Health under Construction

A lifestyle intervention for construction workers at risk for cardiovascular disease

Iris Groeneveld

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Body @ Work

BODY@WORK

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The study presented in this thesis was conducted at the EMGO+ Institute for Health and Care Research, Department of Public and Occupational Health of the VU University Medical Center. 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 study described in this thesis originated from Body&Work, Research Center on Physical Activity, Work, and Health, which is a joint initiative of the VU Medical Center (Department of Public and Occupational Health), VU University Amsterdam, and TNO Quality of Life.

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CHAPTER 1

General introduction

'The spread of information by general propaganda proved easy, but a change in habits seemed to require personal contact'

Rose et al., United Kingdom Heart Disease Prevention Project, 1980 (1).

Cardiovascular disease

Incidence and consequences

Cardiovascular disease (CVD) is the number one cause of death globally (2). In the Netherlands, in 2007, of all deaths, 30% of men and 32% of women died of CVD, of which 10.6% was under age 65. Half of all deaths were caused by coronary heart disease (CHD) and cerebrovascular disease, followed by heart failure. Between 1980 and 2007, CVD mortality decreased by half, mostly as a result of improved treatment. Accordingly, the number of yearly hospitalizations increased by 23% (3). In the Netherlands, in 2005, 5.5 billion Euros were spent on health care associated with CVD, thereby being the diagnosis generating the second highest costs for health care (4). Besides mortality, morbidity, and high costs, CVD is associated with a reduced quality of life (5).

Genesis

CVD is characterized by narrowing and weakening of arteries or veins, a process that may cause bleeding and insufficient oxygen supply, eventually leading to fatal or non-fatal damage to peripheral tissue, lungs, heart, and brains (6). Narrowing of vessels is induced by a process called atherosclerosis, i.e. formation of fatty streaks and plaques inside the vessel wall, accompanied by a chronic state of inflammation. Platelets are attracted to the site of inflammation, and can contribute to the formation of a blood clot (7), which may obstruct blood flow when released. The narrowing of blood vessels due to atherosclerosis will make the heart work harder and the blood pressure rise, leading to hypertension. Hypertension accelerates the process of atherosclerosis.

Precursors

One of the causes of atherosclerosis is an elevated circulating level of low-density lipoprotein (LDL) cholesterol and triglycerides, and a low level of high-density lipoprotein (HDL) cholesterol. Excess body fat, especially visceral body fat, adds to this abnormal serum lipoprotein profile. By releasing signaling proteins, adipose tissue is also thought to contribute to damage of the vessel walls (8). Another factor associated with CVD risk is Hemoglobin A1c (HbA1c). Elevated HbA1c is associated with a continuously elevated fasting blood glucose level, impaired insulin sensitivity, and diabetes type 2; a disease that is highly intertwined with CVD (9-11).

Lifestyle as a risk factor for CVD

Consequences and prevalence

An unhealthy lifestyle, i.e. an unhealthy diet, insufficient physical activity (PA), and smoking, contributes to the abovementioned biological precursors of CVD. Smoking has the largest

impact on CVD risk. The population attributable risk for smoking, i.e. the proportion of deaths in the population that could be prevented if smoking would be eliminated, is 35%. The population attributable risks of not consuming fruit and vegetables daily, and having less than four hours per week PA, are 13.7% and 12.2% respectively (12). Despite the disadvantages, an unhealthy lifestyle is common among the Dutch population. In 2003, of all adults aged 18-30, more than 90% did not fulfill the guidelines for fruit and vegetable consumption, and 92% of young adults derived more energy from saturated fatty acids than the recommended maximum of 10% (13). In 2005, 44% of all adults did not fulfill the guideline for moderate intensity PA, i.e. at least 5 days per week, a minimum of 30 minutes per day (14). In 2006, the prevalence of smoking among Dutch adults was 30% (15).

CVD risk reduction

By improving lifestyle, the risk of CVD will decrease. The influence of an overall healthy lifestyle on the risk of CVD has been shown in several large cohort studies. In the INTERHEART study, non-smokers with sufficient exercise and daily consumption of fruit and vegetables intake appeared to have a 79% lower risk of an acute myocardial infarction than smokers with a poor lifestyle (16). The Chicago Heart Association Detection Project showed that the life expectancy of non-smoking men aged 18-39 years with a normal blood pressure and normal cholesterol levels was 9.5 years higher than smoking men in the same age group with high blood pressure and high LDL cholesterol levels (17).

Smoking

Smoking cessation has the largest impact on CVD risk reduction. Smoking cessation immediately improves cholesterol levels and blood pressure (18;19). Soon after smoking cessation, the risk of coronary and cerebrovascular heart disease declines. Five or more years after smoking cessation, CVD risk is almost at the level as never-smokers (20;21).

Diet

Several foods can be targeted to improve diet quality, some of which will be mentioned. First, most snacks, usually eaten outside of regular meals, are energy-dense since they contain a relatively large amount of refined sugars and/or fatty acids. Decreasing snack intake has positive effect on body weight (23). Second, when replacing foods rich in saturated fatty acids with foods rich in unsaturated fatty acids, LDL cholesterol levels decrease and HDL cholesterol levels increase (25). On the opposite, some foods are recommended to be consumed in abundance, such as fruits and vegetables. Although the biological mechanisms are not entirely clear, several nutrients and phytochemicals, including fiber, minerals, and vitamins, are hypothesized to lead to a reduction in CVD risk. Moreover, the low energy density of fruits and vegetables may contribute to overweight prevention (22). Alcohol should not be consumed in excess, since it affects body weight, whereas moderate alcohol consumption is recommended because of its beneficial effect on serum lipids, lipoproteins, and blood clotting proteins (23). Apart from targeting

separate foods, there is another strategy for reducing CVD risk: lowering overall calorie intake may have favorable effects on body weight.

Physical activity

With respect to PA, both aerobic PA and resistance training contribute to the prevention of CVD. For adults, at least 30 minutes of moderate intensity physical activity per day, preferably on all days of the week, is recommended for limiting health risk. At least 60 minutes of moderate intensity PA per day is recommended to prevent body weight (re)gain (24). By increasing levels of PA, body weight loss and improvements in HDL cholesterol can be achieved (25), as well as reductions in diastolic blood pressure, triglycerides, and fasting glucose (26). Aerobic PA of vigorous intensity can lead to greater reductions in body weight loss and fasting glucose (26), and will acutely induce improvements in systolic blood pressure and HDL cholesterol (27). Resistance training is associated with beneficial changes in body composition, concerning lean and fat mass, HDL cholesterol and total cholesterol, and systolic and diastolic blood pressure (28). When combining an energy restricted diet with PA, a significantly greater weight loss can be achieved than with diet alone (29;30).

Additional benefits of a healthy lifestyle

Improving lifestyle has more benefits for health than lowering CVD morbidity and mortality alone. Smoking cessation lowers the risk of chronic obstructive pulmonary disease, lung, oral, and pancreatic cancer (31). Consumption of vegetables reduces the risk of intestinal and stomach cancer, and consumption of fruit is negatively associated with lung cancer (32). Adherence to a Mediterranean diet is associated with a reduction in the risk of cancer, Parkinson's disease, and Alzheimer's disease (33). High levels of PA were associated with reduced risk of cognitive impairment, Alzheimer's disease, dementia (34), and decreased risk of colon cancer (35).

Lifestyle behavior change

Theoretical models

As said, changing lifestyle behavior is important for health. During the previous decades, numerous theoretical models for health-related behaviors and behavior change have been developed. All of those models, such as the Health Belief Model (36), the Social Cognitive Theory (37), the Self-Regulation Theory (38), and the Theory of Planned Behavior (39), propose a different set of determinants as essential for behavior (change). Baranowksi et al. (2003) conducted a systematic review on theory-based interventions for changing obesity-related behaviors, and concluded that the Theory of Planned Behavior was best applicable (40). According to this theory, attitude, subjective norm, and perceived behavioral control are the most important determinants of the intention to change behavior. A frequently used model, derived from the Theory of Planned Behavior, is the 'attitude, social influence, efficacy' (ASE) model (41). Next to its dependence on determinants, behavior change is regarded as a cyclical process consisting of different stages. For the stages of change principle, various models have been developed, such as the Trans Theoretical Model (42)

and the Precaution Adoption Process Model (43). In each stage of change, different determinants are considered important (44). Behavior change models can be used to guide lifestyle behavior change interventions, although they should not be considered as equally applicable to all populations and to all different lifestyle-related behaviors. Even though there is no universal model of behavior change, it is clear that behavioral determinants need to be addressed in order to achieve behavior change.

Behavior change strategies

As can be concluded from the above, providing information or education on healthy behavior is usually insufficient to induce behavior change (45;46). The behavior change approach should be targeted at the individual, taking into account a person's current behavior, his information needs, and his stage of change and corresponding determinants. An intervention strategy that contains those characteristics, and which has been proven efficacious in previous studies (47;48), is called 'tailored'. A tailored intervention can be delivered by electronic, print, or telephone communication. A strategy that is not only tailored, but also has the advantage of direct interaction with the person, is individual counseling. To maximize the likelihood that individual counseling leads to behavior change, during the counseling sessions, the person's individual needs and opinions should be taken into account.

Motivational interviewing

A specific type of individual counseling that is client-centered is motivational interviewing (MI). MI was originally developed to aid changing addictive behavior, and appeared a promising strategy for lifestyle change in the previous decades (49). MI is based on the stages of change principle and involves a set of techniques for facilitating behavior change. The counselor is supposed to listen more than to talk, to ask open questions, and to summarize what has been said. By being supportive and collaborative, the resistance for change can be lowered (50). Still, the counselor should also use a more directive component, trying to raise ambivalence and increase motivation (51). When using MI, the counselor and client discuss the client's attitude and his perceived ability to change (52). Other behavioral determinants applicable to the client's situation can also be addressed. MI was shown to be moderately efficacious for facilitating diet modifications, in combination with nutrition education (53), and brief MI interventions were shown to increase exercise (54). There was conflicting evidence for the effectiveness of MI on smoking cessation (55). It should be noted that across the studies included in these reviews, heterogeneity existed in the training of counselors and the delivery of MI.

Workers' health

Workplace lifestyle interventions

Workers have been recognized as a relevant target population for lifestyle interventions, as shown in previous workplace health promotion programs. Workers constitute an appropriate population in that large numbers of adults of various socio-economic statuses,

lifestyles, and CVD risk profiles can be reached at once, through the occupational health service or the employer (56). Moreover, lifestyle interventions may have additional benefits with respect to productivity and sickness absence of workers, thereby lowering costs for the employer and society (57). Several intervention strategies aimed at lifestyle behavior change among workers have been investigated.

As said, individual counseling was shown effective for changing lifestyle. Also among workers, this strategy has been proven successful (58). For example, Proper et al. (2003) concluded increased PA levels (59) among white-collar workers, and Rodriguez-Artalejo et al. (2003) found a significant effect on smoking abstinence among bus-drivers (60), both as a result of individual counseling. Whether MI is also effective at the workplace has not been extensively explored. An advantage of most workplaces, as compared to other settings, is that the environment can fairly easily be changed, by e.g. increasing the availability of healthy food products or promoting stair use. As a sole intervention, environmental changes have been proven moderately effective (61). When combined with an individual-based approach, in line with the socio-ecological model (62), environmental changes have repeatedly been shown effective (63). However, this comprehensive approach is not applicable to all branches, such as the construction industry.

