculated from sum of skin-folds because of the limited number of participants. However, because effects of two other interventions that calculated body fat percentage more reliably from bioelectrical impedance or hydrostatic weighting, we feel this result is very unreliable.

A first strength of this meta-analytic review compared to other reviews is that we only included randomised controlled trials. This design most adequately reduces bias (71). Nevertheless, we acknowledge that other study designs may provide information that adds to the existing knowledge of lifestyle interventions (72). Because the study by Anderson et

al. included other study designs (ie, non-randomised studies, cohort designs, time series) and concluded that these results were similar, it seems results are consistent across research designs. Second, we excluded studies aimed at treatment or weight loss, and studies among overweight (BMI≥25 kg m^{-2}) populations, as obesity prevention may be a more important and cost-effective way for improving population health than individual treatment of overweight subjects (73). Third, as the decision to include or exclude a particular study is subjective, we chose not to exclude studies of poor quality. Although inclusion of methodologically sound studies only ('best evidence meta-analyses') may prevent that a good meta-analysis of badly designed studies will result in bad statistics, we found it more interesting to include these studies to allow the reader to make an own judgement of the conclusions. Moreover, our results did not indicate stronger evidence for good quality studies. Fourth, we chose to use the last available measurement for pooling, instead of standardising the effects at for example 6 months. Because most people who lose weight regain weight over time, using long-term data may better approach the true effect. Nevertheless, we found no effect of follow-up duration on body weight or body mass index in workplace physical activity and dietary behavior interventions, most likely because all follow-up durations were long-term (6-18 months). Finally, by applying the GRADE method, it was possible to provide a more transparent overview of our decisions in the confidence in the overall effects.

There are some limitations as well. First, the central study aim of the included study differed from our study aim. Because only recently there is a rise in studies that specifically aim to improve physical activity, dietary behavior, or both, we had to widen our inclusion criteria. Our results may therefore be underestimated. Second, we cannot exclude publication bias. The distribution of effect sizes were not skewed in the funnel plots and the results therefore do not suggest publication bias. Nevertheless, only half of the studies included in this review provided sufficient information for pooling. This possible publication bias should be considered when interpreting the outcomes of our meta-analyses. Finally, most studies did not provide information on methodological quality, especially with regard to the randomization procedure, blinding, co-intervention, and intention-to-treat analysis. This led to the downgrading of the level of evidence for the several outcome measures. Taking into account that this was the only item we downgraded on for the outcome body mass index, we urge future studies to report methodological quality for a better assessment of the overall quality.

Conclusion

Implications for practice

This meta-analytic review showed interventions focusing on improving physical activity *and* dietary behavior are moderately effective in reducing body weight of employees with -1.19 kg, and that adding an environmental component may reduce body weight with an additional -0.29 kg. Based on the fact that we did not have to downgrade for the item directness, these effects are generalizable to the worksite setting. However, we were not able to assess differences among subgroups of employees. Nevertheless, the prevention

paradox must be considered. The effect of weight gain prevention interventions on population level may be substantial, but the influence and perceptible benefits on the health of most people is relatively small. For one person to benefit, many people have to change their behavior, even though they receive no benefit or even perceive harm from the change (74). The review by Shaw *et al* showed that exercise interventions (especially when combined with dietary interventions) were found to be effective for improving secondary outcomes (such as cardiovascular disease risk, blood pressure and blood glucose) even if weight loss did not occur (75). Moreover, a public health policy report in the Netherlands determined that a broad implementation of physical activity in combination with dietary interventions may realistically reduce the prevalence rate of overweight by 1-3 percentage points and the prevalence of inactivity by 1-2 percentage points over 5 years (76). If this succeeds, it was estimated 15,000 to 41,000 diabetes cases, 17,000 to 40,000 heart disease cases, and 43,000 to 100,000 musculoskeletal disorders can be prevented during the next 20 years. Additionally, by implementing environmental and individual interventions, a cost-effectiveness ratio per life year gained was estimated to be €6,000. Thus, these studies support the use of physical activity and dietary behavior interventions, including an environmental component, to prevent weight gain among employees.

Implications for researchers

The evidence for the effectiveness of interventions targeting physical activity and dietary behavior in achieving small reductions of body weight remains moderately convincing, but more convincing than in previous reviews. Future research should particularly focus on environmental opportunities in addition to behavioral strategies. Moreover, when more studies are available, we may find more components that contribute to reducing weight. More studies are also needed that report on waist circumference, waist-hip ratio, and sum of skin-folds before sound conclusions can be formulated for these outcome measures. Finally, studies should pay more attention to reporting randomization procedures, blinding, co-intervention, and intention-to-treat analysis (19), in order to gain insight in methodological quality.

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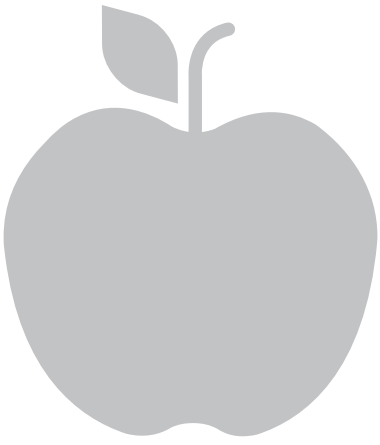
Chapter 3

Design of the Balance@Work project: systematic development, evaluation and implementation of an occupational health guideline aimed at the prevention of weight gain among employees



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Abstract

Background Occupational health professionals may play an important role in preventive health promotion activities for employees. However, due to a lack of knowledge and evidence- and practice based methods and strategies, interventions are hardly being implemented by occupational physicians to date. The aim of the Balance@Work project is to develop, evaluate, and implement an occupational health guideline aimed at the prevention of weight gain among employees.

Methods Following the guideline development protocol of the Netherlands Society of Occupational Medicine and the Intervention Mapping protocol, the guideline was developed based on literature, interviews with relevant stakeholders, and consensus among an expert group. The guideline consists of an individual and an environmental component. The individual component includes recommendations for occupational physicians on how to promote physical activity and healthy dietary behavior based on principles of motivational interviewing. The environmental component contains an obesogenic environment assessment tool. The guideline is evaluated in a randomised controlled trial among 20 occupational physicians. Occupational physicians in the intervention group apply the guideline to eligible workers during 6 months. Occupational physicians in the control group provide care as usual. Measurements take place at baseline and 6, 12, and 18 months thereafter. Primary outcome measures include waist circumference, daily physical activity and dietary behavior. Secondary outcome measures include sedentary behavior, determinants of behavior change, body weight and body mass index, cardiovascular disease risk profile, and quality of life. Additionally, productivity, absenteeism, and cost-effectiveness are assessed.

Discussion Improving workers' daily physical activity and dietary behavior may prevent weight gain and subsequently improve workers' health, increase productivity, and reduce absenteeism. After an effect- and process evaluation the guideline will be adjusted and, after authorisation, published. Together with several implementation aids, the published guideline will be disseminated broadly by the Netherlands Society of Occupational Medicine.

Trial Registration ISRCTN73545254 / NTR1190

Background

Overweight is one of the world's most challenging public health problems [1]. The prevalence of overweight has reached epidemic proportions in most Western countries, including the Netherlands. Currently, over 30% of the Dutch working population is overweight and around 6% is obese [2]. The prevalence of overweight is expected to increase substantially over the next years [3]. The average gain in weight is calculated to vary between 0.4–0.9 kg per year [4,5]. This trend is a cause for concern as overweight has been associated with an increased risk for type 2 diabetes, cardiovascular diseases, and some cancers, as well as with higher absenteeism rates and lower productivity levels [6-9]. Consequently, the overweight-related mortality, direct costs (health care costs) and indirect costs (costs of sick leave, loss of production) may increase [10,11].

Despite worldwide awareness of the obesity epidemic, tackling this public health problem remains difficult [12]. Individual treatment of overweight subjects has proven difficult because the large behavioral changes necessary for weight loss are difficult to achieve. Moreover, body weight is often regained on the long term [13,14]. Population-based prevention of weight gain, aimed at personal and environmental factors, may prove to be more efficient.

Overweight is the result of a gradual gain in weight over time as energy intake (i.e. dietary behavior) exceeds energy expenditure (i.e. physical activity). In order to prevent weight gain, a small change of 100 kcal/day is assumed necessary, which may be walking 2000 steps more per day or replacing an energy dense snack by a healthier snack [15]. This may best be achieved by inducing small behavior changes because these are more feasible to achieve and maintain [16].

The workplace is considered an appropriate setting for lifestyle promotion, as a major part of the adult population can be reached [2]. In the Netherlands, employees can be reached through health risk appraisals conducted by occupational physicians (OP). This voluntary health risk appraisal, which may consist of anthropometric measurements (such as body composition, aerobic fitness and blood values) and a subsequent advice by the OP, makes both research and intervention feasible among Dutch employees. An extensive literature study concluded that primary prevention lifestyle interventions are effective and feasible within the Dutch occupational health setting [17]. Nevertheless, OPs hardly implement weight gain prevention interventions due to a lack of knowledge and evidence-based methods and strategies. To date, activities of OPs are predominantly aimed at reducing absenteeism. Moreover, of the few OPs who do implement preventive interventions, the strategies vary and are not based on the current evidence. Based on the literature study and additional interviews, it was concluded that a need exists among OPs how to promote physical activity and dietary behavior in an effective way.

The Netherlands Society of Occupational Medicine recognises the need for improvement of the professional quality of the OPs and thus emphasises the need for a clinical practice guideline. Practice guidelines are systematically developed statements, designed to assist physicians with decisions about appropriate health care for specific clinical circumstances

[18]. Practice guidelines consist of 1) a guideline text, which is formulated as a structured stepwise sequence of recommendations for practice, 2) a one page summary leaflet and 3) a background document, in which the levels of evidence for the recommendations are indicated and reference to the most important literature is given. The systematic development, evaluation and implementation of a weight gain prevention practice guideline in a careful and well-designed process is thus innovative and of major relevance. In order to perform a proper cost-, effect- and process evaluation of the guideline, the evaluation of the guideline is conducted in a randomised controlled trial. The Balance@Work project consists of three phases: phase 1. development, phase 2. evaluation, and phase 3. implementation of an occupational health guideline aimed at the prevention of weight gain among employees. This paper describes the development of an occupational health guideline, the design of the evaluation and the design of the implementation.

Methods

Phase 1. Development of the weight gain prevention guideline

For the systematic development of the weight gain prevention guideline and associated intervention, the practice guideline development protocol of the Netherlands Society of Occupational Medicine was applied in combination with the Intervention Mapping (IM) protocol [19,20] (Figure 1a and 1b). Both protocols facilitate a stepwise process for theory- and evidence based development of guidelines and health promotion interventions respectively. In phase 1 we describe our approach to each step applied to the prevention of weight gain among employees, focusing particularly on steps 1-4 of the IM protocol. As all steps of the Netherlands Society of Occupational Medicine protocol complement those of the IM protocol, these steps were incorporated in phase 1.

1. Composing an expert group
2. Context analysis and formulation of key questions
3. Search of the literature and critical appraisal of the existing evidence
4. Formulation of recommendations and first draft of guideline
5. Commentary phase
6. Final test version of the guideline

Figure 1a. Guideline development protocol of the Netherlands Society of Occupational Medicine [19].

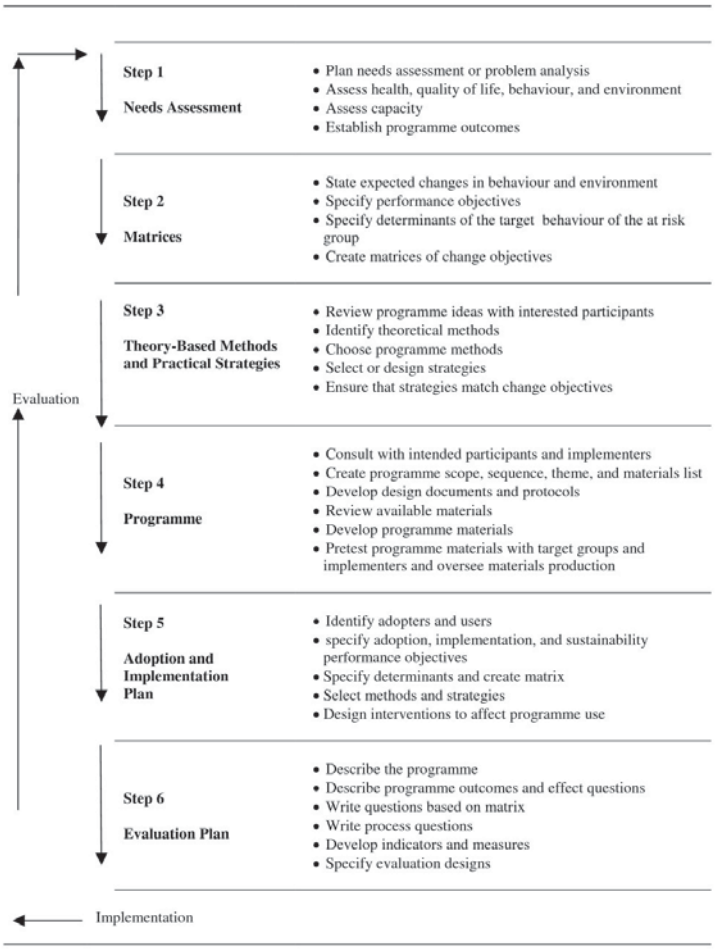

Figure 1b. Intervention mapping protocol [20].

Step 1. Needs assessment

The aim of the needs assessment was to identify the overall program objective, i.e. what is the overall program meant to accomplish [20]. The needs assessment includes a structured analysis of behavioral risk factors and environmental conditions that contribute to the health problem (i.e. weight gain among workers) via a combination of methods, such as a literature review and interviews with relevant stakeholders (i.e. OPs, employees and employers). Additionally, steps 1-3 of the Netherlands Society of Occupational Medicine protocol were added as these steps fit well with the needs assessment. The literature search was conducted in PubMed using keywords regarding our participants (i.e. worker, employee, adult, workplace, occupational physician), intervention (i.e. controlled trial, physical activity, nutrition, health promotion, obesity prevention) and outcome measures (i.e. physical activity, nutrition, body weight). Additionally, individual studies, reviews of

scientific literature and (inter)national reports on obesity and preventing weight gain were obtained. Identified risk behaviors and environmental factors were discussed in focus group interviews among seven OPs and 33 employees, and face-to-face interviews among three employers, in order to gain further in-depth knowledge of each stakeholders' needs regarding the occupational health guideline and the associated intervention. The interviews were conducted using a predefined semi-structured protocol and were digitally recorded. Following steps 1-3 of the Netherlands Society of Occupational Medicine protocol, an expert group was formed consisting of four OPs and four experts in the field of lifestyle. Involving decision makers from the start helps to move the guideline and associated intervention towards practice-based evidence, rather than just classical evidence-based practice [21]. The expert group met plenary five times during one year to discuss the context and key questions, the literature, and the existing evidence.

The needs assessment led to the identification that personal and environmental factors on both sides of the energy balance attribute to weight gain. On the energy expenditure side, a lack of physical activity as a part of daily routines was particularly identified as a risk behavior to cause weight gain [22]. Among daily physical activities, different domains can be distinguished: 1) transport-related activities, 2) work-related activities, and 3) leisure time activities and sport participation [23]. Additionally, sedentary behavior (characterized by an energy expenditure less than 2 MET, with 1 MET equivalent to the consumption of 3,5 ml $O_2 \cdot kg^{-1} \cdot min^{-1}$), across all domains of physical activity was identified as a risk behavior for weight gain [24]. Regarding energy intake, a diet high in fat or carbohydrates and low in fiber, frequent snacking and frequent consumption of sugar-containing soft drinks were identified as risk behaviors which relate most to weight gain [1]. Finally, the influence of the 'obesogenic environment', i.e. an environment that discourages physical activity and encourages over consumption, was identified as a major risk factor for weight gain [15].
Across literature, a variety of high risk groups for weight gain were identified, such as: young starters, shift workers, blue collar workers as well as sedentary workers, those with a low social-economic status but also women with a high social-economic status, those with high job stress, those with care for children, those who stop smoking and postmenopausal women [4,25-32]. But as gradual excessive weight gain occurs across all these groups, the target group for the weight gain prevention guideline and associated intervention was specified as: workers with unhealthy physical activity and/or dietary behavior and/or workers who are overweight, according to (inter)national standards. Additionally, in order to accomplish environmental changes that facilitate behavioral changes among workers, employers were defined as a second target group.
From the needs assessment the following overall program objective emerged: to stimulate daily physical activity and healthy dietary behavior in order to prevent weight gain among Dutch workers with unhealthy behavior and/or weight, by means of a practice guideline for OPs targeting personal and environmental factors.

Step 2. Performance and change objectives

The second step of IM further specified the expected changes as a result of the intervention in four program objectives. Next, performance objectives were specified for each of the four program objectives (what workers are supposed to do as a result of the program), from which the most important and changeable behavioral and environmental determinants were selected [20]. The first task was to translate the selected personal risk behaviors of the needs assessment into health-promoting behavior, based on existing literature and results from the interviews. Two program objectives for increasing physical activity and two program objectives for increasing healthy dietary behavior were identified (table 1). With respect to physical activity behavior, increasing physical activity across all domains (i.e. transport-related, work-related, leisure time and sports) was encouraged. Moreover, due to the fact that sitting time during work increased over the last decades and that sedentary behavior is regarded as an independent risk factor of adverse health [33], decreasing sedentary behavior was specified as an objective. Regarding nutrition, the consumption of fruit was promoted, and a decrease in consumption of snacks was stimulated. The consumption of soft drinks was not targeted as only small observational studies found an association between soft drinks and weight gain in adults [34,35].

Table 1. Program objectives of the Balance@Work project.

1. Employees increase their levels of physical activity
2. Employees decrease their levels of sedentary behavior
3. Employees increase their consumption of fruit
4. Employees reduce their energy intake derived from snacks

The next step was to specify performance objectives for each of the program objectives. These constitute the specific behavioral outcomes of the program expected from the target group. Specification of the performance objectives was done via a combination of methods, namely a review of the literature, interviews with relevant stakeholders and a review of theoretical models such as Goal setting theory [36], Implementation intentions [37], the Theory of Planned Behavior [38], the Precaution Adoption Process Model [39], and the EnRG framework [40]. Based on the self-regulation theory, eight performance objectives were specified for each program objective [41]. The performance objectives for the first program objective are illustrated in table 2.

The question remains how workers can be stimulated to improve their daily physical activity and dietary behavior and thus prevent weight gain. Changeable personal and environmental determinants were therefore selected that may facilitate change. This task again involved the application of information from literature, interviews, behavioral determinant theories, behavioral change theories and social ecological models. To illustrate our conceptual model, figure 2 describes the Balance@Work model, which is based on the NHF-NRG intervention and evaluation model [42].

Table 2. Performance objectives for individual and environmental changes related to increasing the level of physical activity (program objective 1).

Individual changes related to program objective 1.
1. Employees monitor their level of physical activity
2. Employees indicate reasons to be physically active
3. Employees indicate barriers for being active
4. Employees identify solutions to take away barriers to being physically active
5. Employees decide to become more physically active
6. Employees make plans to become more physically active
7. Employees increase their physical activity
8. Employees evaluate whether the causes of insufficient activity are taken away, evaluate the effects and maintain their level of PA by enhancing their routine and preventing relapse
Environmental changes related to program objective 1.
1. OPs monitor the level of physical activity of employees
2. OPs* monitor current health policy
3. OP and employers have a positive attitude towards increasing physical activity
4. OPs* identify environmental risk factors for inactivity
5. OPs* indicate barriers for providing opportunities for employees to increase the level of physical activity
6. OPs* identify solutions to take away barriers to being physically active
7. OPs* make plans to provide opportunities for employees to increase the level of physical activity
8. OPs* provide opportunities for employees to increase the level of physical activity
9. OPs* evaluate whether the causes of insufficient activity are taken away, evaluate the effects and maintain opportunities for employees to increase the level of physical activity by company health policy and attention for relapse prevention.

* in collaboration with the employer

Personal determinants

Based on the Theory of Planned Behavior (TPB), attitude, subjective norm and perceived behavioral control were identified as relevant behavioral determinants towards being more physically active across all domains of physical activity, and towards the consumption of fruit and low energy dense products [43,44]. The TPB specifies that these determinants on their turn influence the intention to adopt a certain behavior. A positive intention however does not always lead to an actual change in behavior (the 'intention-behavior gap'), especially in complex, habitual behaviors like daily physical activity and dietary behavior [45]. Because the presence of strong habits may limit the effect of intention as a predictor of behavior, habit strength was identified as relevant determinant [46]. Finally, knowledge, awareness and skills were found relevant in earlier weight gain prevention studies [42,43]. Determinants of behavior change were identified based on the Precaution Adoption Process Model (PAP-M). The PAP-M assumes that people behave qualitatively different at different stages of change [39]. Although the validity of behavioral change theory may be discussed, evidence exists that interventions that have applied the stages of change concept are more effective (at the short term) than non-stage matched interventions due to the distinction between motivation and action [44,47]. The stages are therefore incorporated in the Balance@Work model.

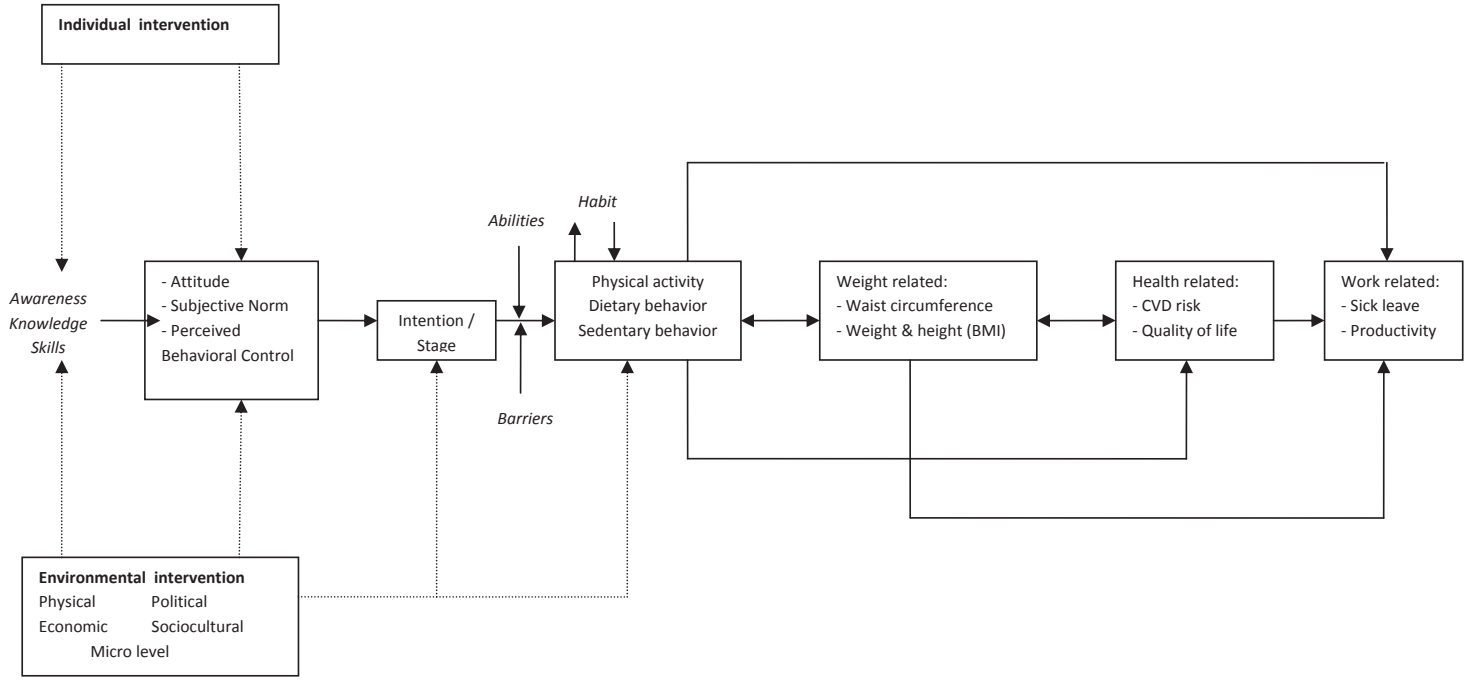

Figure 2. Balance@Work Model.
Legend Figure 2 - Describing the Balance@Work intervention, aimed at improving physical activity and dietary behavior of employees in order to prevent weight gain.

Environmental determinants
Several studies found an effect of the environment on the identified energy-balance related behaviors [40,48]. Relevant environmental determinants of energy-balance related behaviors were previously identified as: availability (for example bike sheds and a variety of healthy foods), management commitment and support (is health incorporated in the company's policy and does the company have a workers' representative council?), social support from co-workers, company policies (such as catering policies) and costs (food pricing, subsidised transport) [16,43]. Additionally, to overcome the intention-behavior gap, environmental opportunities should be facilitated by decision makers in order to create an environment that enables workers to change energy-balance related behaviors. Thus, environmental change interventions can best be aimed at these decision makers [44].

Finally, a matrix was developed of performance objectives crossed with the determinants, resulting in specific learn and change objectives (Additional File 1).

Step 3. Selecting theory-based methods and practical strategies.
This step involves the selection of theory-based methods and practical strategies from literature that should lead to the desired changes. A theoretical method is a general technique or process for influencing change in personal and environmental determinants [20]. Thus, theory-based methods should improve workers' abilities and the environmental opportunities to effectively act on their motivations (i.e. overcome the intention-behavior gap). Behavioral change methods selected from the vast amount of literature were; tailored feedback, personalized risk, self-monitoring, decisional balance, re-evaluation of beliefs, reinforcement, goal setting, active learning, rewarding, mobilizing social support, skills training, and environmental changes [20,43,49]. Methods were then translated into practical strategies in order to accomplish a successful shift from motivation to action and maintenance. In translating methods into strategies, the theoretical conditions must be considered that apply to the method used [50]. For example, risk feedback may only be effective for increasing awareness when certain conditions are met, such as including both personal risk feedback (compared to a standard) and normative feedback (compared to a reference group).
Central in this self-regulation process is the formation of action goals, pursuing these goals and overcoming barriers [44]. This can be discussed during the workers' health surveillance counseling session. Because OPs stated that employees often fail to comply with health advice and express resistance to change, a more client-centered counseling technique was selected for OP based on motivational interviewing. Motivational interviewing has proven feasible and effective in primary prevention interventions targeting energy-balance related behaviors [51,52]. It aims to elicit a person's ambivalence, motivation and possibilities for change. Workers are encouraged to express thoughts, feelings and ambivalence in order to reach a decisional balance. They are then asked to decide what they may want to change, and specify implementation intentions to reach goals. Because OPs stated to have limited time, behavioral change counseling was applied. Behavioral change counseling is an adapted form of motivational interviewing, suitable for brief consultations in healthcare settings

[53]. During counseling, the OP is asked to 1. provide direct advice only when asked and 2. address resistance to change, as resolving resistance is the first step to change [54].
Previous weight gain prevention research suggests that in people not yet motivated to prevent weight gain, the focus during counseling should be on awareness and attitude by means of self-monitoring, personalization of risk, tailored feedback, discussing decisional balance and beliefs. Among those who are motivated to prevent weight gain, attention should be aimed at increasing the perceived behavioral control in overcoming barriers [55] and at improving skills and stimulating social support. Additionally, formulating implementation intentions help to change habits. In order to maintain healthy behavior, rewarding and positive feedback have proven to be effective [56]. Moreover, tailored advice, use of a minimal intervention and using several contact moments showed promising results. An overview of determinants, theoretical methods and practical strategies are described in Table 3.

Step 4: Design of the guideline and intervention program

Step four describes the scope and sequence of the intervention and requires translation of the methods and strategies into intervention materials (table 3). The first draft of the guideline was subjected to commentary of five independent experts in the field of lifestyle. This resulted in a final test version of the guideline (step 4-6 of the Netherlands Society of Occupational Medicine protocol). Based on a critical appraisal of the evidence, experiences from the interviews, practical and ethical considerations, and consensus among the expert group, a practice guideline for OPs was developed. For the entire guideline and intervention, preventing weight gain was re-formulated as promoting physical activity and a healthy diet, in order to set a positive tone. The guideline consists of three sections: a. prevention at the environmental level (advice for the employer); b. prevention at the individual level (advice for the employee); and c. evaluation and maintenance (figure 3). The starting point for OPs to stimulate a healthy lifestyle could either be section a or b. Eventually, both sections should be addressed and re-evaluated in a cyclic manner.
With regard to prevention at the environmental level (*section a*), an environment scan was developed. This checklist helps the OP to discuss opportunities for a healthier work environment with the employer. The checklist contains previously identified determinants of weight gain, categorized for the selected physical activity behaviors (transport-related behavior, work-related activities and leisure-time activities including sport participation such as the availability of bike sheds, food policies and a company discount for the gym) and dietary behaviors (snacks and fruit consumption, for example healthy choices in vending machines and free fruit at work). By checking what the company already offers, the environment scan also shows which opportunities are lacking. For the selected determinants, feasibility and barriers for implementation can be noted. Based on this overview, environmental goals can be prioritised. To stimulate the implementation of short and long term goals, a start and evaluation date can be set with the employer. Based on the environment scan an advice for improving the obesogenic environment can be generated by the OP for the employer and the workers' representative council.

Table 3. Personal and environmental determinants, theoretical methods, practical strategies and tools identified for increasing the level of physical activity among employees (program objective 1).

Determinant	Theoretical method	Practical strategy	Tools
Knowledge	Tailored feedback	Provide verbal tailored feedback on national recommendations, benefits and possibilities	Stage matched feedback during counseling. Information in print materials and in diary.
Awareness	Personalized risk	Provide verbal personal and normative feedback	Stage matched feedback during counseling. Risk communication chart.
	Self-monitoring	Facilitate and stimulate written monitoring of own behavior	Balance@Work toolkit consisting of: a. Waist circumference measuring tape with a coloring scheme that indicates a healthy waist circumference. b. Pedometer. c. Diary containing information and logs to keep track of nutrition, physical activity and steps per day. d. Print materials on physical activity and nutrition.
Attitude	Decisional balance	Discuss the decisional balance	Stage matched feedback during counseling.
	Re-evaluation of beliefs	Provide positive feedback on changes in attitude and discuss irrational thoughts	Agenda setting chart in diary. Scales assessing importance, confidence and willingness to change. Decision matrix in diary.
Perceived behavioral control	Reinforcement	Increase confidence by providing positive feedback and discuss difficult situations	Stage matched feedback during counseling.
	Goal setting	Invite to formulate implementation intentions	Evaluation of realistic short and long term goals, reason for goals, barriers and solutions in diary.
Habit	Active learning	Formulate action and coping plans	Stage matched feedback during counseling.
	Goal setting	Invite to formulate implementation intentions	Evaluation of realistic short and long term goals, reason for goals, barriers and solutions, and rewards for reached goals in diary.
	Rewarding	Invite to formulate rewards	
Skills	Active learning	Encourage to formulate implementation intentions and train relapse prevention skills	Stage matched feedback during counseling. Evaluation of current skills and needed skills.
	Reinforcement	Provide positive feedback on skills	

Subjective norm	Mobilizing social support Skills building to reduce social pressure	Invite to formulate who can provide support Encourage to train relapse prevention skills	Stage matched feedback during counseling. Evaluation of who can provide social support in diary.
Availability	Environmental changes	Encourage to formulate environmental changes that facilitate a healthy work environment	Information in print materials. Environment scan consisting of: a checklist which provides insight in opportunities to create a healthier work environment. Examples of items are: are bike sheds and change facilities present? is the cafeteria adapted to stimulate healthy nutrition? is a rewarding system present? Feasibility and barriers for changing the environment can be scored together with the employer, as well as a start and evaluation date.
Management commitment and support	Mobilizing management support Rewarding	Encourage management participation Provide incentives	
Social support	Mobilizing social support from collegues	Encourage participation of collegues	
Company policy and costs	Mobilizing management to provide policy that encourages a healthy work environment	Encourage management and the workers' representative council to facilitate changes	

With regard to prevention at the individual level (*section b*), a stepwise minimal intervention strategy was made to facilitate the OPs individual counseling based on behavioral change counseling. As employees expressed their concern towards participating in a program provided by the OP in focus group interviews (due to expected consequences from the employer as a result of poor health), the guideline explicitly states that OPs are to maintain good contact with employees, emphasize confidentiality of results and resolve resistance to change. During the counselling sessions, first the agenda is addressed (which performance indicator or other subject would the employee like to target). Next, motivation for change is assessed and the OP provides stage matched advice to change behavior. OPs are provided with several tools derived from motivational interviewing to discuss ambivalence and increase motivation; a) an agenda setting chart, containing all target behaviors from which employees can choose what to discuss, b) a risk communication chart containing graphic information on risks for diabetes, hypertension and heart disease for different weight levels c) a chart with scales of willingness, importance and confidence to change behavior and d) a decision matrix containing pros and cons of the current behavior and target behavior. Additionally, employees are provided with a toolkit containing a waist circumference measure tape, a pedometer, existing information flyers and a diary in which target behavior can be monitored. During the counselling sessions, the OP moves the employee towards a decision balance and increases perceived behavioral control by formulating a maximum of three implementation intentions. Barriers can be discussed for each goal and the

employee can set rewards for reached goals. Additionally, in order to identify environmental opportunities for reaching goals, the work environment is discussed as well as possibilities for social support.

In total, 5 counselling sessions are planned. During the first session, motivation for change is addressed. After 3 weeks a second session takes place in which goals are evaluated and updated. To enhance motivation and adherence to the personal goal behaviors, a third and fourth session are planned after 6 and 12 weeks. Due to time issues these two sessions can be by phone rather than face-to-face. Again, goals are evaluated and eventually updated. At the end of the intervention period after 6 months, a final counselling session will focus on the goals that have or have not been achieved, and on maintenance of healthy behavior.

Ultimately, the aim of the guideline is to incorporate attention for weight gain prevention in the company's health policy, which is supported by all relevant stakeholders (evaluation and maintenance, *section c*). Interviews among employers and employees revealed that an evaluation and/or maintenance plan for health initiatives are rarely exist. This section was therefore addressed separately in the guideline.

Regarding prevention at the environmental level, the guideline recommends to evaluate to what extent the health policy is carried out after 6 months. In case the health policy is not or (only) partly implemented, possible reasons and barriers should be discussed. In order to maintain attention for the health policy, this issue should be addressed at least once a year in a meeting with the employer and the workers' representative council. Additionally, ongoing efforts should be made to evaluate risk factors that may induce relapse.

With respect to prevention at the individual level, short term goals should be evaluated after 12 weeks. When goals are reached, the OP is asked to compliment the employee on this achievement and to discuss long-term goals for maintaining this healthy behavior. Goals that have not been reached are discussed and the action plan is revised. Additionally, an active provision of information should be realized in order to maintain attention for healthy behavior, for example during other consultations than preventive medical examinations.

According to the commentary phase of the Netherlands Society of Occupational Medicine protocol, the draft guideline was sent to a sample of experts in the field of lifestyle. Comments, mainly concerning clarification of text and terminology, were discussed and the text was adapted.

A	**Prevention at the environmental level** advice for the employer					
1	Inventory obesogenic risk factors in the work environment using the environment scan.					
2	Inventory if current health policy is adequate.					
3	Inform and advise the employer and workers' representative council.					
B	**Prevention at the individual level** advice for the employee					
	During all next steps: maintain good contact with the employee, emphasize confidentiality of results and address resistance to change.					
1	Identify individuals at risk for weight gain.					
2	Set the agenda: which performance objective or other subject would the employee like to address.					
3	Inventory motivation for change and provide stage matched advice to change behavior:					
	Unaware	*Unengaged*	*Deciding about action*	*Deciding not to act*	*Deciding to act*	*Acting*
	Target: knowledge, awareness and attitude. Methods: -tailored feedback -self-monitoring -personalized risk -discuss decisional balance and beliefs	Target: attitude, perceived behavioral control, motivation. Methods: -discuss decisional balance and beliefs -reinforcement -tailored feedback -active learning	Target: attitude, perceived behavioral control to overcome barriers, intention, subjective norm Methods: -discuss decisional balance and beliefs -reinforcement -goal setting -tailored feedback -skill training -social support	Target: attitude Methods: -discuss decisional balance and beliefs	Target: perceived behavioral control to overcome barriers, skills, subjective norm Methods: -positive feedback -skill training -set realistic goals -active learning -reinforcement -form action plan -skill training -social support	Target: perceived behavioral control to overcome barriers, skills, habit, subjective norm Methods: -positive feedback -active learning -evaluate goals -form action plan -skill training -social support -rewarding - relapse prevention skills
4	Plan next counseling session					
C	**Evaluation and Maintenance**					
1	Evaluate prevention at the environmental level after 6 months using the environment scan.					
2	Evaluate prevention at the individual level after 6 months using the employees action plan.					
3	Maintain prevention at the environmental level by setting prevention of weight gain on the company agenda once a year and address relapse prevention.					
4	Maintain prevention at the individual level by addressing the employees long term goals and provide permanent attention for weight gain prevention through active information.					