Dutch construction industry

In the Netherlands, among workers in the construction industry, who constitute 3% of the Dutch working population (64), an unhealthy lifestyle is common. In 2005, 63.7 % of Dutch male construction workers who attended the periodical health screening at the occupational health service were overweight or obese, as compared to half of the total Dutch male working population. According to the Framingham risk score, 25.1% of Dutch male construction workers had a higher than moderate risk for coronary heart disease. These high prevalences are true for both blue-collar workers, who are involved in construction activities (roughly two thirds of all workers in the construction industry), and white-collar workers, who are involved in administration, supervision, and management. Since the predominantly male population of workers in the construction industry is aging, the proportion at risk of CVD risk is likely to increase.

In 2005, the proportion of workers in the construction industry that attended the periodical health screening was 47.1%. During the periodical health screening, among others, musculoskeletal functioning, auditory and visual functioning, and mental health are assessed. In case of health complaints, dysfunction, or disease, follow-up is offered by the occupational health service, according to a standardized protocol. The guidelines for the periodical health screening, as well as protocols for follow-up, are developed by Stichting Arbouw, a national organization involved in monitoring and improving working conditions and occupational health of workers in the construction industry. Depending on the type and severity of the health problem, the worker is referred to a medical doctor, or offered one or more consultations with an occupational physician, occupational nurse, or social worker. If

necessary, his workplace environment is adjusted in agreement with the employer. In recent years, assessment of smoking status, PA, body weight, blood pressure, cholesterol, and HbA1c were added to the periodical health screening protocol. However, for workers at risk for CVD, no guideline for CVD risk reduction yet existed, other than providing short oral or written advice on improving lifestyle. When considering the high prevalence of overweight and CVD risk in this aging population, and the evidence for the effectiveness of workplace lifestyle interventions, an intervention for workers in the construction industry with an elevated risk of CVD was warranted and potentially effective.

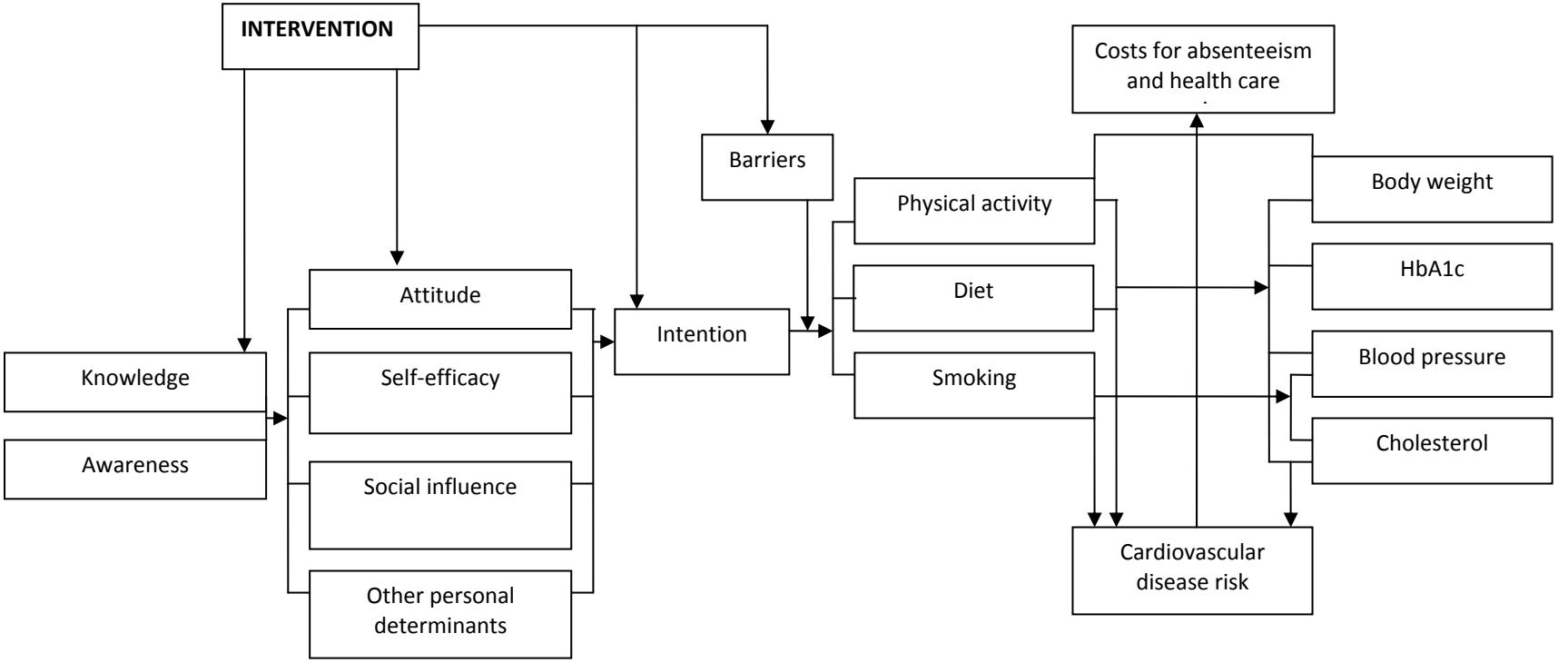
Aim, objectives and outline

In this study, an individual-based lifestyle intervention for male workers in the construction industry with an elevated risk of CVD will be developed and evaluated. The intervention will aim at improving diet and PA, or smoking cessation, using a client-centered counseling approach in which behavioral determinants are addressed. The intervention is hypothesized to lead to beneficial effects on lifestyle, as well as on the CVD precursors body weight, cholesterol, blood pressure, and HbA1c. Also, it is hypothesized to be cost-effective and cost-beneficial, by lowering costs related to absenteeism and health care use. A conceptual model of the Health under Construction study is outlined in **Figure 1**. In this thesis, three objectives are addressed:

1) To provide an overview of the evidence for the effectiveness of workplace lifestyle interventions on precursors of CVD;
2) To describe the design of the Health under Construction study, the characteristics of the participants, and the evaluation of the intervention process;
3) To present the short- and long-term effects of the Health under Construction study on lifestyle and precursors of CVD, as well as an economic evaluation.

Objective 1 is addressed in **chapter 2.** The issues mentioned in objective 2 are described in **chapters 3**, **4**, and **5**. The outcomes of objective 3 are presented in **chapters 6**, **7**, and **8**. The thesis is concluded with a general discussion, as presented in **chapter 9**.

Figure 1. Conceptual model of the Health under Construction study.



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CHAPTER 2

Lifestyle-focused interventions to reduce cardiovascular disease risk at the workplace: a systematic review

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Scand J Work Environ Health. 2010 May;36(3):202-15.

Abstract

Objectives The goal of this review was to summarize the evidence for an effect of lifestyle-targeted interventions at the workplace on the main biological risk factors for cardiovascular disease (CVD).

Methods We performed an extensive systematic literature search for randomized controlled trials (RCTs) that met the following inclusion criteria: i) targeted at workers; ii) aiming at increasing physical activity and/or improving diet; iii) measured body weight, body fat, blood pressure, blood lipids and/or blood glucose. We used a nine-item methodological quality list to determine the quality of each study. A best-evidence system was applied, taking into account study quality and consistency of effects.

Results Our review included 31 RCTs, describing a diversity of interventions, e.g. counseling, group education, or exercise. Of these studies, 18 were of high quality. Strong evidence was found for a positive effect on body fat, one of the strongest predictors of CVD risk. Among populations 'at risk', there was strong evidence for a positive effect on body weight. Due to inconsistencies in results between studies, there was no evidence for the effectiveness of interventions on the remaining outcomes.

Conclusions We found strong evidence for the effectiveness of workplace lifestyle-based interventions on body fat and, in populations at risk for CVD, body weight. Populations with an elevated risk of CVD seemed to benefit most from lifestyle interventions, and supervised exercise interventions appeared the least effective intervention strategy. To gain better insight into the mechanisms that led to the intervention effects, participants' compliance with the intervention and the lifestyle changes achieved should be reported in future studies.

Introduction

In Western countries, the prevalence of cardiovascular diseases (CVD) and CVD-related disabilities remains high (1). CVD can be divided into three major categories: Cerebrovascular disease, coronary heart disease, and peripheral vascular disease. All three disease categories are associated with excess body weight and fat, an elevated blood pressure, disturbed blood glucose, and an abnormal serum lipid profile, i.e. low high-density lipoprotein (HDL) cholesterol, high low-density lipoprotein (LDL) cholesterol, and high triglyceride levels (2). These abnormalities are mainly caused by unhealthy lifestyle behaviors, including smoking. Smoking leads to hypertension and low levels of HDL cholesterol (3;4). Diet is also strongly associated with several CVD risk factors. A diet rich in saturated fat negatively influences serum lipid profile (5;6), and excessive salt and alcohol intake contribute to hypertension (7;8). A diet rich in calories, combined with insufficient physical activity, leads to weight gain and obesity (9) and, more importantly, excess body fat (10). Not only the content of meals but also eating patterns are associated with overweight and CVD risk (11). For example, skipping breakfast increases the likelihood of eating more energy-dense snacks throughout the day. Physical inactivity is another lifestyle behavior associated with an elevated CVD risk (12-14), not least due to its contribution weight gain. Since lifestyle is a strong but modifiable risk factor for CVD, it has been the subject of research for many years.

For workers, an unhealthy lifestyle and being overweight not only affect CVD risk, but may also have major disadvantages related to work. Insufficient PA is negatively related to physical work capacity (15) and positively related to sick leave (16). Furthermore, in two recently published systematic reviews, it has been shown that obesity is a significant predictor of long-term sick leave (17), and disability pensions (18). Schmier et al. (2006) also concluded that obesity is related to more injuries (19). Altogether, physical inactivity and obesity are important drivers of indirect costs (19;20).

Thus, changing smoking, dietary, and physical activity behavior has many benefits. Several studies investigated the effects of lifestyle-focused interventions on CVD risk. A Cochrane systematic review concluded evidence for the effectiveness of lifestyle interventions (21). In the previous 20 years, some narrative and systematic reviews on health promotion aimed at workers have been performed, focusing on physical activity (22-26), diet (27), smoking (28), or health promotion in general (29-32). However, most reviews have not reported the evidence for effects on biological risk factors, which are objectively measurable, reliable, and strong predictors of CVD risk. Also, not all of the reviews applied a systematic approach to their search or the determination of evidence. Finally, the majority did not make a distinction between interventions aimed at populations at risk for CVD and those aimed at populations including both healthy persons and persons at risk ('mixed' populations'). Our goal was to summarize the evidence for the effectiveness of interventions aimed at improving PA and dietary behavior on body weight and fat, blood pressure and glucose, and serum lipids among workers. Interventions aimed at smoking

cessation were not included, since smoking cessation is not associated with body weight loss. First, we describe evidence based on all the studies together. Second, we describe separately evidence derived from studies aiming at populations at risk for CVD and those targeted at mixed populations. Third, we describe evidence for the effectiveness of the three most frequently used intervention methods.

Methods

Literature search

First, we performed a literature search of several electronic databases, i.e. EMBASE, Pubmed, PsychINFO, SPORTDiscus, and the Cochrane Central Register of Controlled Trials. We then screened the reference list of a key systematic review on multiple risk factor interventions for primary prevention of coronary heart disease (21); personal databases of the first two authors of this paper were also searched for additional publications. We sought randomized controlled trials (RCTs) and controlled trials (CTs), evaluating worksite lifestyle or health promotion interventions (such as individual counseling, group education, or self-help), aimed at the promotion of physical activity and/or a healthy diet. Due to their inferior design, controlled trials would only be included when the number of RCTs would be too low to draw conclusions (33). As for the study population, we included interventions aimed at blue- and white-collar workers of all ages and both genders. Furthermore, interventions had to be implemented in the occupational setting, i.e. at the workplace and/or during working hours and/or facilitated by the employer. Outcome measures were defined as biological risk factors for CVD. The search was limited to studies published in English, between 1 January 1987 and 31 December 2008.

Outcome measures

Several biological CVD risk factors were defined as outcome measures: body weight, body mass index (BMI), total, HDL, and LDL cholesterol, triglycerides, systolic and diastolic blood pressure, blood glucose, and body fat. Because some measures were highly comparable or only measured sporadically, they were clustered. Body weight and BMI were clustered into 'body weight/ BMI'. The body fat-related measures were categorized into four categories: (i) overall body fat, as measured by dual energy X-ray absorptiometry (DXA) or bioelectrical impedance; (ii) 'central' body fat, as measured by waist circumference, waist-hip ratio, or DXA; (iii) 'peripheral' body fat, as measured by DXA or skin folds; and (iv) hip circumference. Peripheral and central body fat both have a positive relation with CVD, but the influence of the latter is largest.

Selection and data extraction

The first and second authors evaluated all titles and abstracts; both based their decision on the previously established inclusion criteria. In case an abstract contained insufficient information, or where both authors disagreed, the full paper was read. If disagreement remained, the third author made the final decision. In the situation where certain quality criteria on study design were not mentioned in the article, we checked if the authors

referred to a previous publication that contained more detailed information on these topics. After having collected all relevant publications, the first author extracted the data. Due to the variety of outcome variables, measurement methods, and timing of measurements used in the studies, a meta-analysis was considered inappropriate.

Quality criteria list

The criteria list used for assessing the methodological quality of each study was based on the Delphi list, developed by authors, epidemiologists, and statisticians (34). The list was adjusted to meet the specific purpose of this systematic review. Two items were added, referring to dropout and the length of follow-up, as previously described by Proper et al. (35). We pilot tested the adjusted version of the quality criteria list and independently scored two articles. Some items were described in more detail because of interpretation difficulties. Once the first three authors had agreed upon the modified list, as shown in **Table 1**, the first two authors independently assessed the methodological quality of each study. Items were scored negative where they were neither mentioned nor properly explained. In case of disagreement, the third author also scored the article.

Table 1. List of items used for assessing the methodological quality of studies.

	Criterion	Definition
A	Randomisation Procedure	Positive if there was a clear description of the randomisation procedure, and if randomisation was adequately performed.
B	Similarity of study groups	Positive if the study groups were similar at the beginning of the study with regard to age and/or sex and all relevant outcome measures.
C	Inclusion/ exclusion criteria	Positive if clear inclusion and/or exclusion criteria, at the level of the individual, were specified.
D	Dropouts	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).
E	Objectivity[a] and blinding of outcome assessor	Positive if an automatic device was used for the measurement by a blinded or non-blinded outcome assessor; positive if the outcome was read from a scale by a blinded outcome assessor; negative if the outcome was read from a scale by a non-blinded outcome assessor; negative if outcomes were self reported by the participant.
F	Compliance	Positive if the compliance was satisfactory according to the opinion of the reviewer.
G	Follow up	Positive if follow up was six months or longer.
H	Intention-to-treat analysis	Positive if an intention-to-treat analysis was performed.
I	Control for confounders	Positive if the analysis controlled for potential confounders.

[a]This criterion is met if it holds true for at least one of the outcome measures.
Items adapted from Verhagen et al. 1998

Best-evidence synthesis

Conclusions about the effectiveness of the interventions were based on a best-evidence synthesis. For each outcome, four levels of evidence for the effect of the intervention were discerned. The level of evidence depended on the quality of the studies showing this effect, and the consistency of the results. The levels of evidence, adapted from Van Poppel et al. (36), were described as: level 1 (strong evidence = multiple high quality RCTs with consistent outcomes); level 2 (moderate evidence = 1 high quality RCT *and* ≥1 low quality RCTs, all with consistent outcomes); level 3 (limited evidence = only 1 high quality RCT *or* ≥1 low quality RCTs, all with consistent outcomes); level 4 (no evidence = only 1 low quality RCT or contradictory outcomes of the studies). A study was categorized as being of high quality in case > 50% of the methodological quality items scored positively; otherwise a study was categorized as being of low quality. Consistency of results for a certain outcome measure was reached when at least 75% of relevant studies had results in the same direction, i.e. significantly positive in the intervention group, no difference between groups, or significantly positive in the control group. Where there were ≥ 2 high quality RCTs, the conclusion was based on these RCTs only. If not, the results of the low quality RCTs were also taken into account.

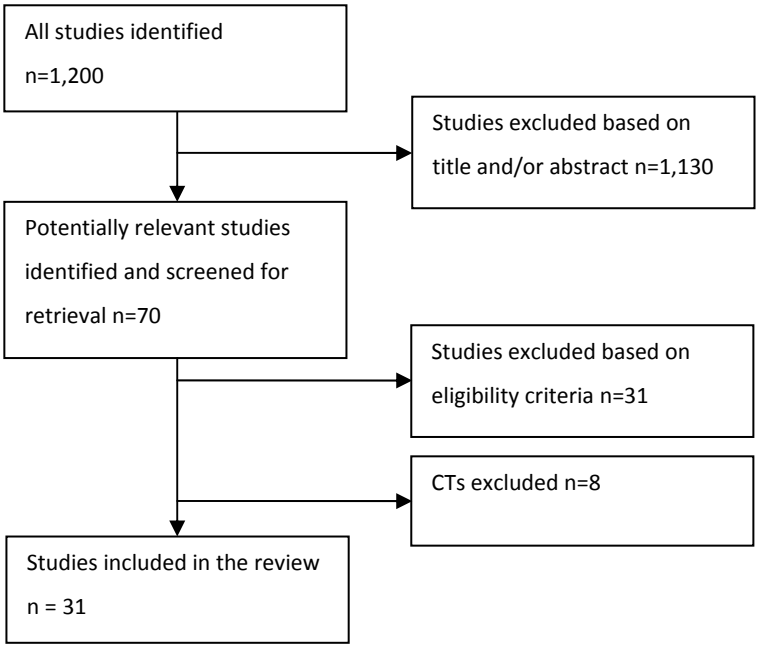
In addition to applying the best-evidence synthesis to all the studies together, we applied it to studies that aimed at populations at risk for CVD only, i.e. studies in which 'having ≥ 1 CVD risk factors at or above a certain cut-off value' was one of the inclusion criteria (as defined by the authors of the studies themselves). We also applied the best-evidence synthesis to studies aimed at mixed populations only, i.e. studies that had no inclusion criteria related to CVD risk status. Moreover, the evidence for the effectiveness of lifestyle interventions was determined for the three main intervention types separately, i.e. individual counseling, group education, and supervised exercise.

Results

Study selection

Figure 1 shows the flow diagram of the studies identified and rejected. The electronic database search resulted in 1,193 studies. The personal database search identified four additional studies, and three were found in the reference lists. Of these 1,200 studies, 1,130 were excluded as a first step, mostly due to a lack of a control group or because the study did not describe the outcome measures sought. After having read the whole text, another 31 studies were excluded because they did not fulfill the eligibility criteria. This left us with 39 studies, of which 79.5% (n=31) were RCTs. This number was considered sufficient to draw conclusions. Finally, 32 publications describing 31 RCTs were included (37-68). Concerning the methodological quality, the first two researchers disagreed on 11.8% of the items. Despite a consensus meeting, disagreement remained for one item. After consulting the third reviewer, the scoring process was completed.

Figure 1. Flow diagram of retrieved and rejected studies



Description of studies

Of 31 studies, 18 were of high quality (39;41-43;46;47;49;55;56;58-64;69-71). Study populations varied between 37 and 2,791 workers. Most studies (n=21) were designed as two-arm RCTs that evaluated one or more intervention strategies in the intervention group. In 10 studies, more than one intervention group was involved. The three intervention strategies most frequently used were individual counseling (n=18), group education (n=15), and supervised exercise (n=11). Between studies, these strategies showed large differences in frequency, intensity, and duration. Other methods, such as general written advice, a prescribed diet, self-help materials, environmental changes, or monetary incentives, were investigated only sporadically. Of the total, 12 studies aimed at populations at risk for CVD, and 19 targeted mixed populations. In **Table 2**, the characteristics of all studies and the intervention methods are presented in detail. In the last column, all significant effects are indicated.

Body weight/ BMI

Body weight and/or BMI were reported in 20 studies, 14 of which were of high quality. Seven high quality RCTs showed a significant difference between groups in favor of the intervention group, whereas six high quality RCTs showed no effect, and one showed a significantly positive effect in favor of the control group. Thus, there was no evidence for

an effect on body weight/ BMI. When considering studies aimed only at populations at risk (n=12), there was strong evidence for an intervention effect on body weight/ BMI; one high quality RCT showed no effect on body weight and six high quality RCTs showed a significantly positive intervention effect. Among mixed populations (n=19), there was no evidence for an effect on body weight/ BMI. There was no evidence for an effect on body weight for any of the three main intervention strategies.

Body fat

Even though three low quality RCTs showed no intervention effect, all three high quality RCTs in which overall body fat was measured showed a significantly positive effect in favor of the intervention group. Thus, strong evidence was concluded for a beneficial effect on overall body fat. As for central body fat, the results were mixed, and there was no evidence for an effect on this outcome measure. Peripheral body fat was measured in three high quality RCTs, two of which showed a significant favorable intervention effect, resulting in no evidence. Hip circumference was measured in two high quality studies, both showing no effect. Therefore, strong evidence for *no* intervention effect on hip circumference was concluded. Among populations at risk for CVD, the evidence for an effect on overall body fat and peripheral body fat was limited, since it was measured in only one study. When considering studies aimed at mixed populations, there was strong evidence for no effect on central body fat and hip circumference, based on four and two high quality RCTs respectively. Among studies using counseling as part of the intervention (n=18), there was strong evidence for a positive effect on peripheral body fat and limited evidence for an effect on overall body fat. The latter was also true for studies using group education (n=15). In studies evaluating exercise interventions (n=11), there was strong evidence for (i) a positive intervention effect on overall body fat, and (ii) no effect on hip circumference, the latter conclusion based on two high quality RCTs.

Blood pressure

Systolic blood pressure was measured in 18 studies, 12 of which were of high quality. Of those 12 studies, 25% (n=3) showed a positive effect and 75% (n=9) showed no effect. Thus, strong evidence for no intervention effect on systolic blood pressure was concluded. Diastolic blood pressure was reported in 17 studies, 11 of which were high quality RCTs. Of these, two showed a significantly positive effect in favor of the intervention group, one showed a significantly positive effect in favor of the control group, and 8 showed no effect. These data led to the conclusion of no evidence for an intervention effect on diastolic blood pressure. There was no evidence for an effect on either systolic or diastolic blood pressure in populations at risk. In studies aimed at mixed populations, there was strong evidence for no effect on systolic blood pressure or diastolic blood pressure, based on six and five high quality RCTs respectively. From counseling interventions studies, no evidence for an effect was concluded. In studies using group education, there was strong evidence for no effect on systolic blood pressure, based on five high quality RCTs. The

same was true for studies using exercise. Moreover, in exercise-based studies there was no evidence for an effect on diastolic blood pressure.

Serum lipids
Of the 21 studies reporting ≥1 total, HDL, or LDL cholesterol measure, 15 were high quality, and no evidence was concluded for an intervention effect. Triglycerides were significantly positively influenced by the intervention in two high quality studies, but no effect was found in five high quality studies. Thus, no evidence for an intervention effect on triglycerides was concluded. In populations at risk for CVD, there was no evidence for an effect on total or LDL cholesterol and triglycerides. There was strong evidence for no effect on HDL cholesterol, as concluded from five high quality RCTs. In mixed populations, there was no evidence for an effect on any of the serum lipids, except for triglycerides, for which we found strong evidence for no effect. Among studies using counseling as (part of the) intervention, there was strong evidence for no effect on LDL cholesterol and no evidence for effects on the other serum lipids. We concluded strong evidence for no effect on triglycerides from studies using group education. Exercise-based studies provided strong evidence for no effect on total, LDL and HDL cholesterol.