Figure 3. Occupational health guideline.

Phase 2. Evaluation of the weight gain prevention guideline

The guideline is currently evaluated in a randomised controlled trial among 20 OPs including approximately 600 employees. Phase 2 describes the design of this trial, population, sample size and outcome measures, as well as a plan for adoption, implementation and evaluation (Step 5 and 6 of the IM protocol).

Study design

OPs were randomly assigned to the intervention or control condition by an independent researcher using Random Allocation Software (version 1.0, Isfahan University of Medical Sciences, Iran). Randomization of OPs took place before the baseline measurement, as the first counseling session of the intervention group took place directly after the baseline measurement. OPs in the intervention group were trained during two days in the guideline and associated intervention, including behavioral change counselling by a professional trainer. OPs in the control group were asked to provide care as usual. OPs were asked not to reveal their condition to participating workers. The study protocol was approved by the Ethics Committee of the VU University Medical Center.

Study population

OPs were recruited through a direct mailing by the Netherlands Society of Occupational Medicine to their member registry. OPs providing services to one or more companies of medium to large size (> 100 workers) and conducting preventive medical examinations were eligible to participate. OPs invited employees to participate via their usual channels (written letter, intranet, face-to-face in consultation hours). Inclusion criteria were: 1. unhealthy physical activity and/or dietary behavior and/or overweight, 2. currently not being on sick leave for 21 days or longer, 3. able to complete a Dutch questionnaire and 4. having signed an informed consent form. Unhealthy physical activity was defined as workers who do not meet physical activity guidelines [57]. Unhealthy dietary behavior was defined as workers who do not meet the Dutch national dietary guidelines for fruit- and vegetable consumption and fat [58]. Overweight and obesity were defined by a waist circumference larger than 94 cm and 102 cm respectively for men and larger than 80 cm and 88 cm respectively for women [59]. Obese workers could additionally be referred to the Dutch guideline for treatment of Obesity [60]. Workers were excluded when pregnant or in case a disease or condition was present which made physical activity impossible.

Sample size

The sample size was calculated according to the number of cases needed to identify an effect on waist circumference. Waist circumference was chosen over BMI as it is a more sensitive indicator of abdominal fat mass [61]. A previous study indicated that a difference in waist circumference of 1,5 cm between the intervention and control condition may be clinically relevant [43]. In an intention-to-treat analysis, 175 workers per condition are needed to detect a relative difference of 1,5 cm (standard deviation 4,5 cm) in waist circumference with a power of 80% and an alpha of 5%. As workers are clustered within OPs we adjusted

for dependence of measurements with an intraclass correlation of 0.20. Taking a loss to follow-up of 20-40% into account among workers and OPs until the final measurement, the initial study population should consist of approximately 300 workers among 10 OPs in each study group (figure 4).

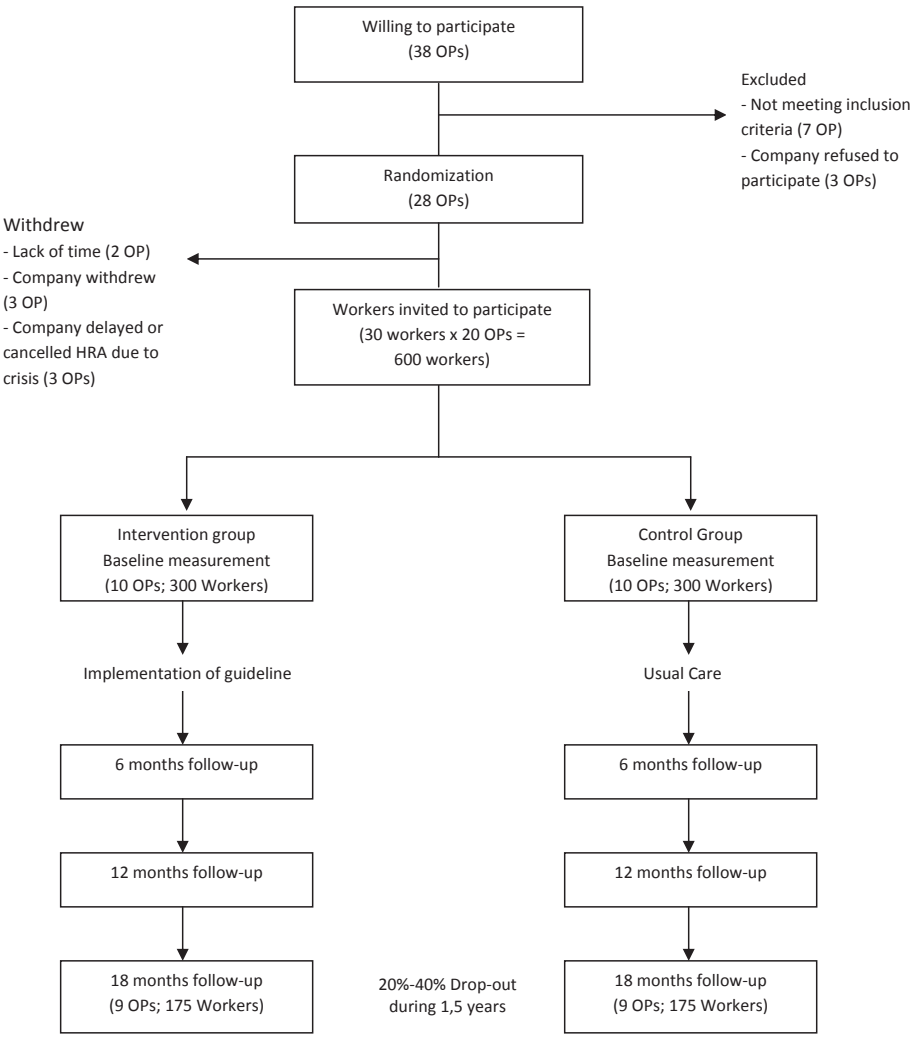

Figure 4. Flow chart of the study population.

Measurements

Questionnaires are sent to employees prior to the initial health risk appraisal. Questionnaires are collected by OPs or their assistants during the health risk appraisal. Biomedical measurements are performed by trained OPs or their assistants following a standard protocol. Follow-up measurements take place after 6, 12 and 18 months.

Primary outcome measures

Waist circumference. Waist circumference is measured as midway between the lower rib margin and the iliac crest to the nearest 0.1 cm [59,62]. Participants are measured in standing position without heavy outer garments and with emptied pockets, breathing out gently. To standardize waist circumference measurement, OPs or assistants were provided with a Seca 201 waist circumference measure (Seca, Hamburg, Germany). Additionally, waist circumference is measured in a random sample of workers (10-20%) at each measurement by an independent researcher.

Physical activity. Daily physical activity is measured with The Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH). The SQUASH assesses activities across 4 domains: 1) commuting activities (walking and cycling to/from work), 2) physical activity at work, 3) household activities and 4) leisure time activities (walking, cycling, gardening, chores and sports). Participants are asked to report the number of days per week spent on each activity during an average week in the past month, as well as the number of minutes per day and the intensity of each activity. The SQUASH is a fairly reliable (spearman's correlation coefficient= 0.58) and reasonably valid (spearman's correlation coefficient=0.45) questionnaire [63]. Total levels of daily physical activity are assessed by two items on the number of days per week moderate intensity activities are performed (such as walking and cycling) for at least 30 minutes (this can be built up by blocks of 10 minutes) and how often per week vigorous intensity leisure time activities ("which make you sweat") are performed during 20 minutes. These items relate to international physical activity guidelines [57] as well as to the Dutch guidelines [64].

Dietary behavior. Dietary behavior is operationalized as the intake of fruit, vegetables, fruit juice and snacks. These items were selected from the validated Short Fruit and Vegetable questionnaire (validity r=0.50) [65] and the Fat list (validity r=0.70) [66]. The number of days per week and the number of daily servings of fruit, vegetables and fruit juice is measured with five items on citrus fruit, other fruits, cooked vegetables, raw vegetables and fruit juice. The consumption of energy dense snacks is assessed by the number of days per week and the number of servings per day in 7 categories (peanuts, chips, cakes, candy bars, biscuits, other cookies and fries). Cut-off points for each behavior are adapted from recommendations of the National Nutrition Centre (The Hague, The Netherlands).

Secondary outcome measures

*Sedentary behavior: S*edentary behavior is specified for work and for leisure time. Sedentary behavior at work is asked as the number of minutes per day spent on computer use, meetings and other activities. Leisure time sedentary behavior is asked as the number of minutes per

day spent on watching tv, computer use and other activities. Answers are specified for week days and weekend days [67]. Additionally, total duration of sedentary behavior is asked per week as well as per weekend day during the last 7 days (IPAQ).

Determinants of behavior change. Based on the TPB, attitude, subjective norm, perceived behavioral control and intention are included on a 5-point Likert scale for physical activity, dietary behavior and watching one's weight [55]. Additionally, 3 items on barriers and 4 items on habit strength are added [46]. Motivational stage of change, based on PAP-M, is assessed for cycling to work, physical activity at work, leisure time physical activity, fruit consumption, snack consumption and watching one's weight [39].

Weight-related factors. Body weight and body height are measured with the participants standing without shoes and heavy outer garments. Weight is measured to the nearest 0,5 kg. Height is measured to the nearest 0,1 cm. Participants are asked to push their heels softly to the wall, or the back of stadiometer [62]. BMI is calculated from measured height and weight as kg/m^2.

Health-related factors. Systolic and diastolic blood pressure (in mmHG) are measured in a seated position, after several minutes of rest. OPs are asked to follow the standard Dutch protocol for blood pressure measurements [68]. Total serum cholesterol is measured, and if feasible for OPs, HDL and LDL cholesterol are measured as well (mmol/l). As OPs apply the guideline during their daily practice, the type of instruments used for blood pressure and cholesterol measurements may vary between OPs. The type of instruments used is asked retrospectively, and OPs are requested to use the same instruments throughout the trial.
Cardiovascular disease risk profile is calculated using the European Systematic Coronary Risk Evaluation instrument (SCORE) based on systolic blood pressure (mmHG), cholesterol levels (mmol/l) gender, age and smoking status [69]. Quality of life is measured by the validated EuroQol [70]. Presence of chronic disease and medication use are asked for hypercholesterolemia, hypertension, angina, heart disease, myocardial infarct, COPD, arthritis, cancer, depression and diabetes.

Work related factors. Productivity and absenteeism are measured by the HPQ. In the HPQ, work productivity is conceptualized as a measure of actual performance in relation to possible performance (i.e. presenteeism) [71]. Productivity is assessed with two items, measuring absolute and differential productivity (i.e., productivity compared with others). Absenteeism is measured as the absolute number of workdays missed in the past 4 weeks because of problems with physical or mental health. The HPQ shows good concordance with employer records of work absence and work productivity [72,73].

Process evaluation

The process evaluation will assess eight aspects after the intervention period at 6 months by questionnaire and focus group interviews: context (organizational characteristics that affect the intervention), recruitment (sources and procedures used to recruit OPs and employees), reach (attendance rates of employees), dose delivered (the amount of intervention components actually delivered by the OP), dose received (the extent to which employees use materials or components recommended by program), participant's attitudes (the OPs and employees attitudes toward the quality of the intervention in terms of credibility and usefulness), fidelity (the extent to which the intervention was delivered as planned), and the link between results and process (to explain possible success or failures of the intervention) [74,75]. Moreover, OPs and workers are asked to rate the intervention with an overall score on a scale 1-10. Regarding fidelity, the extent to which OPs adhere to the guideline is assessed with performance indicators. Additionally, the OPs competence in behavior change counselling is assessed by rating three taped counselling sessions with the behavior change counselling index [76]. From each tape 10 minutes are randomly selected and scored by the MI trainer, who then provides feedback to the OPs. The behavior change counselling index shows acceptable levels of validity, reliability and responsiveness [76].

Economic evaluation

An economic evaluation will be conducted alongside the trial and include a cost-effectiveness analysis and a cost-utility analysis. Both analyses will be performed from a societal perspective and a company perspective. The time horizon will be 18 months, similar to the trial. The analysis will be performed according to the intention-to-treat principle. From the societal perspective, in the cost-effectiveness analysis the difference in incremental costs (in €) between the conditions will be related to the difference in waist circumference (in % change) between the intervention and control group. The costs include intervention costs (costs that are directly related to the intervention, such as the costs of training OPs and costs of intervention materials), direct health care costs (for example, costs of physiotherapy and hospitalisation) and indirect health care costs (such as costs for a healthy lifestyle, such as sports contribution fees and sports clothing). Costs will be valued using Dutch guideline prices for economic evaluation. With respect to the company perspective, the costs of the intervention and other costs related to the company will be included (such as reduced productivity and absenteeism) and compared to the difference in waist circumference (in cm) between the conditions. Absenteeism and productivity are measured every 3 months with the HPQ using cost-diaries [73]. The cost-utility analysis will focus on the difference in costs (in €) between the conditions per QALY (Quality Adjusted Life Year) gained. Utilities will be measured using the social tariff of EuroQol with Dutch reference values. Bootstrapping will be used for pair-wise comparison of the mean differences in costs between the two groups. Confidence intervals (95%) will be obtained by bias corrected and accelerated bootstrapping. Cost-effectiveness and cost-utility ratios will be calculated by dividing the difference in the mean costs between the study groups by the difference in the mean effects. Acceptability curves will be calculated, showing the probability that the guideline

is cost-effective at a specific ratio. Furthermore, sensitivity analyses will be performed to assess the robustness of the results. All analyses will be performed using SPSS 15.0 (SPSS Inc. Chicago, Illinois, USA).

Data analysis

The effectiveness of the weight gain prevention guideline will be analyzed after 6 months (short term) and after 18 months (long term) by means of multilevel analyses. Multilevel analyses accounts for the clustering of observations of workers within the same OP, as well as repeated measurements within one worker. Due to randomization at the OP level, short term data will be analyzed with two levels: 1. worker and 2. OP. Long term data will be analyzed with three levels: 1. time (3 follow-up measurements at 6, 12 and 18 months), 2. worker and 3. OP. Both crude and adjusted analyses will be performed. The multilevel analyses using the follow-up measurement (i.e. 6 months) as dependent variable will be adjusted possible confounders such as, gender, age and education. These variables will also be checked for effect modification. The long-term effect of the intervention will be analyzed using all three follow-up measurements (i.e. 6, 12 and 18 months) adjusted for possible confounders. Effect modification is checked. All statistical analyses will be performed according to an intention-to-treat principle. The investigator analysing the data is blinded to the randomization. A two tailed significance level of $p<0.05$ is considered statistically significant. Analyses will be performed with SPSS 15.0 (SPSS Inc. Chicago, Illinois, USA) and MLwiN for multilevel statistical analyses.

Phase 3. Implementation of the weight gain prevention guideline

Based on the (cost-) effectiveness evaluation and process evaluation, the guideline will be adapted. At this stage, the expert group will be consulted for advice on finalising and implementing the definite guideline in OPs in the Netherlands. Additionally, the Diffusion of Innovation Theory is used, which describes the decision-making process which occur through a series of communication channels over a period of time among the members of a similar social system [77]. The final guideline will consist of 1) the guideline text, which is formulated as a structured stepwise sequence of recommendations for practice, 2) a one page summary leaflet and 3) a background document, in which the levels of evidence for the recommendations are indicated and reference to the most important literature is given. Additionally, implementation tools will be produced, such as knowledge tests, checklists, desktop summaries, and employer and employee versions of the guideline. After authorisation by the Netherlands Society of Occupational Medicine, the guideline will be published and disseminated among OPs and occupational health services across the Netherlands. Training in application of the guideline will be organised. Additionally, the guideline may be incorporated in post-graduate and refresher courses and in the primary OP-training at the schools of occupational medicine. The control group will receive the training after the follow up period of the trial is terminated.

Discussion

The purpose of this paper was to outline the rationale and development of a new occupational health guideline aimed at preventing weight gain. With a focus on both physical activity and dietary behavior, using individual counselling and considering environmental influences, this guideline may have great potential. Practice guidelines are particularly useful if there is a large variation in current practice; if they contain new evidence with an important impact on health management; if they affect many individuals at high risk or involve such high costs that even small changes in practice could have major impact on health outcomes or resources [18]. An occupational health guideline aimed at the prevention of weight gain may therefore be important because 1) there is a need to address overweight on a larger scale in the Netherlands, as overweight is associated with an enormous public health impact as well an economic burden, 2) it enhances the professional quality of OPs and 3) it provides OPs with a practical guideline on how to advice on preventing weight gain.

Several limitations must be mentioned in this study design. First, as the guideline consisted of several components it may not be possible to evaluate the separate effect of each guideline component. Second, not all parameters could be standardized, such as the recruitment of workers which is done in a variety of ways by different OPs. This, however, reflects the practice-based nature of guidelines and may also be a strength of this study, as each OP provides tailored feedback [21]. Finally, the two day training may be too short as the behavioral change counselling technique is new to most OPs.

This study has several strong points as well. To our knowledge, this is the first study to extensively evaluate a practice guideline aimed at prevention. Moreover, after evaluation the guideline will be implemented broadly in the Netherlands. Also, as the guideline is developed together with relevant stakeholders, most of the intervention components can be implemented at larger scale without concerns. Finally, participating occupational physicians are distributed throughout the Netherlands in different types of companies, resulting in a heterogeneous employee sample.

The systematic development of the guideline according to the evidence-based guideline development protocol of the Netherlands Society of Occupational Medicine, in combination with the IM protocol is an innovative element in combining evidence- and practice based medicine. Based on a (cost) effectiveness and process evaluation, the guideline can be adapted before implementation on a larger scale in OPs throughout the Netherlands.

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Additional File 1. Performance objectives related to changes in individual determinants with regard to increasing the level of physical activity of employees (program objective 1).

Performance objectives	**Individual determinants**					
	Knowledge	Awareness	Attitude	Skills	Perceived behavioral control	Subjective Norm
1. Employees monitor their level of physical activity.	Employees know the PA recommendations	Employees become aware of their own PA levels Employees monitor and report the their own PA		Employees learn how to compare their PA to these recommendations	Employees feel confident about registering their daily PA	
2. Employees indicate reasons to be physically active	Employees know about the health benefits of being physically active	Employees become aware of the personal relevance of being physically active	Employees feel positive about being physically active	Employees can describe their reasons for being physically active	Employees feel confident about being physically active	Employees indicate that being physically active with colleagues, friends and family can be stimulating
3. Employees indicate barriers for being active	Employees know about their barriers for being physically active	Employees become aware of the personal relevance of being physically active		Employees can describe their barriers for being active		
4. Employees identify solutions to take away barriers to being physically active	Employees learn how to identify difficult situations and can indicate personal solutions	Employees become aware of barriers that prevent them from being physically active	Employees feel positive about overcoming barriers with their solutions	Employees learn to compare and describe solutions to barriers	Employees feel confident about overcoming barriers to being physically active	Employees are aware that colleagues, friends and family can help overcome barriers to being physically active
5. Employees decide to become more physically active		Employees become aware of what to change to become more physically active	Employees feel positive about becoming more physically active	Employees learn how to be more physically active	Employees feel confident about being more physically active	Employees make colleagues, friends and family aware to help them become more physically active
6. Employees make plans to become more physically active	Employees know how to become more physically active	Employees become aware of what to do to become more physically active	Employees feel positive about their plan for being more physically active.	Employees learn to set feasible goals (characterized by small behavioural changes)	Employees feel confident about being able to act according to the formulated implementation intentions, especially in difficult situations	Employees engage colleagues, friends and family to help them become more physically active
7. Employees increase their physical activity	Employees know how to increase their physical activity		Employees feel positive about increasing their physical activity	Employees can increase their physical activity	Employees feel confident about increasing their physical activity	Employees increasing their physical activity with help of colleagues, friends and family
8. Employees evaluate whether the causes of insufficient activity are taken away, evaluate the effects and maintain their level of PA by enhancing their routine and preventing relapse	Employees know how to evaluate and maintain their physical activity	Employees are aware of the relevance to evaluate and maintain their physical activity	Employees feel positive about evaluating and maintaining their physical activity	Employees can evaluate behavioral changes, indicate causes for success or failure and maintain their physical activity	Employees feel confident about evaluating and maintaining their physical activity	

Chapter 4

Process evaluation of an occupational health guideline aimed at preventing weight gain among employees

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Abstract

Objective To evaluate the process of an occupational health guideline aimed at preventing weight gain.

Methods Quantitative data on seven process items were assessed, and linked to effects on employees' waist circumference and body weight at 6-months.

Results Occupational physicians (n=7) implemented the guideline partly with respect to the environmental level, but performed well at the individual level. Behavioral change counseling was performed 'to some extent'. Employees (n=274) showed high reach (86%), satisfaction (7.1) and attendance rates (4.4 of out 5 sessions). Significant effects were found on waist circumference (-1.5 cm to -2.1 cm) and body weight (-0.9 kg to -1.4 kg) among employees with higher attendance and satisfaction rates.

Conclusions Workplace health promotion via an occupational health guideline is feasible, but the environmental component and behavioral change counseling need revisions before practical application.

Background

Occupational health services research has become considerably more important over the past years, due to the demand for effectiveness of care, the need for costs management and the development of guidelines aimed at health promotion [1]. Research on the effectiveness of guidelines shows that they often do improve clinical practice, but the impact of practice guidelines on quality of care is often hampered by factors such as low compliance rates and a lack of dissemination and implementation strategies [2]. Understanding what happens during an intervention and how that has affected program impact is therefore an increasingly important part of occupational health services research [1,3].

In the Balance@Work project, the effectiveness of a draft occupational health guideline aimed at preventing weight gain among employees is evaluated in a randomized controlled trial [4]. As overweight and especially obesity are related to high morbidity, mortality and healthcare costs [5-7], preventing weight gain through the promotion of physical activity and healthy dietary behavior is important for achieving and maintaining a good health throughout life [8]. The guideline consists of an environmental component for which occupational physicians (OPs) provide advice to employers on how to assess and intervene on the obesogenic work environment, and an individual component describing how OPs can promote physical activity and healthy dietary behavior of employees, during five counseling sessions within six months. As a third element in the guideline, evaluation and maintenance by OPs of previously mentioned components was imposed.

Following the consolidated standards of reporting trials (CONSORT), this process evaluation reports in detail how the intervention was administered [9]. Although outcome evaluation has the most impact on decision making of new health policy, a lack of effect may have been due to the fact that the program was not implemented as intended (type III error) [10]. A process evaluation can thus clarify if flaws are due to the content or performance of the guideline, and may provide recommendations for improvements for occupational health practice [11,12]. Process evaluation is especially necessary in multifaceted and multisite trials, where the intervention may be implemented and received in different ways [13]. Moreover, because effects of preventive interventions on outcome measures such as waist circumference and body weight may be small, process data may in some cases provide more sensitive measures of quality than outcome data [14]. Therefore, the aim of this study was to evaluate important process parameters of the Balance@Work intervention.

Methods

The process evaluation was carried out as a part of the Balance@Work project. The study protocol was approved by the Ethics Committee of the VU University Medical Center and all participants signed informed consent. Details of the study design have been published elsewhere [4].

Participants

OPs providing services to one or more companies of medium or large size (> 100 workers) were eligible to participate. OPs willing to participate were randomized to the intervention or control condition by an independent researcher with a computer generated list (n=28). Next, OPs were asked to recruit at least 30 employees, via their usual channels (such as written letters, intranet, or consultations). Employees with unhealthy physical activity and/or dietary behavior, or who were overweight according to (inter)national guidelines [15-17] were eligible to participate. Employees were excluded when pregnant, in case a disease or condition was present which made physical activity impossible, if sickness absence lasted for 21 days or longer, or if they were unable to complete a Dutch questionnaire.

The Balance@Work intervention

The draft occupational health guideline was developed according to the protocol of the Netherlands Society of Occupational Medicine and the Intervention Mapping protocol [18,19]. Based on literature, interviews with relevant stakeholders and consensus among an expert group, three sections were distinguished in the guideline: a) prevention at the environmental level (advice for the employer); b) prevention at the individual level (advice for the employee); and c) evaluation and maintenance.

With regard to prevention at the environmental level, an environment scan was developed, which consisted of an overview of environmental risk factors from literature that could contribute to prevention of weight gain (for example; availability of bike sheds and shower facilities, pricing strategies in cafeteria). Based on this overview, environmental goals could be prioritized, and feasibility and barriers for implementation could be discussed with the employer and workers' representative council at baseline and at 6-months follow-up.

With regard to prevention at the individual level, the guideline recommends a minimal intervention strategy for OPs on how to promote employees' healthy lifestyle. For this purpose, intervention OPs were trained during 2 days in behavioral change counseling (including role-playing), an adapted form of motivational interviewing suitable for brief consultations in healthcare settings [20]. OPs were asked to conduct five 20-30 minute, face-to-face counseling sessions during the 6-months intervention period. Eligibly of employees was first assessed using an inclusion checklist. Next, OPs applied the minimal intervention strategy by assessing motivation for change, resistance, and providing stage-matched advice. At follow-up, goals were evaluated and maintenance was discussed OPs were provided with several tools to facilitate change in employees' behavior. Additionally, employees were provided with a toolkit containing a waist circumference measure tape, a pedometer, information leaflets on physical activity and nutrition from the Netherlands Heart Foundations and Netherlands Nutrition Centre, and a diary to monitor behavior.

The last section of the guideline considered the evaluation and maintenance of previous sections. Regarding prevention at the environmental level, the guideline recommended to evaluate to what extent the health policy was carried out after 6 months, using the environment scan. In order to maintain attention for the health policy, it was recommended that the obesogenic environment should be addressed at least once a year with employers and the workers' representative council. Additionally, OPs were asked to evaluate environmental

risk factors that may induce relapse. With respect to prevention at the individual level, OPs were advised to actively provide information with for example monthly posts on intranet, in order to maintain attention for healthy behavior.

Data collection

Following the recommendations of Linnan and Steckler [3], seven process items were assessed; recruitment, reach, context, dose delivered, dose received, satisfaction and fidelity (Table 1). Additionally, the link between process items and change in waist circumference and body weight was assessed with multilevel linear regression analyses. Data was obtained from questionnaires after the 6 months intervention period and was analyzed at two levels: OPs and employees randomized to the intervention group.

Table 1. Process evaluation components and their definition, data collection level and method.

Component	Definition	Level	Data collection method
Recruitment	Sources and procedures used to approach and attract potential participants, the number of randomized OPs and the number of employees that filled out the baseline questionnaire.	OP and Employee	OP follow-up questionnaire and employee baseline questionnaire.
Reach	Number of employees who attended the counseling sessions, reason for missed counseling sessions and the percentage of drop-outs including reason.	OP and Employee	OP registration forms and employee follow-up questionnaire.
Context	Organizational characteristics that affect intervention implementation, including physical, social, political, and economic features.	OP	OP follow-up questionnaire and environment scan.
Dose delivered	The number of intervention materials or components actually delivered by OPs, and the duration and form of the counseling sessions.	OP	OP registration forms and OP follow-up questionnaire.
Dose received	The extent to which participants use materials, resources, or techniques recommended by program.	Employee	Employee follow-up questionnaire.
Satisfaction	Participants' attitudes toward the content, use and limitations of the guideline (OP) or towards the intervention, materials and OP (Employee).	OP and Employee	OP and employee follow-up questionnaires.
Fidelity	The extent to which the intervention was delivered as planned: if OPs adhered to the guideline and adequately performed behavior change counselling.	OP	OP registration forms and taped counselling sessions.
Link between process items and waist circumference and body weight	Multilevel linear regression analyses of process components that may explain the intervention.	OP and Employee	OP registration forms, anthropometric measurements and employee follow-up questionnaire.

Recruitment
At the OP level, recruitment was defined as the sources and procedures used to recruit OPs, the number of OPs that were initially recruited, and the number of OPs that was actually randomized. Additionally, reasons for participation were asked.
At the employee level, recruitment was defined as the sources and procedures OPs used to recruit employees, the number of employees who completed the baseline questionnaire, and the most common reasons for participation and non-participation.

Reach
Reach was defined as the number of employees that attended the counseling sessions. Attendance rates were scored by OPs on registration forms for each counseling session during the intervention period. Reasons for not attending counseling sessions were asked in the employee questionnaire at six months. Furthermore, the number and reason for drop-out were collected continuously by OPs and the principle researcher. If the reason for drop-out was unknown or unclear, OPs and employees were contacted by phone.

Context
Context refers to organizational characteristics that affect intervention implementation, including physical, social, political, and economic features. One multiple choice question on the perceived influence of management support, the economic crisis, time constraints, materials and an open-ended category 'other' was administered in the OP questionnaire at the end of the 6 months intervention period. Additionally, the baseline and follow-up environment scans were analyzed, to assess existing health promotion activities within companies at baseline, and improvements at follow-up.

Dose delivered
Dose delivered was defined as the number of intervention materials or components actually delivered by OPs. In the OP questionnaire, twelve items (yes/no) assessed if OPs had used: the guideline, the environment scan, the registration forms, leaflets for employers, employee eligibility checklist, the minimal intervention strategy, time schedule, protocol for anthropometric measurements, and the four counseling tools (agenda setting chart, risk communication chart, a chart with scales of willingness, importance and confidence to change behavior and a decision matrix). Moreover, the number of counseling sessions delivered by OPs, the duration and the form (face-to-face or by phone) were assessed from the registration forms. Finally, OPs were asked reasons for missed counseling sessions in the 6-months questionnaire.

Dose received
Dose received was defined as the extent to which employees received and used components or materials as recommended by the program. At the end of the 6-months intervention period, employees were asked if they attended any of the counseling sessions with the OP and used the provided materials: the waist circumference measure tape, pedometer,

information leaflets and diary. One open-ended question asked reasons for not using any of the materials.

Participant satisfaction

We assessed satisfaction among OPs regarding the content, use and limitations of the guideline as (dis)agreement with 22 statements on a five-point Likert scale (Table 2). Satisfaction with the 12 materials or components stated under dose delivered, was assessed with yes or no questions. Finally, OPs were asked to rate the guideline with an overall score on a scale 1-10.

Employee satisfaction was measured in several ways. First, employees were asked if they found the materials (waist circumference measure tape, a pedometer, information flyers and a diary) interesting, clear, and applicable. Second, participants' attitude toward the OP was assessed with a short version of the Patient Satisfaction with OP questionnaire [21], in which seven statements were asked on a five-point Likert scale ranging from 'no agreement' to 'full agreement'. Finally, employees were asked to rate the intervention with an overall score on a scale 1-10.

Table 2. Occupational physicians (n=7) agreement with statements on the content, use and limitations of the guideline.

Statements	Agreement (n)
Content of the guideline	
1. The content of the guideline is clear and understandable	6
2. The guideline has a sound scientific basis	5
3. The guideline considers individual characteristics of employees	6
4. The guideline provides enough opportunity for an own assessment	7
5. The guideline provides enough opportunity to take employee preferences into account.	7
Use of the guideline	
6. The guideline fits with the way we work at our occupational health service	5
7. The guideline is feasible for postgraduate courses	5
8. The layout makes the guideline easy to use	3
9. I have not read or remembered the guideline thoroughly	1
10. I find it difficult to change my routines	3
11. I have seen more employees due to this guideline than I would normally have	7
12. I expect to improve my guidance of employees because of this guideline	5
13. I have not achieved good results among my group of employees	2
14. Employees are not cooperating to the guideline	2
15. Working according to this guideline should be compensated financially	1
Limitations of the guideline	
16. Certain components of the guideline are incorrect.	0
17. The guideline is too complex	0
18. I miss certain knowledge to apply the guideline correctly	1
19. The guideline is not feasible due to time constraints	3
20. Working according to this guideline is time consuming	4
21. The time schedule for contact moments is not realistic	4
22. The guideline is feasible, but participating in the research project is time consuming	5

Fidelity

Fidelity refers to the extent to which the intervention was delivered according to protocol. Fidelity was assessed in two ways. First, guideline adherence by OPs was assessed from the registration forms with twelve performance indicators (PIs) found relevant by the research team (Table 3). Performance indicators can be used to assess whether the most important recommendations of the guideline were carried out by OPs. Each performance indicator that was met received a score 1, corresponding with guideline adherence. Each performance indicator that was not met received a score 0, reflecting no guideline adherence. An average performance rate was calculated, for which a higher performance rate corresponded with higher guideline adherence.

Second, adherence to behavior change counseling by OPs was assessed by rating three taped counseling sessions per OP with the behavior change counseling index (BECCI) [20]. From each tape 10 minutes were randomly selected and scored by a professional trainer. The eleven items of the BECCI were scored on a 5-point scale ranging from 0 (not at all) to 4 (a great extent), and reflect the degree to which each behavioral change action was carried out. By calculating the mean score, the extent to which OPs practice behavioral change counseling as a whole could be obtained. For example, a mean score of 2.9 shows that behavioral change counseling was carried out 'a good deal', and a score 1.5 shows behavioral change counseling was carried out between 'minimally' and 'to some extent'. Finally, an overall judgment was made if the counseling was client-centered by assessing if the OP spoke (less than) half of the time. The behavior change counseling index shows acceptable levels of validity, reliability and responsiveness [20].

Effects on waist circumference and body weight

Multilevel linear regression analyses were performed to determine effects of process items on waist circumference (cm) and body weight (kg) at follow-up, corrected for baseline values, age and gender. Waist circumference was measured as midway between the lower rib margin and the iliac crest to the nearest 0.1 cm. Participants were measured in standing position without heavy outer garments and with emptied pockets, breathing out gently. To standardize waist circumference measurement, OPs or assistants were provided with a Seca 201 waist circumference measure (Seca, Hamburg, Germany). Body weight was determined without shoes and heavy outer garments, to the nearest 0.1 kg. The following process items were analyzed: the number of counseling sessions (continuous), use of materials (1=yes, 0=no), seven statements on satisfaction with OP (1=(fully) agree, 0=neutral and (fully) disagree), rating on a scale 1-10 (1=≥8, 0=<8), and performance indicators (total scores). Analyses were performed using Multilevel software version 2.1 [22]. P-values less than 0.05 were considered statistically significant.

Table 3. Performance indicators of guideline adherence, their description and performance rate.

	Performance indicator	Description	OP (n=7)	Employee (n=201)
	Prevention at the environmental level			
1	Inventory obesogenic risk factors in the work environment	Risk factors for unhealthy behavior and/or weight have been assessed in the obesogenic work environment with the environment scan.	7 (100%)	
2	Inform and advice employer and workers' representative council	Based on the risk factors, given the current health policy, the employer and workers' representative council are informed and advised.	1 (14%)	
	Prevention at the individual level			
3	Use of the checklist to Identify individuals at risk for weight gain.	Groups at risk for weight gain are identified using the employee eligibility checklist.		155 (77%)
4	Set objectives: which would the employee like to address	Individual objectives are set		189 (94%)
5	Inventory motivation for change and make an action plan	An action plan is formed		179 (89%)
6	Duration consult	First consult: minimal 15 minutes		201 (100%)
7	Timing consults	Second consult after approximately 3 weeks.		132 (66%)
8	Delivery method	Three face-to-face sessions in the first, second and fifth consult.		160 (80%)
	Evaluation and Maintenance			
9	Environmental level	At 6 months, the health policy is evaluated with the environment scan.	3 (43%)	
10	Individual level	At 6 months, the individual plan is evaluated		178 (89%)
11	Maintain prevention at the environmental level by setting prevention on the company agenda and addressing relapse prevention	The (improved) health policy is put on the agenda There is attention for relapse prevention	2 (29%)	
12	Maintain prevention at the individual level by addressing employees' long term goals.	Plans are discussed with the employee to continuate healthy environment.		129 (64%)
		Total guideline adherence:	47%	82%

Results

Recruitment

OPs were recruited by the Netherlands Society of Occupational Medicine via a direct mailing to their member registry in January 2009 (>2,100 OPs). Initially, 38 OPs (2%) expressed an interest to participate, mainly because they wanted to learn how to deal with resistance of

employees towards lifestyle advice, to have a starting point for new health management, or because of corporate social responsibility. After a second, more detailed written description of the project, ten OPs were excluded because they did not meet inclusion criteria (n=7) or their company refused to participate (n=3). Thus, 28 OPs were randomized. Between randomization and the baseline measurement, twelve OPs withdrew due to a lack of time (n=3), their company withdrew (n=4), or their company cancelled the project due to the economic crisis (n=5). Therefore, the Balance@Work project started with seven intervention OPs and nine control OPs.

Employees were recruited between March 2009 and March 2010 by OPs via multiple strategies, such as a personal written invitation, advertisements on intranet or the staff magazine, via management, or during face-to-face consultations. None of the OPs found recruitment difficult. The number of invited employees per OP ranged from 40 to 350. The main reasons mentioned by employees to participate were; to reduce weight, to maintain health, to improve physical activity, and curiosity towards the intervention. Most common reasons for employees not to participate were; no time, no interest, no confidence in a positive result, and already being healthy. In total, 274 intervention employees filled out the baseline questionnaire.