Blood glucose
Of three studies that measured blood glucose, one high quality RCT showed no effect and another showed a significantly positive effect. That said, there was no evidence for an effect on blood glucose. There was no evidence in populations at risk or mixed populations, limited evidence for an effect among studies that used counseling, and no evidence among group education or exercise-based studies.

Discussion
Main findings
Based on the 31 studies examined, we found that there was no evidence for a positive effect of workplace lifestyle interventions on body weight, blood pressure, serum lipid profile, blood glucose, and triglycerides. However, there was strong evidence for a favorable intervention effect on overall body fat, which is a better predictor for CVD than body weight; when fat mass is lost and muscle mass is gained, body weight remains unchanged.

The effectiveness of a lifestyle intervention often depends on whether the participants enrolled in the study have an elevated disease risk or not. Studies aimed at high risk populations may yield different results, have a larger health impact, and be more cost-effective (72) than those targeting mixed populations. To provide insight into this issue, we separately evaluated the studies aiming at populations (i) with an elevated CVD risk and (ii) for whom no CVD risk-related inclusion criteria were defined, i.e. mixed populations. We found that among the latter, there was strong evidence for no effect on most outcome measures. For high risk populations, however, even though there was

strong evidence for no effect on HDL cholesterol, there was strong evidence for an effect on body weight. For the other outcome measures, there was limited or no evidence - due to heterogeneous results or small sample sizes. We agree with Fleming et al. (2008) that lifestyle interventions aiming at low risk populations may be of marginal benefit and resources are better spent on those with an elevated risk of CVD (73). With respect to intervention strategies, we found that counseling, group education, and exercise were most frequently used. Studies focused on individual counseling and group education were more likely to find positive intervention effects than those examining supervised exercise. In fact, among studies looking at supervised exercise, for half of the outcome measures, there was strong evidence for no effect. These inconsistencies are probably related to differences in study populations.

The lack of evidence for most outcome variables resulted from inconsistencies between the studies' results. These inconsistencies are probably related to study populations, intervention strategies, and measurement methods. Other factors that may have contributed to the inconsistencies in results could be differences in participants' compliance with the intervention, and the lifestyle changes that they actually achieved. Unfortunately, most articles lacked information in this respect, e.g. the frequency and duration of sessions attended and the number of self-help assignments completed. The exact contents of the counseling or group educations were also usually not mentioned. Finally, from most studies it was unknown to what extent the interventions led to the intended dietary or physical activity change. Therefore, it was difficult to conclude what exactly happened to the participants during the study, and what was the mechanism that led to the effects.

When considering the results, not only significance, but also clinical relevance should be considered. The clinical relevance of a change in a certain CVD risk factor depends on its initial value and the presence of other risk factors, as illustrated by various (coronary heart disease) risk assessment instruments such as the Framingham risk score (74). Considering body weight, every kilogram of body weight loss was proven to correspond to a 16% reduction in diabetes risk (75). Thus, small changes in body weight and body fat may already be clinically relevant. Consequently, the findings of strong evidence for intervention effectiveness on body fat, and body weight in populations at risk, are certainly interesting.

Comparable studies

Ebrahim et al. (2006) published an extensive Cochrane systematic review on lifestyle interventions for lowering coronary heart disease risk in different settings, which was updated in 2006 (21). They found insignificant changes in blood pressure, but significant falls in blood cholesterol. Important to note is that Ebrahim and colleagues suggested that the changes in cholesterol levels may have been attributable to the use of cholesterol lowering medication. Prescription of medication was not part of the intervention protocol

in any of the studies included in our systematic review. Nevertheless, participants may have used medication before the study had started. Proper et al. (2003) published a systematic review similar to ours (76). They summarized the evidence for an effect on physical activity, fitness, and health among workers. Despite that they included only physical activity interventions, their conclusions were comparable to ours, i.e. inconclusive evidence for an effect on body composition, and no evidence for an effect on blood pressure and serum lipids. More recently, Conn et al. (2009) showed that physical activity interventions based on supervised exercise and motivational and educational strategies led to significant improvements in lipids and anthropometrics (77). In contrast to our study, Conn and colleagues included RCTs as well as non-controlled trials and unpublished reports; study designs that we considered less valid. In a systematic review on body weight loss among workers, Anderson et al. (2009) found a net body weight loss of 1.3 kg based on nine RCTs (78). Since we did not pool our data, our findings cannot be compared to theirs. With respect to the quality of the studies, we differed strongly with the paper of Kjaergard et al. (2001) who reported that year of publication was not positively related to study quality (79). In our review, of all included studies that were published in or after 2000, 78.6% (n=11) were of high quality, whereas of the studies published between 1987-1999, only 41.2% (n=7) were of high quality. This may have been a result of the stricter quality criteria of scientific journals in recent years.

Limitations and strengths

One of the limitations of our study concerned the best-evidence synthesis. When determining the evidence for effectiveness on a certain outcome measures, adding one high quality study may change the conclusion from 'no evidence' to 'strong evidence'. Besides, the cut off point of 75% for consistency between results often leads to the conclusion that there is no evidence for an effect. However, there is no consensus about which levels of evidence criteria should best be used (80). Another drawback was related to the fact that our quality assessment was based on the data as reported in the articles. In reality, in some articles, relevant data on, for example, randomization procedure, blinding, and type of analysis, were not presented. This may have led to an underestimation of the study's quality. One way to solve this problem would have been to ask all authors individually to provide missing information. However, in a study of Gibson et al. (2006), two thirds of the authors simply did not respond to their request for additional information (81). Lastly, measurements of waist circumference and skin folds are less accurate than DXA and bioelectrical impedance. Still, we decided to cluster all studies in which body fat was measured. In our opinion, when separating them according to the type of measurement would result in an inadequate number of studies to draw conclusions. Furthermore, when changes in body fat are determined over time, inaccuracy of measurements is less of a problem than when determining body fat cross-sectionally. Several strengths of this systematic review can also be mentioned. All relevant publications on workplace lifestyle-focused interventions were systematically collected and evaluated. We described not only the intervention effects, but also the methods and

population type used. The quality list was well adapted to the type of intervention studies. By independently scoring all articles, we maintained objectivity. Most importantly, in order to determine the population for whom lifestyle interventions seem most effective, we looked separately at studies aimed at populations at risk and mixed populations. Moreover, in order to define the most promising intervention strategy, we explored the evidence in three frequently used intervention strategies separately.

Conclusions

This systematic review fills a gap of knowledge on the effectiveness of lifestyle interventions on the main CVD risk factors among workers. Considering the cardiovascular health- and work-related risks of excessive weight and obesity, the findings of strong evidence for effectiveness on body fat and, among populations at risk, body weight are interesting for employers. For intervention planners and policy-makers it is worth knowing that populations at risk seemed to benefit more from lifestyle interventions than mixed populations, while supervised exercise interventions appeared the least effective intervention strategy. The lack of evidence for effects on most of the remaining CVD risk factors was mainly due to inconsistencies in results. In order to gain better insight into the mechanisms that led to the intervention effects, participants' compliance with the intervention, and their lifestyle change achieved should be reported in future studies.

Table 2. Characteristics of included studies.

Author (Quality)[a]	Study population	Intervention and control conditions	Follow up	Outcome measures	Results[b]
Aldana et al., 2005 (6/9)	145 workers, medical personnel and staff (m/f); used for analyses: 141 at T1, 137 at T2	Topics: Diet and PA I: 4 weeks, 4 x per week meetings on e.g. health risks and lifestyle change, + workbooks and assignments + access to shopping tours and cooking demonstrations + questions answered + encouragement to present dietary and exercise goals C: Waiting list	T1: 6 weeks T2: 6 months	1) Body weight (kg) 2) BMI 3) Tot. chol. (mmol/l) 4) HDL chol. (mmol/l) 5) LDL chol. (mmol/l) 6) Triglyc. (mmol/l) 7) SBP (mmHg) 8) DBP (mmHg) 9) Overall body fat (%)	Sign. larger improvements in body weight, BMI, tot. chol, HDL chol. and body fat at T1 and T2, and LDL chol. at T1, in intervention group. 1) I: - 2.9 vs. C: -0.4 (T1), I: -4.4 vs. C: -1.0 (T2): 2) I: -1.1 vs. C: -0.2 (T1), I: -1.6 vs. C: -0.03 (T2) 3) I: -0.41 vs. C : +0.27 (T1), I : +0.02 vs. C : + 0.35 (T2). 4) I: +0.08 vs. C: -0.11 (T1), I: -0.01 vs. C: -0.11 (T2) 5) I: -0.32 vs. C: +0.19 (T1) 9) I: -1.1 vs. C: -0.3 (T1), I: -2.4 vs. C: -0.4 (T2).
Anderson et al., 1999 (2/9)	204 blue-collar workers (m/f); aged 18-64; tot. chol. ≥ 5.18 mmol/l; used for analyses 167 (?) at T1, 122 (?) at T2	Topic: Diet I1: 4 education classes, aimed at skill building I2: self-help nutrition education program, aimed at skill building C: HRA results and printed materials	T1: 6 months T2: 12 months	1) Body weight (kg) 2) BMI 3) Tot. chol. (mmol/l) 4) SBP (mmHg) 5) DBP (mmHg)	No significant differences between groups in any of the outcome measures.
Atlantis et al., 2006 (7/9)	73 workers (m/f); sedentary casino employees; 42 used for analyses	Topics: Diet and PA I: 24 weeks ≥ 3 days/ week 20 min. supervised moderate to high intensity aerobic exercise + 24 weeks ≥ 3 days/ week 30 min. moderate to high intensity body weight-training + health education on nutrition and exercise through group seminars + 6 months 1 day/ month 60 min. counseling + manual + prizes C: Waiting list	24 weeks	1) Body weight (kg) 2) BMI 3) WC (cm)	Significantly larger decrease in WC in favor of the intervention group. 3) I: -4.3 vs. C: -1.1

Barratt et al., 1994 (4/9)	683 workers (m/f); hospital staff; tot. chol ≥ 5.2 mmol/ l; used for analyses: 417 at T1, 430 at T2	Topic: Diet I1: Workbook + quizzes + shopping guidelines + recipes + 3 min. video + monitoring of suggested dietary changes I2: 5 x 1 hour group session led by dietician concerning fiber, fat and dietary change + workbook + tasting recipes C: Screening only	T1: 3 months T2: 6 months	1) Body weight (kg) 2) Tot. chol. (mmol/l) 3) HDL chol. (mmol/l)	Significant greater decrease in body weight in favor of intervention 2, at T2. 1) I2 : -0.35 vs. C: unknown (T2)
Bloch et al., 2006 (6/9)	171 workers (m/f); e.g. school and casino employees; LDL-chol. ≥3.37 mmol/l *or* LDL chol. ≥ 2.59 mmol/l and diabetes type 2 or coronary heart disease; 155 used for analyses	Topics: Diet and PA I1: C + $100 check if achieving study goal of lowering LDL chol. I2: 4 Classes on e.g. cholesterol, fat, food labels, lifestyle change, and heart disease, cooking, shopping + 6 telephone calls on goals, reinforcement, review of emails. C: Cholesterol health tips by weekly email + cholesterol screening results	6 months	1) Tot. chol. (mmol/l) 2) HDL chol. (mmol/l) 3) LDL chol (mmol/l) 4) Triglyc. (mmol/l)	Significant greater decrease in total and LDL chol. in favor of both intervention groups. 1) I1: -0.67 vs. I2: -0.67 vs. C: -0.33 3) I1: -0.46 vs. I2: -0.46 vs. C: -0.14
Braeckman et al., 1999 (5/9)	770 blue-collar workers (m); aged 35-59; 638 used for analyses	Topic: Diet I: Video presentation and Q&A + feedback on screening results in counseling session + food changes and messages in cafeteria + posters and leaflets + Diet group sessions + newsletter; all aimed at awareness and knowledge C: No intervention	3 months	1) BMI 2) Tot. chol. (mmol/l) 3) HDL chol. (mmol/l) 4) WHR	Significant difference in BMI in favor of control group. Significant difference in HDL chol. in favor of control group. 1) I: +0.1 vs. C: -0.2 3) I: -0.01 vs. C: +0.08
Byers et al., 1995 (5/9)	864 workers (m/f); tot. chol. ≥ 5.18 mmol/l; used for analyses 553 at T1, 510 at T2	Topic: Diet I: 1 month, 2 hours in multiple sessions, education concerning cholesterol, aimed at knowledge and skills + 30-minute video + 5 minutes of nutrition counseling after cholesterol testing + brochures C: 5 minutes of nutrition counseling after cholesterol testing + brochures	T1: 6 months T2: 12 months	1) Tot. chol. (mmol/l)	Significant greater decrease in tot. chol. in favor of intervention group at T2. I: -0.18 vs. C: -0.08 (T2)

Chesney et al., 1987 (5/9)	158 workers (m/f) ; mean of 4 diastolic pressures between 90 and 104 mmHg; 118 used for analyses	Topic: PA (and diet and smoking in I5) I: 13 x 50-minute instruction sessions: I1: Muscle relaxation training + homework I2: I1 + cognitive restructuring I3: I1 + (bio-) feedback on temperature and muscle activity during sessions I4: I1 + I2 + I3 I5: I2 + self- monitoring on health behaviors and contracting with instructor for behavior change C: Blood pressure monitoring	T1: 9 weeks T2: 18 weeks T3: 27 weeks T4: 36 weeks T5: 45 weeks T6: 54 weeks	1) SBP (mmHg) 2) DBP (mmHg)	Sign difference between groups in clinic DBP at T4, in favor of control group. 2) I: -4.0 vs. C: -6.3 (T4)
Connell et al., 1995 (4/9)	1,432 workers (m/f); office workers, nurses, and instructional staff; 801 used for analyses	Topic: Diet, PA and smoking I1: I2 + I3 I2: Monthly individual health counseling and/or self-help materials. I3: Booklet with computer-tailored personalized health risk appraisal and behavior change recommendations. C: Screening results	12 months	1) BMI 2) Tot. chol. (mmol/l) 3) SBP (mmHg) 4) DBP (mmHg)	All three interventions significantly negatively related (β) to BMI and SBP. 1) I1: β = -0.05, I2: β = -0.05, I3: β = -0.04. Amount of change unknown. 3) I1: β = -0.13, I2: β = -0.09, I3: β = -0.09. I1 compared to C: -5, I2: ~ -3, I3: ~ -3. SBP reduction in C: unknown.
Edye et al., 1989 (7/9)	2,489 white-collar workers (m/f); government employees; elevated CVD risk, no CVD; 1,937 used for analyses	Topics: Diet, PA and smoking I: 15-20 min. counseling by physician, discussing knowledge, attitude and advice, + 3 x 20 min. counseling by nurse for reinforcement, + body weight and BP measurement. C: Explanation of risk factors.	3 years	1) Body weight (kg) 2) Tot. chol. (mmol/l) 3) SBP (mmHg) 4) DBP (mmHg)	Significant greater decrease in SBP in intervention group. 3) I: -2.96 vs. C: -1.82
Fielding et al., 1995 (7/9)	252 blue- and white-collar manufacturing workers (m/f); nonfasting tot. chol. ≥6.22 mmol/l; 234 used for analyses	Topics: Diet and PA I: Screening and referral + monthly 10-minute individual sessions, concerning e.g. fat intake, medical treatment + monthly written information, + cholesterol measurement + priority enrolment in worksite health promotion classes. C: Screening and referral only	12 months	1) Tot. chol. (mmol/l)	No significant differences in change between groups.

Fisher et al., 1995 (3/9)	65 workers (m/f); college faculty and staff members; 65 used for analyses	Topics: Diet and PA I: 3 times per week 45 minutes prescribed individualized exercise + 3 times per week 45-minute group exercise activities, + nutrition and health management education C: not described	6 months	1) Body weight (kg) 2) Tot. chol. (mmol/l) 3) LDL chol. (mmol/l) 4) HDL chol. (mmol/l) 5) Triglyc. (mmol/l) 6) SBP (mmHg) 7) DBP (mmHg) 8) Overall body fat (%)	Significant between-group differences in weight, HDL chol. and triglyc., in favor of intervention group. 1) I: -1.22 vs. C: +1.01 4) I: +0.02 vs. C: -0.08 5) I: -12.15 vs. C: +13.69
Gemson et al., 1995 (5/9)	161 white-collar workers (m/f); aged ≥30 years; 90 used for analyses	Topics: Diet and PA I: Health risk appraisal + printed copy and review of results + counseling C: Health risk appraisal + counseling	6 months	1) Body weight (kg) 2) Tot. chol. (mmol/l) 3) SBP (mmHg)	No significant differences in change between groups.
Gilson et al., 2007 (3/9)	70 white-collar workers (m/f); 64 used for analyses	Topic: PA I1: 15 minutes continuous, brisk walking every working day I2: accumulation of steps through the working day, during normal tasks. C: No intervention	10 weeks	1) SBP (mmHg) 2) DBP (mmHg) 3) Body fat (%) 4) WC (cm)	No significant differences in change between groups.
Glasgow et al., 1995 (4/9)	2,791 (?) blue- and white-collar workers (m/f); 1,222 (?) used for analyses	Topics: Diet and smoking I: Contests, feedback and advice + self-help materials and presentations + change of worksite, e.g. change cafeteria food choices, display posters + participate in community events, publish articles. C: Waiting list	24 months	1) Tot. chol. (mmol/l)	Difference in change between groups unknown.
Gomel et al., 1993 (4/9)	431 workers (m/f) of ambulance service; used for analyses: 403 at T1, 369 at T2, 364 at T3	Topics: Diet, PA and smoking I1: C + 50 minutes advice on lifestyle changes I2: C + 6 x 50-minutes counseling sessions + lifestyle change manual I3: C + I1 + lifestyle change manual + 2 counseling sessions + lottery tickets when having achieved lifestyle change targets C: Assessment of CVD risk + feedback	T1: 3 months T2: 6 months T3: 12 months	1) BMI 2) Tot. chol. (mmol/l) 3) Overall body fat (%)	Significant increase in BMI in all conditions. Differences between I groups and C group unknown.

Grandjean et al., 1996 (2/9)	37 blue-collar workers (f); previously sedentary; 37 used for analyses	Topic: PA I: 24 weeks, at least 3 days / week, 20-60 minutes a day aerobic training by walking, jogging and/or cycling of increasing intensity. C: No PA outside normal daily routine.	24 weeks	1) Body weight (kg) 2) Tot. chol. (mmol/l) 3) LDL chol. (mmol/l) 4) HDL chol. (mmol/l) 5) Triglyc. (mmol/l) 6) Overall body fat (%)	Significant difference in body weight change, in favor of intervention group. 1) I: -2.0 vs. C: +0.7
Harrell et al., 1996 (3/9)	1,504 workers (m/f); law enforcement trainees; higher educated; passed a physical exam; 1,504 (?) used for analyses.	Topics: Diet and PA I: 4 hours of lecture on health nutrition and fitness + 12 hour of testing + 27 hour of supervised aerobic training and strengthening exercises. C: usual physical training programs	9 weeks	1) Overall body fat (%)	Significant differences in change between intervention and control group. 1) I: -5.6 vs. C: -1.2
Lee et al., 1997 (5/9)	37 white- and blue-collar workers (f); university employees; used for analyses: 32 at 12 weeks and 26 at 24 weeks	Topic: PA I: Weekly classes with education on exercise and low-impact aerobic exercise + booklet with guidelines for independent exercise 2 or 3 times a week for 12 weeks C: Waiting-list	T1: 12 weeks T2: 24 weeks	1) BMI 2) Tot. chol. (mmol/l) 3) HDL chol. (mmol/l) 4) Triglyc. (mmol/ l) 5) SBP (mmHg) 6) DBP (mmHg) 7) Tot. skinfolds (cm) 8) WC (cm) 9) Hip circ. (cm)	No significant differences between groups for any of the variables.
Leslie et al., 2002 (5/9)	122 workers (m); at large industrial worksite; aged 18-55; BMI >= 25; 91 used for analyses	Topic: Diet I: During 12 weeks 1 x 60 min. + 6 x 15-20 min. dietetic consultations, and: I1: Energy deficit diet (- 600 kcal of energy requirement) + meat I2: Energy deficit diet - meat I3: Low-calorie diet (1500 kcal) + meat + 5emails I4: Low-calorie diet - meat + 5 emails C: Waiting list	12 weeks	1) Body weight (kg) 2) BMI 3) Tot. chol. (mmol/l) 4) LDL chol. (mmol/l) 5) HDL chol. (mmol/l) 6) Triglyc. (mmol/l) 7) WC (cm)	Significant mean difference in body weight change in favor of intervention groups. 1) I1+I2 vs. C: -5.2; I3+I4 vs. C: -6.2

Lindquist et al., 1999 (3/9)	104 white-collar workers (m/f) at government taxation office; 104 used for analyses	Topics: Diet, PA and smoking. I: Weekly workshops on stress, coping, lifestyle education + individual 45 min. counseling + personal action plan + weekly phone calls during 8 weeks. C: Waiting list	12 weeks	1) SBP (mmHg) 2) DBP (mmHg)	No significant differences between groups.
Makrides et al. 2008 (6/9)	566 workers (m/f); 19-66; ≥ 2 risk factors, i.e. smoking, SBP ≥140, DBP ≥90, tot. chol. ≥6.22 mmol/l, taking BP- or lipid lowering medica-tion, BMI>27 and/or WHR >0.9 (men) and >0.8 (women), physical inactivity; 397 used for analyses	Topic: Diet and PA I: 12-week program including individual exercise prescription, supervised exercise classes, home exercise program, group education on e.g. nutrition, exercise and stress reduction + nutrition analysis and counseling + smoking cessation program + telephone follow up. C: Waiting list.	T1: 3 months T2: 6 months	1) BMI 2) Tot. chol. (mmol/l) 3) HDL chol. (mmol/l) 4) SBP (mmHg) 5) DBP (mmHg) 6) WHR	Significant difference in change in BMI at T1 and T2, and in total chol. and WHR at T2, in favor of intervention group. Mean difference in change between groups: 1) -0.61 (T1), -0.57 (T2) 2) -0.13 (T1), -0.12 (T2) 6) -0.01 (T1), -0.007 (T2)
Murphy et al., 2006 (5/9)	37 workers (m/f); at civil service; aged =<65; not physically active; non smoking, low BP and tot. chol., 33 used for analyses	Topic: PA I: 8 weeks, 2 days per week outdoor walking program with progressive duration, 25 to 45 minutes a day. C: no intervention	8 weeks	1) BMI 2) SBP (mmHg) 3) DBP (mmHg) 4) Tot. chol. (mmol/l) 5) HDL chol. (mmol/l) 6) LDL chol. (mmol/l) 7) Triglyc. (mmol/l) 8) Overall body fat (%) 9) WC (cm) 10) Hip circ. (cm)	Significant difference in change for SBP and overall body fat, in favor of intervention group. 2) I: -5.0 vs. C: +2.0 8) I: -0.1 vs. C: +1.8
Muto et al., 2001 (5/9)	326 workers (m) of building company; ≥ 1 abnormality in BMI, BP, tot. or HDL chol, triglycerides or fasting blood glucose;	Topics: Diet and PA. I: 6 months after baseline, in first week 4 days education through lectures, individual counseling, group sessions and self education + goal setting. Within 1 year: 4 x self-evaluation + feedback.	T1: 12 months T2: 24 months	1) Body weight (kg) 2) BMI 3) Tot. chol. (mmol/l) 4) HDL chol. (mmol/l) 5) Triglyc. (mmol/l) 6) SBP (mmHg)	Significant differences in change for body weight, BMI, SBP and total chol. (T1, T2), in DBP (T1), and in triglycerides (T2) in favor of intervention group. 1) I: -1.6 vs. C: +0.1 (T1), I: -1.0 vs. C: +0.5 (T2) 2) I: -0.5 vs. C: 0.0 (T1), I: -0.3 vs. C: +0.2 (T2)