Reach

During the 6-months intervention period, none of the OPs dropped out. Among employees, 237 (86%) filled in the 6-months questionnaire. Reasons for employees to drop-out (n=37) were: lack of time, lack of motivation, missed appointments, change of job, sickness absence, or no reason was given. Based on 201 registration forms from 6 OPs, employees attended 4.4 out of 5 counseling sessions on average. Reasons for not attending counseling sessions (n=16) were: no need, no priority, missed appointments, sickness absence, already being healthy, or no reason was given.

Context

Of the seven intervention OPs, three responded that there were no barriers to implementing the Balance@Work intervention within their company. Four responded that the project took more time than planned due to aspects such as administration and planning. Additionally, two of these OPs stated that employees were difficult to reach and maintain, one had limited materials at her disposal and one had trouble carrying out the intervention because of different company locations. One OP was able to incorporate the guideline into an existing health risk appraisal, the other six OPs set up separate counseling sessions for the Balance@Work study. Lack of management support and the economic crisis were not stated as barriers.

With regard to the content of the baseline environment scans, all companies invested in promoting physical activity and a healthy dietary behavior. For example, all companies promoted transport- and work-related activities (such as a bike plan and sports facilities), and more than half of the companies promoted leisure-time activities (such as sport discounts), provided free fruit at work or offered healthy alternatives in order to reduced energy intake

from snacks. Nevertheless, only three companies discussed the obesogenic environment with management or the workers' representative council. At the 6 months follow-up measurement, three companies showed improvements in the environment scans, such as sports groups and discounts, changes in the cafeteria due to a new caterer, and free fruit at work. Of the companies with improvements, only one OP, however, attributed the recent environment changes to the guideline. The other OPs found changing the environment difficult, because there were already (sufficient) events or facilities present, there was not enough time to implement changes, and it received no priority from the employer.

Dose delivered

The materials were used by most OPs, except for the leaflets for employers, agenda setting chart and risk communication chart. Of the five counseling sessions, 86% was delivered by OPs. Of these counseling sessions 86% was conducted face-to-face and 14% by phone. The average duration of the sessions was 26 minutes (range 15-60 minutes) for the first meeting, and 18 minutes (range 10-30 minutes) on average for the next four sessions. OPs stated their reason for missed counseling sessions were mainly due to time constraints, such as holidays, and missed appointments.

Dose received

Based on self-reported data of employees, 72% attended a counseling session. Moreover, 60% read the information flyers, 42% used the waist circumference measure tape, 34% used the pedometer, and 20% used the diary to monitor target behaviors. One participant did not receive the intervention materials. Main reasons stated by 92 employees for not using materials were: lack of time, lack of motivation, no priority, no need not useful, too much work to use materials, the pedometer did not work, or lost the materials.

Participant satisfaction

Satisfaction of OPs with the content, use and limitations of the guideline was assessed using 22 statements (Table 2). The content of the guideline was evaluated as clear, understandable, and with a proper scientific basis by the majority of the OPs. Moreover, most agreed that the guideline took individual characteristics and preferences of OPs and employees into account. Regarding use of the guideline, OPs felt the guideline fit their work and to be feasible for postgraduate courses. Moreover, all OPs stated to have seen more employees than usual because of the guideline, and most of them expected to improve their performance and to achieve good results. According to OPs, improvements could especially be made on layout of the guideline and on support for OPs in changing their routines. With regard to limitations of the guideline, none of the OPs stated that the guideline was too complex or incorrect. Nevertheless, one OP stated to miss certain knowledge to apply the guideline correctly, three OPs stated the guideline was not feasible due to time constraints, and four stated that working according to this guideline was time consuming and that the time schedule for contact moments was not realistic. However, five OPs attributed time constraints to participating in the research project, and not to using the guideline itself. OPs were satisfied

with the materials as stated in dose delivered, but all found waist circumference difficult to measure. Overall, OPs rated the guideline 7.6 (SD 0.5) on a scale 1-10.
Employees found the counseling sessions and information leaflets most interesting, clear and applicable. However, less than half of the employees found the diary, step counter and waist circumference measure interesting and applicable. Notably, over 80% of the employees agreed with all seven OP satisfaction questions. Overall, employees rated the Balance@Work intervention with a 7.1 (SD 1.0) on a scale 1-10.

Fidelity
Guideline adherence assessed with twelve performance indicators is presented in Table 3. The mean performance rate for the environmental components of the guideline was 47%. Informing the employer and workers' representative council (PI 2), and evaluation and maintenance (PI 9 and 11) could especially be improved. The mean performance rate for the individual components of the guideline was 82%. The timing of consults (PI 7) and individual maintenance plans (PI 12) could be improved. Overall, guideline adherence was moderate.
The OPs competence in behavior change counseling was assessed by a professional with the BECCI. Five OPs were able to provide 11 taped counseling sessions. Per OP, scores ranged from 1.4 - 2.5, indicating behavioral change counseling was performed between 'minimally' and 'a good deal'. The mean BECCI score across all taped counseling sessions was 2.1. Thus, OPs generally performed actions 'to some extent'. Higher scores were seen for items 'agenda setting' (i.e. the OP invites the employee to decide what to talk about) and 'empathic listening'. Improvements could especially be made on 'talking about current behavior' and 'talking about behavior change', 'how employees feel about a topic' and 'proving information sensitive to patients concerns and understanding'. All OPs talked (less than) half of the time, indicating that the counseling was performed client-centered.

Effects on waist circumference and body weight
Significant reductions in waist circumference or body weight were seen for employees that attended more counseling sessions based on self-report (-1.5 cm [95% CI -3.0 to -0.1] and -0.8 kg [95% CI -1.8 to 0.3]) and based on registration forms (-2.1 cm [95% CI -3.1 to -1.1] and -1.2 kg [95% CI -1.9 to -0.4]). Significant reductions were also seen for employees who agreed that the counseling sessions improved their physical activity and dietary behavior (-2.1 cm [95% CI -3.3 to -0.9] and -0.9 kg [95% CI -1.8 to -0.1]), and rated the Balance@Work intervention an 8 or higher (-1.9 cm [95% CI -3.1 to -0.7] and -1.4 kg [95% CI -2.2 to -0.5]). No effects were found for employees who used the materials (diary, pedometer, waist circumference tape and information leaflets), and for performance indicators (data not shown).

Discussion
The aim of this paper was to describe the process of the Balance@Work intervention. The results show that reach and satisfaction in general was high. Moreover, employees with higher attendance and satisfaction rates showed significant improvements on waist

circumference and body weight. However, the results from the items fidelity and context show that the environmental component and the behavioral change counseling need revisions in order to increase potential of the guideline for practical application.

The recruitment of OPs via the Netherlands Society of Occupational Medicine allowed for a fast and easy recruitment. Compared to participation rates of 9%-22% from other worksite health promotion programs however, our participation rate of 2% is low [23]. This may indicate that our group of OPs is selective and highly motivated, and thus cannot be considered representative for all Dutch OPs. Nevertheless, no extra recruitment efforts were made as we reached a sufficient number of OPs for our study. Moreover, reasons for those OPs who withdrew between randomisation and baseline were all related to the companies and not to motivation of OPs. As all OPs remained in the study at follow-up, it seems that the guideline met their need for evidence- and practice based methods and strategies to promote physical activity and healthy dietary behavior [4].

Overall, the guideline was partly implemented by OPs as intended with respect to the environmental level, but performed well at the individual level compared to other studies examining the effectiveness of guideline-based care [24-26]. At the environmental level, the baseline environment scans showed that all companies already invested in workplace health promotion before our trial. Contrary to expectations however, only one OP attributed improvements in the environment scans at follow-up to performing the guideline. Thus, there seems to be a gap between assessing the obesogenic environment and actually changing this environment. The guideline may not have provided sufficient practical guidance or materials for OPs to implement simple environmental changes within 6 months that have shown to be effective, such as prompts on posters to increase stair use [27], or point-of-purchase signs and food labeling to improve dietary behavior [28]. Such changes may be difficult to induce, but are viewed by experts as essential for obesity prevention [29,30]. Second, although management support was not stated as a barrier, OPs found that their suggested changes did not receive priority from employers. A challenge thus appears to encourage employers to participate. More attention could be paid in the guideline training to physician-employer communication skills [31]. Also, the guideline should encourage the formation of a linkage board. A linkage board can encourage collaboration among all relevant stakeholders, and has previously resulted in effective implementation [19,23]. Specific intervention agreements could even be documented and signed by all stakeholders, in order to ensure that all stakeholders perform their part [32].

The high guideline adherence of OPs at the individual level suggests that this part of the guideline was sufficiently practice-based. The specific attention in the guideline and training for dealing with resistance of employees towards OPs seems to have worked well. OPs did not perceive recruitment of employees to be difficult, and in line with other studies that intervened on employees through OPs, reach was high [33-36]. Moreover, most OPs were able to perform at least three face-to-face counseling session, within the time frame of actual consults (20-30 minutes). Assessment of the counseling sessions with the BECCI however, showed that OPs generally counseled ‘to some extent’. This may be an overestimation as not all OPs returned taped sessions. Additionally, OPs stated that they

felt their counseling skills were insufficient to help employees when stagnation occurred and had a need for more guidance in changing their own routines. A 2-day training with role play was previously sufficient to produce significant improvement in behavioral change counseling skills [37]. Also, better use of counselling skills during weight loss discussions may predict patient weight loss [38]. The training should therefore be improved by focusing more on practicing behavioral change counselling with role play, relapse prevention and changing own routines, and less on project information. Finally, as the personal feedback to OPs was provided near the end of the intervention period and studies have shown that on-demand feedback and advice increases skillfulness [39], OPs should be given more feedback during the intervention period and made aware of refresher counseling courses that are available online which provide direct feedback.

Due to the lack of effect on performance indicators, no part of the guideline could be identified as more effective. The performance indicators however did show that the low attention for maintenance is a pressing problem. Although most OPs evaluated goals with employees at follow-up, they did not discuss long term goals. Moreover, only two OPs stated that maintenance, including attention for relapse prevention, had been set on the company agenda. To date, it remains difficult to achieve sustained attention for weight gain prevention within the workplace [40]. OPs generally work on short contracts and may therefore not have the opportunity to invest in long term plans. To support OPs and employers in constituting evaluation and maintenance plans, examples of successful worksite health promotion initiatives could be added to the guideline [40]. Moreover, performance of the guideline should be linked to existing structures, such as health risk appraisals, to further stimulate continuation and maintenance of health initiatives at the workplace.

Both OPs and employees were satisfied with the intervention. Their positive feedback possibly results from the development of the intervention in collaboration with the key stakeholoders, according to the Intervention Mapping protocol [19]. Improvements could still be made. The lay-out of the guideline was not appreciated, and measuring waist circumference was perceived as difficult. Moreover, OPs stated that the time schedule of five sessions in 6 months was dense, and missed appointments could not always be rescheduled. Nevertheless, time constraints were rarely attributed to executing the guideline itself, but merely to participating in the research project. Employee satisfaction with the OP was very high, possibly because employees felt they could talk freely as OPs counseled client-centered instead of dominant [41]. Most employees did not use the intervention materials, and evaluated them as less interesting, clear and applicable. Cleary, the counseling sessions are a key intervention component.

The significant effects of higher satisfaction and attendance rates on waist circumference and body weight suggests that the most motivated employees will reach better results. This is not surprising, as those who consider the sessions useful are more inclined to adhere to it, and thus more likely to decrease their weight. Similarly, a study on improving fruit and vegetable consumption in children, found that those who enjoyed the project showed significant effect of the intervention compared to those who liked it the least [42]. Thus, focusing on ways to motivate employees may pay off in effects [43].

Conclusion

The results of this process evaluation indicate that the guideline was partly implemented by OPs as intended on the environmental level, but performed well at the individual level. Improvements should be made on both the content and performance of the guideline before implementation, such as better practical guidance or materials for OPs to implement simple environmental changes, the formation of a linkage board, providing examples of successful worksite health promotion initiatives, and linking the guideline to existing health risk appraisals. Moreover, the training should focus more on relapse prevention, physician-employer communication skills, feedback and changing OPs' routines. Finally, more attention should be paid to correctly measuring waist circumference, as measurement error will influence results. These suggestions may also apply for developers of other lifestyle interventions. As workplace health promotion via this occupational health guideline enables successful reach, satisfaction, and effectiveness among employees with higher attendance and satisfaction rates, the guideline may have good potential after these adaptations for broader successful implementation of among occupational health services in the Netherlands.

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Chapter 5

The application of an occupational health guideline reduces sedentary behavior and increases fruit intake at work: results from an RCT

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Abstract

Objective To evaluate the effectiveness of a draft occupational health practice guideline aimed at preventing weight gain on employees' physical activity, sedentary behavior and dietary behavior, and on body weight-related outcomes.

Methods A randomized controlled trial was performed comparing guideline-based care to usual care among 16 occupational physicians and 523 employees in the Netherlands between 2009 and 2011. Occupational physicians in the intervention group followed the draft guideline by providing advice to employers on how to assess and intervene on the obesogenic work environment, and conducted five face-to-face behavioral change counseling sessions with employees to improve their lifestyle. Data of employees were collected by questionnaire and physical measurements at baseline and 6-months follow-up. Linear and logistic regression analyses were performed to determine effects.

Results The intervention showed significant effects on sedentary behavior at work (β -28 min per day, 95% CI -2; -54) and on fruit intake (β 2.1 pieces per week; 95% CI 0.6; 3.6). No significant intervention effects were found for physical activity, sedentary behavior in leisure time or during weekend days, snack intake and body weight-related outcomes.

Conclusion Guideline-based care resulted in a more favorable sedentary behavior at work and increased fruit intake, but did not improve employees' physical activity, snack intake or body weight-related outcomes.

Trial registration ISRCTN/73545254 and NTR/1190.

Introduction

Over 30% of the working population in the Netherlands is overweight, predisposing them to chronic health problems such as cardiovascular diseases and type 2 diabetes [1-3]. Preventing weight gain, through the promotion of physical activity and a healthy dietary behavior is thus an important public health goal [4]. The workplace provides good potential for preventing overweight and obesity, as a substantial amount of daily calories are consumed in the work setting, and opportunities exist to provide health-related information and support regular physical activity [5]. Workplace-based lifestyle interventions have the potential to reduce body weight, to improve health and to reduce sick leave of employees [6-9]. The systematic provision of such interventions in occupational health, however, is lacking [10].

More employers now recognize the need to intervene on the growing population of employees at risk for illness due to overweight and obesity [11], also because of the unfavorable relationship between overweight and obesity and sick leave [9]. Consequently, employers' willingness to conduct preventive health management is growing. In the Netherlands, occupational health services (OHS) assist employers in improving working conditions, and in preventing sick leave and disability at work [12]. These services are provided by occupational physicians (OPs) and other occupational health and safety professionals. When implementing services, developing policies, and evaluating progress, occupational physicians should ideally incorporate evidence-based methods and strategies [13]. In practice however, preventive health management often lacks systematic planning and the use of the best available evidence [14]. In order to assist physicians in decisions, and subsequently improve the professional quality of OPs, a draft occupational health guideline was developed aimed at preventing weight gain [15].

The effectiveness of this draft guideline is evaluated in a randomized controlled trial [10], comparing guideline-based care to usual care. Specific program objectives derived from the process of intervention mapping were that employees should increase their levels of physical activity, decrease their levels of sedentary behavior, increase fruit consumption, and/or reduce the energy intake derived from snacks in order to prevent weight gain. The present study examines the effectiveness of the application of the draft guideline on physical activity, sedentary behavior and dietary behavior, as well as on body weight-related measures (i.e. waist circumference, body weight and BMI).

Methods

Study population

OPs were recruited by the Netherlands Society of Occupational Medicine via a direct mailing to their member registry (> 2,100 OPs). OPs were asked to recruit one or more companies of medium or large size (> 100 workers). Next, OPs recruited employees via a health risk appraisal consisting of anthropometric measurements and a subsequent health advice. Inclusion criteria for the present study were: unhealthy levels of daily physical activity or dietary behavior (i.e. no compliance to public health physical activity or nutrition recommendations) [16-18] and/or being overweight (i.e. waist circumference >80 cm for women and >94 cm for men), able to complete a Dutch questionnaire at baseline, not on

sick leave for more than 21 days, not pregnant or having a disease or condition that would make physical activity impossible. Details of the study design have been published elsewhere [10]. The study protocol was approved by the Ethics Committee of the VU University Medical Center and all participants signed informed consent. The trial was registered at ISRCTN/73545254 and NTR/1190.

Randomization, blinding and sample size

OPs who consented to participate were randomly assigned to the intervention or control group by an independent researcher using Random Allocation Software (version 1.0, Isfahan University of Medical Sciences, Iran). After randomization, the principal researcher notified OPs to which group they were allocated. As OPs themselves were the intervention providers, they could not be blinded for allocation. OPs were asked not to reveal their group to employees or assistants performing measurements. The sample size of workers was calculated according to the number of cases needed to identify an effect on waist circumference. An a priori power calculation to detect a difference of 1.5 cm (SD 4.5 kg) [19] with 80% power and an alpha of 5%, determined that 175 employees per group were needed at follow-up. Taking a loss to follow-up of 20-40% into account and clustering of employees within OPs (intraclass correlation of 0.20), a total of 600 employees among 20 OPs were required at baseline [10].

Intervention and control group

OPs in the control group were asked to provide care as usual, which generally consisted of the health risk appraisal with anthropometric measurements and a subsequent health advice. OPs in the intervention group were asked to provide guideline-based care.

The draft occupational health guideline was developed according to the protocol of the Netherlands Society of Occupational Medicine and the Intervention Mapping protocol [20,21]. Based on literature, interviews with relevant stakeholders and consensus among an expert group, three sections were distinguished in the guideline: a) prevention at the environmental level (advice for the employer); b) prevention at the individual level (advice for the employee); and c) evaluation and maintenance of previously mentioned sections.

With regard to prevention at the environmental level, an environment scan was developed for OPs to discuss with employers, at baseline and at 6-months follow-up. The environment scan consists of an overview of environmental risk factors from the literature, that could contribute to preventing weight gain (for example; availability of bike sheds and shower facilities, pricing strategies in cafeteria). Based on this overview, environmental goals could be prioritized, and feasibility and barriers for implementation could be discussed with the employer, and with the workers' representative council. With regard to prevention at the individual level, a minimal intervention strategy was developed for OPs on how to promote employees' healthy lifestyle in five 20-30 minute counselling sessions during 6 months. For this purpose, OPs were trained during two days in applying behavioral change counseling, an adapted form of motivational interviewing suitable for brief consultations in healthcare settings [22].

In the first counselling session, after having discussed their risk profile and current health status, employees could choose which target behavior they would like to discuss (increasing physical activity, decreasing sedentary behavior, increasing fruit consumption, or reducing the energy intake derived from snacks). Next, ambivalence and motivation for change was assessed by discussing pros and cons of behavior change, and willingness, importance, and perceived confidence to change behavior. OPs then moved employees towards a decision balance and increased perceived behavioral control by asking employees to formulate maximally three implementation intentions. Last, employees set short- and long-term goals. In subsequent sessions, progress and barriers were discussed and short-term goals could be adjusted. No specific weight loss advice was provided, as the guideline aimed to prevent weight gain by improving employees' physical activity and healthy dietary behavior. To monitor their behavior, employees were provided with a toolkit containing a waist circumference measure tape, a pedometer, leaflets on physical activity and nutrition from the Dutch Heart Foundations and the Netherlands Nutrition Centre, and a diary to monitor behavior.
Participants who missed an appointment were reminded by OPs and the research team to make a new appointment. A maximum of five efforts over the course of two months was made to remind non-responders by phone, e-mail and regular mail.

Outcome measures
Outcome measures of the study were physical activity, sedentary behavior, dietary behavior, and body weight-related outcomes (i.e. waist circumference (cm), body weight (kg), and BMI (kg/m2)), assessed at baseline and 6-months follow-up. Behavioral outcomes (i.e. physical activity, sedentary behavior, and dietary behavior) were assessed by questionnaire. Waist circumference, body weight and body height were measured by unblinded OPs (n=5 out of 7 in the intervention group and n=6 out of 9 in the control group) or by blinded clinic employees.

Physical activity
Daily physical activity was measured with the Short QUestionnaire to ASsess Health enhancing physical activity (SQUASH) (reproducibility r=0.58; validity r=0.45) [23]. The SQUASH assesses activities across 4 domains: 1) commuting activities (walking and cycling to or from work), 2) physical activity at work, 3) household activities and 4) leisure time activities (walking, cycling, gardening, chores and sports). Participants recalled the number of days per week spent on each activity during an average week in the past month, and the number of minutes per day and the intensity of each activity. Total levels of physical activity were calculated as the minutes per week of moderate and vigorous intensity physical activity. Also, two questions were related to the public health physical activity recommendations [16,17]. These included questions on the number of days per week that moderate intensity activities were performed (such as walking and cycling) for at least 30 minutes, and the frequency of vigorous intensity leisure-time activities per week ("which make you sweat") that were performed at least 20 minutes.

Sedentary behavior

Sedentary behavior was assessed for work and leisure time, on week and weekend days using a questionnaire that has not yet been tested for validity. Sedentary behavior at work was asked for the average number of minutes per day during the last 7 days spent on computer use, meetings and other activities. Leisure time sedentary behavior was asked for the average number of minutes per day during the last 7 days spent watching tv, computer use and other activities [24]. Total levels of sedentary behavior were asked following the sedentary activity domain of the generic IPAQ, as the average time spent sitting on a weekday and weekend day during the last 7 days [25]. The reliability of the long questionnaire form for the Netherlands is good (Spearmans' ρ=0.87).

Dietary behavior

Fruit intake was assessed with the validated Short Fruit and Vegetable questionnaire (validity r=0.50) [26] as the number of daily servings of fruit per week. Fruit intake was related to the public health recommendation of consuming two or more pieces of fruit per day [18]. The consumption of energy dense snacks was assessed using the Fat list (validity r = 0.70) [27] as the number of daily servings of snacks per week. Snacks were distinguished in seven categories, namely peanuts, chips, cakes, candy bars, biscuits, other cookies and large snacks.

Weight-related measures

Waist circumference was measured as midway between the lower rib margin and the iliac crest to the nearest 0.1 cm. Participants were measured in standing position without heavy outer garments and with emptied pockets, breathing out gently [28]. To standardize waist circumference measurement, OPs or assistants were provided with a Seca 201 waist circumference measuring tape (Seca, Hamburg, Germany). As it was not possible to blind OPs, control measurements were performed by independent researchers in a random sample of 76 workers at baseline and 6-months follow-up (8% of all measurements). Additionally, self-reported waist circumference was assessed from 412 employees at 6-months follow-up (91%) using a non-stretchable paper measuring tape (range 0-130 cm) and written measurement instructions. The difference between OP measured and independent researcher measured waist circumference ranged from -12 cm to 6 cm. No difference was found between intervention OPs and independent researchers (n=32; 0.2 cm SD=1.7; p=0.5), but significant under-reporting was found by control OPs compared to independent researchers (n=44; -2.2 cm SD=3.6; p<0.01). The difference between OP measured and self-reported values ranged from -18 cm to 22 cm. Compared to OPs, both intervention and control employees significantly under-reported their waist circumference by -1.5 cm (n=210; SD=3.9; p<0.01) and -1.4 cm (n=202; SD=3.4; p<0.01). Body weight (kg) and body height (cm) were measured with the participants standing without shoes and heavy outer garments. Participants were asked to push their heels softly to the wall, or the back of the stadiometer. BMI was calculated from measured height and weight as kg/m2.

Statistical analyses

Intervention and control OPs were checked for baseline differences for demographic characteristics (age, gender, years working as an occupational physician), behavior-related variables (physical activity, dietary behavior, smoking and alcohol use), and job-related characteristics of their worker population (blue and/or white collar population, experience with counselling on lifestyle, prevention, or according to guidelines). Moreover, differences on these variables were checked for study completers and OPs lost-to-follow-up.

Intervention and control employees were also checked for baseline differences for several characteristics and outcome variables. To determine the effects of the draft guideline at 6 months, linear multilevel regression analyses were performed with the variable of interest as the outcome, and group allocation and its baseline value as the independent variables. Due to the randomization at OP level, multilevel analysis were performed in order to adjust for the possible dependency of participants' observations within OPs [29,30]. Next, change in waist circumference and body weight were dichotomized as *increased* (reference category=0) and *maintained or decreased* (1) and analyzed with logistic multilevel analyses using a 2nd order predictive quasi likelihood method. Finally, compliance (*yes* or *no*) to meeting public health guidelines for physical activity and fruit intake was assessed with logistic multilevel regression analyses. Analyses were checked for potential confounders age, gender and irregular work hours. Confounding was assigned when >10% change occurred in the regression coefficient. Effect modification was considered for age, gender and BMI measured at baseline, using a p-value<0.10 of the interaction term to indicate effect modification. P-values <0.05 were considered to be significant. All analyses were performed using SPSS software (version 15.0) and MLwiN (version 2.18).

Results

Participants

The flow chart of the participants is presented in Figure 1. After recruitment, 38 OPs expressed an interest to participate. Ten OPs were excluded because they did not meet inclusion criteria or their company refused to participate. Thus, 28 OPs were randomized. Between randomization and the baseline measurement twelve OPs withdrew due to a lack of time, their company withdrew, or their company cancelled the project due to the economic crisis. Therefore the Balance@Work project started with seven OPs in the intervention group and nine OPs in the control group. No significant differences were found between OPs that completed the study and OPs who withdrew between randomization and baseline on demographic, behavior-related or job-related characteristics of their worker population. Moreover, intervention OPs did not differ significantly from control OPs at baseline. During the 6-month intervention period, none of the OPs were lost-to-follow-up.

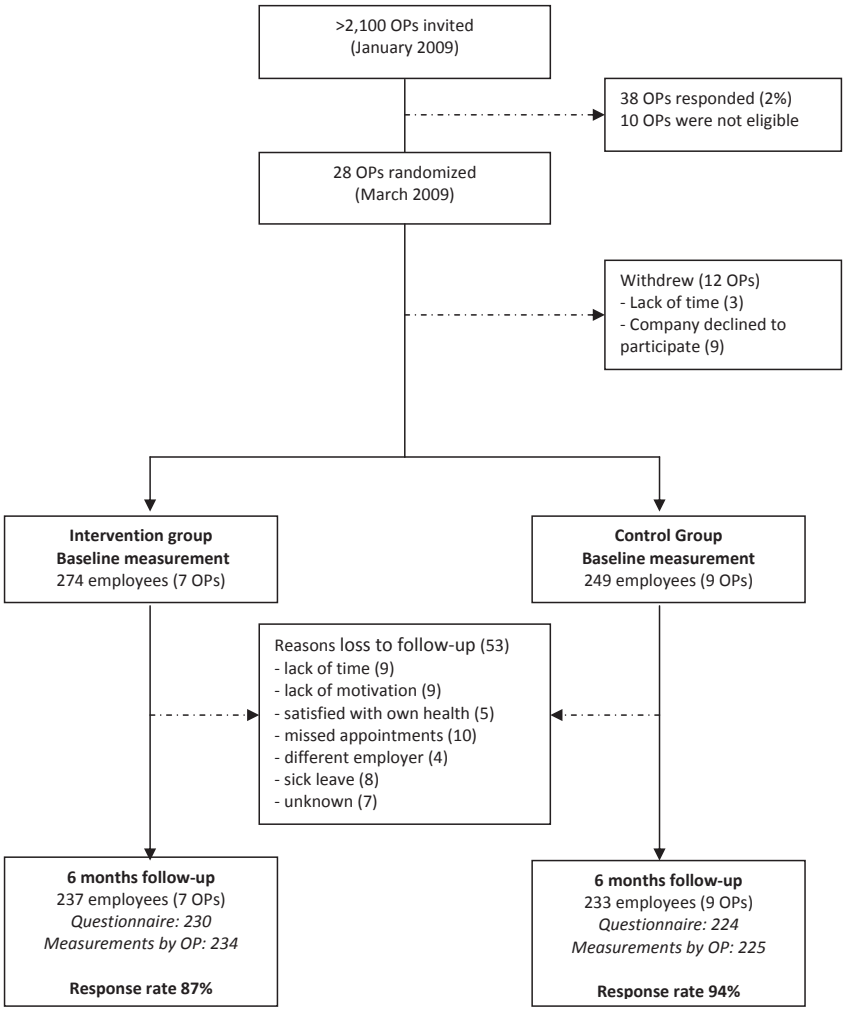

Figure 1. Flow diagram of participants in the Balance@Work study.

OPs recruited 524 participants between March 2009 and March 2010. All employees met the inclusion criteria, but one underweight subject was excluded from analyses because of having a weight gain goal. Baseline characteristics of the two study groups are described in Table 1. Intervention employees differed significantly from control employees on two characteristics at baseline, intervention subjects were younger (46 versus 48 years) and worked less irregular work hours (19% versus 29%). During the 6-month intervention period, subjects from both groups were lost-to-follow-up (n=37 in the intervention group and n=16 in the control group). These subjects (n=53) were significantly younger, females, and had a lower income than study completers.

Table 1. Baseline characteristics of the study population by treatment group.

	Intervention n = 274	**Control n = 249**	**All n = 523**
Gender (% male)	62	65	63
Age, mean (SD)	46 (8)	48 (9)	47 (8) *
Education (% College/University)	55	51	53
Nationality (% Dutch)	89	92	91
Income, mean € per month (SD)	2118 (676)	2214 (781)	2162 (727)
Married/cohabitating (%)	81	85	83
Smoking (% yes)	15	15	15
Body Mass Index (BMI, %)			
Normal weight (18.5≤BMI<25)	33	27	30
Overweight (25≤BMI<30)	40	45	42
Obese (BMI≥30)	27	29	28
Chronic disease (% yes)	40	38	39
Medication use (% yes)	32	31	32
Type of worker (%)	15		16
Blue collar	70	17	72
White collar	15	73	13
Client contact		10	
Irregular work hours (%)	19	29	24 *

*Significant difference p<0.05.

Intervention effects

Physical activity

Table 2 presents the values for moderate, vigorous and total levels of physical activity for baseline and 6 months follow-up, as well as the results of the linear regression analyses. No statistically significant intervention effects were found for moderate, vigorous and total levels of physical activity. The intervention effect on moderate physical activity was modified by BMI. Obese intervention group participants (BMI≥30; n=120) significantly increased their moderate intensity physical activity compared to obese controls (β 150 min per week, 95% CI 24; 276). Normal weight (BMI<25; n=134) and overweight (BMI≥25; n=193) intervention participants did not significantly change in moderate intensity physical activity (β 20 min per week, 95% CI -76; 116; and β -33 min per week, 95% CI -136; 79, respectively).

The results for meeting public health guidelines of moderate and vigorous intensity physical activity are presented in Figure 2. No significant intervention effects were found for meeting these physical activity guidelines.

S*edentary behavior*

No significant intervention effect was found for total levels of sedentary behavior, although both groups slightly decreased in their total sitting time (-57 vs -15 minutes per day) (Tabel 2.). No effects were found for sedentary behavior in leisure time, but the intervention group significantly reduced sedentary behavior at work on weekdays compared to the control group (β -28 min per day, 95% CI -54; -2).

Table 2. Physical activity, sedentary behavior, dietary behavior and body weight-related measures at baseline and follow-up, by treatment group.

	n	Baseline mean (SD)	6 months mean (SD)	Change	B (95% CI)‡
PA moderate (min/week)					
Intervention	229	414 (401)	415 (435)	1	48
Control	219	408 (461)	378 (428)	-30	(-16; 112)
PA vigorous (min/week)					
Intervention	229	87 (159)	103 (161)	16	3.4
Control	219	109 (189)	124 (211)	15	(-19; 26)
PA total (min/week)					
Intervention	213	513 (390)	533(435)	20	35
Control	201	550 (510)	540 (498)	-10	(-43; 114)
SB work weekdays (min/day)					
Intervention	203	446 (201)	431 (143)	-15	-28
Control	193	453 (187)	450 (177)	-3	(-54; -2) **
SB work weekend days (min/day)					
Intervention	69	138 (114)	144 (103)	6	10
Control	81	160 (96)	148 (113)	-12	(-19; 39)
SB leisure time weekdays (min/day)					
Intervention	218	255 (167)	242 (117)	-13	-9
Control	219	255 (143)	253 (152)	-2	(-33; 15)
SB leisure time weekend days (min/day)					
Intervention	214	384 (179)	377 (160)	-7	-6
Control	201	383 (173)	377 (176)	-6	(-40; 28)
SB total (min/day)					
Intervention	210	876 (356)	819 (378)	-57	-20
Control	206	833 (321)	818 (361)	-15	(-85; 45)
Fruit (pieces per wk)					
Intervention	213	10.4 (10.0)	11.9 (10.1)	1.5	2.1
Control	212	10.8 (10.5)	10.0 (8.2)	-0.8	(0.6; 3.6)**
Snacks (pieces/week)					
Intervention	205	19 (13)	15 (11)	-4	0.8
Control	204	18 (14)	14 (10)	-4	(-0.9; 2.5)
Waist circumference (cm)					
Intervention	233	94.1 (12.3)	94.0 (12.6)	-0.1	0.3
Control	222	98.0 (13.2) *	97.2 (12.1)	-0.8	(-1.3; 1.9)
Weight (kg)					
Intervention	233	85.5 (16.2)	84.9 (16.1)	-0.6	0
Control	223	87.5 (16.2)	87.0 (16.1)	-0.5	(-1.1; 1.1)
BMI (kg/m2)					
Intervention	233	27.5 (4.8)	27.3 (4.7)	-0.2	0
Control	223	28.0 (4.6)	27.8 (4.5)	-0.2	(-0.3; 0.3)

PA: physical activity; SB: sedentary behavior; BMI: body mass index.
*Significant difference ($p<0.05$) between groups at baseline.
** Significant difference between groups at follow-up, corrected for baseline values and OP level.
‡ Adjusted model corrected for age, gender, and irregular work hours.

Dietary behavior

A statistically significant increase was found in fruit intake as a result of the intervention (Table 2). Participants in the intervention group consumed 1.5 more pieces of fruit per week, while participants in the control group decreased their fruit intake by almost 1 piece of fruit per week (β 2.1; 95% CI 0.6; 3.6). No significant effect was found for meeting the public health recommendation of consuming two or more pieces of fruit per day (Figure 2). Moreover, no significant effects were found on total snack intake, and intake per snack.

Body weight-related measures

The intervention did not result in significant effects on waist circumference, body weight and BMI (Table 2). Both study groups showed slight decreases in these variables, but yielded no difference between groups. The intervention effect on waist circumference was modified by gender and BMI. Waist circumference reduced among women in the intervention group compared to women in the control group (n=295; β -0.8 cm, 95% CI -2.6; 1.1), and increased among men in the intervention group compared to men in the control group (n=160; β 1.7 cm, 95% CI -0.3; 3.7), but these differences were not significant. Moreover, waist circumference reduced among normal weight participants in the intervention group compared to normal weight controls (n=134, β -1.4 cm, 95% CI -2.8; 0), did not change among overweight participants (n=198; β 0 cm, 95% CI –1.3; 1.3), but significantly increased among obese intervention participants compared to obese controls (n=123; β 2.6 cm, 95% CI 0.7; 4.5). Finally, no significant difference was found between groups among participants who had *maintained or decreased* versus those who had *increased* their waist circumference and body weight (OR 0.9; 95% CI 0.5; 1.3; and OR 1.0; 95% CI 0.6; 1.6, respectively).

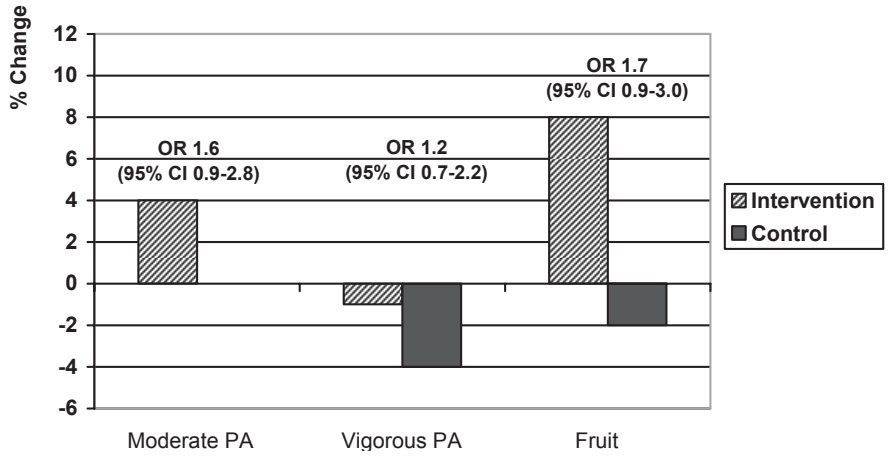

Figure 2. Change in meeting public health guidelines for physical activity and fruit intake.

Discussion

The aim of this study was to evaluate the effectiveness of a draft occupational health practice guideline aimed at preventing weight gain among employees in the Netherlands in a randomized controlled trial. At 6 months, the draft guideline was effective in obtaining a more favorable sedentary behavior at work (-15 vs -3 minutes per day) and in increasing fruit intake (+1.5 vs -0.8 pieces per week). No significant effects were found on physical activity, total or leisure-time sedentary behavior, snack intake and body weight-related outcomes.

The lack of effect on total levels of sedentary behavior is in line with a recent systematic review of six studies [31]. The assessment of domain-specific sedentary behavior in our study has thus proven useful to detect the intervention effect on sedentary behavior at work. However, as the work and leisure time domains were assessed using a questionnaire that has not yet been tested for validity, our results should be interpreted with caution. Moreover, the clinical relevance of our finding is unknown [31]. Previous studies have shown that sitting is negatively associated with health [32-35], especially in extended periods of sitting [36]. It may therefore be reasonable to assume that benefits occur along a continuum, with greater reductions in sedentary behavior associated with increased benefits. The low precision of detecting effects via self-reported measures however, remains an issue of concern [37]. Future studies may benefit from using objective measures for a more accurate assessment of sedentary behavior, such as tri-axial accelerometers or heart rate monitoring. Nevertheless, objective measures should be used in addition to subjective measures, as they do not distinguish between activities in different domains [37]. Clearly, more research is needed on ways to effectively reduce sedentary behavior at the workplace, and to identify what change is clinically relevant [38,39].

In line with other studies, fruit intake increased as a result of the intervention through education and counseling of participants [40-43]. This change is relevant according to the World Health Organization, who states that there is convincing evidence that a diet high in fruit and vegetables reduces the risk of obesity, diabetes and cardiovascular disease [4]. More recently, others have shown that a minimal intervention such as providing free fruit at the workplace, increases average fruit intake [44], and may decrease body weight [45]. As fruit consumption has declined in the Netherlands [18], we recommend increasing workplace fruit availability and accessibility as an effective, low-cost alternative in the guideline besides education and counselling.

The lack of effect on physical activity outcomes and snack intake contrasts several reviews that concluded significant positive effects for physical activity and fat intake [40,46,47]. Moreover, the lack of an effect on body weight-related outcome measures is not in line with two recent meta-analyses of workplace physical activity and nutrition interventions, that concluded moderate evidence for a net weight loss of -1.3 kg and -1.2 kg, and a net decrease in BMI of -0.5 and -0.3 kg/m^2, respectively [6,48]. Several possible explanations for our small, non-significant findings can be considered.

First, the fact that our study used a population approach (i.e. primary prevention) instead of a high risk approach (i.e. secondary prevention) may have led to the small effects, because less health gains may be expected in a relatively healthy population. A high risk

approach (i.e. aimed at subjects 'at risk') allows for individuals to benefit more, as seen in studies among workers at risk for cardiovascular disease [8], young employees aged 20-40 years [49], and among overweight and obese subjects (BMI ≥ 25 kg/m^2) [50]. Population approaches however, have the potential to be most (cost) effective in the long-term, the so called 'prevention paradox' [51]. Although this intervention does not appear to be cost-effective, the joint distribution of differences in cost and effects could show clear cost-effectiveness when neither cost nor effect differences are individually significant [52]. This analyses will be subject of another article. In clinical practice, both approaches are needed.
Second, control employees improved as well in the present study. This may have been caused by attending the health risk appraisal (consisting of anthropometric measurements and a subsequent health advice) and completing questionnaires, which in itself may have motivated participants to change their behavior [53]. Moreover, long-term effects need to be assessed, as intervention participants may be able to sustain behavior change better at long-term follow-up than the control group.
Third, similar to the assessment of sedentary behavior, the use of subjective methods for assessing physical activity and dietary behavior may have limited the ability to detect effects. The SQUASH questionnaire may have limited value to provide accurate information on actual physical activity levels, compared to the Physical Activity Scale (PAS) 24-hour 7-day recall, accelerometry and the Actiheart [54,55]. Also, the use of self-reported dietary outcomes may lead to an over-estimation of effects on diet, due to reporting bias [40]. Nevertheless, we chose to use self-reported measures over objective measures because the latter are more time-consuming, expensive, less appropriate in large intervention studies with multiple measurements per participant over time, and less feasible in clinical practice. Also, there is currently no single method that can be considered the 'gold standard' for the assessment of overall physical activity or diet in public health settings [56]. Thus, more research is needed on ways to accurately assess physical activity or diet in public or occupational health settings.
Fourth, the substantial differences between OP measured, independent researcher measured, and self-reported waist circumference indicates that the accuracy of measuring waist circumference was low, especially among control OPs and employees [57]. The under-reporting by control OPs indicates that the actual waist circumference of control employees may lie 2.2 cm higher. At baseline, control employees waist circumference was under-reported by -1.7 cm (n=32; 95% CI -3.2; -0.3), and at 6 months follow-up by -3.5 cm (n=12; 95% CI -4.8; -2.1). Thus, the change in waist circumference between baseline and follow-up may be smaller among the control group than suggested in Table 2. Considering the difference with the change in the intervention group, our current results may be an underestimation. As self-reported measures tended to be less accurate, OP measured waist circumference remains the best of the two options.
Finally, process data of this study showed that counselling of intervention OPs was not performed to the full extent, and all intervention companies invested in health promotion before the trial [58]. Also, although three companies showed improvements in the environment scans (such as sports groups and discounts, changes in the cafeteria due to a

new caterer, and provision of free fruit at work) only one OP attributed recent environment changes (i.e. sport groups) to the guideline [58]. Nevertheless, reach, satisfaction and attendance in general was high. Secondary analyses showed that among intervention participants those with higher attendance (5 vs <5 counseling sessions) and satisfaction rates (8 vs <8 on a scale 1-10) significantly improved waist circumference (-1.5 to -2.1 cm) and body weight (-0.9 to -1.4 kg)[58]. However, based on additional interviews we found that participants under one intervention OP significantly gained in waist circumference and body weight, whereas waist circumference and body weight reduced among participants of the remaining intervention OPs (+3.1 vs -0.3 cm and +2.4 vs -0.6 kg). Thus, although the draft guideline was not effective on weight-related outcomes, better results may be achieved among participants with higher attendance and satisfaction rates [58], and among OPs with higher guideline adherence [59].

Strengths of this study are the practice-based nature and the low number of participants lost-to-follow-up. Moreover, the risk of contamination was minimized due to randomization of groups at the OP level. Finally, similar co-interventions were reported among employees in the intervention and control group regarding advice from other health care professionals on their weight (15%, 15%), physical activity or nutrition behavior (47%, 40%), or other subjects (33% and 44%), respectively.

There are some limitations as well. OPs were not blinded, which may have induced bias of results towards a favored outcome [60]. However, as our positive outcomes on sedentary behavior and fruit intake were measured at the individual level, and not by OPs, bias may have been limited. Moreover, it could be argued that any intervention by physicians during 6 months may lead to effects because of the attention employees receive [53]. Nevertheless, the effects on fruit and sedentary behavior were specific goals of the intervention, and may thus be due to the intervention. Also, sitting during transport was not included in our study because we did not expect to find an effect on transport sitting, as this was not a goal of our intervention. Finally, participants lost-to-follow-up were significantly younger, females, and had a lower income, but this did not differ significantly between the intervention or control group. In conclusion, guideline-based care resulted in a more favorable sedentary behavior at work and an increased fruit intake, but did not result in effects on physical activity, total or leisure-time sedentary behavior, snack intake and weight-related outcomes. Although the draft guideline was not effective on all outcome measures, our results provide good direction for adjustments that should be made to the guideline before implementation. For example, it would be useful to examine ways to increase guideline adherence among OPs, and enhance attendance and satisfaction rates among participants, as this may pay off in effects. Also, more research is needed on which subjective and objective instruments are most appropriate for public health research.

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Chapter 6

Long-term effects of an occupational health guideline on employees' body weight-related outcomes, CVD risk factors and quality of life: results from an RCT

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Abstract

Objective To evaluate the effectiveness of a draft occupational health guideline aimed at preventing weight gain on employees' body weight-related outcomes, cardiovascular disease (CVD) risk factors and quality of life.

Methods In a randomized controlled trial including 16 occupational physicians (OPs) and 523 employees, guideline-based care was compared to usual care by OPs between 2009 and 2011 in the Netherlands. Guideline-based care consisted of 1) providing advice to employers on how to assess and intervene on the obesogenic work environment, 2) conducting five face-to-face behavioral change counseling sessions with employees to improve their lifestyle, and 3) evaluation and maintenance. Data were collected at baseline, 6, 12 and 18 months follow-up. To evaluate the effects of the intervention, multilevel analyses were performed.

Results No significant differences were found between the intervention and control group on body weight-related outcomes, CVD-risk factors or quality of life. Stratified analyses showed an increase in waist circumference among men (β 2.5 cm, 95% CI 0.5; 4.5) and obese intervention participants (β 2.7 cm, 95% CI 0.6; 4.7) compared to control participants.

Conclusion The draft occupational health guideline was not more effective than usual care. Therefore, the guideline in its current form cannot be recommended for implementation.

Trial Registration ISRCTN/73545254 and NTR/1190.

Introduction

Obesity and cardiovascular diseases (CVD) are two of the leading preventable causes of death worldwide (Mathers et al., 2009). In 2008, over 2.8 million deaths were due to overweight or obesity, and over 17 million deaths were caused by CVD (Alwan & et.al., 2011; Mendis et al., 2011). Both obesity and CVD are associated with an increased risk of morbidity, as well as with a reduced life expectancy (Guh et al., 2009). Moreover, obesity- and CVD-related health care use and medical costs have risen dramatically over the past years (Yach et al., 2006). As obesity and CVD prevalence and costs are expected to continue to rise (Low et al., 2009), efforts to prevent obesity and CVD are warranted.

Overweight, and in particular obesity, are directly related to CVD as an independent risk factor for CVD, but also indirectly related to CVD as an independent risk factor for biomedical risk factors such as atherosclerosis, high blood pressure, high blood cholesterol and type 2 diabetes (Poirier et al., 2006). To reduce the burden of disease, lifestyle interventions addressing shared modifiable risk factors such as physical activity and nutrition, have shown to be promising methods for prevention (Lee et al., 2003; Mente et al., 2009). For example, regular physical activity may reduce the risk of cardiovascular disease, including high blood pressure and diabetes (Stamler et al., 1999; Yusuf et al., 2004), as well as prevent weight gain (Verweij et al., 2011a; Weinstein & Sesso, 2006). Moreover, a diet low in satured fat may reduce total cholesterol (Hooper et al., 2011), and a diet high in fruits and vegetables may reduce the risk of CVD (Health Council Netherlands, 2006), and decrease body weight (Alinia et al., 2009). A recent Cochrane review of interventions using counselling and education aimed at behaviour change however, showed no reduction in total or CHD mortality or clinical events in general populations (Ebrahim et al., 2011).

Improving physical activity and dietary behavior through lifestyle interventions is not only beneficial for health, but may also enhance quality of life, decrease health care costs and increase productivity by decreasing illness and absenteeism (Mendis et al., 2011). Few such interventions have been conducted by occupational physicians, while the occupational health care setting provides good opportunities to reach employees (Groeneveld et al., 2010b; Proper et al., 2005). In the Balance@Work project, the effectiveness of an occupational health practice guideline aimed at preventing weight gain among employees in the Netherlands is evaluated (Verweij et al., 2009). The intervention effects on physical activity and dietary behavior after 6 months follow-up are subject of another article. The aim of this study is to evaluate the effectiveness of the guideline during 18 months follow-up on body weight-related factors, CVD-risk factors and quality of life.

Methods

The cluster randomized controlled trial was conducted between 2009 and 2011 as part of the Balance@Work project. Details of the study design have been published elsewhere (Verweij et al., 2009). The study protocol was approved by the Ethics Committee of the VU University Medical Center and all participants signed informed consent.

Study population

OPs were recruited by the professional association of OPs, Netherlands Society of Occupational Medicine, via a direct mailing to their member registry (>2,100 OPs). OPs were asked to recruit one or more companies of medium or large size (>100 workers). OPs recruited employees via a health risk appraisal consisting of anthropometric measurements and a subsequent health advice. Employees were considered eligible to participate when they met the following criteria: 1) having unhealthy levels of daily physical activity or dietary behavior (i.e. not complying to public health physical activity or nutrition recommendations) (Haskell et al., 2007; Health Council of the Netherlands., 2006; Kemper HGC, 2000) and/or being overweight (i.e. waist circumference >80 cm for women and >94 cm for men); 2) being able to complete a questionnaire in Dutch at baseline; 3) not being on sick leave for more than 21 days; 4) not being pregnant or having a disease or condition that would make physical activity impossible.

Randomization, blinding and sample size

Randomization to the intervention or control group was performed at the OP level. The randomization procedure was performed by an independent researcher using Random Allocation Software (version 1.0, Isfahan University of Medical Sciences, Iran). The intervention made blinding of participating OPs not possible. OPs were asked not to reveal their group to employees or assistants performing measurements. An a priori power calculation to detect a difference in waist circumference of 1.5 cm (SD 4.5) (Kwak et al., 2007) with 80% power and an alpha of 5%, determined that 175 employees per group were needed at follow-up. Taking a loss to follow-up of 20-40% into account and clustering of employees within OPs (intraclass correlation of 0.20), a total of 600 employees among 20 OPs were required at baseline (Verweij et al., 2009).

Control group

OPs in the control group were asked to provide care as usual, which generally consisted of a health risk appraisal with anthropometric measurements and a subsequent health advice.

Intervention group

OPs in the intervention group were additionally asked to provide guideline-based care. The development of the draft occupational health practice guideline has been described in detail elsewhere (Verweij et al., 2009). Briefly, the guideline consists of three sections: a) prevention at the environmental level (advice for the employer); b) prevention at the individual level (advice for the employee); and c) evaluation and maintenance.

For the first section, an environment scan was developed that provided an overview of environmental risk factors that could contribute to preventing weight gain (e.g. availability of bike sheds and shower facilities, pricing strategies in cafeteria). Based on this overview, environmental goals could be prioritized, and feasibility and barriers for implementation could be discussed with the employer, and with the workers' representative council at baseline and at 6-months follow-up.

For the second section, prevention at the individual level, a minimal intervention strategy was developed for OPs on how to promote employees' healthy lifestyle in five 20-30 minute counseling sessions during 6 months. For this purpose, OPs were trained during two days in applying behavioral change counseling, an adapted form of motivational interviewing suitable for brief consultations in healthcare settings (Verweij et al., 2009). In the first counseling session, after having discussed their risk profile and current health status, employees could choose which target behavior they would like to discuss (increasing physical activity, decreasing sedentary behavior, increasing fruit consumption, or reducing the energy intake derived from snacks). Next, ambivalence and motivation for change was assessed by discussing pros and cons of behavior change, and willingness, importance, and perceived confidence to change behavior. OPs then moved employees towards a decision balance and increased perceived behavioral control by asking employees to formulate a maximum of three implementation intentions. Last, employees set short- and long-term goals. In subsequent sessions, progress and barriers were discussed and short-term goals could be adjusted. No specific weight loss advice was provided, as the guideline aimed to prevent weight gain by improving employees' physical activity and healthy dietary behavior. Moreover, obese employees could be referred to the Dutch guideline for treatment of obesity (Quality Institute for Health Services Netherlands (Kwaliteitsinstituut voor de Gezondheidszorg CBO), 2008). To monitor their behavior, employees were provided with a toolkit containing a waist circumference measure tape, a pedometer, a diary, and leaflets on physical activity and nutrition from the Dutch Heart Foundations and the Netherlands Nutrition Centre.
Finally, the last section of the guideline considered the evaluation and maintenance of previous sections.

Outcome measures
Outcome measures of this study were body weight-related outcomes (i.e. waist circumference (cm), body weight (kg), and BMI (kg/m2)), biomedical risk factors (i.e. systolic and diastolic blood pressure (in mmHG), total serum cholesterol (mmol/l)), and quality of life assessed at baseline and 6, 12 and 18 months follow-up. The physical measurements were performed by OPs or their assistants. Quality of life was assessed by questionnaire.

Body weight-related outcomes
Waist circumference was measured as midway between the lower rib margin and the iliac crest to the nearest 0.1 cm. Participants were measured in standing position without heavy outer garments and with emptied pockets, breathing out gently (Verweij et al., 2009). To standardize waist circumference measurement, OPs or assistants were provided with a Seca 201 waist circumference measuring tape (Seca, Hamburg, Germany). As blinding of OPs was not possible, control measurements were performed by independent researchers in a random sample of 141 employees during all measurements (8%). No differences were found between OP measured waist circumference and independent researcher measured waist circumference (-0.4 cm; SD=4.5; p=0.3), among and between intervention and control OPs.

Additionally, self-reported waist circumference was assessed from 1,010 employees during all follow-up measurements (80%) using a non-stretchable paper measuring tape (range 0-130 cm) and written measurement instructions. Compared to OPs, employees significantly under-reported their waist circumference by -1.4 cm (SD=3.9; $p<0.01$). No difference was found between intervention or control participants. As employee measures tended to be less accurate, OP measured waist circumference remains the best of the two options.
Body weight and body height were measured with the participants standing without shoes and heavy outer garments. Participants were asked to push their heels softly to the wall, or the back of the stadiometer. BMI was calculated from measured height and weight as kg/m2.

CVD-risk factors
Systolic and diastolic blood pressure (mmHG) were measured according to the standard Dutch protocol for blood pressure measurements (Quality Institute for Health Services Netherlands (Kwaliteitsinstituut voor de Gezondheidszorg CBO), 2006) on employees in a seated position, after several minutes of rest. During the first consult, both arms were measured twice. In follow-up consults, the arm with the higher pressure was used if there was a difference of >10 mmHg between measurements. Otherwise, OPs were advised to measure the same arm (preferably the left arm) across the remaining measurements in order to standardise measurements (Clark et al., 2006). As blood pressure measurements were performed once by some OPs at follow-up, but performed twice by others, the first reading was used across all measurements (Kleefstra et al., 2007). Readings of participants whose arms were measured interchangeably across measurements were excluded from analyses (n=13).
Total serum cholesterol (mmol/l) was assessed by the Reflotron or Accutrend finger capillary assay or by lab assessments. HDL and LDL cholesterol were measured among two intervention OPs (n=76) and four control OPs (n=69) at baseline. Therefore, these measurements were disregarded in this study.

Quality of life
We measured quality of life by the validated EQ-5D (Hoeymans et al., 2005). Five questions were asked on self-reported mobility, self-care, activities of daily living, pain, and anxiety. The three answer categories were dichotomized into ‘no problems’ versus ‘some problems’ and ‘problems’, to address the fact that relatively few problems exist in general populations. Health status today was assessed using a visual analogue scale (VAS) ranging from 0 (worst imaginable health state) to 100 (best imaginable health state). Two additional questions were asked on ‘how would you rate your health in general (‘not good’ versus ‘good’) and ‘compared to the last year my health today is…’ (‘worse’ versus ‘the same or better’).

Statistical analyses

Baseline differences between the intervention and control group were checked using *t*-tests for continuous variables and chi-square tests for categorical variables. To evaluate the intervention effects, multilevel analyses were performed for all outcome variables in order to adjust for the possible dependency of observations (Twisk, 2006). Three levels were identified: 1) time (four occasions), 2) employees, and 3) OPs. For each outcome variable, two analyses were performed. A crude analysis was performed to determine the differences between the intervention and control group at 6, 12 and 18 months follow-up, adjusted for the corresponding baseline outcome variable. Next, an adjusted analysis was performed to account for potential confounders (gender, age, irregular work hours). Confounding was assigned when >10% change occurred in the regression coefficient. Effect modification was considered for age, gender, BMI and the 10-year risk of fatal cardiovascular disease measured at baseline. A p-value<0.10 of the interaction term was used to indicate effect modification. The 10-year risk of fatal cardiovascular disease was estimated using the European Systematic COronary Risk Evaluation instrument (SCORE), using gender, age, smoking status, total cholesterol and systolic blood pressure (Conroy et al., 2003). Age was extrapolated to 60 years to address the problem of a high relative but low absolute risk in younger persons (Lakerveld et al., 2008). The continuous SCORE variable was dichotomized at a minimum risk of 10% for CVD, to assess the risk status of our population. P-values <0.05 were considered to be significant. All analyses were performed using PASW software (version 18.0) and MLwiN (version 2.18).

Results

Participants

After recruitment, 38 OPs expressed an interest to participate. 28 OPs were eligible and were randomized to either the intervention or control group. The Balance@Work project started with seven intervention OPs and nine control OPs because twelve OPs withdrew after randomization (Figure 1). No significant differences were found between OPs who completed the study and OPs who withdrew between randomization and baseline on demographic, behavior-related or job-related characteristics of their worker population. Moreover, intervention OPs did not differ significantly from control OPs at baseline. During the 6-month intervention period, none of the OPs were lost-to-follow-up. After 6 months, three OPs were lost to follow-up due to ending of their contracts and a reorganisation, as a result of which the Balance@Work team took over the follow-up measurements. Moreover, six OPs perceived difficulties in collecting data during the follow-up measurements due to pregnancy, sick leave, resistance of an employer, switching jobs, time constraints and one OP passed away. Therefore, several follow-up measurements were discontinued (Figure 1).

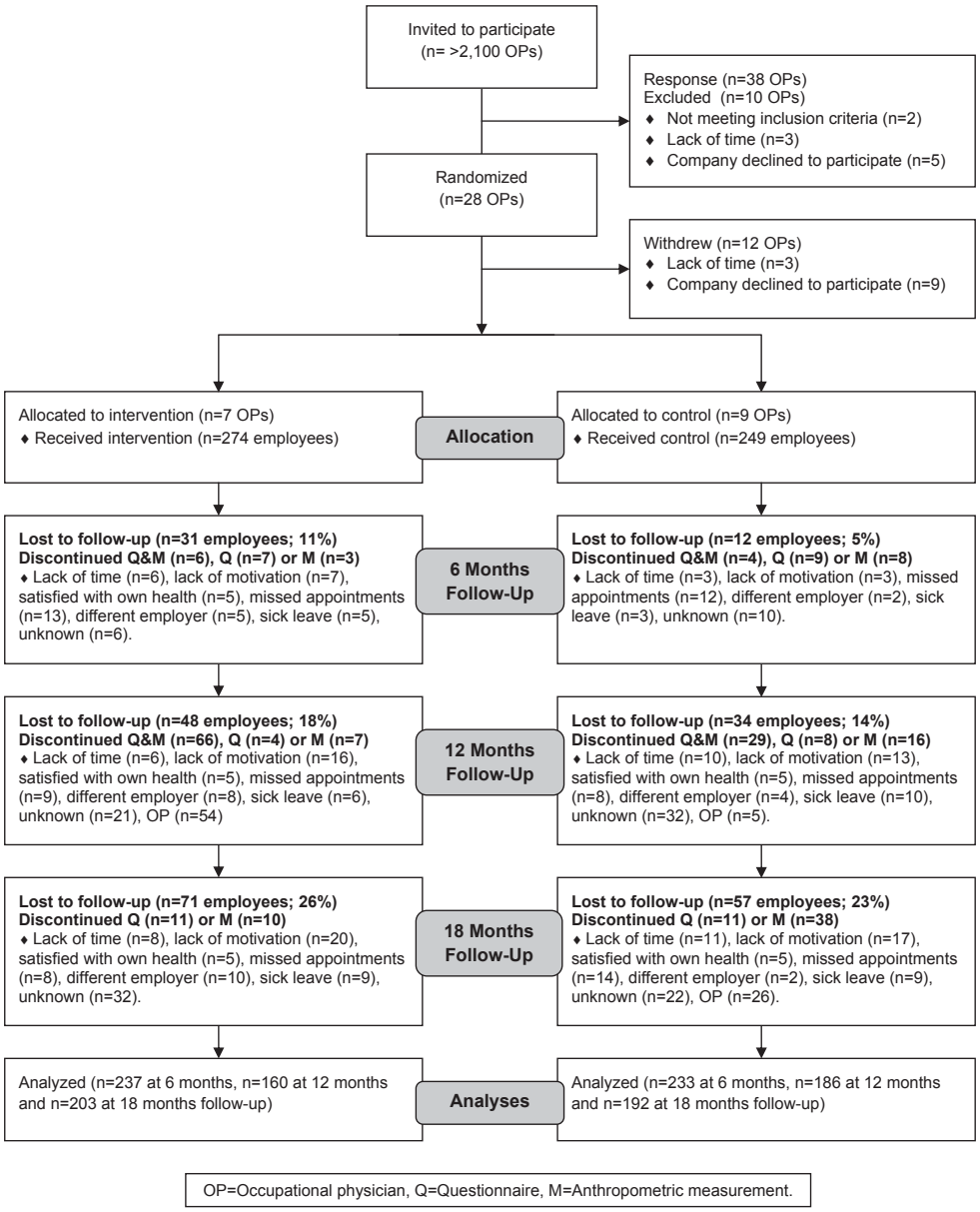

Figure 1. Flow chart of participants during the phases of the Balance@Work study, conducted in the Netherlands between 2009 and 2011.

OPs recruited 524 participants between March 2009 and March 2010. All employees met the inclusion criteria. One underweight subject was excluded from analyses because of having a weight gain goal. The baseline characteristics of the two study groups are described in Table 1. Intervention employees were significantly different from control employees on

age and irregular work hours at baseline. Intervention subjects were younger (46 versus 48 years) and worked less irregular work hours (19% versus 29%). After 18 months, 71 intervention employees (26%) and 57 control employees (23%) were lost-to-follow-up. These subjects were significantly younger, more often female, and had a lower income than study completers, but this did not differ significantly between the intervention or control group.

Table 1. Baseline characteristics of the study population by treatment group.

	Intervention n = 274	**Control n = 249**	**All n = 523**
Gender (% male)	62	65	63
Age, mean (SD)	46 (8)	48 (9)	47 (8) *
Education (% College/University)	55	51	53
Nationality (% Dutch)	89	92	91
Income, mean € per month (SD)	2118 (676)	2214 (781)	2162 (727)
Married/cohabitating (%)	81	85	83
Smoking (% yes)	15	15	15
Body Mass Index (BMI, %)	33	27	30
Normal weight (18.5≤BMI<25)	40	45	42
Overweight (25≤BMI<30)	27	29	28
Obese (BMI≥30)			
Chronic disease (% yes)	40	38	39
Medication use (% yes)	32	31	32
10-year risk of fatal CVD (% yes)	7	8	8
Type of worker (%)	15	17	16
Blue collar	70	73	72
White collar	15	10	13
Client contact			
Irregular work hours (%)	19	29	24 *

*Significant difference p<0.05.

Intervention effects

Body weight-related outcomes

Table 2 presents the values for waist circumference, body weight and BMI for baseline and 6, 12 and 18 months follow-up per study group, as well as the results of the multilevel linear regression analyses. In general, no statistically significant intervention effects were found for waist circumference, body weight and BMI. Contrary to what could be expected based on the group means, the multilevel analyses at 12-months follow-up showed a significant increase in waist circumference among the intervention group (β 2.7 cm, 95% CI 0.8; 4.6). This difference disappeared in the longitudinal analyses using all follow-up measurements. Moreover, gender and BMI modified the intervention effect on waist circumference. Waist circumference increased among men and women in the intervention group compared to the control group (β 2.5 cm, 95% CI 0.5; 4.5; and β 0.4 cm, 95% CI -1.4; 2.0, respectively).

These differences were significant among men. Also, waist circumference increased among normal weight, overweight and obese participants in the intervention group compared to controls (β 0.1 cm, 95% CI -1.9; 2.1; β 0.6 cm, 95% CI -1.1; 2.4, and β 2.7 cm, 95% CI 0.6; 4.7, respectively). These differences were significant among obese intervention participants compared to obese control participants.

Table 2. Intervention effects at 6, 12, and 18 months, and after 18 months on body weight-related measures and risk factors for cardiovascular diseases.

	Intervention		Control		
	n	**mean (SD)**	**n**	**mean (SD)**	**B (95% CI)**
Waist circumference (cm)					
Baseline *	274	94.5 (13.1)	248	98.0 (13.5)	
6 months	233	94.0 (12.6)	222	97.3 (12.1)	0.4 (-1.4; 2.2)
12 months	151	95.1 (13.0)	175	97.2 (12.5)	2.7 (0.8; 4.6)**
18 months	193	93.3 (12.7)	154	96.8 (12.2)	1.1 (-0.8; 3.0)
overall change					**1.2 (-0.6; 2.9)**
Body weight (kg) ††					
Baseline	274	86.0 (16.8)	248	87.5 (17.0)	
6 months	233	84.9 (16.1)	223	87.1 (16.1)	-0.1 (-1.5; 1.3)
12 months	148	83.0 (15.6)	174	87.1 (16.4)	0.3 (-1.1; 1.7)
18 months	190	84.6 (16.0)	153	86.7 (15.8)	0.9 (-0.5; 2.3)
overall change					**0.3 (-1.0; 1.6)**
Body mass index (kg/m2) ††					
Baseline	274	27.6 (5.0)	248	28.0 (4.9)	
6 months	233	27.3 (4.7)	223	27.8 (4.5)	0 (-0.4; 0.4)
12 months	148	27.0 (4.7)	173	27.6 (4.6)	0.1 (-0.3; 0.5)
18 months	190	27.0 (4.6)	152	27.4 (4.4)	0.3 (-0.1; 0.7)
overall change					**0.1 (-0.3; 0.5)**
Systolic blood pressure (mmHG) †					
Baseline *	273	133.2 (17.5)	248	138.0 (20.3)	
6 months	227	132.6 (19.3)	217	134.1 (15.5)	1.3 (-2.8; 5.5)
12 months	146	127.3 (15.7)	168	133.2 (15.7)	1.4 (-3.0; 5.8)
18 months	186	134.2 (18.0)	134	135.5 (16.4)	2.0 (-2.4; 6.4)
overall change					**1.7 (-2.4; 5.8)**
Diastolic blood pressure (mmHG) †					
Baseline *	273	83.6 (10.4)	248	85.6 (10.8)	
6 months	227	83.4 (10.1)	217	83.5 (9.6)	1.1 (-0.4; 2.6)
12 months	146	80.6 (9.2)	168	83.9 (9.7)	-1.2 (-3.0; 0.5)
18 months	186	83.1 (9.7)	134	85.3 (9.8)	0 (-1.8; 1.8)
overall change					**0.3 (-1.0; 0.6)**
Cholesterol (mmol/l)					
Baseline *	221	5.0 (0.9)	239	5.3 (1.0)	
6 months	178	4.9 (0.9)	221	5.1 (0.9)	-0.1 (-0.3; 0.1)
12 months	121	5.0 (0.9)	163	5.2 (0.9)	0.1 (-0.2; 0.3)
18 months	156	5.2 (0.9)	144	5.3 (1.0)	0.1 (-0.1; 0.3)
overall change					**0 (-0.2; 0.2)**

*Significant difference (p<0.05) between the intervention and control group at baseline.
** Significant difference between groups at follow-up, corrected for baseline values and clustering of repeated measurements within workers, and of workers within OPs.
Model corrected for age (†), or for age and irregular work hours (††).

Table 3. Intervention effects at 6, 12, and 18 months on quality of life indicators.

	Intervention		Control		
	n	**%**	**n**	**%**	**OR (95% CI)**
Mobility §					
Baseline	274	11	247	13	
6 months	230	9	223	13	0.6 (0.3; 1.3)
12 months	156	11	181	13	0.9 (0.4; 2.1)
18 months	191	13	181	9	1.7 (0.7; 3.7)
overall change					**0.9 (0.6; 1.5)**
Self-care §					
Baseline	274	1	247	2	
6 months	229	0	229	0	0.9 (0.1; 16)
12 months	156	2	181	1	3.8 (0.4; 39)
18 months	191	3	181	1	5.3 (0.6; 47)
overall change					**3.2 (0.8; 14.0)**
Activities of daily living §					
Baseline	274	25	247	22	
6 months	230	18	223	17	1.0 (0.5; 2.2)
12 months	156	19	181	24	0.7 (0.3; 1.4)
18 months	191	14	181	17	0.7 (0.3; 1.6)
overall change					**0.8 (0.4; 1.3)**
Pain § †					
Baseline	274	43	247	36	
6 months	230	38	223	32	1.4 (0.8; 2.7)
12 months	156	33	181	39	0.8 (0.4; 1.5)
18 months	191	34	181	32	1.0 (0.5; 2.0)
overall change					**1.1 (0.7; 1.7)**
Anxiety §					
Baseline	274	16	247	14	
6 months	230	15	223	11	1.6 (0.8; 3.0)
12 months	156	11	181	16	0.6 (0.3; 1.3)
18 months	191	8	181	13	0.6 (0.3; 1.2)
overall change					**0.9 (0.6; 1.4)**
Health in general §§ ††					
Baseline	274	87	248	87	
6 months	230	90	223	90	0.9 (0.4; 1.9)
12 months	156	90	181	87	1.2 (0.5; 2.8)
18 months	191	89	181	90	0.9 (0.4; 2.0)
overall change					**1.0 (0.6; 1.6)**
Health today ¶ ††					
Baseline	274	16	248	20	
6 months	230	16	223	18	0.9 (0.4; 1.9)
12 months	156	15	181	22	0.9 (0.4; 2.1)
18 months	191	16	181	21	1.1 (0.5; 2.4)
overall change					**1.0 (0.5; 1.7)**
	n	**mean (SD)**	**n**	**mean (SD)**	**B (95% CI)‡**
Health today (VAS) ¶¶ ‡					
Baseline *	273	72 (15)	247	75 (13)	0.4 (-1.8; 2.7)
6 months	230	75 (14)	224	77 (12)	-0.4 (-3.1; 2.2)
12 months	155	74 (15)	181	77 (13)	3.0 (0.5; 5.5)**
18 months	190	77 (13)	180	76 (14)	**1.0 (-0.8; 2.8)**
overall change					

*Significant difference ($p<0.05$) between the intervention and control group at baseline.
** Significant difference between groups at follow-up, corrected for baseline values and clustering of repeated measurements within workers, and of workers within OPs.
Model corrected for age (†), for irregular work hours (††), or for age, gender and irregular work hours (‡).
§ Dichotomous; 0=no problems, 1=problems.
§§ Dichotomous; 0=not good, 1= good.
¶ Dichotomous; compared to last year; 0=worse, 1=the same or better.
¶¶ Visual analogue scale; 0=worst imaginable health state, 100=best imaginable health state.

CVD-risk factors

No significant intervention effects were found on systolic and diastolic blood pressure. Also, no effects were found on total serum cholesterol (Table 2). Although all values slightly decreased in both groups at 6 months follow-up, all values regained at 12 and 18 months follow-up.

Quality of life

The intervention did not result in significant effects on quality of life indicators (Table 3). A significant increase among the intervention group was found on health status (assessed by VAS-scale) at 18 months follow-up (β 3.0, 95% CI 0.5; 5.5), but this difference disappeared in the longitudinal analyses using all follow-up measurements.

Discussion

The aim of this study was to evaluate the effectiveness of a draft occupational health guideline aimed at preventing weight gain among employees in the Netherlands. No significant effects were found on body weight-related outcomes, CVD-risk factors or quality of life. Stratified analyses showed an increase in waist circumference among men and obese intervention participants.

The results of this study on body weight-related outcomes contrasts two meta-analyses of workplace physical activity and nutrition interventions, that found moderate evidence for a net decrease in body weight of -1.3 kg and -1.2 kg, and in BMI of -0.5 kg/m^2 and -0.3 kg/m^2, respectively (Anderson et al., 2009; Verweij et al., 2011a). Contrary to our study, the majority of the studies in the meta-analyses aimed to reduce CVD-risk or improve physical fitness, via programs that often included exercise schemes, and that were generally more intensive than ours. A more intensive intervention might thus be needed produce better effects. However, the programs used in many of the trials far exceed what may be feasible in routine clinical practice (Ebrahim et al., 2011; Verweij et al., 2011a).

The significant increase in waist circumference among the intervention group at 12-months follow-up may be the result of non-random missing data, that occurred due to time constraints at one intervention company. Although it has previously been shown that multilevel analyses is very flexible with handling missing data (Twisk, 2006), our results suggest the multilevel analyses was influenced by non-random missings at the 12-months measurement. Future research should examine this finding. As for our results, additional sensitivity analyses showed no important difference in effects (data not shown).

Remarkably however, obese and male intervention participants increased in waist circumference. A possible explanation may be that the guideline was not suitable for obese employees. Attendance rates among obese participants were significantly lower compared to normal or overweight participants (data not shown). Moreover, others have shown that more intensive interventions may be necessary for obese workers, including guided dieting and physical activity, psychological interventions, and when necessary medication or surgery (Quality Institute for Health Services Netherlands (Kwaliteitsinstituut voor de Gezondheidszorg CBO), 2008). Obese employees may therefore best be referred to the

Dutch guideline for treatment of obesity (Quality Institute for Health Services Netherlands (Kwaliteitsinstituut voor de Gezondheidszorg CBO), 2008). The increase in waist circumference among male intervention participants was not influenced by attendance rates, but based on additional interviews we found that dissatisfied participants under one intervention OP significantly gained in waist circumference and body weight (data not shown).