	lifestyle changes advised by physician; used for analyses: ?	C: mailed advice to make lifestyle changes following annual health examination.		7) DBP (mmHg)	3) I: -0.19 vs. C: +0.08 (T1), I: -0.17 vs. C: +0.12 5) I: - (?) 32.1 vs. C: +0.2 (T2) 6) I: -1.3 vs. C: +2.4 (T1) , I: +0.5 vs. C: +2.9 (T2) 7) I: -1.0 vs. C: +1.5 (T1) 8) I: -2.2 vs. C: +2.0 (T1)
Nilsson et al., 2001 (5/9)	128 workers (m/f); e.g. nurses, cleaners, and drivers; with elevated CVD risk; used for analyses: 92 at T1, 89 at T2	Topics: Diet, PA and smoking I: 16 group sessions a year + individual counseling, based on e.g. lectures discussions, video sessions and outdoor activities. C: standard written and oral advice about CVD risk factors	T1: 12 months T2: 18 months	1) BMI 2) Tot. chol. (mmol/l) 3) LDL chol. (mmol/l) 4) HDL chol. (mmol/l) 5) SBP (mmHg) 6) DBP (mmHg) 7) WHR	Significant differences in change in BMI, DBP, and HDL chol. in favor of intervention group 1) I: -0.7 vs. C: +0.1 (T1), I:-0.5 vs. C: -0.0 (T2) 4) I: +0.11 vs. C: +0.02 (T1), I: +0.06 vs. C: +0.04 (T2) 6) I: -5.4 vs. C: -1.1 (T1), I: -5.7 vs. C: -0.4 (T2)
Nisbeth et al., 2000 (5/9)	85 white-collar workers (m); aged 25-45 years; 74 used for analyses	Topics: Diet, PA and smoking II: 15 min counseling, including information about aerobic exercise and healthy diet, construction of exercise and dietary plan+ recommendation to discuss diet with spouse + some recipes + stop smoking advice C: no intervention	12 months	1) Body weight (kg) 2) BMI 3) Tot. chol. (mmol/l) 4) HDL chol. (mmol/l) 5) LDL chol. (mmol/l) 6) Triglyc. (mmol/l) 7) SBP (mmHg) 8) DBP (mmHg)	Significant difference in change in body weight and BMI, in favor of intervention group. 1) I: -0.2 vs. C: +1.4 2) I: -0.06 vs. C: +0.42
Pritchard et al., 1997, 2002 (5/9)	66 workers (m) of national business corporation; BMI ≥25; 58 used for analyses	Topics: Diet and PA I1: For 12 months, personalized low fat diet using weight loss guide, + monthly 24-hour recalls + food diaries I2: For 12 months, minimum of 3 x per week 30 minutes exercise, at 65- 75% of maximal heart rate. I3: I1 + I2. C: No intervention	12 months	1) Body weight (kg) 2) Overall body fat (%) 3) Central body fat (%) 4) Periph. body fat (%) 5) Tot. chol. (mmol/l) 6) HDL chol. (mmol/l) 7) LDL chol. (mmol/l) 8) Triglyc. (mmol/l) 9) SBP (mmHg) 10) DBP (mmHg)	Significant differences in change in body weight, overall, central, and peripheral body fat, and triglycerides, in favor of the intervention groups. 1) I1:-6.4, I2:-2.6, I3:-4.5, C: +0.3 2) I1: -3.8, I2: -1.9, I3:-3.1, C:-0.1 3) I1:-1.0, I2:-0.5, I3:-1.0, C:+0.07 4) I1:-1.5, I2:-0.8, I3:-1.3, C:-0.01 8) I1:+0.26, I2:-0.72, I3: -0.65, C:-0.12.

Prochaska et al. 2008 (4/9)	1,401 medical university employees (m/f); ~981 (?) used for analyses	Topic: Diet and PA I1: C + 3 motivational interviewing sessions, face to face or by telephone. I2: Online tailored intervention program (as many sessions as desired), based on Transtheoretical Model (TTM). C: HRA + advice on first step necessary to begin progressing in lifestyle change.	T1: 6 months	1) BMI (< 25)	No significant differences in percent at criteria for BMI (< 25) by treatment groups.
Proper et al., 2003 (9/9)	299 white-collar workers (m/f); civil servants; 190 used for analyses	Topics: Diet and PA I: during 9 months, 7 x 20 minutes of individual counselling according to stage of change + brochures C: Brochures	9 months	1) BMI 2) Tot. chol. (mmol/l) 3) SBP (mmHg) 4) DBP (mmHg) 5) Periph. body fat (%)	Significant differences in change in peripheral body fat and tot. chol. in favor of intervention group. 2) I:-0.2 vs. C: 0.0 (β = -0.18) 5) I: -1.4 vs. C: -0.6, (β= -0.79)
Reynolds et al. 1997 (4/9)	635 workers of telephone companies (m/f); tot. chol. < 6.87 mmol/l; used for analyses: 452 at T1 and 412 at T2	Topic: Diet I1: Results of cholesterol screening + self-help booklet on healthy food items. I2: Self-help booklet on healthy food items. C: No intervention.	T1: 3 months T2: 6 months	1) Tot. chol. (mmol/l)	Significant difference in reduction of total chol. at T1 and T2, in favor of control group. Exact figures unknown.
Von Thiele Schwarz, 2008 (4/9)	195 women from a large public dental health organization; 162 used for analyses	Topic: PA I1: On 2 days, 1-2.5 hours of mandatory medium- to-high intensity exercise, during self-chosen activity. I2: 1 to 2.5 hour reduction in working hours C: no intervention	T1: 6 months T2: 12 months	1) Tot. chol. (mmol/l) 2) HDL chol. (mmol/l) 3) LDL chol. (mmol/ l) 4) Triglyc. (mmol/l) 5) SBP (mmHg) 6) DBP (mmHg) 7) WHR	At T2, a significantly larger increase in WHR in the reduced working hours group as compared to both exercise and control group. Results at T1 were not presented. 7) I1: +0.03, I2: +0.05, C: -0.01 (T2)

[a]The quality score is reported, defined as the number of quality items scored positively as opposed to the total amount of quality items, e.g. 5/9. [b]Only the outcomes measures are presented for which the intervention effects were statistically significant ($p<0.05$), as determined by between-group differences at follow up or linear regression analyses. T1: follow up 1; T2: follow up 2; T3: follow up 3; BMI: body mass index; HDL: high-density lipoprotein; LDL: low-density lipoprotein; SBP: systolic blood pressure; DBP: diastolic blood pressure; I: intervention group; C: control group; HRA: health risk appraisal; PA: physical activity; WC: waist circumference; CVD: cardiovascular disease; BP: blood pressure; WHR: waist-hip-ratio.

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CHAPTER 3

Design of a RCT evaluating the (cost-) effectiveness of a lifestyle intervention for male construction workers at risk for cardiovascular disease: The Health under Construction study

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Abstract

Background Of all workers in Dutch construction industry, 20% has an elevated risk of cardiovascular disease (CVD). A major risk factor for CVD risk is an unhealthy lifestyle. The aim of our study is to design a lifestyle intervention for construction workers with an elevated CVD risk, and to evaluate its (cost-) effectiveness.

Methods/ Design In a RCT, 692 participants will be randomized to either the control or the intervention group. The control group will receive usual care. For the intervention group, a lifestyle intervention has been designed based on interviews and current literature. The intervention will last 6 months and will comprise 3 face to face and 4 telephone contacts, consisting of individual counseling aimed at increasing daily physical activity (PA) and improving dietary behavior, and/or smoking cessation. Counseling will take place at the occupational health service (OHS), and will be done according to motivational interviewing (MI). Additional written information about healthy lifestyle will also be provided to those in the intervention group. At baseline, after 6 and after 12 months, measurements will take place. Primary outcome variables will be the lifestyle behaviors of concern, i.e. daily PA, dietary intake, and smoking status. Secondary outcome variables will be body mass index (BMI), systolic and diastolic blood pressure, total and HDL blood cholesterol, Hba1c and cardio respiratory fitness (CRF). Sickness absenteeism and cost-effectiveness will be assessed as well. Multilevel analysis will be performed to compare all outcome measures between the intervention group and the control group.

Discussion By improving lifestyle, CVD risk may be lowered, yielding benefits for both employee and employer. If proven effective, this lifestyle intervention will be implemented on a larger scale within the OHSs in construction industry.

Background

In the Netherlands, cardiovascular diseases (CVD) are responsible for one third of all deaths each year. Besides to premature death and a decreased quality of life, CVD morbidity leads to high costs for health care and loss of productivity (1). An unhealthy lifestyle, e.g. smoking, unhealthy diet and/or insufficient daily physical activity (PA), is a major cause of CVD (2). Well known consequences of an unhealthy lifestyle are overweight, an unfavorable total/ HDL cholesterol ratio, and an elevated blood pressure (3,4). Improved lifestyle may contribute to an improved CVD risk profile. As to smoking cessation, it has been shown that those who have quit smoking quickly reduced the risk of CVD (2,5). As to diet, there are several ways to decrease the CVD risk. For instance, diminishing intake of saturated fat will lower LDL and total cholesterol (2). A diet low in salt has a beneficial effect on blood pressure (6). Fruits and vegetables are rich in micronutrients and fiber and therefore protective against CVD (7). Moreover, obesity, a major CVD risk factor, may be prevented by lowering calorie intake (8). As to PA, there is sufficient evidence that regular PA is beneficial for health, not only by preventing weight gain but also by improving cardio respiratory fitness (CRF) (9,10). In 1995, the Centers for Disease Control and Prevention (CDC) and the American College of Sports Medicine (ACSM) achieved consensus about the level of PA needed for good health. This recommendation stated that every adult should accumulate 30 minutes or more of moderate intensity PA on most, preferably all, days of the week (11). Next to this Public Health recommendation on moderate PA, the ACSM stated that each adult should perform vigorous exercise for 20 minutes or more, at least 3 times a week in order to improve CRF (12). Like in the general Dutch population, an unhealthy lifestyle is commonly seen in Dutch construction industry. Even though the percentage of construction workers that fulfilled the guideline for moderate PA in 2005 (61%) was higher than that of the general Dutch male population (51%) (13), the prevalence of overweight and obesity in the construction industry was considerably higher than in the general Dutch population (64% vs. 51% and 15% vs. 10 %, respectively). Only 18% of construction workers fulfilled the guideline for vigorous PA, as compared to 25% of the general Dutch male population. Furthermore, one third of all workers in the construction industry are smokers (14). Since a substantial part of the ageing population in construction industry has an unhealthy lifestyle, CVD morbidity and mortality in this population is likely to rise in the following years. Sickness absenteeism due to CVD and other chronic diseases may also increase. In collaboration with Arbouw, a national organization involved in monitoring and improving working conditions and occupational health of workers in construction industry, we will investigate the effectiveness and cost-effectiveness of an individual lifestyle intervention for male construction workers at risk for CVD. The aim of the intervention is to lower the risk for CVD by changing one or more lifestyle behaviors. As the intervention will be focused on improving three lifestyle topics, i.e. diet, PA, and smoking, we hypothesize that in the intervention group diet will be improved, the amount of PA will be increased, and the number of smokers will be lowered. As these lifestyle components are important CVD risk factors, we further hypothesize that mean BMI, blood pressure, HbA1c and total

cholesterol will be lowered and HDL cholesterol will be increased as a result of the intervention. In this article we will describe the design of this study, which has been named 'Health under Construction'.