The overall lack of effectiveness of the guideline may also be due to several other factors. First, the guideline may have been poorly implemented, limiting the ability to detect effects. Although attention for both environmental and individual influences was incorporated in the current draft guideline (Shain & Kramer, 2004), process data indicated that the environmental component and counseling were not performed to the full extent by intervention OPs (Verweij et al., 2011b). Moreover, co-intervention was applied by one control OP, and control employees received four health risk appraisal with feedback for evaluation purposes as well, which in itself may have motivated control participants to change their behavior (Hawthorne effect (Landsberger, 1958)). These findings suggest that the contrast between the intervention and control group may have been too small. The question remains if the guideline could be effective in case of optimal implementation. Secondary analyses among intervention participants at 6 months follow-up suggested greater results can be achieved on waist circumference and body weight among those with higher attendance (5 versus<5 counseling sessions) and satisfaction scores (8 versus<8 on a scale 1-10) (Verweij et al., 2011b). These differences however, were not sustained at 18 months follow-up.

Second, the evaluation of the guideline among a general workforce may have provided little room for improvement in the outcome measures. Two systematic reviews recently described that interventions using counselling and education aimed at behaviour change may not reduce CVD morbidity or mortality in general populations (Ebrahim et al., 2011; Groeneveld et al., 2010a; Robroek et al., 2011). Comparable programs among high-risk populations indeed found better results, such as modest reductions in blood pressure, cholesterol and weight, possibly because high risk participants are more likely to achieve measurable changes in behavior (Groeneveld et al., 2010a; Groeneveld et al., 2010b; van Wier et al., 2011). The high risk approach however, does not solve the origin of the problem (Rose, 1985). It may be worthwhile to evaluate an adapted form of the guideline among high risk groups, such as populations at risk for CVD, hypertension, or diabetes. To achieve a meaningful degree of prevention and protection at the workplace, ultimately a combination of primary, secondary and tertiary interventions may be needed (Rose, 1985).

A final point that should be considered is the quality of the measurement instruments. Despite the use of standardized protocols, the fact that our study was performed in daily practice made it impossible to standardise blood pressure and cholesterol measurements. This is important for evaluative research, as variations in blood pressure and cholesterol measurements may lead to different results (Kleefstra et al., 2007; Tolonen et al., 2005). Nevertheless, we do not feel that these variations affected our study greatly considering our lack of results. As for measuring quality of life, the generic EQ-5D may not have been appropriate in our population due to ceiling effects (EuroQol Group, 2004). The EQ-5D is a standardized health-related quality of life questionnaire developed to provide a simple,

generic measure of health for clinical and economic appraisal (Hoeymans et al., 2005). Among populations with a high GDP (gross domestic product) per capita, such as the Netherlands, however high mean VAS ratings are found (EuroQol Group, 2004). Moreover, few problems are often report on the quality of life domains by general populations (Hoeymans et al., 2005). Thus, the assessment of quality of life for evaluation purposes may have limited value in intervention studies using general populations, such as ours.

Strengths of this study include the practice-based nature of the guideline and the minimized risk of contamination due to randomization at the OP level. There were some limitations as well. Due to randomization at the OP level, intervention and control employees were significantly different at baseline with respect to age and irregular work hours. We attempted to dissolve this selection bias by controlling for these variables in all analyses. Moreover, 24% of the employees were lost-to-follow up after 18 months. Although high drop-out rates are a common problem among this type of research (Groeneveld et al., 2010b; Robroek et al., 2011) the internal validity of our results may be lower as those lost to follow-up were younger, females, and had a lower income than study completers. Also, only a small group of all OPs in the Netherlands (2%) participated in our study, implying generalizability of our results may be low. Finally, many OPs perceived difficulties collecting data for the follow-up measurements, indicating supporting structures for OPs, such as a linkage group, may be necessary for long-term performance of the guideline (Verweij et al., 2011b).

Conclusion

The draft occupational health guideline was not effective in preventing weight gain, reducing CVD-risk factors, or improving quality of life during 18 months follow-up among the intervention group compared to the control group. Therefore, the guideline in its current form cannot be recommended for implementation. It may be worthwhile to evaluate an adapted, more intensive, form of the guideline among high risk groups. Also, more attention could be paid to maximizing attendance and satisfaction rates, as this may favourably affect results. Finally, future research should determine feasible ways to effectively prevent weight gain via occupational health services among general populations at the worksite.

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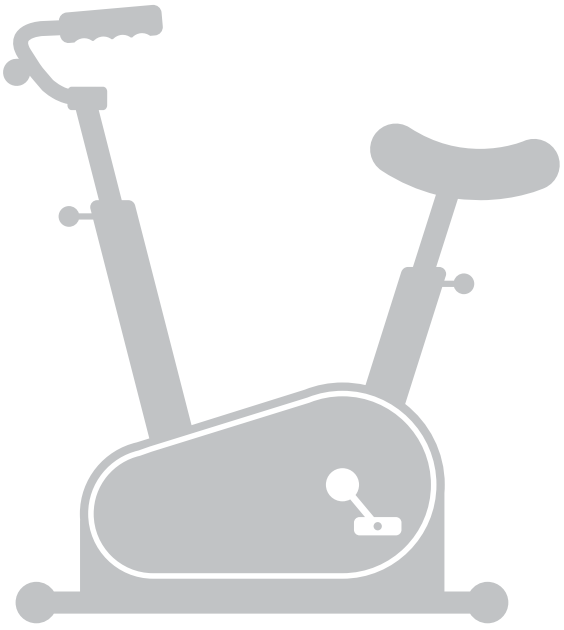
Chapter 7

Economic evaluation of an occupational health guideline for preventing weight gain among employees



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Abstract

Objective: This study evaluates the economic outcomes of an evidence-based guideline for occupational physicians (OPs) aimed at the prevention of weight gain.

Methods: We performed an economic evaluation alongside a cluster randomized controlled trial from both a societal and employer's perspective. The guideline consisted of a company-environment scan and an employee-directed intervention of up to five individual counseling sessions with an OP. Sixteen OPs randomized to the guideline (n=7) or usual care group (n=9) recruited 275 and 249 employees, respectively. Employees with unhealthy lifestyle behaviors or who were overweight were eligible to participate. Costs were collected using three-monthly retrospective questionnaires. Quality of life was measured with the EQ-5D, at baseline, 6, 12 and 18 months. Waist circumference and body weight were measured at baseline and 18 months.

Results: The occupational health care guideline resulted in less health effects but lower costs than usual care. Unfavorable differences were found between the guideline and usual care group on waist circumference (+1.6 cm, 95% CI 0.27;2.90) and weight (+1.1 kg, 95% CI 0.01;2.15); there was no difference in QALYs gained (-0.006, 95% CI -0.029;0.017). The mean cost-difference was €-99 (95% CI -2918;2772). Probabilities of cost-effectiveness were consistently below 55%. Net employer loss was €-158 (95% CI -2865;2672). Sensitivity analyses mostly showed unfavorable outcomes.

Conclusion: The occupational health care guideline for preventing weight gain among employees was not cost-effective compared with usual care. From a Dutch employer's viewpoint, no financial return from implementing the guideline was shown.

Trial Registration: ISRCTN/73545254 and NTR/1190.

Background

The global increase in overweight and obesity is widely acknowledged as a major public health problem.[1] Obesity is associated with high health care costs,[2] as well as increased sick leave, disability and productivity loss in the working population.[3] Occupational physicians (OPs) could play an important role in the prevention of overweight and obesity. In the Netherlands, about 44% of the population is employed and almost all of these employees have access to an OP. Therefore, an evidence-based occupational health guideline for the prevention of weight gain among employees was developed.[4]

Economic evaluations aid implementation decisions by giving insight in the trade-off between costs and benefits. In the Netherlands, employers are the major payers of occupational health care and prevention. They may be most interested in knowing their financial return from investments in preventive measures. Nevertheless, since health outcomes are not directly considered in financial return analyses and costs and benefits may also fall on other payers within society, cost-effectiveness analyses (CEA) and cost-utility analyses (CUA) from a societal perspective are also of importance.

The aims of the present study were to conduct a CEA with regard to weight related outcomes, a CUA from the societal perspective and a financial return analysis from the Dutch employer perspective, in which the care according to the occupational health guideline was compared with usual care.

Methods

Design of the study

An economic evaluation was conducted alongside the Balance@Work Study, a cluster randomized controlled trial carried out in the Netherlands from 2009 to 2011. The follow-up of the study was 18 months. Full details of the study design and the draft guideline have been published previously.[4] The study design and informed consent procedure were approved by the Medical Ethics Committee of the VU University Medical Center and all participants provided written informed consent.

Study population

OPs providing services to one or more companies with over 100 workers were recruited through a direct mailing by the Netherlands Society of Occupational Medicine (in Dutch, 'NVAB;). Twenty-eight OPs were randomized and requested to recruit at least 30 employees with unhealthy physical activity and/or dietary behavior, or who were overweight.[4] Employees were excluded when pregnant, in case a disease or condition was present which made physical activity impossible, when absent from work for 21 days or longer, or if they were unable to complete a questionnaire in Dutch. Between randomization and baseline measurements, 12 OPs withdrew because of lack of time (n = 3) or because the company they were servicing withdrew (n = 9). This left 7 OPs in the guideline and 9 in the usual care group.

Interventions

The intervention consisted of an environmental scan at baseline and after 6 months, judgment whether or not the company facilities were conducive to prevention of weight gain.[4] OPs discussed the results with the employer and workers' representative council. The guideline further consisted of five 20- to 30-minute individual counseling sessions with an OP, of which two sessions could be done by phone, to be completed within six months. OPs received training in behavioral change counseling techniques, i.e. motivational interviewing, aimed at physical activity and diet. Additionally, OPs and employees were provided with informational tools. At baseline employees received a waist circumference measure tape, a pedometer, information leaflets on physical activity and nutrition from the Netherlands Heart Foundations and Netherlands Nutrition Centre, and a diary to monitor daily physical activity and diet.

The control group received care as usual, consisting of health advice by the OP directed at the findings of the health risk assessment performed at baseline.

Study measures

Health-related outcomes

The primary outcome of the study was waist circumference with body weight as secondary outcome. Baseline body measurements were done during a health risk appraisal by the OPs or their assistants, who were trained and followed a standard protocol.[4] Waist circumference was measured midway the lower rib margin and the iliac crest to the nearest 0.1 cm, using a tape measure (Seca 201, Seca, Hamburg, Germany). Weight was measured to the nearest 0.5 kg with a scale available at the office of the OP. The EuroQol-5D (EQ-5D) was used to assess quality of life.[5] Health utilities were estimated with the Dutch tariff.[6] Quality adjusted life years (QALYs) were calculated by multiplying the utilities with the amount of time a participant spent in a particular health state. Transitions between health states were linearly interpolated. Measurements took place at baseline and after 6, 12 and 18 months.

Costs

Information on health care utilization, participant costs and productivity loss was obtained through six retrospective 3-month questionnaires.

Health care utilization consisted of primary health care (general practitioner, allied health care) and secondary health care (medical specialist, hospitalization) and was valued with Dutch standard costs.[7] When these were not available, prices reported by professional associations were used. Participants' costs concerned self-reported costs associated with improving physical activity, such as sports club memberships and sports equipment. Costs of productivity loss included absenteeism and presenteeism, i.e. lower performance while at work.

Absenteeism was assessed using an item of the PROductivity and DISease Questionnaire (PRODISQ), asking workers to report their total number of sick leave days during the past three months.[8] These were multiplied with the number of hours that an employee reported

to work per day. Labor costs associated with one hour sick leave were calculated per worker by dividing their yearly labor costs (self-reported net salary, with added taxes and benefits) by their total number of workable hours per year.[7] We used the Friction Cost Approach (FCA) with a friction period of 23 weeks (i.e. period needed to replace a sick worker) and an elasticity of 0.8. [7,9,10] An elasticity of 0.8 implies that full-time absenteeism corresponds to an 80% loss in productivity.[11]

Presenteeism was assessed using an item of the WHO Health and Work Performance Questionnaire (WHO-HPQ), asking workers to rate their overall work performance during the previous four weeks on a 11-point scale, ranging from "worst performance"(0) to "best performance"(10).[12] Assuming linearity, the average work performance during the 3 months' follow-up period (WPown) was calculated. A worker's level of presenteeism was calculated using the following formula:

Presenteeism Score = (10 – WPown)/10.

Presenteeism hours were calculated by multiplying a worker's Presenteeism Score by the number of hours worked in the previous three months, i.e. working hours minus sick leave. Presenteeism hours were valued with the employee's hourly labor cost. [13,14]

Prices were adjusted for the year 2009, the year of the first measurement, using consumer price indices.[15] No discounting was done for the costs in month 13 to 18 since this would have had little effect on the total costs. All prices used are given in Appendix 1.

Guideline costs

Bottom-up micro-costing was used to estimate the cost of using the guideline.[16] An estimated 488 OPs (22%) in the Netherlands are paid by companies to give lifestyle advice. [17-19] In the Netherlands, occupational guidelines are in general updated every five years. Costing was based on projections of the NVAB that 6% of the 448 OPs would start using the guideline in the first year, rising to 30% in the fifth year. OPs are expected to apply the counseling to 50 employees from three companies per year. Thus, in total 21,950 employees (0.3% of the Dutch workforce) would be counseled in five years' time.

Guideline costs consisted of fixed and variable costs. The fixed costs covered costs of the development of the guideline and printing of materials, training of the OPs, costs for selecting and inviting the participants, and both OP costs and employer time costs for the environmental scan. Printing of materials was valued using charges paid. Time investments were valued using labor costs. A second calculation was done to facilitate the financial return analyses from the employer's perspective, using commercial prices charged to companies for time invested by the OP. Total fixed costs per participant were €43.76 using labor costs and €100.24 using commercial prices.

Variable costs per participant depended on the number and duration of contacts that had been registered by the OP. Duration of the sessions, including administration, was estimated by the OPs at 30 minutes for the first session and 20 minutes for session 2-5. Costs included labor costs for the OP and labor costs for the employee. In the financial return analyses, OP time was valued with commercial prices. Guideline costs per employee consisted of the total of fixed and variable costs.

Statistical analyses

Multiple imputation

Intention-to-treat analyses were performed and missing data imputed using multiple imputation techniques. The imputation model included, among others, age, sex, educational level, baseline outcome values, available midpoint (6 and 12 months) and follow-up outcome values, number of counseling sessions attended, and available health care costs, participant costs, sick leave days and presenteeism at each cost measurement. Imputations were done separately for the intervention and control group. Because of the extreme skewed data and excess of zeros per cost component, resource use (except for number of counseling sessions, absenteeism and presenteeism) was imputed on an aggregated cost level. Ten different data sets were created in SPSS (version 17.0.2, Chicago, Ill) using Fully Conditional Specification and Predictive Mean Matching procedures.[20] These data sets were analyzed as specified below. The estimates were pooled with methods described by Rubin.[21] This method does not allow for an estimation of standard deviations, so the standard error of the mean (SEM) is presented to describe variability.

Cost-effectiveness and cost-utility analyses

Regression analysis was used to compare health-related outcomes between the intervention and control groups. Follow-up outcomes were adjusted for baseline values.[22] To compare costs between groups, confidence intervals around the mean differences in costs were estimated using the bias-corrected and accelerated bootstrap method with 2000 replications. Incremental cost-effectiveness (ICER) and cost-utility ratios (ICUR) were estimated by dividing the difference in total costs between the treatment groups by the difference in adjusted health-related outcomes. To graphically present uncertainty around the ratios cost-effectiveness planes (CE-planes) with 2000 bootstrapped cost-effectiveness pairs were plotted [23], and cost-effectiveness acceptability curves (CEACs) produced using the net health benefits approach.[24]

Financial return analyses

Using the costs and benefits of the program, three outcomes were calculated; 1) Net Benefits (NB), 2) Benefit Cost Ratio (BCR), and 3) Return On Investment (ROI).[25,26] Costs were defined as the costs of providing guideline-based care. Benefits were defined as the difference in monetized productivity loss (i.e. absenteeism and presenteeism costs) between both groups during follow-up. NB consisted of the guideline costs subtracted from its benefits. BCR was calculated by dividing the benefits by the costs. ROI was the division of NB by the costs, multiplied by 100. To quantify precision, 95% CIs around the NB were estimated by means of ABC intervals.[27] Financial returns are positive if the following criteria are met: NB>0, BCR>1, and ROI>0.

Sensitivity analyses

Sensitivity analyses were conducted to test the robustness of the results. First, analyses were performed using cases with complete data for both outcomes and costs, i.e. complete-cases (SA1). Second, productivity losses were estimated using standard mean labor costs of the Dutch population, i.e. €30.02 per hour [7] (SA2). Third, analyses were performed in which absenteeism costs were estimated using the Human Capital Approach (HCA) instead of the FCA (SA3). In the HCA, total sick leave days are neither "truncated" as in the FCA, nor is elasticity considered. Fourth, since overall consensus about whether or not to include presenteeism costs in economic evaluations does currently not exist, analyses were performed in which presenteeism costs were excluded (SA4).[28]

Results

Participants

The flow of OPs and employees can be found in Figure 1. After completion of the intervention period, three OPs were lost to follow-up, of whom one did not report on use of the intervention among his employees. Subsequently, the employees of these OPs were measured by the Balance@Work team. Six OPs had difficulties in performing follow-up measurements, resulting in missing data (Figure 1).

The OPs recruited 524 participants. After 18 months, 70 intervention employees (26%) and 54 control employees (22%) were lost to follow-up. Reasons for loss to follow-up were in majority loss of motivation or not reported. One participant was excluded because she wanted to gain weight. The baseline characteristics of the two groups are described in Table 1. Some differences were found between participants completing all cost and body measurements and participants with at least one of these measurements missing, especially in the intervention group (Table 1). These variables were included in the imputation model. Imputed data concerned 20% of the cost variables, 20% of utilities and 34% of the 18-month follow-up body measurements.

Effectiveness

Statistically significant differences in effects were found in favor of the control group. Compared with the control group, the intervention group gained 1.6 cm in waist circumference and 1.1 kg in weight (Table 2). There were no differences in QALYs gained.

Costs

Table 2 shows that presenteeism was statistically significant higher by 52 hours in the intervention group. Mean intervention costs were €218 using OP labor costs and €497 using OP charges. Total costs were similar, i.e., €25 565 for the intervention group and €25 664 for the control group.

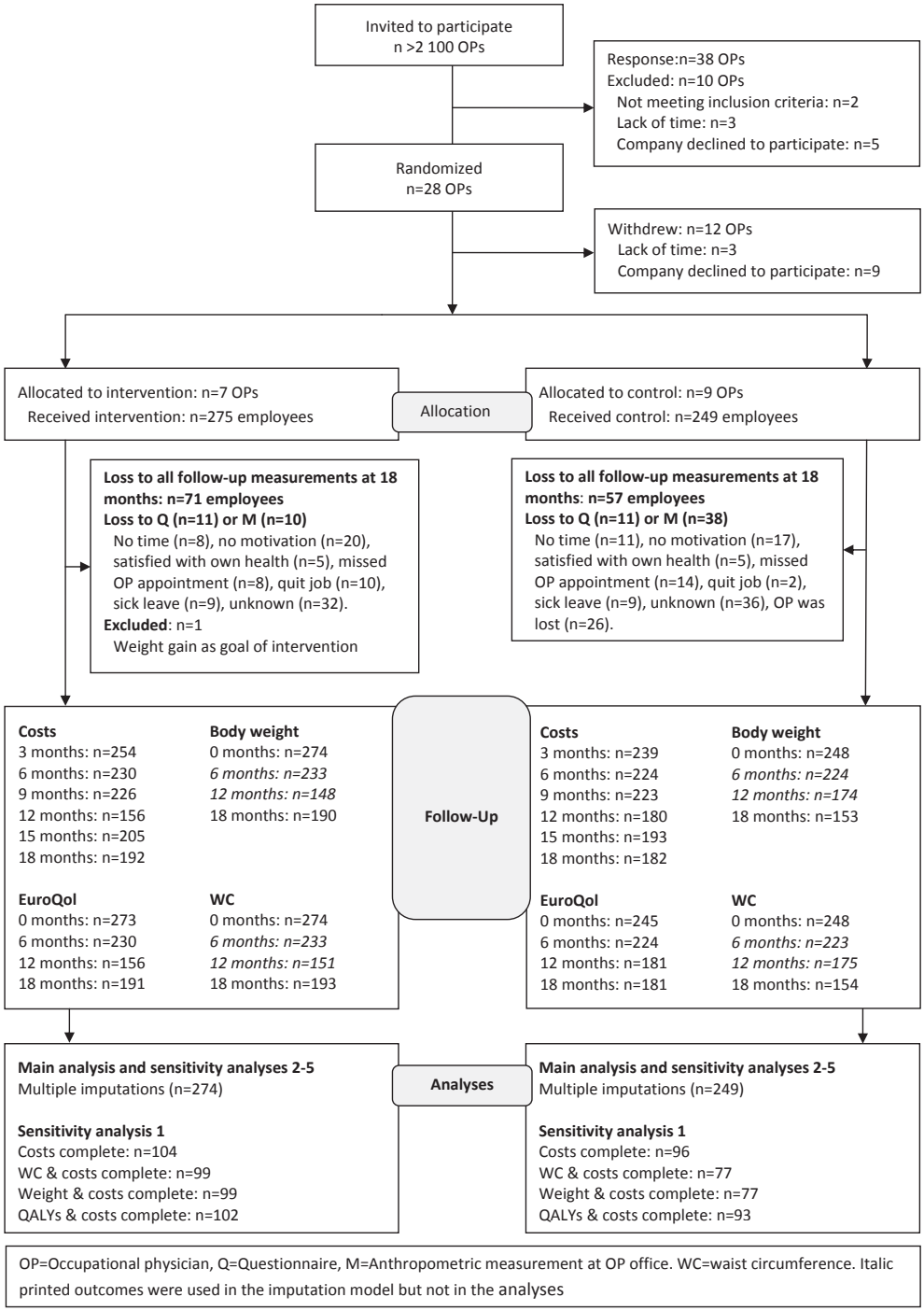

Figure 1. Participant flow

Table 1. Baseline characteristics of all randomized participants and of participants with complete data[a] and those with incomplete data

	Control group				Intervention group			
	All n=249	**Complete n=77**	**Incomplete n=172**	**Complete versus incomplete (95% CI)**	**All n=274**	**Complete n=99**	**Incomplete n=175**	**Complete versus incomplete (95% CI)**
Male, n (%)	162 (65)	57 (74)	105 (61)	+13%* (NA)	169 (62)	53 (54)	116 (66)	-12%* (NA)
Age, mean (SD), y	47 (8.7)	50 (7.5)	46 (9.0)	3.6** (1.3;5.9)	45 (7.8)	46 (8.0)	45 (7.8)	1.1 (-0.9;3.0)
Level of education: college or higher, n (%)	126 (51)	35 (46)	92 (53)	-8% (NA)	150 (55)	74 (74)	76 (44)	+30%*** (NA)
Irregular working hours, n (%)	73 (29)	26 (34)	47 (27)	+7% (NA)	53 (19)	5 (5)	48 (27)	-22%*** (NA)
White collar worker, n (%)	203 (83)	59 (78)	144 (86)	-8% (NA)	230 (86)	91 (95)	139 (80)	+15%** (NA)
Labor costs/hour, mean (SD), Euros, n=433	40 (14)	40 (14)	40 (15)	-0.8 (-3.3;4.9)	37(12)	39 (12)	36 (12)	3* (0.1;6.6)
Sickness absenteeism in previous 3 months, mean (SD) - working days - working hours	2.6 (8.1) 19.3 (60.0)	3.2 (9.7) 22.4 (68.1)	2.3 (7.4) 17.9 (56.1)	0.8 (-1.4;3.1) 4.5 (-11.7;20.8)	1.1 (3.9) 8.9 (31.1)	1.2 (4.7) 9.9 (37.6)	1.1 (3.4) 8.3 (26.9)	0.2 (-0.8;1.1) 1.6 (-6.1;9.4)
Presenteeism previous 3 months, mean (SD), (%)	23 (12)	23 (13)	23 (11)	0.0 (-0.03;0.04)	23 (12)	24 (12)	23 (12)	0.6 (-2.2;3.6)
Health utility, mean (SD)	0.89 (0.13)	0.92 (0.13)	0.88 (0.14)	0.04* (0.003;0.07)	0.88 (0.13)	0.90 (0.12)	0.87 (0.13)	0.03 (-0.01;0.06)

[a]Complete data: complete cost data (i.e. all six cost questionnaires, compliance to the intervention and data on number of working days and hours per week and salary were available) and complete body measurements (i.e. baseline and 18-month follow-up were available) Incomplete data: at least one of these measurements missing; *p<0.05, **p<0.01, ***p<0.001. Abbreviations: n, number; SD, standard deviation; CI, confidence interval; NA, not applicable

Table 2. Pooled outcomes at baseline and 18 month follow-up

Outcome	Intervention group n=249		Control group n=274		Intervention versus control
	Baseline mean (SEM)[b]	Follow-up mean (SEM)	Baseline mean (SEM)	Follow-up mean (SEM)	Mean difference (95% CI)
WC, cm	94.5 (0.79)	95.3 (0.91)	98.0 (0.86)	96.7 (0.84)	1.6* (0.27;2.90)
Body weight, kg	86.0 (1.05)	86.4 (1.03)	87.6 (1.07)	86.9 (1.09)	1.1* (0.01;2.15)
QALYs[a] achieved	-	1.37 (0.011)	-	1.38 (0.009)	-0.006 (-0.029;0.017)
Resource use					
Counseling sessions	-	4.2 (0.09)	-	-	-
Sickness absenteeism, FCA, hrs	-	89 (14)	-	94 (13)	-5 (-41;31)
Presenteeism, hrs	-	559 (14)	-	507 (13)	52** (15;89)
Costs per category					
Intervention	-	218 (4)	-	0 (0)	218 (NA)
Primary health care	-	398 (48)	-	390 (46)	8 (-122;140)
Secondary health care	-	410 (89)	-	381 (57)	29 (-161;248)
Participant	-	564 (44)	-	580 (48)	-16 (-144;107)
Absenteeism	-	3043 (540)	-	3524 (569)	-481 (-1852;972)
Presenteeism	-	20 932 (723)	-	20 789 (914)	143 (-2158;2416)
Total costs	-	*25 565 (908)*	-	*25 664 (1194)*	*-99 (-2918;2772)*

[a] The maximum amount of QALYs that can be achieved in 18 months is 1.5 units. *p<0.05, **p<0.05.
Abbreviations: n, number; WC, waist circumference; QALY, Quality Adjusted Life Year; SEM, standard error of the mean; CI, confidence interval; FCA, friction cost approach; NA, not applicable. Note: Costs are expressed in 2009 Euros

Cost-effectiveness

The ICER for waist circumference was -62, indicating a societal saving of €62 at the cost of a 1 cm increase in waist circumference with guideline care compared with usual care (Table 3). The ICER for body weight of -92 indicated a saving of €92 at a 1 kg increase in weight. The CE-plane for waist circumference (Figure 2a) shows substantial uncertainty. The CEACs show that for both outcomes the probability that the guideline is cost-effective was around 52% when society is not willing to pay at all. The probability decreased when willingness-to-pay increases (Figure 2b).

Figure 2a.

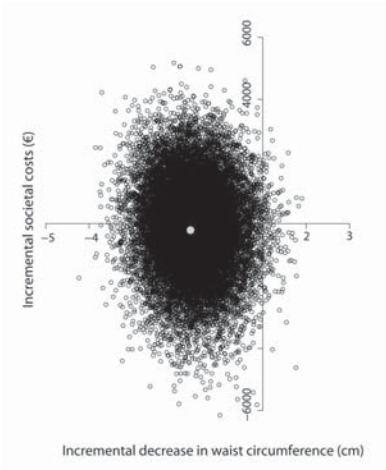

Figure 2c.

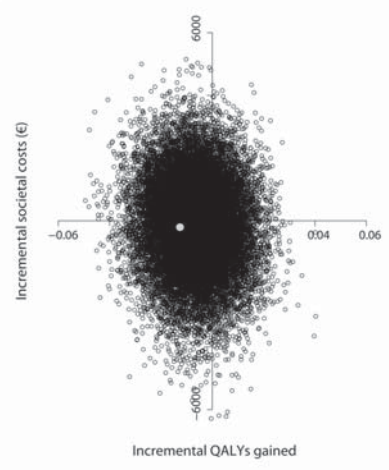

Figure 2b.

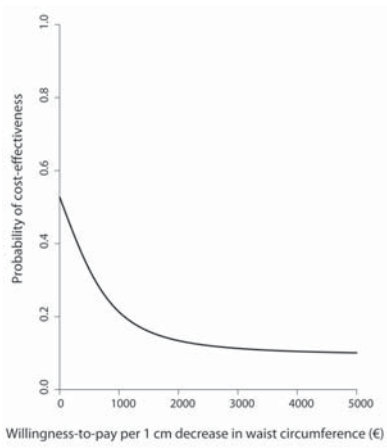

Figure 2d.

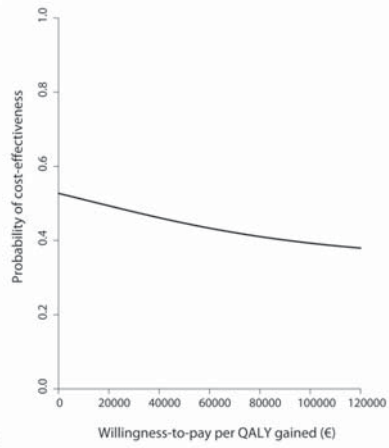

Figure 2a. Cost-effectiveness plane for waist circumference of the guideline group compared with usual care

Figure 2b. Cost-effectiveness acceptability curve for waist circumference of the guideline group compared with usual care

Figure 2c. Cost-effectiveness plane for QALYs gained in the guideline group compared with usual care

Figure 2d. Cost-effectiveness acceptability curve for QALYs gained in the guideline group compared with usual care

Table 3. Incremental cost-effectiveness ratios and distribution of the joint cost-effect pairs in the cost-effectiveness plane

Analysis[a]	Sample size per group		ΔC (95% CI)	ΔE (95% CI)		Distribution in CE plane (%)			
	Control	Intervention	Euros	Waist circumference, cm	ICER	NE[b]	SE[c]	SW[d]	NW[e]
Main analysis *Imputed datasets*	249	274	-99 (-2918;2772)	1.6* (0.27;2.90)	-62	0.4	0.5	52.0	47.1
SA1 *Complete cases*	77	99	651 (-3414;4097)	0.4 (-1.4;2.1)	1705	20.8	12.2	21.6	45.4
SA2 *Mean Dutch labor costs*	249	274	1653* (35;3286)	1.6* (0.27;2.90)	1041	0.7	0.0	2.2	97.0
SA3 *HCA*	249	274	22 (-3117;3013)	1.6* (0.27;2.90)	14	0.3	0.4	48.6	50.6
SA4 *Excluding presenteeism*	249	274	-242 (-1846;1385)	1.6* (0.27;2.90)	-153	0.2	0.5	61.8	37.4
	Control	**Intervention**	**Euros**	**Body weight, kg**	**ICER**	**NE[b]**	**SE[c]**	**SW[d]**	**NW[e]**
Main analysis *Imputed datasets*	249	274	-99 (-2918;2772)	1.1* (0.01;2.15)	-92	0.7	1.1	51.1	47.1
SA1 *Complete cases*	77	99	651 (-3414;4097)	0.7 (-0.6;1.9)	964	7.1	6.4	29.3	57.1
SA2 *Mean Dutch labor costs*	249	274	1653* (35;3286)	1.1* (0.01;2.15)	1529	1.7	0.1	2.2	96.0
SA3 *HCA*	249	274	22 (-3117;3013)	1.1* (0.01;2.15)	20	0.7	1.0	47.7	50.6
SA4 *Excluding presenteeism*	249	274	-242 (-1846;1385)	1.1* (0.01;2.15)	-224	0.6	1.2	60.7	37.5
	Control	**Intervention**	**Euros**	**QALY**	**ICUR**	**NE[b]**	**SE[c]**	**SW[d]**	**NW[e]**
Main analysis *Imputed datasets*	249	274	-99 (-2918;2772)	-0.006 (-0.029;0.017)	16 118	12.4	16.3	35.9	35.4
SA1 *Complete cases*	93	102	707 (-2745;4144)	0.006 (-0.022;0.035)	117 872	41.1	25.4	9.6	23.9
SA2 *Mean Dutch labor costs*	249	274	1653* (35;3286)	-0.006 (-0.029;0.017)	-269 097	28.3	1.4	0.9	69.4
SA3 *HCA*	249	274	22 (-3117;3013)	-0.006 (-0.029;0.017)	-3649	13.6	15.9	32.8	37.7
SA4 *Excluding presenteeism*	249	274	-242 (-1846;1385)	-0.006 (-0.029;0.017)	39 441	5.9	23.3	39.1	31.7

[a] In the analysis ΔC= mean difference in total costs of intervention vs. control, ΔE= mean difference in outcome, ICER (ICUR) is calculated as ΔC/ ΔE. In the intention to treat analysis missing data were multiply imputed. The complete cases analysis was restricted to participants with complete cost and effect data. [b] Northeast quadrant of the CE-plane: the intervention is more effective and more costly than usual care. [c] Southeast quadrant of the CE-plane: the intervention is more effective and less costly than usual care. [d] Southwest quadrant of the CE-plane: the intervention is less effective and less costly than usual care. [e] Northwest quadrant of the CE-plane: the intervention is less effective and more costly than usual care; *p<0.05. Abbreviations: CI, confidence interval; ICER (ICUR), Incremental Cost-Effectiveness (Utility) ratio; HCA, human capital approach.

Cost-utility

The ICUR showed that €30 193 was saved per QALY lost due to the guideline in comparison with usual care (Table 3). The CE-plane (Figure 3a) showed considerable uncertainty. The probability that the guideline is cost-effective for QALYs gained was 52% at a ceiling ratio of €0 and decreased with an increasing willingness to pay (Figure 3b).

Financial return

Table 4 shows a negative net employer benefit of €-158. The wide 95% confidence interval (-2865 ; 2672) showed that there was large uncertainty around this outcome. For each Euro invested, 0.68 Euros were retrieved, whereas the return on investment was -32%.

Sensitivity analyses

The sensitivity analyses revealed that the results found in the main analyses were not robust. When analyses were restricted to complete cases (SA1), cost differences were in favor of the control group (Table 3). The ICERs for weight loss and waist circumference represented losses in health at increased spending, whereas the ICUR showed QALYs gained at increased costs. The probability of cost-effectiveness remained below 40%, regardless of willingness-to-pay. The probability of cost-utility did not exceed 50%.

SA2 resulted in higher costs in the intervention group and probabilities of cost-effectiveness for all outcomes reduced to below 20% at any ceiling ratio. The other sensitivity analyses showed probabilities of cost-effectiveness below 62% for all outcomes.

The sensitivity analyses for financial return are presented in Table 5. All showed financial losses, with the NB ranging from €-15 to €-1910. The latter NB, based on the mean Dutch labor costs, was statistically significant.

Discussion

An occupational healthcare guideline to prevent weight gain among employees had unfavorable effects on weight-related outcomes, no significant effect on QALYs gained and a low probability of cost-effectiveness compared with usual care. From the perspective of a Dutch employer the guideline resulted in a financial loss.

In another Dutch study occupational nurses and some OPs provided face-to-face diet and physical activity counseling sessions to construction industry employees at increased risk for cardiovascular disease.[29] Counseling was more effective than no counseling. One year after baseline an ICER of -145 (€293/-2.0 kg) was found, with a probability of cost-effectiveness of 60% at €250/kg increasing to 90% at €2000/kg. However, employer's NB was also negative, €-254 (95% CI -1536; 1070). The differences between the studies may be explained by counseling by occupational nurses compared to counseling by physicians. A review found that allied health professionals and multidisciplinary teams produced better results than physicians only.[30]

Table 4. Intervention costs, benefits, net benefit (NB), benefit cost ratio (BCR), and return on investment (ROI) per employee

Analysis	Sample size		Costs	Benefits			Financial return		
	Control	Intervention	Intervention (Euros)	Absenteeism (95% CI)	Presenteeism (95% CI)	Total (95% CI)	NB[1] (95% CI)	BCR[2]	ROI (%)[3]
Main analysis *Imputed datasets*	249	274	497	481 (-972;1852)	-143 (-2416;2158)	338 (-2490;3058)	-158 (-2865;2672)	0.68	-32
SA1 *Complete cases*	96	104	536	804 (-200;2338))	-1275 (-4434;1923)	-471 (-3603;3120)	-1007 (-4340;2576)	-0.88	-187
SA2 *Mean Dutch labor costs*	249	274	497	147 (-939;1197)	-1561*** (-2631;-452)	-1413 (-2864;59)	-1910* (-3359;-440)	-2.84	-384
SA3 *HCA*	249	274	497	360 (-1652;1934)	-143 (-2416;2158)	217 (2950;3081)	-280 (-3261;2722)	0.44	-56
SA4 *Excluding presenteeism*	249	274	497	481 (-972;1852)	-	481 (-972;1852)	-15 (-1407;1426)	0.97	-3

[1] Indicates the amount of money returned after intervention costs are covered; [2] Indicates the amount of money returned per Euro invested in the intervention; [3] Indicates the percentage of profit per Euro invested in the intervention;*p<0.05, ***p<0.001. Abbreviations: CI, confidence interval; NB, net benefit; BCR, benefit cost ratio; ROI, return on investment; SA, sensitivity analysis; HCA, human capital approach; NA, not applicable. Note: Costs are expressed in 2009 Euros.

The cost differences proved to be very sensitive to different valuations of productivity loss. When productivity loss was valued using mean Dutch labor costs, the absenteeism cost difference decreased from €-481 to €-147, whereas the presenteeism cost difference increased from €143 to €1561 (see Table 5). This results from underlying interactions. The €-481 difference when labor cost were based on self-reported salary can be explained by lower absenteeism among higher income employees in the intervention group, i.e. an interaction between group and income. Post-hoc analyses (results not shown) seem to confirm this. Additionally, at baseline absenteeism was somewhat lower in the intervention group; this could have been carried through over the following months. In contrast, there was more presenteeism in the intervention group. Post-hoc analyses (results not shown) showed that in the main analysis this difference was ruled out because, equivalent to absenteeism, presenteeism was lower (i.e. the average work performance was better) among higher income employees. In conclusion, only small reductions in absenteeism costs are likely due to the guideline while increased presenteeism has an important and negative impact on the total cost differences when labor costs are equalized.

Limitations and strengths

A limitation is the amount of missing data. Despite meticulous pursuit, data were missing for up to 34% of the measurements, a common problem with this type of research in daily practice.[31] Furthermore, the self-report of all resource use may have led to underestimation of the costs. In particular absenteeism and presenteeism may have suffered from recall bias as the period on which to report was relatively long.[32]

A strength is the use of multiple imputation techniques, a recommended method to handle missing data.[21,33] Furthermore, we conducted an economic evaluation alongside a randomized controlled trial, which is the most valid design to evaluate effectiveness and allows for prospective data cost data collection.

Conclusion

Compared with usual care, care according to an occupational healthcare guideline to prevent weight gain among employees had a low probability of societal cost-effectiveness and cost-utility. From the viewpoint of a Dutch employer, using the guideline resulted in a financial loss. Implementation of the guideline in its current form is not advised.

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Appendix 1. Price weights used for valuation of resource use, per visit unless otherwise mentioned

Type of utilization	Price weight[a]
Direct healthcare costs	
Intervention: occupational physician	
Labor costs (h)	59.37
Charges paid by companies (h)	200
Primary care	
General practitioner	28[b]
Physiotherapist	36
Therapist (Cesar, Mensendieck)	35
Dietitian	27
Dentist	19.39
Psychologist	77[c]
Sports physician	79
Other primary care	22.60 – 100 [c, d]
Secondary care	
Clinic visit	72
Psychiatrist	103
Admission general hospital (d)	435
Admission academic hospital (d)	575
Outpatient	251
Emergency department	151
Direct patient costs	
Complementary therapists	50 - 135[c, d]
Sports & sports equipment	as reported by participant
Indirect productivity losses	
Sickness absenteeism and presenteeism (h)	based on salary as reported by participant

[a] Euros, corrected to the year 2009, [b] Price for consultation at the practice; [c] Range of the price weights for the different providers, [d] Price according to professional association

Chapter 8

Barriers and facilitators to implementation of an occupational health guideline aimed at preventing weight gain among employees in the Netherlands

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Abstract

Objective To assess barriers and facilitators to implementation of an occupational health guideline aimed at preventing weight gain.

Methods Barriers and facilitators to implementation were assessed among 14 OPs and employers, and analyzed following a systematic approach using Atlas-ti.

Results Barriers and facilitators mentioned by OPs and employers were related to the socio-political context, the organization, the OP, and the guideline. Recommendations include the formation of a linkage group, collaboration with other experts, formation of peer support groups, and communicating benefits of investments, expectations and ethical considerations. It is recommended to incorporate these barriers and facilitators in the guideline, including strategies how to overcome barriers and stimulate facilitators.

Conclusions The identified barriers and facilitators can be used to increase the chance of successful implementation of the final guideline into occupational health practices throughout the Netherlands.

Introduction

In the Netherlands, over 2,000 occupational physicians (OPs) assist employers and employees in occupational health issues, safety, and sickness absence management by providing occupational health care to the working population. Since 1998, the Netherlands Society of Occupational Medicine develops and implements evidence-based practice guidelines for OPs. Practice guidelines are documents with recommendations to assist OPs with decisions about appropriate health care for specific clinical circumstances [1]. While the majority of the guidelines focus on sickness absence management, a shift is now seen towards prevention [2-4].

Currently, overweight and obesity are major health problems, also in the field of occupational health [5]. Overweight, but especially obesity, is associated with higher sickness absence rates and lower productivity levels [6] [7], and both are important contributors to several chronic disorders such as cardiovascular diseases and diabetes mellitus type 2 [8,9]. To address the increasing prevalence of overweight and obesity, and the associated burden of disease and financial burden, an occupational health guideline was developed aimed at preventing weight gain among employees [10]. The effectiveness of the occupational health guideline was compared to usual care in a randomized controlled trial on body composition and energy balance-related behaviors of employees [11].

Moreover, a process evaluation was conducted alongside the trial to explain how the intervention was administered, in order to clarify if flaws were due to the content or performance of the guideline[12].

Nevertheless, as the effect and process evaluation concerned the guideline, and as health services research consistently shows a gap between evidence-based practice and actual clinical care [13], more information is needed on other factors that can affect the innovation process, such as financial resources, resistance among users and complexity of the innovation, as a result of which the actual implementation may not or only partly occur [14]. To bridge this gap, in-depth understanding of barriers and facilitators to implementation is important, as implementation strategies are logically aimed at the most relevant factors [15]. Based on interviews with OPs and employers, the aim of this study was to 1) identify barriers and facilitators to implementation of the draft guideline and 2) provide recommendations for future implementation of the final guideline into occupational health care in the Netherlands.

Methods

This study was carried out as part of the Balance@Work project. The study protocol was approved by the Ethics Committee of the VU University Medical Center and all participants gave informed consent. Details of the study design have been published elsewhere [10]. Relevant aspects of the qualitative design of this study are reported following the COnsolidated criteria for REporting Qualitative research (COREQ) [16].

Study setting and intervention

The Balance@Work study was designed as a randomized controlled trial to investigate the effectiveness of the weight gain prevention guideline. The draft guideline was developed in 2008 from literature, interviews with relevant stakeholders, and consensus among a guideline working group, consisting of practitioners and experts [10]. In 2009, 28 OPs providing services to one or more companies of medium or large size (>100 workers) were recruited by the Netherlands Society of Occupational Medicine to participate in the evaluation of the guideline. To avoid contamination between employees allocated to the intervention or control condition, randomisation was performed at the OP level by an independent researcher using Random Allocation Software (version 1.0, Isfahan University of Medical Sciences, Iran). Between randomization and the baseline measurement, twelve OPs withdrew due to a lack of time, their company withdrew, or their company cancelled the project because of the economic crisis. Therefore the Balance@Work project started with seven intervention OPs and nine control OPs. These OPs were able to recruit 523 employees, who had unhealthy levels of daily physical activity or dietary behavior (i.e. did not comply to public health physical activity and nutrition recommendations [17-19]) and/or were overweight (i.e. waist circumference >80 cm for women and >94 cm for men). During the 6-months intervention period none of the OPs, but 35 employees, were lost-to-follow-up [11].

OPs in the control group were asked to provide care as usual, which generally consisted of a health risk appraisal with anthropometric measurements, and a subsequent health advice. OPs in the intervention group were asked to provide guideline-based care. The guideline consisted of three sections: a) prevention at the environmental level (advice for the employer) described how to assess and intervene on the obesogenic work environment; b) prevention at the individual level (advice for the employee) described how OPs can promote physical activity and healthy dietary behavior of employees, during five counseling sessions based on principles of motivational interviewing; and c) evaluation and maintenance of previously mentioned sections. With regard to prevention at the environmental level, an environment scan was developed for OPs to discuss with employers, at baseline and at 6-months follow-up. The environment scan addressed the obesogenic environment (e.g. an environment that promotes unhealthy food choices and discourages physical activity [20]. Because it is difficult to maintain weight loss in an unsupportive environment, the environment scan consisted of an overview of environmental risk factors extracted from literature, that could contribute to preventing weight gain (for example: availability of bike sheds and shower facilities, pricing strategies in cafeteria). Based on this overview, environmental goals could be prioritized, and feasibility and barriers for implementation could be discussed with the employer and the workers' representative council. With regard to prevention at the individual level, a minimal intervention strategy was developed for OPs on how to promote employees' healthy lifestyle in five 20-30 minute counseling sessions during 6 months. For this purpose, OPs were trained during two days in applying behavioral change counseling, an adapted form of motivational interviewing suitable for brief consultations in healthcare settings [21]. During the first counseling session, after having discussed their risk profile

and current health status, employees could choose which target behavior they would like to discuss (increasing physical activity, decreasing sedentary behavior, increasing fruit consumption, or reducing the energy intake derived from snacks). Next, ambivalence and motivation for change was assessed by discussing pros and cons of behavior change, and willingness, importance, and perceived confidence to change behavior. OPs then moved employees towards a decisional balance and increased perceived behavioral control by asking employees to formulate maximally three implementation intentions. Last, employees set short- and long-term goals. In subsequent sessions, progress and barriers were discussed and short-term goals could be adjusted. No specific weight loss advice was provided, as the guideline aimed to prevent weight gain by improving employees' physical activity and healthy dietary behavior. To monitor their behavior, employees were provided with a toolkit containing a waist circumference measuring tape, a pedometer, a diary, and leaflets on physical activity and nutrition from the Dutch Heart Foundation and the Netherlands Nutrition Centre. In order to effectively achieve behavioral change in practice, all of the above mentioned strategies were selected from theory- and evidence-based practice [10]. Moreover, stakeholders were involved in every step of the development and evaluation process (e.g. practice-based evidence) [15,22].

To assess what happened during the intervention and how that affected program impact, several important process parameters were evaluated among intervention OPs and employees (e.g. recruitment, reach, context, dose delivered, dose received, satisfaction, fidelity and the link between process items and outcome measures) [12]. Despite this abundant data, little was known about facilitating and impeding factors to implementation among OPs that had worked according to the draft guideline.

Data collection

To measure the degree of implementation, interviews were conducted after the intervention period among all OPs (n=7) and employers (n=7) allocated to the intervention group.

Theoretical framework

Barriers and facilitators are defined as factors that impede or facilitate behavioral change [23]. Various theories and models for change show a multitude of factors that influence implementation of clinical guidelines [24-26]. These frameworks however, mainly focus on the individual professional. The framework developed by Fleuren et al. (2004) [14] focuses on factors related to health care organizations (Figure 1). The general outline of this framework was derived from the Theory of Planned Behavior [27], Social Cognitive Theory [28] and from previous research on innovation in AIDS education in Dutch schools [29]. The framework describes that in each stage of an innovation process (e.g. dissemination, adoption, implementation, and continuation) the desired change may or may not occur due to various barriers and facilitators. Based on literature review and a Delphi study among implementation experts, Fleuren et al. (2004) identified 49 factors that may impede or facilitate implementation. These were classified into five implementation levels: characteristics of the social-political context (e.g. laws, policy, regulations and social

networks), the organization (e.g. management support and resources), the user (e.g. knowledge and skills of the OP), the innovation (e.g. observability, ethical considerations and advantages in practice of the guideline), and characteristics of the innovation strategy (e.g. training, materials, and feedback). We used this framework to structure barriers and facilitators perceived by OPs and employers. Because the phases dissemination and adoption already occurred when OPs and employers consented to participate in the Balance@Work project, the focus of the present study is on factors concerning the phases implementation and continuation. Moreover, as the characteristics and effectiveness of the innovation strategy are described in the process evaluation, this study focuses on the first four implementation levels described by Fleuren et al. (2004).

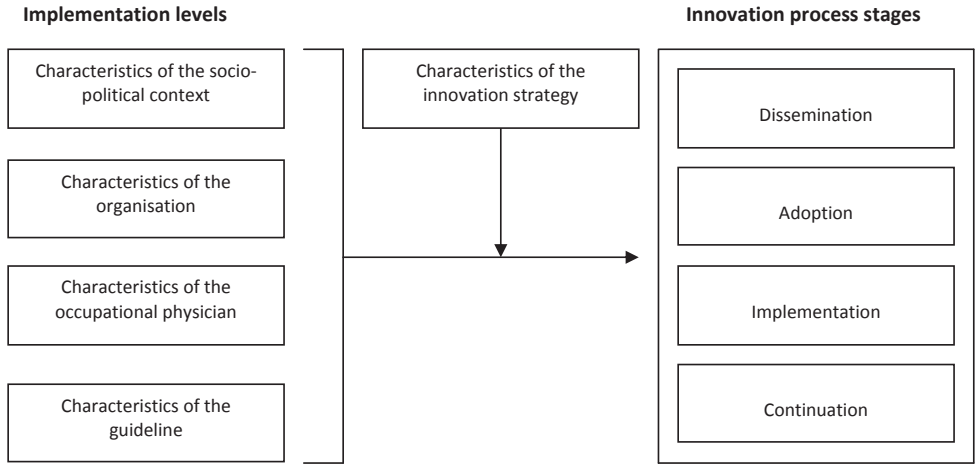

Figure 1. Implementation levels and stages of the innovation processes (copy of original with permission from Fleuren et al. 2004 [14]).

Semi-structured interviews

A semi-structured interview guide was used to assess barriers and facilitators related to implementation of the guideline. OPs and employers were asked four primary questions, which included: 1. what was new for you when working according to this guideline?; 2. what made that you started working differently (e.g. according to the guideline)?; 3. what would you advice colleagues (e.g. do's and don'ts)? and 4. why would you (not) continue to use the guideline? Subsequently, specific questions were introduced if participants did not mention these topics, such as; why were your expectations (not) met?; which specific sections of the guideline did you (not) perform?; and what are your recommendations for future implementation of the guideline?

The semi-structured interviews were held after the 18-months trial period, between September 2010 and January 2011. One focus group interview among three OPs was conducted at the Netherlands Society of Occupational Medicine during one hour. The interview was conducted by an independent, experienced OP (AN) with a degree in

psychology. The principal researcher (LV) took notes and asked clarifying questions. Because a second focus group interview could not be organized, the principle researcher interviewed the remaining four OPs in pairs by phone during one hour, following the same interview guide. Employers were interviewed individually by phone by the principle researcher during 15 minutes. All interviews were digitally recorded and participants signed informed consent.

Data analyses

The interviews were transcribed by two authors (LV and EL). Possible barriers and facilitators were extracted from the transcripts by coding relevant passages of text, and analyzed following a systematic approach using the qualitative software program Atlas.ti (version 5.2) [30]. Following the constant comparison process, every selected passage was compared to the rest of the text in order to identify all nuances in the data [31]. The identified factors were then clustered to reduce and refine key factors according to the different implementation levels [14]. Based on the key factors, further analyses were performed to detect and check correspondence and differences between factors. In order to ensure uniform coding, the identified barriers and facilitators were discussed in a consensus meeting until agreement was reached [31]. Transcripts were not returned to participants for comments. For the selected barriers and facilitators, relevant quotations were derived from the text to illustrate the meaning that participants attached to the factors. Quotations were translated from Dutch to English by the principal researcher (LV), and checked by a second research team member (EL).

Results

Participant characteristics

OPs were on average 47 years old (range 35-54 years), and two of the seven OPs were men. On average, OPs had 14 years of experience (range 7-21 years) as an OP. Four were employed at an external occupational health service (OHS), two at an internal OHS and one OP was self-employed. Employers were all human resource managers, of whom three were men. All worked for large size companies (>300 employees), including a university, a bank, a nursing home, a spice factory, a packaging company, a municipality, and a consumer goods company. The recruited employees were white-collar workers (70%), blue-collar workers (15%), or had client contact (15%).

Implementation factors

Table 1 presents the identified barriers and facilitators to implementation of the guideline, as explained by OPs and employers. Factors were often perceived as both a facilitator and barrier to implementation, namely when a factor was or was not met, respectively. Employers mostly mentioned factors that addressed the socio-political context and the organization, while OPs generally addressed their own role and the guideline.

Table 1. Perceived barriers and facilitators to implementation of the guideline, explained by OPs and employers.

Implementation level	Factor	Barriers (B) and facilitators (F), mentioned by	
		Occupational Physicians	Employers
Socio-political context	Compatibility with societal developments		F
Organization	Management support	B	F
	Benefits of investments	B & F	B & F
	Compatibility with policy and culture	F	B & F
	Resources	B & F	B & F
Occupational physician	Personal determinants: knowledge and skills	B & F	B & F
	Support from colleagues	B	
	Compatibility with current practice	B & F	
Guideline	Relative advantage	F	F
	Observability	B & F	
	Expectations	B & F	B & F
	Ethical considerations	B & F	B & F

Socio-political context

Regarding the socio-political context, one factor was mentioned by employers.

Compatibility with societal developments

Implementation was facilitated according to some employers because the guideline was compatible with current societal developments. One employer explained his company's increased attention for prevention as follows: 'That also has to do, if I broaden it, with societal developments. There is more attention for it, and more attention is asked for it. So at some point that also penetrates an organization such as ours.'

Organization

At the organizational level, four factors were mentioned by OPs and employers. These were management support, benefits of investment, compatibility with policy and culture, and financial and material resources.

Management support

During the interviews, most employers mentioned that they supported implementation of the guideline. One employer simply illustrated: 'We are enthusiastic about this [the guideline].' However, most OPs perceived management support as a barrier to implementation, because OPs felt management was not prepared to actively assist them. For example, one OP said: 'I did not really find the employer to be very motivated. They fill it [the environment scan] in rather quickly during lunch, but if there was really attention for it, or that they promised improvement, well, no.'

Benefits of investment

The factor benefits of investment refers to statements on perceived benefits. Both OPs and employers mentioned that perceived benefits may work as a facilitator to implementation, as illustrated by an OP who stated: 'It is not just weight loss, but employee satisfaction that we can benefit from.' Nevertheless, one employer explained that the lack of clear benefits may also work as a barrier to implementation: 'It is especially important (…) that you can show what is gained, is it worth the investment (…). But if it is proposed as do something new, and you have to invest, but we cannot really show what the benefits are, then it will be very difficult.'

Compatibility with policy and culture

Although most employers stated that they did not know whether the guideline contributed to their health policy, some employers found compatibility of the guideline with their policy and culture to work facilitating. One employer illustrated: 'I think that this is a theme that relates to what our organization stands for, and to what we already do.' OPs agreed that implementation was facilitated when this factor was met, but highlighted that this factor could also be a barrier to implementation when it was not met: 'With these kind of topics (physical activity, nutrition) it should not only be part of the behavior of OPs, but it should be part of the behavior of the company.'

Resources

Employers all stated that financial resources were not a barrier to implementation, as illustrated by one employer who said: 'It concerns people's health, so in that sense it [money] is not a problem.' Among OPs however, resources that were perceived as barriers were the OPs job position (self-employed, internal position or external position via occupational health services), agreements in contracts, and time issues. Regarding job position, a self-employed OP stated to have the advantage of managing his own time. An OP from an internal OHS stated to be able to schedule appointments more easily. On the other hand, an OP who worked via an external OHS stated: 'I usually don't find it [weight gain prevention] to fit within the contract that we have with a client. (…) You don't get extra time for it, so it was at the expense of other things I did.' Subsequently, all OPs mentioned that agreements in contracts are a crucial factor to consider for implementation. A self-employed OP found his contract based on hours to facilitate implementation, but an OP from an external OHS found her contract to hamper implementation: 'We have a contract based on obligations, and if I have to charge [the employer] for every half hour that I initiated…I may be able to sell it, but that is more difficult.' Finally, time was mentioned by most OPs and employers as both a barrier and facilitator to implementation. One OP warned: 'In a usual care setting it will probably be difficult, to talk to people 4-5 times a year.' Nevertheless, one employer stated to take time issues into account: 'I told her [the OP], if it were to take some more time, you won't hear from me.'

A lack of material resources, such as the lack of sport facilities and the lack of on-site measurement equipment, were mentioned by some OPs as barriers to implementation. For example, one OP said: 'I had to loan the measurement equipment and bring it to another location, well that was a drag every time.' Nevertheless, another OP mentioned that the availability of predefined registration forms was a facilitator to implementation: 'Those forms are indeed useful [for evaluation], to write things down as notes to yourself. But also as a reminder of what was decided, or discussed, with a person.'

Occupational physician

At the OP level, three factors were mentioned by OPs, namely personal factors, support from colleagues, and compatibility with current practice. The first factor was also highlighted by employers.

Personal factors

The personal factors refer to the OPs' knowledge and skills needed to implement the guideline. OPs and employers mentioned knowledge and skills as both barriers and facilitators to implementation. Regarding knowledge, an OP clarified 'This guideline assumes, compared to other guidelines, that we have a certain level of basic knowledge. I think that the level of basic knowledge on such processes [weight gain prevention counseling] is highly overestimated. Those are things that we (…) generally do not do in our practice.' As for skills, an OP clarified: 'When it concerns real counseling for weight loss or such, well, we have dieticians or others available in our country, they can do that a 100 times better than us.' Nevertheless, an employer addressed that the OPs' skills worked facilitating to implementation: 'I think that the OP played a big part herself, in making people enthusiastic.'

Support from colleagues

The lack of support from colleagues was perceived as a barrier to implementation by some OPs. One OP clarified: 'If you work in addiction care, then there are more people working that way, and you can (…) exchange how everyone approaches certain things. For me, this was not the case. We work solitary.'

Compatibility with current practice

OPs generally felt the guideline was compatible with their tasks, which facilitated implementation. One OP illustrated: 'A lot of people find they are overweight and do not know very well what they can do about it. And in that sense we have a clear role, together with general practitioners (GPs), to help them over that hill. I can see my added value in this. And maybe even more than a GP, because the access to my consultation hours is easier than a GPs.' On the other hand, solely conducting consultations on lifestyle was a barrier to continuation, as illustrated by an OP: 'It is very strange to dedicate an entire consultation to that [weight gain prevention] (…). I notice it has now become a regular part of my consultations, but I do not have consultations that solely address this anymore.'

Guideline

Regarding the guideline itself, four factors were mentioned by OPs and employers. These were relative advantage, observability, expectations, and ethical considerations.

Relative advantage

The factor relative advantage describes the extent to which the guideline is perceived as advantageous, as mentioned by OPs and employers. Most OPs felt implementation was facilitated by advantages, such as having a systematic way of working, tools and a structure to fall back on, having attention for the obesogenic environment, detecting comorbidity, developing client-centered counseling skills, and the frequency of follow-up consultations. Strikingly however, continuation was not facilitated after the 6-months intervention period, as all OPs answered the straightforward question 'do you still use the guideline?' with 'no'. Among employers, most found the guideline advantageous as no negative consequences were observed and employees could benefit from participation. Additionally, some employers highlighted that the guideline may facilitate continuation, as illustrated by an employer who said: 'it can help me, if we participate and if it is received positive, to put these kind of projects, and health management in general, on the map more explicitly than in the past.'

Observability

The factor observability refers to the degree to which results of the guideline are observable. All OPs found that the counseling technique facilitated implementation, because employees responded positively, and the technique was useful in other situations as well (such as sickness absence management). Moreover, OPs stated that the guideline facilitated continuation because employees organized healthy initiatives themselves. An OP illustrated: 'they [employees] used to go out to dinner, but now they go spinning. So something is starting to emerge, that there are other ways. It becomes more natural, and not something we [OP and employer] organize.' Barriers to implementation were also observed by OPs. For example, some OPs observed their counseling skills were insufficient when employees stagnated in improving their body weight or behavior.

Expectations

Participants' expectations worked as a facilitator to implementation when expectations were met, but as a barrier when expectations were not met. For example, an OP illustrated 'I hoped to put it [weight gain prevention] higher on the agenda, and that worked out.' Nevertheless, another OP stated: 'I expected that (…) it would be easier to move people to change.' One employer also illustrated expectations were a barrier to implementation: 'We expected to boost our health policy. That expectation was not met, in part due to the way our OP introduced it. We expected to receive more support from the Balance@Work organization.'

Ethical considerations

Both OPs and employers mentioned their responsibility for employees' healthy lifestyle. An employer illustrated that implementation was facilitated by their perceived responsibility: 'it remains the responsibility of the organization, from the vantage point of good entrepreneurship, to treat our employees well.' However, one OP experienced that ethical considerations could also work as a barrier to implementation, as the management team halted on-going changes to the cafeteria because people would otherwise go to a snack joint around the corner. This OP was of opinion that: 'the management team is avoiding their responsibility to change things, because you get a lot of criticism. I see that more often. People recognize that things have to be done, but whether they really do, is two steps too far.'

Discussion

The aim of this qualitative study was to identify possible barriers and facilitators to implementation of a draft occupational health guideline aimed at preventing weight gain among employees, and to provide recommendations for future implementation of the final guideline into occupational health care in the Netherlands. The results section summarized factors that should be considered when implementing the guideline. Based on these results, recommendations are provided below.

Regarding the first implementation level, the socio-political context, employers mentioned that implementation was facilitated because the guideline was compatible with current societal developments. This phenomenon has recently been mentioned by Swinburn (2011) as the 'prevention infection', illustrating that stakeholders are picking up on what is happening in society regarding obesity prevention, and are willing to implement health initiatives themselves [32]. The facilitating influence of this factor may be large for implementation of the guideline. The fact that employers are willing to invest in a healthy and productive workforce provides good opportunities to prevent weight gain in the workplace, and thereby may contribute to countering the obesity-related morbidity, mortality and health-care costs [33]. Moreover, Gortmaker et al. (2011) recently stated that this type of leadership may be necessary to increase the influence of policies that are necessary to monitor, prevent and control obesity [34].

The second implementation level, the organizational context, showed that four barriers and facilitators influenced implementation of the guideline. The first factor, management support, is a well-known barrier that can lead to obstruction of change when insufficient [35]. In the interviews, OPs explained that especially *active* support was lacking. Addressing this factor in the guideline may be necessary, because if OPs or employees believe that their management does not listen to them or care about them, they may be more likely to become apathetic [36]. Moreover, health-promotion programs have shown to work better when corporate policies send the message that managers care about their workers' well-being [37]. To increase management support, managers could be informed how their behavior impacts the probability that OPs will follow the guideline [36]. Moreover, OPs may need to explicitly discuss goals with management. Thus, forming a linkage board and improving physician-employer communication skills may facilitate management support [12].

Clear communication about the benefits of investments may also facilitate management support. On describing the role of employers in obesity prevention, Heinen and Darling (2009) argued that employers can serve their own economic interests by addressing obesity, because preventing obesity does not necessarily require new expenditures, and much benefit can be gained from creatively reallocating existing resources and benefits [33]. Thus, the guideline could list specific benefits for OPs to communicate to employers. Heinen and Darling (2009) also illustrated the facilitating influence of a culture of health at work, by provided examples of companies in which obesity prevention was facilitated when health became the norm [33]. Because this is not common in most companies, such examples could be added to the guideline as well. Finally, resources were mentioned by OPs and employers as an important factor to consider in the guideline. The interviews showed that especially OPs from an external OHS had contracts that were less compatible with the guideline. Although our results suggest that contracts based on an hourly fee for services may be more compatible to the guideline than a contract based on achievements, good agreement should be made irrespective of the type of contract, so that expenses such as time and material resources are covered [24]. The increased societal attention for prevention may facilitate uptake of preventive activities in contracts, but other initiatives may be necessary as well, such as including the opinion of a workers' representative counsel, and policy and financial incentives made by governments [38]. Moreover, OPs are recommended to discuss the added value of prevention with employers, in order to facilitate uptake of agreements regarding prevention in contracts, and thus creating possibilities to conduct preventive activities. The Netherlands Society of Occupational Medicine will do well to support OPs by providing training and tools for OPs on how to explain the added value of prevention with employers. Regarding the third implementation level, the OP, a lack of knowledge and skills was perceived as a barrier to implementation by some OPs. Moreover, some OPs stated that limited support was available from colleagues [25]. The lack of knowledge and skills contrasts data from the process evaluation, in which OPs did not perceive the guideline as too complex, and only one OP stated to miss certain knowledge to apply the guideline correctly [12]. Possibly, the fact that process data was assessed exactly after 6 months, and the implementation data was assessed after the trial 18-months trial period may explain some of this difference. Nevertheless, these quotes suggest that knowledge and skill levels should be assessed during the guideline training. Also, following the guideline training with peer medical audit groups may facilitate knowledge transfer and skill building amongst OPs. Finally, to increase compatibility with current practice, it should be considered to collaborate with qualified and experienced health professionals (such as registered dietitians or exercise health professionals), as they may be more suitable and less expensive [39,40], However, barriers such as management support and agreements in contracts should first be overcome by OPs and employers before successful collaboration may be possible.

The fourth implementation level concerns the guideline itself. Literature suggests that besides being compatible with current practice, best practices are largely viewed as providing relative advantage and generating observable improvements [41,42]. Despite the fact that many observable advantages were mentioned by OPs and employers, OPs indicated not to have used the guideline after the intervention period. This lack of attention for continuation

may be overcome by embedding parts of the guideline in policy in order to integrate health as a behavior of a company, such as addressing the environment scan for year plans and forming a linkage board [33]. Better support by stakeholders may stimulate OPs to continue applying the guideline. Moreover, governments and health insurances could play a facilitating role in health promotion. In previous years, several preventive measures have been initiated by the government, such as the 'Healthy Choice Logo' [43] that aims to facilitate healthy food choices, and the 'Beweegkuur' [44], a lifestyle program for individuals at risk of diabetes type 2 via the general practitioner. Health insurers have indeed reimbursed such programs. Nevertheless, although these examples show that population health promotion initiatives are feasible, effects on improving and maintaining a healthy lifestyle, especially on the longer term, are often unknown and need more attention. Moreover, uptake of a description of key elements for successful implementation in the guideline may facilitate actual implementation of the guideline [45].
Another factor, participants' expectations, were also mentioned as a barrier and facilitator. This factor comprises the expectation that a given behavior will lead to a particular consequence [28]. A lack of outcome expectancy, i.e. if participants believe that a recommendation will not lead to an improved outcome, has the consequence that participants will be less likely to adhere to recommendations. Among physicians, a lack of outcome expectancy has especially been reported for preventive guidelines and counseling [24], highlighting the need to address outcome expectancies in the guideline training. Finally, some questions arose about who must take action to prevent weight gain (e.g. who is responsible for what?). According to ecological models, the responsibility for the overweight epidemic cannot be attributed to one single party, as overweight is the result of a complex web of causal factors, many of which lie outside an individuals' control [46]. The balance between personal and collective responsibility should therefore be taken into account when implementing the guideline, not only from an ethical point of view, but also because societal objections may hamper the effectiveness of the guideline [47].

The identification of the most relevant barriers and facilitators to implementation allows for the design of appropriate and effective implementation strategies [23]. A recent study highlighted that multiple implementation strategies may be more effective than single implementation strategies, especially when these strategies address different barriers to change [15]. Besides the already mentioned strategies, such as the formation of a linkage group, collaboration with other experts, formation of a peer support group, improving physician-employer communication skills and communicating benefits of investments, expectations and ethical considerations, the guideline should provide a description of key elements for successful implementation. To simplify the guideline, a one-page summary leaflet will be produced. Also, barriers and facilitators to dissemination and adoption should be considered. Finally, the barriers and facilitators mentioned by the stakeholders could be presented in a flow-chart, including strategies for each step to overcome the barriers.

Strengths and limitations

This study has several strengths and limitations. Strengths include the assessment of factors regarding the socio-political context and organizational level. These levels are often neglected in randomised controlled trials, while they can be important barriers to implementation of innovations [48]. Also, numerous studies focused on barriers and facilitators to guideline implementation among physicians [24-26], but none focused specifically on occupational physicians, or on lifestyle-related guidelines. Moreover, the factors mentioned in this study were obtained from relevant stakeholders, and selected according to a systematic approach and theoretical framework [49]. Finally, a strength of this study is that the obtained factors were derived from a heterogeneous sample of OPs and employers, resulting in a broad overview of barriers and facilitators that may also be useful for other developers of clinical practice guidelines.

Meeting the identified barriers and facilitators to implementation however, may not have full impact on guideline implementation in reality, as these factors were mentioned by a small sample of motivated participants [15,42], and did not concern dissemination and adoption of the guideline [14]. Another limitation is that the researchers and OPs were acquainted with each other, which may have caused bias [16]. Also, the Balance@Work methods and strategies were mainly focused on changing employees behavior, while attention for changing OPs behavior may also be important [24]. Moreover, interviewed employees were disregarded in this study because they mainly addressed factors that were related to the process evaluation of the guideline. However, employees should not be neglected as stakeholder when implementing the guideline.

Conclusion

There is a broad societal basis and organizational support among OPs and employers for implementation of the guideline, but resources, structures and support for continuation should receive more attention in the guideline and training. Results from the present study can be used to increase the chance of successful implementation of the guideline into occupational health practices throughout the Netherlands, and thereby may contribute to the prevention of weight gain.

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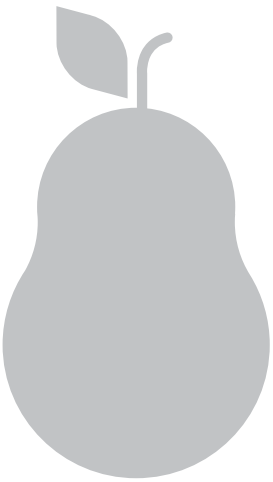
Chapter 9

Measurement error of waist circumference: gaps in knowledge



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Abstract

Objective It is not clear whether measuring waist circumference in clinical practice is problematic because the measurement error is unclear, as well as what constitutes a clinically relevant change. This study summarizes what is known from state-of-the-art research.

Design To identify the magnitude of the measurement error of waist circumference measurements from literature, a search was conducted in Pubmed from 1975 to February 2011.

Results The measurement error may vary between 0.7 cm and 15 cm. Taking a realistic range of a measurable waist circumference into account (60-135 cm), we argue that a short-term clinically relevant change in waist circumference of 5% may lie between 3.0-6.8 cm and a maintained clinically relevant change of 3% between 1.8-4.1 cm.

Conclusions Based on these results, we conclude it may be difficult to distinguish clinically relevant change from measurement error in individual subjects, due to the large measurement error and unclear definition of clinically relevant change. More research is needed to address these gaps in knowledge. To minimize measurement error, we recommend using a uniform measurement protocol, training and repeated measurements.

Introduction

Clinical guidelines recommend physicians to base their obesity-related cardiovascular risk management on abdominal as well as general obesity (1;2). Abdominal obesity (as measured by waist circumference) has been conveyed as a better, independent, predictor of obesity related-disorders than general obesity (as measured by BMI)(3-5). The presence of abdominal obesity can thus indicate the need for interventions in subjects who would otherwise not be considered at risk based on general obesity alone (1). Measuring abdominal obesity using the waist circumference has been marked as feasible because it is easy to learn, takes no more time than measuring body height and weight, and requires minimal costs (6).

Waist circumference is now more often used to monitor changes as a result of interventions, not only by trained researchers but clinicians in primary care setting as well (7-9). However, physicians report they find it hard to measure (10-12). Moreover, studies showing good reliability of waist circumference measurements are mainly performed by health professionals trained in anthropometrics (1.3 to 6.5 cm) (13-15) while studies in which measurements are conducted by physicians show larger variability (0.7 to 12 cm) (16-18).

The consequences of variability for clinical practice are not clear yet. This depends on whether the variability is so large that clinically relevant changes within subjects or clinically relevant differences between subjects, cannot be measured reliably. Three problems can be identified here. First, only few reliability studies are available. Second, many studies report reliability (e.g., the intraclass correlation coefficient (ICC)), but not an absolute measurement error (e.g. in cm). This information is needed to interpret change scores in individual subjects in clinical practice (19). Third, it is not clear what a clinically relevant change in waist circumference is, because there is insufficient evidence on the dose-response relationship between reductions in waist circumference and obesity-related morbidity and mortality (11;20;21). Thus, it is necessary to summarize what is known from state-of-the-art research and identify gaps in knowledge. The aims of this study are therefore to 1) explain the difference between reliability and measurement error and highlight why it is important to determine the measurement error of waist circumference, 2) discuss what is known about the measurement error of waist circumference and which factors may cause this, 3) discuss what is known about clinically relevant changes in waist circumference, 4) discuss how knowledge about clinically relevant changes can help to interpret the magnitude and importance of the measurement error of waist circumference, and finally 5) provide recommendations for future research and clinical practice on the measurement error of waist circumference.