Methods/ Design

Study design

In this randomized controlled trial (RCT) we aim to include 692 workers with an elevated CVD risk. The intervention will consist of individual-based lifestyle counseling, plus short written materials about CVD and healthy lifestyle. The control group will receive care as usual. Measurements will take place at baseline, after 6 and after 12 months. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center.

Setting

The study population will be recruited from all occupational health services (OHSs) throughout the Netherlands that perform periodical health screenings (PHSs) in construction industry. A PHS is offered every four years to all construction workers under the age of 40. Workers above the age of 40 are invited for a PHS every two years. All occupational physicians (OPs) and occupational nurses employed at the abovementioned OHSs were invited to apply for the role of lifestyle counselor in our study. We made a selection based on their motivation, interest in lifestyle, and affinity with the target group.

Study population

The study population exists of workers in Dutch construction industry who have an elevated risk of CVD. Since less than 10% of workers in construction industry is female, we decided to include only men. Two types of construction workers can be distinguished. More than 75% of all workers take part in the actual construction process ('blue-collar workers') and the remaining are mainly involved in planning, supervision en administration ('white-collar workers'). Both blue- and white-collar workers will be included in the study. Their CVD risk will be derived from their PHS results. The PHS consists of a questionnaire to be filled out by the worker at home, and a physical examination, which is performed by an OP or an occupational nurse at the OHS. In the PHS, both work-related health and lifestyle-related health, e.g. smoking, body mass index (BMI), and cholesterol are assessed. Until recently, there was no instrument for determining the workers' risk of CVD based on all risk factors measured in the PHS. For the purpose of this study, we developed such a risk assessment instrument. For this instrument, we used the scores for age, total and HDL cholesterol, blood pressure and smoking, as determined in the Framingham risk score. The Framingham risk score is a widely used sensitive screening instrument for predicting the 10-year risk of coronary heart disease, and is applicable to the US as well as to European populations (15). Our risk assessment instrument differs from the Framingham risk score because of a lack of data on diabetes. Besides, the risk assessment instrument was elaborated by six additional CVD

risk factors, i.e. BMI, alcohol intake, HbA1c, psychological complaints, heart complaints and the amount of weekly PA, measured in the PHS for Dutch construction workers. The cut-offs for these additional CVD risk factors were defined based on expert consensus, recent research and general Dutch standards (16,17). In **Table 1,** all inclusion criteria are presented. Of all blue- and white-collar workers in Dutch construction industry who will be subject to a PHS between January 2007 and October 2007, those meeting the inclusion criteria will be invited to participate. The invitation letter will be accompanied by a brochure with background information about the study, an informed consent form, and a questionnaire. Those who agree to participate, by signing and sending back the informed consent form and the questionnaire, will be included in the study. Exclusion criteria will be 'inability to be physically active', and 'not sufficiently capable of using the Dutch language'.

Table 1. Inclusion criteria for the study population.

Variable	**Criteria**
Gender	Male
Age	18-65 years
Permission	Signed informed consent
Availability	Available for the study for 12 months following inclusion.
Health status	Having a 10-year risk of coronary heart disease higher than average compared to the same age group according to the Framingham risk score, *and* having *one or more* of the following risk factors: • Insufficiently active: Fulfilling none of the public health PA guidelines • Excessive alcohol use: ≥ 35 glasses of alcohol per week • HbA1c ≥ 6.5% • Obesity: BMI ≥ 30 kg/m² • Psychological complaints: Tiredness or stress and/or treated for psychological disorders and/or low motivation to recover from work. • Heart-related complaints: Shortness of breath and/or suffering from chest pain and/or diagnosed with or treated for CVD or its predictors, e.g. high blood pressure.

Randomization and stratification

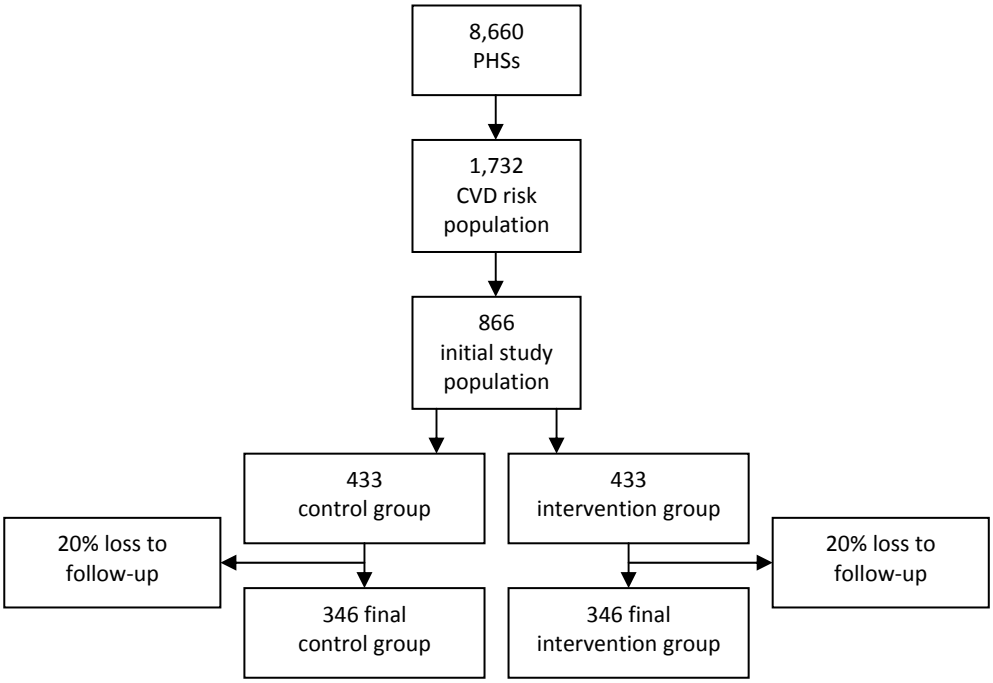
After baseline measurements, all participants will be randomly assigned to the intervention or the control group. The study population will be pre-stratified by type of work (blue-collar or white-collar). Randomization will take place at the individual level. Using Random Allocation Software (Version 1.0, May 2004, Isfahan University of Medical Sciences, Iran) a random list of letters A and B will be generated for both strata. A research assistant will assign a letter to each of the two groups.

Sample size calculation

The sample size is based on detecting a difference in daily PA according to the guideline for moderate intensity PA. Previous PHSs (2005) showed that 38% of construction workers

with an elevated CVD risk was physically inactive according to this guideline. To show a 10% difference between the intervention and the control group after 26 weeks, i.e. 38% inactivity in the control group and 28% inactivity in the intervention group, with a power of 80% and a 95% confidence interval (α=0.05), 692 persons will be needed (346 in each group). As we expect a loss to follow-up of 20%, 866 persons will be included at baseline. Based on an assumed initial non-response of 50%, we will invite 1,732 workers. In the Netherlands, each month approximately 3,334 workers are screened in a PHS. Based on PHS data obtained in 2006, we expect that on average approximately 667 of them (20%) will fulfill the inclusion criteria. Therefore, we expect that the recruitment period will last at least 3 months. The numbers are presented in **Figure 1**.

Figure 1. Flow diagram of recruitment of the study population.



Blinding

The design of the study (individual counseling versus usual care) makes blinding of participants impossible. Neither the counselors can be blinded. The research assistant will perform the randomization procedure, and process the follow-up questionnaires. The principal investigator, who is responsible for the data analysis, will thus be blinded for the allocation. In the invitation letter for follow-up, the worker will be asked not to reveal his group status to the occupational nurse, so that the latter will be blinded as well. However, there is no guarantee that the occupational nurses will be blinded in all cases.

Co-interventions

It is likely that some participants, in the intervention group as well as in the control group, will make use of other CVD risk-related health care, such as medication, other types of treatment, or lifestyle advice by another health care professional. Furthermore, some participants in the control group may start changing their lifestyle during the study, after being confronted with their CVD risk. Such 'co-interventions' cannot be avoided and will therefore be assessed in the questionnaires at baseline and follow-up. Use of additional health care as a result of the counseling, e.g. physiotherapy, dietician advice, or nicotine replacement therapy (NRT), will neither be encouraged nor be discouraged per se since it may have beneficial effects on lifestyle that may not be obtained without the intervention.

Compliance and loss to follow-up

Except for those who have explicitly stated to leave the study, all participants will receive a questionnaire 26 and 52 weeks after baseline, and an invitation for a health check at the OHS. The number of contacts, as well as loss to follow-up, will be recorded by the research assistant. We will try to avoid or reduce loss to follow-up by various means. For example, each counselor will have personal contact with his or her own clients. If the client does not show up at the OHS or answer the telephone at the appointed time, the counselor will call him again to make a new appointment. Furthermore, incentives will be sent to all participants.

Usual care

Since we aim to assess the effectiveness of a lifestyle intervention as compared to usual care, the control group does not receive the intervention of concern neither any addition to usual care except for the follow-up measurements. Thus, each participant in the control group will receive care as usual, provided by his own OP. Usual care for those with an elevated CVD risk consists of informing the worker about his risk profile. This may be done in a brief oral explanation or by post. In some cases, the OP provides brochures about CVD risk factors and/or lifestyle. Whether further care is provided, such as personal lifestyle advice or referral to the general practitioner (GP), depends on the seriousness of the risk and the OP's usual practice.

Development of the intervention

Interviews

Preceding the study, interviews were held with 14 employees, 6 employers and 9 OPs (18). The aim of those interviews was to get insight in the workers' current lifestyle, their attitudes towards changing behavior, their preferences for the type of lifestyle intervention and the feasibility of a lifestyle intervention in construction industry. It appeared that white-collar workers in particular reported a lack of regular PA. Most blue-collar workers said to have daily PA at work. However, hardly any of the interviewed workers reported participating in organized sports. In general, the workers thought to have a healthy diet, but some reported to eat large amounts. Most workers had a positive

attitude towards a lifestyle intervention, under the condition that participation in the intervention would be voluntary. Most workers said they would prefer at least one face to face contact, preferably at the start of the intervention, with a professional health counselor. As to the frequency of the contacts, most workers suggested about once a month. They were generally positive about additional counseling by telephone. The majority of the workers interviewed thought that brochures about lifestyle would be helpful, if provided additionally. Furthermore, toolbox meetings at work were suggested as a good opportunity for giving lifestyle advice. Email or SMS were not considered as appropriate media. Some of the workers said that they would appreciate involvement of their wives in the intervention, especially if the intervention would focus on a change in dietary behavior. The 6 employers who were interviewed emphasized that the intervention should not be pedantic, and that the worker should be confronted with his risk profile and the associated negative health consequences. Moreover, the employers agreed that the person carrying out the intervention should be experienced in counseling and he/ she should have experience with the target population. In the interviews with the OPs, it was confirmed that there is neither consensus nor a guideline for lifestyle-related health promotion aimed at workers in the construction industry. All of them were enthusiastic about the initiative of developing a lifestyle intervention. To date, OPs hardly perform lifestyle counseling, because of a lack of time, knowledge, and possibilities for follow-up. They suggested linking the lifestyle intervention to the PHS. According to the OPs, the workers' CVD risk should be communicated in a way that is easy to understand, e.g. visually. Based on the interviews we concluded that the intervention should preferably be linked to the PHS; contain monthly face to face and/or telephone contacts with one and the same counselor; especially focus on PA in leisure time and the amount of dietary intake; involve the workers' wife if possible. Moreover, CVD risk should be communicated in an understandable way.