1. The difference between reliability and measurement error

The terms reliability and measurement error are part of the concept term ‘‘reproducibility’’, as both address whether measurement results are reproducible in test–retest situations (19). Reliability refers to how well subjects can be distinguished from each other in populations, despite the measurement error. This information is required for instruments that are used

for discriminative purposes (e.g. to characterize individual differences between subjects in order to establish their clinical status and therapeutic needs, for example for discriminating between overweight and obese subjects). Measurement error assesses exactly how close values of repeated measurements within subjects are. This information is required for instruments that are used for evaluative purposes (e.g. to register change over time). The difference between reliability and measurement error is important for clinical practice because when studies present the reliability (e.g. ICC) of waist circumference measurements, a clinician is informed whether the instrument is able to discriminate between (for example overweight and obese) subjects in a sample. The clinician is not informed whether the instrument is suitable for monitoring waist circumference of individual subjects over time. In the latter case, the absolute measurement error around a single measurement of a single change score is important (19). This measurement error is expressed in e.g. the standard error of measurement or the limits of agreement (22). Moreover, measurement error provides an important advantage over reliability for clinical interpretation as it is expressed on the actual scale of measurement (e.g. cm), and not as a dimensionless value between 0 and 1. While information on both reliability and measurement error is necessary for clinical practice, reliability is generally high (15), but the magnitude of measurement error is not clear. In our article we focus on this absolute measurement error, which influences measurements in individual persons (22).

2. Measurement error of waist circumference

To identify the magnitude of the measurement error of waist circumference measurements from literature, a systematic search was conducted in Pubmed from 1975 to February 2011. Search terms for measurement error were selected from a search filter that was developed for finding studies on measurement properties (23), and combined with the text word 'waist circumference'. Studies using self-reported measurements and those among children or adolescents were excluded because these are associated with higher measurement error (15). Data were extracted on the Smallest Detectable Change (SDC) or Smallest Detectable Difference (SDD), which reflect the smallest change or difference in waist circumference of an individual subject that can be detected beyond measurement error (19). The search resulted in 559 studies, of which nine reported on the *intra*- or *inter*observer measurement error of waist circumference (e.g. repeated measurements on the same subjects by one observer, or by different observers, respectively) (Table 1). The methodological quality of studies was assessed by two authors (LV and CT) using the COSMIN checklist for grading studies on measurement properties (Box C, (24)). An overall methodological quality score was obtained by taking the lowest rating of the 11 items ('worst score counts') from the following ratings: excellent, good, fair or poor. For example, if for a study one item scored poor, the overall methodological quality of that study was rated as poor.

The selected studies included between 7-9279 participants, consisting of healthy adults, to employees or patients. The outcome assessors were physicians in three studies, and other health professionals in six studies. The outcome assessors were trained in advance in seven studies or between repeated measurements in two studies. All followed a standard

(although different) protocol. Participants were measured in standing position, except for one study that measured participants in supine position. These measurements were carried out midway between the lower rib and iliac crest in five studies, as the narrowest point between the rib cage and iliac crest in one study and as the uppermost limit of the ileum in another study. One study examined the effect of measurement site (lower rib, iliac crest or midway) on the measurement error (25). Finally, the overall methodological quality of the studies was fair or poor.

Overall, the *intra*-observer measurement error varied from 0.7 cm to 9.2 cm. The *inter*-observer measurement error varied from 1.4 cm to 15 cm (Table 1). In most studies that measured both, the *intra*-observer measurement error was smaller (15). Moreover, smaller *intra*- and *inter*-observer measurement errors were found in larger studies. No notable differences were observed between participant characteristics, outcome assessor, measurement protocol, effects of training, or methodological quality, also in relation to the measurement error. However, greater measurement error was reported from measuring at the iliac crest or midway, compared to the lower rib, possibly because the latter is most easily located (25).

Based on the small number of studies and many differences between the studies, we conclude that it is difficult to draw conclusions on the magnitude of measurement error. Moreover, the variation in measurement error may be caused by a number of other factors not mentioned in Table 1 such as muscle mass, bone structure, lean tissues, looseness of abdominal muscles, posture, phase of respiration and time since last meal (26;27). Additionally, measurement error may be larger among overweight and obese subjects compared to normal weight subjects, due to difficulty in locating anatomical landmarks (14;15;27;28).

3. Clinically relevant change in waist circumference

Whether the measurement error is problematic in clinical practice can only be judged if there is a clear conception of the magnitude of change in, or difference between, waist circumference that is considered important. In other words, we need to identify a minimal important change (MIC) within subjects or minimal important difference (MID) between subjects in waist circumference (29). While several studies suggest that a reduction of waist circumference may be associated with benefits across a wide range of health outcomes, there is limited evidence for what constitutes a minimal important change or difference in waist circumference (30-33). The NIH stated in 1998 that a sustained reduction of 4 cm may be clinically relevant (34). More recently it has been suggested that, similar to body weight and BMI, a reduction in waist circumference of >5% may be considered a clinically relevant change for individual subjects on the short-term, and a maintained waist circumference of <3% from initial waist circumference may be considered clinically relevant for individual subjects on the long-term (35) (personal communication Dr. I. Lemieux, and Prof. Dr. R. Ross). No clear definitions were provided on what short-term change and long-term maintenance are (35).

Table 1. Studies reporting *intra*- or *inter*-observer measurement error of waist circumference measurements.

1st Author year (ref) Country	Design and Population	Outcome assessor and Training	Number of measurements and Protocol	Measurement site	Intra- and inter observer measurement error (SDC and SDD in cm)	Quality
Bosy-Westfahl 2010 (25) Germany	Cross-sectional 16 lean and obese adults	4 nutritionists. Well-educated and trained, regular comparison of results.	3 nonconsecutive measurements, one measurement per site Protocol: (1;38-40) Horizontal tape, after normal expiration, nonelastic plastic tape, standing, no compression of skin	a. Lowest rib (distal border) b. Iliac crest (superior border) c. Midway between both	Intra-observer a. 3.3 cm b. 6.1 cm c. 5.5 cm Inter-observer a. 6.7 cm b. 15.0 cm c. 14.1 cm	Poor
Dhaliwal 2009 (47) Australia	Cross-sectional 9279 subjects from the Australian Risk Factor Prevalence Study (1989). Aged 20-69 years, 93% Australian, UK, European and 5% Asian or African.	2 Observers (n=? at 8 survey sites). Trained.	2 consecutive measurements Protocol: (41;42) Horizontal tape, after full expiration, metal tape, no compression of skin, no clothing around the waist, front of subjects	Narrowest point between the rib cage and iliac crest	Intra-observer 1.8 cm (men) 1.7 cm (women)	Fair
Geeta 2009 (43) Malaysia	Cross-sectional 130 working adults at selected office setting (2005). Aged 18-64, mean age 36 (SD 11), 67% female, 83% Malaysian. Nonpregnant, ≥2 months postnatal, no physical disability or body deformation to stand upright.	2 public health nurses. Trained, unaware of objective, previous measurement blinded.	3 consecutive measurements Protocol: Clinical manual of NHMS III (45) Horizontal tape, after normal expiration, Seca S201 tape, front of subjects	Midway between lowest rib margin and iliac crest	Intra-observer 1.2 cm (lower and upper limits -1.1 to 1.3) Inter-observer 2.1 cm (lower and upper limits -1.9 to 2.3)	Fair
Nordhamn 2000 (14) Sweden	Cross-sectional 25 lean and 26 overweight (BMI<26 and BMI≥ 26) students, university staff and company employees, 50% men.	5 observers from the metabolic unit. Trained.	3 consecutive measurements, 1 measurement after 1-3 weeks Protocol: unknown Supine position	Midway between lower rib and iliac crest	Intra-observer ≈5.3 cm (all) ≈3.8 cm (lean) ≈6.4 cm (overweight) Intra-observer ≈2.5 cm (all) ≈3.2 cm (lean) ≈2.1 cm (overweight)	Fair

Panoulas 2008 (17) UK	Cross sectional 102 patients in an outpatient department of a hospital for the preliminary study, 28 new patients matched to 28 original patients for the clinical practice study (2006).	Preliminary study: 4 doctors, 4 nurses, 2 physiotherapists. Trained. Clinical practice: 3 medical students. Untrained and after written instructions.	Preliminary study: 3 measurements by the 9 other participants. Clinical study: ? Protocol: (39) During expiration, standard measuring tape, no clothing around the waist	Midway between the palpated lowest rib margin and iliac crest in the mid axillary lines	Preliminary study: Intra-observer 0.7 cm Inter-observer 1.4 cm Clinical study, untrained Inter-observer 2.6 cm (n=102), 2.5 cm (n=28) Clinical study, trained Inter-observer 3.3 cm (n=28)	Poor
Sebo 2008 (16) Switzerland	Cross-sectional 24 healthy adult volunteers. Mean age 41 (SD 14), 54% women, 21% overweight, 42% obese.	12 doctors. Untrained and after a 1 hour training (theory, demonstration, practice)	2 consecutive measurements by all 12 doctors, repeated after 1 week. Protocol: (3;44-46) Horizontal tape, end of normal expiration, standard measuring tape, standing, no clothing around the waist, no compression of skin	Midpoint between lowest rib and iliac crest	Inter-observer 12.0 cm (untrained) 7.2 cm (trained)	Poor
Sicotte 2010 (18) Canada	Cross-sectional 12 (at 3 months) and 7 other (at 18 months) HIV-patients in Mali (year unknown).	1 doctor, 2 health professionals, without prior experience. Trained, written instructions, practice every 2 weeks during 3 months.	2 times on 2 consecutive days by the same observer on 2 study occasions. Protocol: unknown Marks on location, horizontal tape, nonstrechable Gulick tape.	Uppermost limits of the ileum	Intra-observer 3.4 cm – 9.2 cm Inter-observer 5.5 cm - 6.5 cm	Poor
Ulijaszek 1999 (15) UK	Review 1. 2 studies between 1987 en 1995 2. 8 studies between 1987-1997	Health professionals	Not specified	Not specified	Inter-observer 1. 3.6 cm (2.8-4.4) Intra-observer 2. 6.5 cm (1.7-11.7)	Fair
Wang 2010 (28) Taiwan	Cross-sectional 76 participants from inpatient wards (year unknown). 33% men, mean age 47 (SD 14), underweight (n=5), normal (n=27), overweight (n=21), obese (n=23).	2 research assistants, without prior experience. Trained, instructions, 20 minute practice	2 times with 10 min. intervals Protocol: unknown Horizontal tape, end of normal expiration, inelastic plastic measuring tape, standing, feet apart and arms hanging freely.	Midpoint between lowest rib and iliac crest	Intra-observer 3.0 cm (all) 1.7 cm (underweight) 1.7 cm (normal), 2.2 cm (overweight) 4.7 cm (obese)	Fair

Following that recommendation, for an overweight woman with a waist circumference of 80 cm this corresponds with a waist reduction of at least 4.0 cm and a maintained waist circumference of at least 2.4 cm. For an obese woman with a waist circumference of 110 cm, this corresponds with a waist reduction of at least 5.5 cm and a maintained waist circumference of at least 3.0 cm. This shows that for subjects with a larger waist circumference, a larger reduction in waist circumference is necessary for change to be clinically relevant. Taking a realistic range of a measurable waist circumference, for example 60-135 cm, this implies that a short-term change between 3.0-6.8 cm and a maintained change between 1.8-4.1 cm may be clinically relevant.

4. The relation between measurement error and clinically relevant change

In order to distinguish clinically relevant change from measurement error, the measurement error (SDC) should be smaller than the clinically relevant change (MIC) (Figure 1a, adapted from (29)). In this case, changes as large as the clinically relevant change will be statistically significant (29). Thus, the smaller the measurement error, the smaller the changes that can be detected beyond measurement error. But if the measurement error (SDC) is larger than the clinically relevant change (MIC), this change cannot be distinguished from measurement error (Figure 1b, adapted from (29)).

The range of measurement error presented in table 1 (0.7-15 cm) indicates that we are probably able to detect a short-term clinically relevant change of 4 cm (5% for a women of 80 cm) or 5.5 cm (5% for a women of 110 cm), as the *intra*-observer measurement error is smaller than 4 cm in all but one study. However, the probability to detect a long-term clinically relevant change of 2.4 cm (3% for a women of 80 cm) or 3 cm (3% for a women of 110 cm) is much lower, as the *intra*-observer measurement error is larger than 3 cm in more than half of the studies. Across the realistic range of waist circumference measurements (60-135 cm), many relevant short-term changes (between at least 3.0-6.8 cm) and maintained changes (between at least 1.8-4.1 cm) can probably not be distinguished from measurement error. Interestingly, the measurement error of waist circumference seems equally problematic for normal weight, overweight or obese subjects. Although the measurement error is larger among overweight or obese subjects, a larger reduction in waist circumference is also necessary to obtain a clinically relevant change.

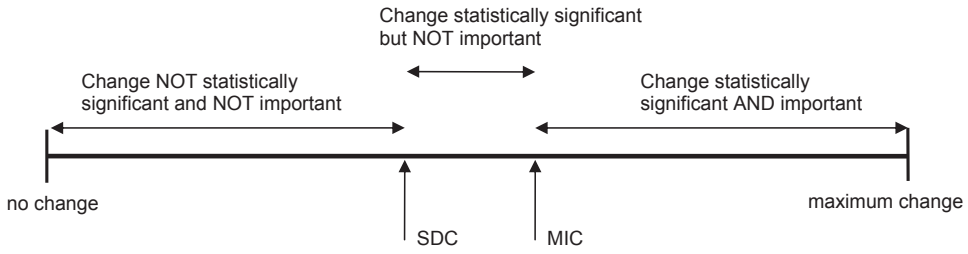

Figure 1a. Interpretation of change: the Smallest Detectable change (SDC) as a parameter of measurement error is smaller than the minimal important change (MIC)

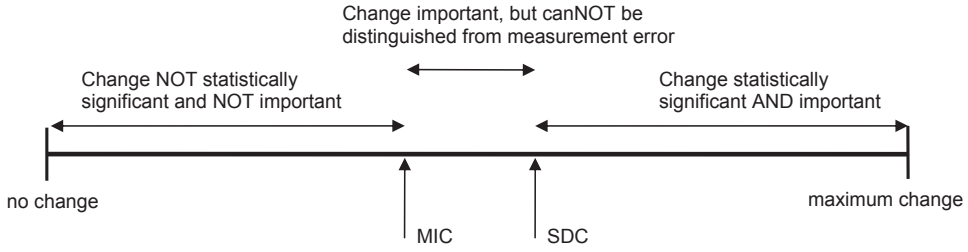

Figure 1b. Interpretation of change: the Smallest Detectable change (SDC) as a parameter of measurement error is larger than the minimal important change (MIC)

5. Recommendations for future research and clinical practice

To summarize, we have shown that there are two important gaps in knowledge. First, the assessment of measurement error identified a wide range (0.7-15 cm) of measurement errors, due to the small number of fair and poor quality studies, and many differences between studies. Second, no clear definition of clinically relevant change could be extracted from literature. Taking a realistic range of a measurable waist circumference (60-135 cm) into account, we argue that a proposed clinically relevant change in waist circumference of 5% at the short-term (approximately 3.0-6.8 cm) may be detectable, but a proposed maintenance of 3% (approximately 1.8-4.1 cm) may not be detectable, because it cannot be distinguished from measurement error. Although this paper does not provide practicing clinicians with empirical insight into the application and interpretation of waist circumference measurements in the clinical setting, the results do highlight that more attention should be paid to reducing measurement error, in order for clinicians and researchers to accurately measure real change in waist circumference rather than measurement error.

Three ways to potentially reduce measurement error in clinical practice are: 1) adopting a standard protocol, 2) training, and 3) repeating measurements (15). Two papers studied the influence of using different measurement protocols on waist circumference measurements. The first found that using different measurement protocol influenced the association between waist circumference, all-cause and cardiovascular disease mortality, cardiovascular disease and diabetes (36). These protocols however, were only compared on measurement site. The second study found that the type of protocol significantly influenced waist circumference measurements by comparing the measurement of waist circumference in 11 different ways (by anatomical site, posture, respiratory phase, and time since last meal) (27). However, as we have shown, other factors may also influence measurement error, and smaller measurement errors are required in order to detect (smaller) changes beyond measurement error. For clinicians, no standard protocol was advised as best. To overcome this gap in knowledge, we support the worldwide request for a uniform measurement protocol, decided on by an expert team (10;25;37;38).

A second way to reduce measurement error is by training. Measurement error is likely to be larger if measurements are carried out by poorly (often recently) trained individuals

(15). Training may thus reduce measurement error by quality control across time and by minimizing the number of observers (15). Unfortunately, it is unclear how (much) training is needed to decrease measurement error, nor whether the effect of training is sustained over time (16;17).
A third way to reduce measurement error is to repeat waist circumference measurements. If the same measurement is repeated for example two or three times, and the average value is taken, the measurement error of this average value is much smaller (by a factor √k with k being the number of repeated measurements) (39). For example, taking the realistic short-term (approximately 3.0-6.8 cm) and long-term (approximately 1.8-4.1 cm) clinically relevant change, two repeated measurements would result in an average measurement error of 2.1-4.8 cm for short-term clinically relevant change and 1.3-2.9 cm for long-term clinically relevant change. Three repeated measurements would result in an average measurement error of 1.7-3.9 cm for short-term clinically relevant change and 1.0-2.4 cm for long-term clinically relevant change. Thus, two measurements seem to be sufficient for detecting short-term changes, but three measurements seem to be necessary to distinguish long-term change from measurement error.

In conclusion, four gaps in knowledge have been identified. First, the magnitude of measurement error in unclear. Second, the definition of clinically relevant change is unclear. We therefore caution clinicians and researchers when interpreting individual changes in waist circumference, as clinically relevant changes in waist circumference may not be distinguished from measurement error. Third, consensus is needed on adopting a uniform protocol. Fourth, there is a lack of knowledge on the effects of training. Considering these gaps in knowledge, it is clear that there is a need for more good quality research and for action. Until then, we recommend consistently using one standard protocol, quality control as part of training and minimizing the number of observers, outsourcing measurements to well-trained clinicians and repeating measurements at least two, but preferably three times. Ultimately, by reducing measurement error, smaller changes in waist circumference may be detected by clinicians beyond measurement error. This is necessary for accurately monitoring changes in waist circumference of individual subjects over time.

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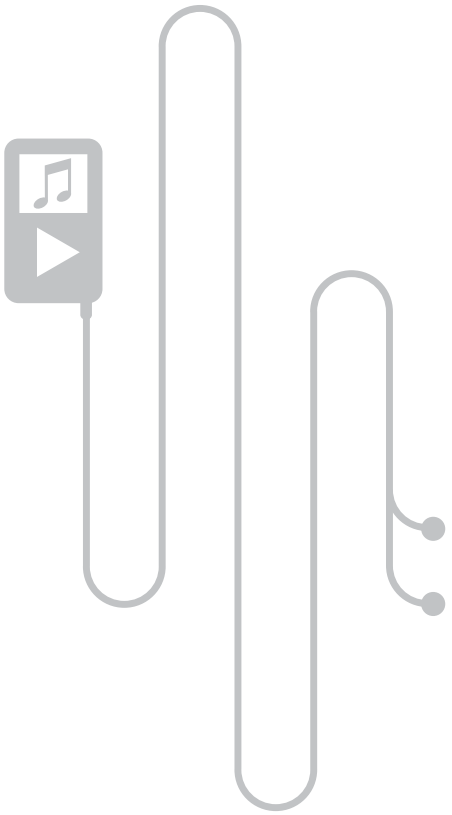
Chapter 10

General Discussion:
Stepping into the Future



The Dutch society faces major challenges in the work setting for the future, including retirement at higher age, a rapidly aging workforce, a growing number of employees with chronic diseases, and fewer young people who enter the workforce [1]. Diverse parties, among others the Dutch government and the Netherlands Society of Occupational Medicine (NVAB), consider improving employees' lifestyle via preventive measures a potentially effective tool to maintain a productive workforce, and prolong or sustain healthy employability of workers for the future [2].

This thesis addresses the need for occupational health professionals to play a more active - key - intervening role with regard to preventing weight gain among employees [3]. To meet this need, a draft evidence-based practice guideline was developed and evaluated among occupational physicians in the Netherlands. Based on the results presented in this thesis, the NVAB will decide whether the guideline in its current form can be authorized and published. This chapter aims to support the NVAB in her decision.

Section 1 of this chapter summarizes and discusses the main relevant findings and conclusions of this thesis. In sections 2 and 3, these findings are used to identify issues that prevail in the research context and the policy and practice context, respectively. Section 2 discusses a selection of considerations that warrant further exploration in relation to methodology, theory failure and program failure. Section 3 discusses shortcomings of the present disease-based care approach, new problems that arise when changing to a health-based care approach, as well as opportunities for a health-based care approach in Dutch policy. Finally, section 4 provides an overall conclusion, and recommendations for the NVAB, the stakeholders in the case description, the research community and for policy makers.

1. Relevant findings

Development of the guideline

Chapter 2 describes a systematic review including meta-analyses that was conducted to support the development of the draft guideline. From this review, we conclude that workplace physical activity *and* dietary behavior interventions can significantly reduce body weight (pooled estimate -1.2 kg). No conclusions could be drawn about effects on waist circumference, sum of skinfolds and waist-hip ratio due to the limited number of studies. Interventions containing an environmental component showed an additional reduction in body weight (pooled estimate -0.3 kg), supporting our decision to recommend the combination of workplace physical activity *and* dietary behavior interventions including an environment component, in order to prevent weight gain.

Chapter 3 describes the systematic development of the draft guideline, and the design for evaluation and implementation of the guideline. OPs in the control group were asked to provide care as usual, which generally consisted of the health risk appraisal with anthropometric measurements and a subsequent health advice. OPs in the intervention group followed the guideline by conducting five face-to-face behavioral change counseling sessions with employees to improve their lifestyle during 6 months, providing advice to employers on how to assess and intervene the obesogenic work environment, and addressing evaluation and maintenance of the guideline. The intervention was evaluated in a RCT design among 16 OPs and 523 employees.

Evaluation of the guideline

The process evaluation in **Chapter 4** describes that among OPs, behavioral change counseling was not performed to the full extent, the environmental scan was performed adequate by only one OP, and none of the OPs adequately addressed evaluation and maintenance of the guideline. Among intervention employees, reach (86%), satisfaction (7.1) and attendance rates (4.4 of out 5 sessions) were generally high. Moreover, intervention employees with higher attendance and satisfaction rates significantly improved their waist circumference (-1.5 cm to -2.1 cm) and body weight (-0.9 kg to -1.4 kg) at 6 months follow-up. Directly after the 6-months intervention period, **chapter 5** concludes that guideline-based care resulted in a more favorable sedentary behavior at work (β -28 min per day, 95% CI -2; -54) and increased fruit intake (β 2.1 pieces per week; 95% CI 0.6; 3.6), but did not improve employees' physical activity, snack intake or body weight-related outcomes. After 18 months follow-up, **chapter 6** shows that guideline-based care was neither more effective on body weight-related outcomes, blood pressure, total serum cholesterol or quality of life than usual care. The increased fruit intake (β 1.9 pieces per week; 95% CI 0.4; 3.4) was sustained (*unpublished data*). Based on the economic evaluation in **chapter 7,** it appears that guideline-based care is neither cost-effective from a societal perspective, nor cost-beneficial from the employers' perspective.

Implementation of the guideline

Besides effectiveness, other factors - such as compatibility with current practice and the OPs knowledge and skills - are important for actual implementation of evidence-based guidelines as well. **Chapter 8** therefore describes barriers and facilitators to implementation of the guideline, as mentioned by OPs and employers. From this study we conclude that there is a broad societal basis and organizational support among OPs and employers for implementing the draft guideline, but that resources, structures and support for continuation are persistent barriers that need more attention.

Finally, gaps in knowledge regarding the clinical utility of waist circumference are discussed in **chapter 9.** Based on literature, we conclude that it may be difficult to accurately monitor changes in waist circumference of individual subjects over time in clinical practice, due to the large measurement error and unclear definition of clinically relevant change.

2. Issues in the research context

Methodological issues

Methodological strengths and limitations of the studies included in this thesis have been discussed in the previous chapters. However, a selection of methodological issues in relation to the study design, study population, and choice of outcome measures warrant further exploration.

Study design

The guideline was evaluated in a randomized controlled trial (RCT) (chapters 4-7). For evaluation of interventions, the RCT is the strongest and most transparent research design for attributing causality to differences between study groups because it is less susceptible to selection bias and confounding than other designs [4]. In our study, randomization was performed at the OP-level in order to minimize contamination between the study groups. The randomization procedure was performed adequately (i.e. by a computer generated list), and analyses were conducted according to the intention-to-treat principle (i.e. all participants were analyzed as randomized). The randomization procedure, however, led to significant differences between intervention and control employees at baseline. Intervention employees were younger (46 versus 48 years) and worked less often in irregular work hours (19% versus 29%). To account for this bias, all results were adjusted for age and irregular work hours.

To account for the dependency of observations (of measurements within employees, and of employees within OPs) and our unbalanced data (the number of employees differed per OP), multilevel analyses were conducted in chapters 4-6. An advantage of performing multilevel analyses is that missing data are adequately addressed by a maximum likelihood estimation procedure that allows for all available data to be used in the analyses [5]. An unexpected problem that we encountered was the occurrence of non-random missing data at the third measurement due to time constraints at one intervention company. Also, it was not possible to perform multilevel analyses for the economic evaluation in chapter 7 because the statistical methods to perform multilevel analyses, bootstrap analyses and joint cost-effectiveness analyses were available in different statistical packages. Ignoring these problems may lead to an over- or underestimation of results and significance. In our analyses, we therefore 1) performed extensive sensitivity analyses to test the robustness of our results and 2) applied multiple imputation techniques in chapter 7 to account for missing data. The sensitivity analyses revealed that effects on body weight-related outcomes and health-related outcomes differed slightly between imputed data, multilevel data and complete cases (unpublished data). Nevertheless, it seems unlikely that our conclusions on the effectiveness of the guideline would change if complete data was present, considering the similar lack of results across analyses. We do encourage future statistical research to examine the issue of non-random missing data in multilevel analyses, as well as the practical application of multilevel economic analyses.

Study population

To date, occupational health care in the Netherlands mainly focuses on sickness absence management and return to work, i.e. secondary and tertiary prevention [6]. Interventions aimed at primary prevention, and the promotion of a healthy lifestyle in particular, are hardly implemented. Evidence suggests that such interventions in an occupational health setting could be effective and feasible [2]. For the guideline, we therefore chose a primary prevention approach. Primary prevention efforts in the workplace are directed at employed populations that are generally healthy. This approach aims to shift the entire distribution of

exposure in a favorable direction by limiting the incidence of disease by controlling causes and risk factors [7]. A drawback of this approach is that it may offer little health benefit to individuals because their absolute risks of disease are relatively low. Similar to our results, population interventions for preventing weight gain have largely shown small, short-term effects on body weight-, health- and work-related measures [8-10]. Comparable programs among high-risk populations indeed found better results on these outcomes, presumably because high risk participants are more likely to achieve measurable changes in behavior [11]. The high risk approach however, only partially solves the origin of the problem [12]. To achieve a meaningful degree of prevention and protection at the workplace, ultimately a combination of primary, secondary and tertiary interventions may be needed [7,13,14].

Considering the methodological quality criteria included in chapter 2, our study is of good quality (score 8) [15]. We were able to obtain a sufficiently large sample size and a long follow-up duration Also, employee attendance and satisfaction rates were generally high. Although the percentage of employees lost to follow-up did not exceed 30%, they were more often younger, females, and had a lower income than employees who completed the study. This may indicate that preferences and applicability of the intervention may differ for these groups. Inevitably, a selection bias of motivated employees and OPs occurred, implying that the generalizability of our results may be lower towards less motivated employees and OPs. In line, as only a small group of all OPs in the Netherlands (2%) participated in our study, generalizability of our results may be limited towards the total population of Dutch OPs. Our study should thus be considered a pragmatic trial (i.e. a trial that provides a compromise between an efficacy and effectiveness trial, as it reflects the heterogeneity of patients in actual clinical practice, minimizes exclusion criteria, and allows for variation in context, diagnosis and treatment), as opposed to an efficacy trial (i.e. a trial that determines if an intervention produces the expected result under ideal circumstances) or an effectiveness trial (i.e. a trial that measures the degree of beneficial effect under “real world” clinical settings) [16,17].

Outcome measures

Waist circumference was selected as the primary outcome measure of our study for its ability to better predict obesity-related disorders than BMI, its high reliability to assess a person’s clinical status (i.e. as overweight or obese), and its feasibility in clinical practice (i.e. easy to learn, quickly measured, at low cost)[18]. Although in our trial reliability was good (chapter 6), OPs stated they found it difficult to measure the waist circumference (chapters 4 and 8) due to difficulties in locating the designated measurement location, and due to variations in anatomical factors such as muscle mass, lean tissue, and posture. This led us to discuss gaps in knowledge regarding the clinical utility of measuring waist circumference in chapter 9. We conclude that there is insufficient evidence to support waist circumference as a good measure for monitoring change in individuals over time in clinical practice because of a large measurement error and an unclear definition of clinically relevant change. For clinical practice, we recommend research to focus on ways to more accurately measure waist

circumference (preferably by technological devices [14]), in order for clinicians to accurately assess an individuals' clinical status (to provide appropriate care), and to accurately monitor small changes in waist circumference beyond measurement error (to assess improvements). The influence of measurement error on our results however may be limited as we compared group mean's, not individual measurements [19].
The use of subjective measurement instruments should also be discussed. In our study we chose questionnaires over objective measures to assess daily physical activity, sedentary behavior and dietary behavior, because we were interested in changes in (sub)behaviors rather than in total energy intake or expenditure. Also, questionnaires are more compatible with clinical practice in terms of time, resources, and feasibility. Others however, suggest that objective measures in addition to subjective measures may provide better estimates of effects, such as heart rate monitors [20][21][22]. We expect that the subjective instruments did not affect the difference in behavior change between groups, as the same instruments were used among both groups. Nevertheless, in order to more precisely detect effects future research could focus on obtaining more solid standards for the assessment of overall physical activity, sedentary behavior or diet in public or occupational health settings [23].

Theory and program failure
Besides methodological issues, our results can be further discussed in the light of possible theory failure or program failure [24]. Theory failure implies that an intervention has been implemented well, but did not lead to improvement on the study outcomes. Program failure indicates that no improvements are found because the intervention was poorly implemented or the program did not adequately address required actions.

Theory failure
In our study, a minimal intervention strategy was evaluated in which employees were offered a maximum of five behavioral change counseling sessions during 6 months. Rationale for this intervention strategy was the restricted time OPs stated to have available during the design of the intervention, and the assumption that the 2-day training with role-play would be sufficient to produce significant improvements in behavioral change counseling skills [25], body weight [26], and lifestyle behaviors [27-29]. This made our intervention well-structured, but probably not intensive enough. In line with our results, a recent review found that minimal fruit interventions are sufficient to increase average fruit intake [22]. However, reviews on worksite physical activity and nutrition programs suggest that more intensive interventions may be necessary to improve physical activity and dietary behavior [15,30-33], including for example more frequent counseling sessions, exercise schemes or group counseling sessions.
A second consideration is that due to practical constraints, the guideline did not explicitly account for all other modifiable risk factors that may influence body weight and lifestyle behaviors as well, such as social stressors at work [34], smoking, alcohol use, psychosocial issues, or the home situation [35]. The behavioral change counseling technique allowed for OPs and employees to address issues other than preventing weight gain. However,

interventions that account for these multiple factors, prioritized and selected by the employee, may be more effective because they facilitates employees' involvement in the program through a variety of entry channels [13]. Future occupational health research needs to focus on ways to adequately address multiple factors in a practical manner.

Program failure

Chapters 4 and 8 describe that the intervention was not fully implemented as intended on all three guideline components. The process evaluation (chapter 4) showed that only one intervention OP was able to change the obesogenic environment. The other six OPs stated it was difficult to address the obesogenic environment because there were already (sufficient) events or facilities present, there was not enough time to implement changes, or it did not get priority from the employer. In hindsight, the guideline could have provided OPs with better practical guidance or materials to implement simple environmental changes that have shown to be effective, such as prompts, point-of-purchase signs, and food labeling. Also, a linkage board might have encouraged support from all stakeholders, and more attention could have been paid in the guideline training to physician–employer communication skills. If such strategies among OPs can indeed improve the obesogenic environment, remains to be further explored.

Program failure may also be implied because the behavioral change counseling technique was provided well but not to the full extent, because co-intervention was applied by one control OP, and because the control group received four health risk appraisal with feedback for evaluation purposes as well. These factors might have limited the contrast between the intervention and control group. A previous study among Dutch OPs and nurses showed that significant intervention effects can be achieved from behavioral change counseling techniques [36]. To achieve this, the guideline could be adapted to consider a phased behavioral change counseling education, including sufficient time and attention for relapse prevention, changing OPs' routines, and support from colleagues (in for example peer medical audit groups) [36]. Despite full proficiency however, our OPs were satisfied with the behavioral change counseling technique as it allowed them to better address resistance of employees, and was useful in other situations, such as sickness absence management, as well.

Finally, some level of program failure is plausible because none of the OPs used the guideline after the 6-months intervention period (evaluation and maintenance section of the guideline), nor did their companies adopt the guideline. During the development of the guideline, employers made us aware that evaluation and maintenance plans rarely exist for company health initiatives. We therefore addressed evaluation and maintenance in a separate section in the guideline. Nevertheless, OPs stated that this section was too difficult for them because the subject of preventing weight gain was neither linked to their work in occupational safety and disease management, nor easy to embed within the company's policy (chapter 8). Integrating health as a behavior of a company may be necessary to achieve evaluation and maintenance of health promotion programs [37], and may enhance effectiveness [38]. We encourage research to focus more on this point. For example,

a linkage board might encourage collaboration among stakeholders and thereby increase the chance of effective implementation.

Summary and interpretations

The issues as discussed above make clear that although the draft guideline contains best evidence and practice recommendations, these recommendations did not sufficiently enhance employee health or the quality of care. In part, this is due to issues in the research context. For example, the low ability to embed the recommended activities of the guideline in current practice. Also, this may be due to the basic principle that the guideline described an optimal situation, rather than formulating recommendations for the existing situation in the Netherlands. Literature and this thesis provide suggestions for improvements that may enhance the effectiveness of an adapted version of the guideline, such as providing a more intensive intervention aimed at multiple individual and environmental factors, that provides better practical guidance and materials for OPs, is implemented well, and able to more precisely detect effects. Also, the guideline could include primary, secondary and tertiary prevention, link health promotion to occupational health and safety, and increase attention for evaluation and maintenance in policy and culture. Adapting the guideline, however, would not ensure that desired effects are produced. Moreover, these adaptations would lead to a guideline that may by far exceed what is feasible for OPs in routine clinical practice [39]. Occupational physicians are generally not trained in prevention in lifestyle issues or in motivational interviewing, and the time needed to conduct these preventive activities exceeds the time they generally have [6]. Also, the draft guideline was evaluated among a motivated group of "innovators" (those first to adopt an innovation [40]), while in practice even more barriers to implementation may apply [39]. Considering the extent of the propositions, an adapted guideline would require another evaluation. These considerations imply that the guideline is part of a continuous improvement cycle. Four years ago, the draft guideline was developed based on the latest research. Evaluation of the guideline now calls for better theory and program forming in research to reduce the chance of failure in future programs. The results of this guideline should therefore not only be considered in the research context, but in the current policy and practice context as well.

3. Issues in the policy and practice context

From treatment to prevention

In order to contain costs and to prolong and sustain healthy employability of employees for the future, the Dutch Institute for Public Health and Environment stated that a shift from treatment to prevention is necessary in public health [41]. Support for such a shift is apparent from others as well [9,14,42]. For example, occupational healthcare in the Netherlands is changing from a main focus on sickness absence and disability, toward more involvement in preventing occupational or work-related diseases and improving participation and functioning at work [3]. On a larger scale, the WHO noted this as the paradigm shift from occupational health to workers' health in order to promote and improve all aspects of workers health. At the core, this approach includes all workers, all health determinants, all

relevant stakeholders, considers shared responsibility and extends beyond the workplace [42]. On all levels, there is a disparity between our scientific knowledge about prevention and the practical and effective implementation of preventive approaches. To address this disparity and successfully shift from treatment to prevention on a larger scale, Matheson et. al. (2011) propose a transition from disease-based care to health-based care [14].

Present disease-based care approach

Matheson et al. (2011) describe several reasons why our current disease-based health care system is not well suited for integrating preventive measures. First, the feature of our health care delivery system to divide complex health problems into smaller, more understandable parts, functions well for acute and simple diseases such as acute appendicitis. For chronic and complex diseases such as obesity, however, multiple factors are often responsible for the disease development or presentation [43]. Consequently, similar to our conlclusion, a system that accounts for these multiple factors may provide better and more effective care. Also, such a system allows for the integration of care, and therefore supports the multidisciplinary approach that is needed for preventing chronic diseases [14].

Second, our disease-based care education system mainly provides biomedical education, and merely provides preventive education on work-related risk factors. Initiatives to provide education on prevention are undertaken in the Netherlands, such as motivational interviewing courses for occupational health professionals, but most education is still largely inadequate and techniques such as motivational interviewing or exercise prescription are rarely incorporated in the basic curriculum [44].

Third, it has been widely recognized that changing health behaviors is difficult. Although many people would like to lose weight or exercise more, one third of our population is overweight, and half of our population fails to meet physical activity guidelines [45]. Generally, people prefer an immediate benefit rather than a delayed benefit, even if the delayed benefit has a larger impact [46]. Moreover, people discount long-term negative consequences of a behavior that provides instant gratification. Immediate consequences of a disease may therefore motivate people to adhere to therapeutic advice, but the lack of immediate consequences of unhealthy behavior often does not motivate people enough to adhere to lifestyle advice [46]. To support changing complex health behaviors in (relatively) healthy people, pricing strategies, legislation, and changes in the physical and social environment are proposed as most promising strategies [41]. In our study, only environmental strategies were described. However, well-conducted, effective studies are still scarce.

Finally, as evident in our study, physicians struggle with preventive care due to barriers such as the lack of support structures, the lack of sufficient training and feedback in prevention, the dominance of their on-going treatment tasks, and the lack of collaboration with other healthcare professionals. As a result, physician-based counseling has mainly led to short-term health improvements, and rarely to sustained health changes or sustained environmental changes. In such a system, it can be questioned if physicians can perform tasks regarding diseases management as well as prevention.

Changing to health-based care approach

To successfully shift from a disease-based care system to a health-based care system, several issues should be taken into account. Currently, there is no profession specifically aimed at prevention and management of chronic lifestyle-related diseases [14]. It remains to be established if such a profession should be created or adapted from existing professions. Nevertheless, such a profession would require education in epidemiology, prevention, counseling skills, lifestyle behavior, behavior change, and monitoring. Moreover, such a profession would emphasize self-care, repeated counseling, collaboration with other physicians - especially for individuals at risk, and performing adequate follow-up, both in group and individual settings. As a starting point for future interventions, individuals could be screened for risk of chronic diseases. Subjects at risk could then receive medical supervision, and subjects at low risk medical direction.

Another issue is that the disease-based care system makes people dependent on the system, but the client-centered health-based care system will require people to take responsibility for their own health [14]. However, solely addressing people on their own responsibility for prevention of complex chronic lifestyle-related diseases, that result from a wide range of voluntary and involuntary causal factors, rises ethical dilemmas (conflicts of ethical values) [47]. Workplace health promotion programs are justified because both employee and employer might benefit. However, dilemmas can arise when participation is not fully voluntary, or when forms of pressure, seduction or compulsion are applied to motivate employees. Furthermore, it has been shown that workers with an unhealthy lifestyle or poor health are more likely to have reluctance against employer interference, due to fear of potential consequences of participation ("blaming the victim") [48]. Because disrespecting ethical values may affect a program's effectiveness or have unintended consequences [12], workplace health promotion programs need to address ethical issues in their communication, design and implementation as well [49]. For example, creating awareness among employees that participation is voluntary, the OP has an independent position, and that there are no consequences to participation may reduce resistance.

To support people in taking responsibility for their own health, technological measures can provide key support [50]. Technology can make health information instantly available, understandable and personally relevant. For example, tracking devices can help people monitor their compliance and adherence to physical activity norms, as people tend to overestimate the time and intensity of physical activity [51]. Also, there is evidence that computer-tailored programs can be more effective in changing lifestyle risk factors than traditional approaches [52]. The use of technology will increase substantially over the next decade [53], reducing its complexity and generating more precise and usable outputs. A recent example is the use of a continuous self-monitoring wristband with software to assess daily energy intake and expenditure, that enhances lifestyle changes through monitoring and real-time feedback [50]. Moreover, it would be useful to implement technology for accurately measuring outcome measures, such as the waist circumference.

Opportunities in the Netherlands

Despite these issues, there is wide support for a health-based care approach in the Netherlands among important stakeholders. For example, the government initiated the "Ik Kies Bewust" logo to facilitate healthy food choices, and the "Beweegkuur", a lifestyle program for individuals at risk of diabetes type 2 via the general practitioner. Moreover, health insurers contribute to this approach by reimbursing programs. The "Convenant Gezond Gewicht", a collaboration of 27 parties ranging from the government and companies to non-profit organizations, is an important initiative that aims to address overweight and obesity across multiple settings: work, school, consumers and leisure time. The Royal College of Physicians (KNMG) has organized a number of conferences and activities to stimulate prevention. Also, in recent years medical associations are producing multidisciplinary health guidelines, such as the 2008 guideline "Diagnose and Treatment of Obesity" and draft guideline "Prevention Consult, module Cardiometabolic Risk". Finally, an increasing number of companies and occupational health services are implementing health promotion activities, such as the Fortis bank lifestyle program. Employers' motives to participate are not just related to absenteeism prevention, but to corporate social responsibility and sustained employability as well. Although few newly approved interventions actually save money, the notion that they may improve health at a reasonable expense could be key to achieving greater support from private and public employers [13]. These examples show that population health promotion initiatives are going-on and feasible. Effects on improving and maintaining a healthy lifestyle, especially on the longer term, however, are still relatively unknown and need more attention.

From an occupational health point of view, a health-based care approach receives support as well [6]. The demographic changes in the working population not only affect occupational physicians, but general practitioners and (para)medical specialists as well. Hence, a multidisciplinary approach will be required for the broad occupational health delivery. Collaborating and integrating occupational health care at an early stage in the treatment process may also increase societal participation of employees with (chronic) diseases [3]. Other ways of organizing occupational health care are indeed starting to emerge. Several clinical occupational health professionals (e.g. medical doctors, occupational health nurses) are now more often employed in multidisciplinary teams in hospitals and primary care centers. Also, the NVAB has become actively involved in developing multidisciplinary guidelines in collaboration with other (para)medical professionals. The role of OPs however, remains an issue for further discussion considering that over the next 20 years, 65% of the practicing OPs will retire while over the last years very few new physicians enroll for the profession of occupational physician [54]. Moreover, although 80% of the employees do not frequently visit the OP, evidence suggests that more employees are reached via the workplace who would normally not visit the general practitioner [55]. Large companies are likely to retain occupational health care in their organization, but for small enterprises occupational healthcare may need to be organized at branch level, or perhaps partly delivered in a primary care setting [3].

Summary and interpretations

From the policy and practice perspective, our current disease-based health care system is not well suited for integrating preventive measures because this system does not account for multiple factors, prevention is not integrated in education, there is a lack of environmental cues to facilitate behavior change, and there are persistent barriers for physicians to conduct preventive care. In order to successfully shift from a disease-based care system to a health-based care system, factors such as a profession, responsibility and technological measures may need to be further addressed. Nevertheless, opportunities do exist as there is a wide support from all stakeholders to perform preventive measures. The question that now remains is: what are practical implications for the draft guideline?

We do not have to wait for research to improve in the continuous improvement cycle. A possibility is to combine the (few) positive findings and trends in our project with the, on high-risk groups oriented approach, guideline on Prevention Consult for cardiometabolic risks, which is currently tested in the Dutch occupational setting. This primary health care guideline aims for OPs to structurally assess the risk of CVD, diabetes and chronic kidney disease via an online tool in people aged 45 years and older. It provides a subsequent health advice or referral to guidance and/or treatment by health professionals such as dieticians, physiotherapists or general practitioners, and to lifestyle programs for example to quit smoking, increase physical activity or healthy nutrition. The Prevention Consult addresses circumstances that were not addressed in our guideline, such as a structural, multidisciplinary approach, aimed at multiple factors, that facilitates collaboration with qualified and less expensive health professionals and that is partly reimbursed by health insurers. Our guideline could contribute to the Prevention Consult by addressing specific interventions for primary prevention of overweight and obesity, possibly in the obesogenic work environment, and considering behavioral change counseling techniques. Considering this discussion, there are still some circumstances that are not addressed in the Prevention Consult, such as engaging a linkage board to facilitate management support and implementation of the guideline in the company's policy and culture, that links health promotion to occupational health and safety and addresses systematic evaluation and maintenance plans. Also, although more factors are addressed than in our guideline, employees will still not be able to address the factors most relevant to them. These considerations may need further exploration in the occupational setting.

4. Conclusion and recommendations

Conclusion

This thesis describes that although guideline-based care led to significant improvements on sedentary behavior at the short term and on fruit intake at the short- and long term, the guideline was not able to induce favorable effects on other behavior-, body weight-, health- and work-related outcome measures. The findings as described above make clear that although the draft guideline contains best evidence and practice recommendations, these recommendations did not sufficiently enhance employee health or the quality of care. In part, this is due to issues in the research context, such as methodological, theory or

program failure. Also, this is due to issues related to the policy and practice context, such as limited support structures for continuation. Nevertheless, participant satisfaction was high and there is a broad societal basis and organizational support among stakeholders for implementing the draft guideline. The guideline is faced with the paradoxal situation that there is a need for a weight gain prevention guideline, but that the research and policy and practice context are not (yet) mature enough to effectively operationalize the guideline. I would therefore not recommend the NVAB to implement the draft guideline in its current form. Adapting the guideline would not ensure effectiveness and may exceed feasibility for routine clinical practice. To retain the knowledge gained in this thesis, a possibility is to embed successful elements of the draft guideline in the guideline on Prevention Consult for cardiometabolic risks. Before doing so, recommendations to create circumstances that may enhance the effectiveness of both initiatives should be taken into account. Considering the guideline as part of a continuous improvement cycle, I advise to address the highlighted issues regarding the research and policy and practice context. Stepping into the future, opportunities as well as challenges exist, that should be further explored and stimulated.

Recommendations

Recommendations for the NVAB considering the guideline

- Embed successful elements of the draft guideline in the, on high-risk groups oriented approach of the guideline on Prevention Consult for cardiometabolic risks
- Potential successful elements that should be further tested include; addressing the obesogenic work environment, primary prevention of overweight and obesity, and behavioral change counseling techniques

Recommendations for the stakeholders (case description)

The general introduction of this thesis poses the main question of the OP, the employer and employee: *how can weight gain be successfully prevented by a workplace health promotion program, in order to reach and maintain a healthy workforce?* Considering the above, in short I recommend the following steps.

In order to reach and maintain a healthy workforce, first a broad support basis should be created [38]. Employers and OPs could facilitate a linkage board within the company including all relevant stakeholders to monitor all steps of the innovation process (dissemination, adoption, implementation and continuation) at all implementation levels (the socio-political context, the organization, the OP and the guideline). Next, a needs assessment or risk analysis in the company will provide direction for which factors to intervene on, and direction for prevention and treatment according to stratification of employees. A health promotion plan can then be developed, in which practical circumstances are addressed such as the OPs contract, resources and how to target the programs to all stakeholders needs. Moreover, behavioral change counseling techniques can address the motivation of people to adhere to lifestyle advice as there is often no immediate consequence of unhealthy behavior, as well as to address possible resistance of employees. Finally, evaluation and maintenance should be addressed.

Recommendations for the research community

Challenges for research include;

- To make improvements regarding clear and explicit theories and methods in order to effectively achieve comprehensive workplace health promotion programs
- To study all steps of the intervention process with valid instruments and to better assess the clinical utility on the use of measuring waist circumference
- Assessing strategies to achieve sustained effectiveness of workplace health promotion programs on the longer-term, and among healthy participants with for example pricing strategies, legislation, and changes in the physical and social environment

Recommendations for policy makers

- Health at work should not be separated from general health and life, emphasizing the role and responsibilities of care providers for all health-related aspects of personal life
- Awareness should be created for ethical considerations, for example that participation is voluntary, that the independent position of the OP is maintained, and that there are no adverse consequences to participation, in order to stimulate employees to take responsibility for their own health
- Technological measures can provide key support
- Ultimately health promotion programs should be aimed at multiple individual and environmental factors, include primary, secondary and tertiary prevention, link health promotion to occupational health and safety, and pay attention to evaluation and maintenance in policy and culture
- Better educate occupational health professionals in prevention and management of chronic lifestyle-related diseases, and more specifically in behavioral change counseling techniques and physician-employer communication skills
- Develop and disseminate tools and resources for OPs to support their health and productivity management efforts
- Reevaluate the OPs position and tasks in light of the future shortage of OPs
- Combine guideline projects with an RCT. While an extensive practice test may lead to a substantial extension of the development period and costs, this may be a valuable approach in complex or relatively new topics.

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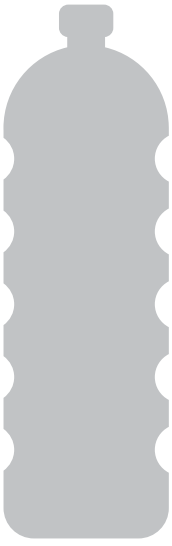
Summary



The prevalence of overweight and obesity has increased substantially in most Western countries, including the Netherlands. To counter the morbidity, mortality and economic consequences of overweight and obesity, there is a need to create interventions that are supportive for making healthy choices. **Chapter 1** describes that at the workplace, evidence-based practice guidelines could support occupational physicians (OPs) to play a key role in preventing weight gain. This thesis investigates the development, evaluation and implementation of a draft evidence-based practice guideline among occupational physicians and employees in the Netherlands.

Development of the guideline

In **Chapter 2,** a meta-analytic review examines the effectiveness of primary and secondary prevention workplace interventions targeting physical activity and dietary behavior on body weight-related outcomes. Data from 22 studies published between January 1980 and November 2009 were extracted by two authors and assessed for methodological quality. The GRADE approach was used to determine the overall quality of evidence for each pooled outcome measure. Moderate quality of evidence was found that workplace physical activity and nutrition interventions significantly reduce body weight (pooled estimate -1.2 kg). Due to a limited number of studies, evidence could not be investigated for effects on waist circumference, sum of skinfolds and waist-hip ratio. Interventions containing an environmental component showed a greater reduction in body weight (pooled estimate -0.3 kg). For future interventions, we recommend workplace physical activity and dietary behavior interventions, including an environment component, in order to prevent weight gain as the clinical relevance of the pooled effects may be substantial on a population level.

In **chapter 3,** we outline the systematic development of the draft guideline, and the design for evaluation and implementation of the guideline. Control OPs were asked to provide usual care, which generally consisted of a health risk appraisal with anthropometric measurements and a subsequent health advice. Intervention OPs were asked to provide guideline-based care. Guideline-based care consisted of 1) providing advice to employers on how to assess and intervene on the obesogenic work environment, 2) conducting five behavioral change counseling sessions with employees during 6 months to improve their physical activity and dietary behavior, and 3) addressing evaluation and maintenance. The guideline was evaluated using a randomized controlled trial design over the course of 18 months among 16 OPs and 523 employees. The primary outcome measure was waist circumference. Secondary outcome measures were lifestyle behavior-related outcomes (physical activity, sedentary behavior and dietary behavior), body weight-related outcomes (body weight and BMI), health-related outcomes (blood pressure, cholesterol and quality of life) and work-related outcomes (sick leave and productivity).

Evaluation of the guideline

Chapter 4 evaluates the process of guideline-based care among intervention group participants. Quantitative data on seven process items were assessed and linked to effects on employees' waist circumference and body weight at 6 months follow-up. Among OPs, the environmental component was adequately conducted by only one out of seven intervention OPs. The behavioral change counseling was performed partly, but none of the OPs adequately addressed evaluation and maintenance of the guideline. Moreover, all OPs found it difficult to measure the waist circumference. Among employees, reach (86%), satisfaction (grade 7.1), and attendance rates (4.4 of out 5 sessions) were generally high. Furthermore, intervention employees with higher attendance and satisfaction rates significantly improved their waist circumference (-1.5 cm to -2.1 cm) and body weight (-0.9 kg to -1.4 kg). From these results we conclude the occupational health guideline is feasible, but the environmental component and behavioral change counseling need revisions before practical application.

Chapter 5 presents the effectiveness of the draft guideline after 6 months on employees' lifestyle behavior-related outcomes (physical activity, sedentary behavior and dietary behavior measured by questionnaire) and body weight-related outcomes (body weight and BMI). Intervention employees were significantly younger (46 versus 48 years) and worked less often in irregular work hours (19% versus 29%) at baseline compared to control employees. To account for this bias, all results were adjusted for age and irregular work hours. During the 6-month intervention period, 53 subjects from both groups were lost-to-follow-up; 37 in the intervention group and 16 in the control group. Guideline-based care resulted in a reduction of the time spent sitting at work (β -28 min per day, 95% CI -2; -54) and increased fruit intake (β 2.1 pieces per week; 95% CI 0.6; 3.6), but did not improve employees' physical activity or snack intake. Also, no significant difference was found between groups among employees who maintained or decreased their waist circumference and body weight (i.e. prevented weight gain) versus those who increased their waist circumference and body weight.

Chapter 6 describes the effectiveness of the draft guideline during 18 months on employees' body weight-related outcomes (body weight and BMI) and health-related outcomes (blood pressure, cholesterol and quality of life). During this period 70 intervention employees (26%) and 54 control employees (22%) were lost to follow-up. Data were analyzed using multilevel analyses in order to adjust for the possible dependency of observations and unbalanced data. This procedure allows for all available data to be used in the analyses. Guideline-based care was neither more effective on body weight-related outcomes nor on health-related outcomes compared to usual care. The effect on increased fruit intake (β 1.9 pieces per week; 95% CI 0.4; 3.4) was sustained at 18 months follow-up (*unpublished data*). Stratified analyses showed an increase in waist circumference among men (β 2.5 cm, 95% CI 0.5; 4.5) and obese intervention participants (β 2.7 cm, 95% CI 0.6; 4.7) compared to control participants. As blinding of OPs was not possible, additional control measurements were performed by independent researchers in a random sample of 141 employees during all measurements

(8%). Also, a total of 1,010 (80%) self-reported waist circumference measurements were assessed from employees during all follow-up measurements using a non-stretchable paper measuring tape (range 0-130 cm) and written measurement instructions. No differences were found between OP measured waist circumference and independent researcher measured waist circumference. However, compared to OPs, employees significantly under-reported their waist circumference by -1.4 cm (SD=3.9; $p<0.01$). As employee measures tended to be less accurate, we conclude OP measured waist circumference remains the best of the two options.

Chapter 7 describes the economic evaluation performed alongside the trial, from both societal and employer's perspective. Costs were collected using three-monthly retrospective questionnaires. Quality of life was measured with the EQ-5D, at baseline, 6, 12 and 18 months. Waist circumference and body weight were measured at baseline and 18 months. For the economic evaluation, missing data were imputed by multiple imputations. The occupational health care guideline resulted in less health effects but lower costs than usual care. Unfavorable differences were found between the guideline and usual care group on waist circumference (+1.6 cm, 95% CI 0.27;2.90) and weight (+1.1 kg, 95% CI 0.01;2.15); there was no difference in QALYs gained (-0.01, 95% CI -0.03;0.02). The mean cost-difference was €-99 (95% CI -2918;2772). Probabilities of cost-effectiveness were consistently below 55%. Sensitivity analyses mostly showed unfavorable outcomes, leading us to conclude that the guideline was not cost-effective compared with usual care. From a Dutch employer's viewpoint, no financial return from implementing the guideline was shown. Net employer loss was €-158 (95% CI -2865;2672).

Implementation of the guideline

Chapter 8 presents barriers and facilitators to implementation of the guideline, as mentioned by 14 OPs and employers during interviews. Data were analyzed following a systematic approach using Atlas-ti. Barriers and facilitators were related to the socio-political context, the organization, the OP, and the guideline. From this study we conclude that there is a broad societal basis and organizational support among OPs and employers for implementing the draft guideline, but that resources, structures and support for continuation are persistent barriers that need more attention. Presenting these factors in the guideline, including strategies how to overcome barriers and stimulate facilitators, could facilitate implementation of the final guideline in the Netherlands.

Chapter 9 investigates the consequences of variability for clinical practice. Based on literature four gaps in knowledge were identified. First, the magnitude of measurement error in unclear. Second, the definition of clinically relevant change is unclear. We therefore caution clinicians and researchers when interpreting individual changes in waist circumference, as clinically relevant changes in waist circumference may not be distinguished from measurement error. Third, consensus is needed on adopting a uniform protocol. Fourth, there is a lack of knowledge on the effects of training. Considering these gaps in knowledge,

it is clear that there is a need for more good quality research and for action. Until then, we recommend consistently using one standard protocol, quality control as part of training and minimizing the number of observers, outsourcing measurements to well-trained clinicians and repeating measurements at least two, but preferably three times. By reducing measurement error, smaller changes in waist circumference may be detected by clinicians beyond measurement error, which is necessary for accurately monitoring changes in waist circumference of individual subjects over time.

In **chapter 10**, the results of this thesis are summarized and discussed. In addition, the relevance of the findings and recommendations for future research as well as practical implications are addressed. In conclusion, application of this systematically developed, well-appreciated but partly feasible draft guideline resulted in an improved sedentary behavior at the short-term and fruit intake at the short- and long-term, but did not result in overall improvements in behavioral outcomes, body weight-related outcomes or health-related outcomes. Also, the guideline was neither cost-effective nor cost-beneficial compared to usual care. Therefore, it cannot be recommended to implement the draft guideline in its current form. Several practical implications are given to provide direction when stepping into the future.

Samenvatting

De prevalentie van overgewicht en obesitas zijn substantieel toegenomen in westerse landen, waaronder in Nederland. Om de daarmee gepaard gaande morbiditeit, mortaliteit en economische gevolgen van overgewicht en obesitas te beperken of voorkomen, bestaat er een noodzaak voor interventies die mensen ondersteunt bij het maken van gezonde keuzes. **Hoofdstuk 1** beschrijft dat op de werkplek, bedrijfsartsen een sleutelrol kunnen spelen bij de preventie van overgewicht middels een richtlijn gebaseerd op wetenschap en praktijk. Dit proefschrift onderzocht de ontwikkeling, evaluatie en implementatie van een concept richtlijn voor bedrijfsartsen ten einde overgewicht en gewichtstoename te voorkomen.

Ontwikkeling van de richtlijn

Hoofdstuk 2 beschrijft een meta-analytische review naar de effectiviteit van werkplek interventies gericht op meer bewegen en gezonde voeding op gewicht uitkomstmaten. Data van 22 studies gepubliceerd tussen januari 1980 en november 2009 zijn geëxtraheerd en beoordeeld op hun methodologische kwaliteit. De GRADE aanpak is toegepast om de algehele kwaliteit van bewijs per gepoolde uitkomstmaat vast te stellen. Er werd matige kwaliteit van bewijs gevonden dat beweeg- en voedingsinterventies op de werkplek het lichaamsgewicht significant reduceerde (gepoolde schatting -1.2 kg). Door het kleine aantal studies kon het bewijs voor effecten op de middelomtrek, de som van huidplooien en de middel-heup ratio niet vastgesteld worden. Interventies met een omgevingscomponent lieten een grotere afname in lichaamsgewicht zien (gepoolde schatting -0.3 kg). Gezien de potentiele substantiële klinische relevantie van de gepoolde effecten op populatieniveau raden we toekomstige werkplek interventies aan, die gericht zijn op meer bewegen, gezonde voeding en die een omgevingscomponent includeren, om overgewicht te voorkomen.

Hoofdstuk 3 beschrijft de systematische ontwikkeling van de concept richtlijn, alsmede het ontwerp voor evaluatie en implementatie van de richtlijn. Bedrijfsartsen in de controle groep werden gevraagd om gebruikelijke zorg te leveren. Dit bestond grotendeels uit een gezondheidsevaluatie met antropometrische metingen en een opvolgend advies. Bedrijfsartsen in de interventie groep pasten de richtlijn toe. De richtlijn bestond uit drie delen 1) advies aan de werkgever over hoe de obesogene omgeving te inventariseren en interveniëren, 2) advies aan werknemers via vijf counseling sessies voor gedragsverandering gedurende 6 maanden en 3) evaluatie en behoud. De richtlijn werd geëvalueerd in een gerandomiseerd gecontroleerd onderzoek gedurende 18 maanden onder 16 bedrijfsartsen en 523 werknemers. De primaire uitkomstmaat was de middelomtrek. Secundaire uitkomstmaten waren leefstijlgedrag gerelateerde uitkomsten (bewegen, voeding, sedentair gedrag), gewicht gerelateerde uitkomsten (lichaamsgewicht en BMI), gezondheid gerelateerde uitkomsten (bloeddruk, cholesterol en kwaliteit van leven) en werk gerelateerde uitkomsten (verzuim en productiviteit).

Evaluatie van de richtlijn

Hoofdstuk 4 beschrijft de proces evaluatie van de interventie. Kwantitatieve data werd onderzocht op zeven proces items en gerelateerd aan effecten op de middelomtrek en BMI van werknemers na 6 maanden. Het omgevingsdeel van de richtlijn was adequaat uitgevoerd door een van de zeven interventie bedrijfsartsen. De individuele counseling was deels uitgevoerd, maar geen van de bedrijfsartsen besteedde aandacht aan evaluatie en behoud van de richtlijn. Ook vonden alle bedrijfsartsen het lastig om de middelomtrek te meten. Onder werknemers waren het bereik (86%), de tevredenheid (cijfer 7.1), en de opkomst (4.4 van 5 sessies) over het algemeen hoog. Interventie werknemers met een hogere tevredenheid en opkomst toonden tevens een significante verbetering aan in middelomtrek (-1.5 cm tot -2.1 cm) en lichaamsgewicht (-0.9 kg tot -1.4 kg). Uit deze resultaten concluderen we dat de concept richtlijn goed uitvoerbaar is, maar dat het omgevingsdeel en de individuele counseling aangepast dienen te worden vóór praktische toepassing.

Hoofdstuk 5 presenteert de effecten van de concept richtlijn na 6 maanden op leefstijlgedrag gerelateerde uitkomsten (bewegen, voeding, sedentair gedrag gemeten met vragenlijsten) en gewicht gerelateerde uitkomsten (lichaamsgewicht en BMI). Interventie werknemers waren significant jonger (46 versus 48 jaar) en werkten minder onregelmatig (19% versus 29%) bij aanvang van de studie dan controle werknemers. Om met deze verschillen rekening te houden zijn alle resultaten gecorrigeerd voor leeftijd en onregelmatige werkuren. Tijdens de interventieperiode zijn 53 werknemers van uitgevallen; 37 in de interventie groep en 16 in de controle groep. Na 6 maanden liet de interventie een positief effect zien ten opzichte van gebruikelijke zorg op sedentair gedrag op het werk (β -28 min per dag, 95% BI -2; -54) en fruit consumptie (β 2.1 stuks per week; 95% BI 0.6; 3.6). Er werden geen effecten gevonden op beweeggedrag of de consumptie van snacks. Tot slot werd er geen effect gevonden tussen werknemers die hun middelomtrek of BMI behielden of afvielen (gewichtsstijging voorkwamen) vergeleken met werknemers waarbij de middelomtrek of BMI toenamen.

Hoofdstuk 6 beschrijft het effect van de concept richtlijn gedurende 18 maanden op gewicht gerelateerde uitkomsten (lichaamsgewicht en BMI), gezondheid gerelateerde uitkomsten (bloeddruk, cholesterol en kwaliteit van leven). In totaal vielen 70 (26%) van interventie werknemers en 54 (22%) van de controle werknemers in deze periode uit. Om alle beschikbare data mee te kunnen nemen in de analyses en om te corrigeren voor de afhankelijke, ongebalanceerde data werden multilevel analyses verricht. Vergeleken met gebruikelijke zorg was de interventie niet effectief op de gewicht gerelateerde uitkomsten en gezondheid gerelateerde uitkomsten. Het effect op fruit consumptie werd behouden na 18 maanden follow-up (β 1.9 stuks per week; 95% BI 0.4; 3.4) (*ongepubliceerde data*). Gestratificeerde analyses lieten een toename in middelomtrek bij mannen zien (β 2.5 cm, 95% BI 0.5; 4.5) en bij obese interventie werknemers (β 2.7 cm, 95% BI 0.6; 4.7) vergeleken met controle werknemers. Tot slot, omdat het blinderen van bedrijfsartsen niet mogelijk was zijn onafhankelijke middelomtrek metingen door onderzoekers verricht in

een willekeurige groep van 141 werknemers (8%) gedurende alle metingen. Tevens zijn in totaal 1,010 (80%) zelf-gerapporteerde middelomtrek metingen van werknemers gevraagd gedurende alle metingen, met een geplastificeerd meetlint (range 0-130 cm) en geschreven instructies. Er werd geen verschil gevonden tussen de bedrijfsarts- en onderzoeker-gemeten middelomtrek. Echter, vergeleken met bedrijfsartsen was er een significante onderrapportage van de middelomtrek door werknemers met -1.4 cm (SD=3.9; p<0.01). Gezien de zelf-gerapporteerde middelomtrek metingen van werknemers minder accuraat waren, blijven de bedrijfsarts gemeten middelomtrek metingen de beste metingen om de resultaten van het onderzoek op te baseren.

In **hoofdstuk 7** is de kosteneffectiviteit van de richtlijn beschreven, vanuit maatschappelijk perspectief en vanuit werkgeversperspectief. Gedurende het onderzoek werd elke 3 maanden gevraagd naar kosten voor een gezonde leefstijl. Kwaliteit van leven werd gemeten met de EQ-5D bij aanvang van de studie en na 6, 12 en 18 maanden. Voor de economische evaluatie werd missende data aangevuld met multipele imputatie methoden. De op richtlijn gebaseerde zorg resulteerde in minder gezondheidseffecten maar ook in lagere kosten dan gebruikelijke zorg. Ongunstige verschillen werden gevonden op middelomtrek (+1.6 cm, 95% BI 0.27;2.90) en lichaamsgewicht (+1.1 kg, 95% BI 0.01;2.15); er was geen verschil in toegenomen QALYs (-0.01, 95% CI -0.03;0.02). Het gemiddelde kosten verschil was €-99 (95% CI -2918;2772). De kans om kosteneffectiviteit te bereiken was consistent lager dan 55%. Sensitiviteit analyses lieten voornamelijk ongunstige uitkomsten zien, waardoor we concluderen dat de richtlijn niet kosteneffectief was. Vanuit werkgevers perspectief werd geen financieel voordeel voor het implementeren van de richtlijn getoond. Het netto verlies voor werkgevers was €-158 (95% CI -2865;2672).

Implementatie van de richtlijn

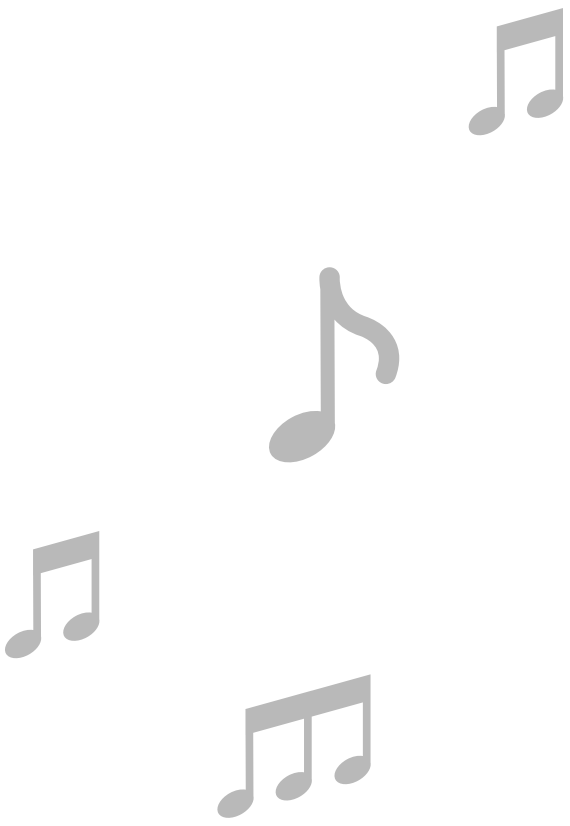
Hoofdstuk 8 beschrijft bevorderende en belemmerende factoren voor implementatie van de richtlijn, zoals genoemd door 14 bedrijfsartsen en werknemers tijdens interviews. Data werd geanalyseerd volgens een systematische aanpak met Atlas-ti. Bevorderende en belemmerende factoren werden gerelateerd aan de socio-politieke context, de organisatie, de bedrijfsartsen en de richtlijn. Uit deze studie concluderen we dat er breed draagvlak en organisatorische steun is onder werkgevers en bedrijfsartsen voor implementatie van de concept richtlijn, maar dat middelen, structuren en steun voor continuatie persistente barrières vormen voor implementatie, waar eerst aandacht aan besteed dient te worden. Het opnemen van dergelijke factoren in de richtlijn, inclusief strategieën om de barrières te overkomen en bevorderende factoren te stimuleren, zou implementatie van een definitieve richtlijn in Nederland kunnen faciliteren.

Hoofdstuk 9 onderzocht de consequenties van variabiliteit in middelomtrek metingen voor de klinische praktijk. Op basis van literatuur zijn vier lacunes in kennis geïdentificeerd. Ten eerste, de mate van meetfout bij het meten van de middelomtrek is onduidelijk. Ten tweede, een definitie van klinisch relevant verschil in middelomtrek is onduidelijk. We behoeden

clinici en onderzoekers daarom voor het interpreteren van individuele veranderingen in middelomtrek, omdat klinische relevante verschillen in middelomtrek mogelijk niet onderscheiden kunnen worden van meetfout. Ten derde, er is geen consensus voor een uniform meetprotocol. Tot slot, er is een gebrek aan kennis over de effecten van training. Er is een duidelijke behoefte voor onderzoek van goede kwaliteit en aan actie. Tot die tijd bevelen we het volgende aan: 1) gebruik consistent één meetprotocol, 2) kwaliteitscontrole als onderdeel van training, 3) zo min mogelijk personen of besteed metingen uit aan goed getrainde clinici en 4) herhaal het meten van de middelomtrek ten minste twee, maar bij voorkeur drie keer. Door het reduceren van de meetfout kunnen kleinere veranderingen in middelomtrek gedetecteerd worden voorbij de meetfout, wat nodig is voor het accuraat monitoren van veranderingen in middelomtrek bij individuen over de tijd.

In **Hoofdstuk 10** zijn de resultaten van dit proefschrift samengevat en besproken. Tevens is de relevantie van de bevindingen geadresseerd en worden er aanbevelingen gedaan voor zowel toekomstig onderzoek als voor de praktijk. De algemene conclusie die uit voorgaande hoofdstukken getrokken kan worden is dat de systematisch ontwikkelde, goed gewaardeerde, maar deels toepasbare concept richtlijn heeft geleid tot een verbeterd sedentair gedrag op de korte termijn en fruit consumptie op de korte- en lange termijn, maar over het algemeen niet heeft geleid tot de gewenste effecten op leefstijlgedrag gerelateerde-, gewicht gerelateerde- en gezondheid gerelateerde uitkomsten. Ook is de richtlijn niet kosteneffectief gebleken. Grootschalige implementatie van de concept richtlijn kan daarom niet aanbevolen worden. Dit proefschrift besluit met enkele praktische implicaties van de richtlijn om richting te geven aan onderzoekers en practici voor de toekomst.

Dankwoord



Zo tegen de zomer leg ik de laatste hand aan het proefschrift en denk ik met plezier terug aan de afgelopen 4 jaar. Er zijn zo veel mensen die hier aan hebben bijgedragen. Collega's, deelnemers, vrienden en familie, ontzettend bedankt!

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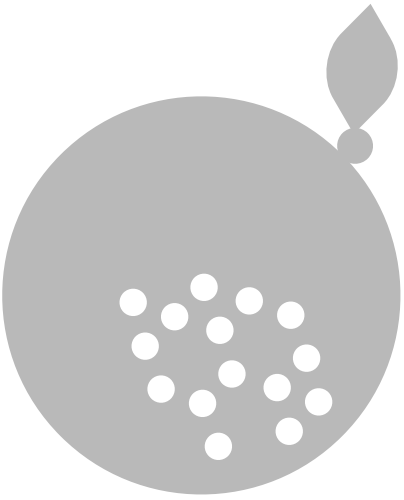
About the author

Lisanne Marlieke Verweij was born on October 19th 1984 in Den Helder, the Netherlands. After graduating from VWO at the Oranje Nassau College Zoetermeer in 2002, she studied Health Sciences at the VU University in Amsterdam. In 2007 she received her Masters degree with specialisations in 'Prevention and Public Health' and 'Public Health Research'. During her study and shortly after graduation she worked at the EMGO+ Institute of the VU University Amsterdam within the Longitudinal Aging Study Amsterdam (LASA) on the association between physical activity performed by older adults and incident arthritis. In 2008 she started her PhD project at the EMGO+ Institute within the department of Public and Occupational Health on the (cost)-effectiveness of an occupational health guideline to prevent workers' weight gain. During her PhD, she attended the Postgraduate Epidemiology Program at the VU University Medical Center. Currently, Lisanne is working as an advisor for guideline development and implementation at CBO, knowledge and implementation institute for improving the quality of health care in Utrecht.

List of publications



Articles related to this thesis

1. Verweij LM, Proper KI, Weel ANH, Hulshof CTJ, Van Mechelen W. Long-term effects of an occupational health guideline on employees' body weight-related outcomes, CVD risk factors and quality of life: results from an RCT. *Submitted.*

2. van Wier MF, Verweij LM, Proper KI, Hulshof CTJ, van Tulder MW, van Mechelen W. Economic evaluation of an occupational health guideline for prevention of weight gain among employees. *Submitted.*

3. Verweij LM, Proper KI, Hulshof CTJ, Weel ANH, Van Mechelen W. The application of an occupational health guideline reduces sedentary behavior and increases fruit intake at work: results of a RCT. Occup Environ Med. 2012;69(7):500.

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Other articles

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