Literature search

A literature search was performed to gain more insight in the effectiveness of previously implemented lifestyle interventions. In the report of Proper et al. (2005), especially individual-based lifestyle interventions appeared to be effective (19). Since we were interested in smoking, diet and PA behavior in particular, we looked at studies aimed at these three lifestyle factors. For smoking, it has been shown that a minimal contact behavioral intervention using the stages of change concept in Dutch general practice significantly improved self-reported abstinence rates at 12-month follow-up (20). Duration and frequency of counseling in a smoking intervention appeared to have a strong dose-response relation with smoking cessation rates (21,22). However, even though individual counseling is potentially effective in smoking cessation, success rates for smoking cessation and abstinence may be increased by using NRTs, such as nicotine plasters, gum, and spray (23). Concerning dietary behavior change, Steptoe et al. (1999) showed that brief dietary behavioral counseling led to decreased dietary fat intake among adults with increased CVD risk in general practice (24). Furthermore, personalized feedback has been

shown to improve attitude and intention, and to significantly increase vegetable intake and decrease fat intake among healthy employees (25). Finally, evidence was found for the effectiveness of individual-based PA interventions, among sedentary adults in general practice (26), as well as in a workplace setting (27). Individual counseling can be performed in several ways. In recent years, counseling has become more client-centered. One potential effective and client-centered technique is motivational interviewing (MI). MI is a non-directive, client-centered counseling method, which was originally developed for use in addiction interventions (28). In recent years, it has also been proven feasible and effective in lifestyle interventions (29-31). According to Rubak et al. (2005), the effect of MI increases with an increasing number of face to face encounters (32). MI is based on five principles, i.e. showing empathy, avoiding discussion, rolling with resistance, supporting self-efficacy, and raising awareness of a dissonance between actual behavior and behavior goals. Important non-directive communication strategies used in MI are: Asking open questions, reflective listening and orderly summarizing. Providing information, provocation, and selective confirmation are more directive strategies. In MI a fluent continuum of readiness to change is presumed (33). The Trans Theoretical Model (TTM) of stages of change (SOC) has played an integral role in the development of MI. Another model describing the stages of behavior change that we found in the literature is the Precaution Adoption Process Model (PAPM) (34). The PAPM distinguishes seven stages: 1) Unaware of the health issue, 2) Aware of the issue but not personally engaged, 3) Engaged in the issue and deciding what to do, 4) Having decided not to act, 5) Planning to act but not yet having acted, 6) Initiating the behavior, and 7) Having maintained the behavior over time. In contrast to the TTM, the PAPM distinguishes between stages 1 and 2 and between stages 4 and 5. In a stage-based intervention, in general, persons unaware or unengaged may need to be made more aware of the risks of their own health situation and the possibility of behavior change. They can be informed, advised and encouraged. With persons in the decision stage, barriers and benefits of behavior change should be discussed, and 'the positive' should be accentuated. Persons in the preparation stage need to set short-term goals that are acceptable, accessible and effective, taking into account past experiences. Persons who just initiated behavior change deserve affirmation for what they have accomplished and encouraging comments. They may need assistance in possible revision of their plans. In this stage, anticipation on possible future barriers may also be necessary. The same strategy holds true for persons who have already maintained behavior over time (35). Persons who have relapsed into former behavior need to be guided through the stages again. Persons who have decided not to change a certain (sub-) behavior may decide to change another (sub-)behavior. To achieve behavior change, relevant determinants of behavior will have to be addressed in the intervention. From the literature we learned that attitude, self efficacy, social influence (the principal components of the ASE-model (36,37)), intention (36,38), environment, and habitual behavior (39) are important behavioral determinants. Finally, we looked at literature about risk communication. Several studies have shown that the explanation of CVD risk to the patient or client should be clear and easy to understand, to prevent confusion or fear

(40) and to enable the client to make a well-informed choice about if and what he wants to change (41). Based on the literature, we decided to develop an individual-based lifestyle intervention, comprising frequent contacts, applying MI, with the PAPM as a basis. Next to the SOC, behavioral as well as environmental determinants will be taken into account during the counseling sessions. The worker's CVD risk will be explained to him in an understandable way.

Outline of the intervention

The intervention will last 6 months, since this is the minimum amount of time to achieve maintenance of changed behavior. For the reasons described above, MI will be used as a counseling method. Based on the evidence for the effectiveness of frequent contacts, and on the preferences of the interviewed workers, three face to face and four telephone contacts will be scheduled. The first contact will always be face to face. The duration of a face to face contact will be 45-60 minutes. The telephone calls will take 15-30 minutes. Face to face contacts will preferably take place after participants' working hours (that is: after 3 pm) at the OHS. If a participant explicitly states that he does not want to visit the OHS, the counselor may arrange a home visit. As suggested by the interviewed workers, the wife or partner of the participant will be invited to accompany the participant to the face to face meeting. Additionally, written materials will be provided. The intervention will be performed by 24 counselors (occupational nurses and OPs) who have been trained for the purpose of this study. Each participant will be in contact with one specific counselor during the entire intervention. Each participant in the intervention group will be allocated to a counselor in his own region of residence. The counselor will strive to arrange the first contact within the first week after inclusion, and arrange further contacts each month, with a margin of one week. The last telephone contact should take place in the 25th week after inclusion at the latest. The schedule for each participant in the intervention group is presented in **Table 2.**

Training of counselors and pilot study

All counselors were trained in MI by an MI expert. Before the training took place, they were asked to read a short introduction to MI and background information about healthy lifestyle (42), which was sent to them by the principal investigator. In a 3-day course they learned the principles of MI and practiced by means of role-plays, after which they gave feedback to each other. In a pilot study among a small group of construction workers (n=19), half of the counselors had a meeting with one or two workers. These counselors recorded their conversation(s) in the pilot study on audiotape. The tapes were evaluated on the 3rd training session, which was held 6 weeks after the first 2-day training session. In this 3rd session, difficulties experienced during the pilot were discussed. Further aims of the pilot study were to assess both the counselors' and the workers' opinions about the face to face contacts, and to test the questionnaire and 8 different brochures about CVD and lifestyle. After the pilot study, comments and suggestions for improvement of the intervention were assessed by the principal investigator by means of evaluation forms.

Besides, 7 randomly chosen participants were personally interviewed about their experiences in the pilot. All workers and counselors were positive about the face to face contacts. After the pilot, no major changes needed to be made in the study protocol. As suggested by the participants of the pilot study, the number of brochures to be provided was reduced.

Table 2. Contacts schedule for each participant in the intervention group.

T in weeks	Event
0	Invitation for first face to face encounter.
1	Face to face contact
4	Telephone contact
8	Face to face contact
12	Telephone contact
16	Telephone contact
20	Face to face contact
23	Telephone contact
26	First follow-up measurement
52	Second follow-up measurement.

Counseling protocol

Using MI, the counselor will guide the participant through the process of becoming aware of the health problem, changing behavior and maintaining the changed behavior, as described in the literature. The following steps will be undertaken to reach these goals.

Step 1: Introduction of health problem

In the first face to face encounter, the counselor will explain the goals and procedure of the intervention. He or she will discuss the participant's knowledge about CVD risk factors and health consequences, as well as his awareness of his own risk. A personal risk profile, on which the participant's values on five important risk factors (BMI, systolic blood pressure, total cholesterol, days per week involved in PA of moderate intensity, smoking) are visually represented, will be given to the participant and will be explained in a clear way. The counselor will not move on to the next subject until the worker understands this information. Current lifestyle and family history will be discussed, to get a complete insight in the participants' lifestyle and health status.

Step 2: Choosing type of intervention

Two types of intervention will be offered: 1) an energy balance intervention and 2) a smoking cessation intervention. Together with the counselor, the smoker will choose one of the two intervention types, based on his personal risk profile and his own preferences. He will be encouraged to make his choice during the first meeting, and to stick to his first

choice. However, if later on during the intervention, the participant desires to switch intervention types or if he prefers to address both smoking and energy balance, this will be possible. In case a participant is not ready make his choice in the first meeting yet, e.g. because he is confused by his risk profile, he will be allowed to make his choice during the 2nd contact. In the energy balance intervention, both diet and PA will be addressed. Depending on the current PA and dietary behavior of the participant, the focus will be on diet or daily PA. In improving dietary and PA behavior, sub-behaviors will be chosen to address, which will be relevant to the participant and feasible, e.g. reducing fat intake or cycling in leisure time.

Step 3: Exploring ambivalence
By discussing advantages and disadvantages of a current sub-behavior (e.g. eating too many snacks, not participating in any sports) as well as of the 'desired' healthy behavior, ambivalence may be raised. On a 'decisional balance quadrant', the worker will fill in the 'pros of his current behavior', 'cons of his current behavior', 'pros of behavior change' and 'cons of behavior change'. In doing so, he may become aware of the discrepancy between his current behavior and the desired behavior, possibly leading to a change in attitude towards the desired behavior. As a result, he may realize that it is worth the effort to change his current behavior.

Step 4: Determining readiness, willingness and ability
In step 4, the participant will be asked to indicate his perceived *importance* of change, his perceived *confidence* in his ability to change, and his *readiness* to change on a scale from 0 (not at all) to 10 (highly) (43). The counselor will ask why he did not choose a lower number, and what should be done to get him higher up the scale. In doing so, the counselor and participant may find out which of these items is the most important barrier for change, so that special attention can be paid to that particular item.

Step 5: Goal setting
Social influence, the worker's environment and other factors that may influence behavior will be discussed to facilitate goal setting. At the end of each meeting, a specific short-term goal will be defined by each participant and his counselor, e.g. visiting the sports centre, reducing the number of snacks per week, or informing family and friends about the intended lifestyle change. This goal will need to be accomplished before the next meeting. In addition, after the first meeting one or more long-term goal(s) will be defined, for example loosing 20 pounds or quitting smoking. These goals need to be accomplished within six months.
Steps 1, 2, 3 and 4 will be discussed preferably in the first session. In the subsequent contacts, progress and obstacles for change will be discussed. Depending on the participant's situation, attitude, social influence, self-efficacy, environmental factors, habits or other determinants may be discussed, to facilitate the process of behavior change. A new short-term goal will be set after each contact. If the participant asks for

information about healthier lifestyle or suggestions for implementation, e.g. where to find a good fitness centre or how to prepare a low-calorie meal, the counselor will provide this information. A small number of participants may not be of Dutch origin. Their lifestyle and especially dietary habits may be different from the Dutch white Europeans (44). This will be taken into account by the counselor when giving advice. The counselor will stress the importance of incorporating the healthy behavior into daily life, since this is the best way to achieve maintenance. In case a participant relapses into previous behavior, the counselor will guide him through the stages again, taking into account the problems of the past experience (33,35,45).

Registration forms

During the first contact the counselor and participant will complete a sheet that contains a summary of what has been discussed in steps 1 and 2, the decisional balance quadrant, the 10-point scales about importance, confidence and readiness, the first short-term goals and the long-term goal(s) (step 3, 4 and 5, respectively). The participant will take this sheet home as a reminder of what was discussed. Further, after each contact, the counselor will fill in the location and duration of the contact, a summary of the topics discussed, and the (new) short-term goal on a short form. All sheets and forms will be sent to the research assistant, who is then able to check if and how the contacts are taking place.

Written information

The counselor will provide several brochures to each participant. The brochure 'cardiovascular diseases' contains general information on lifestyle-related ailments of the heart, the brain and the vessels. The participants in the 'smoking cessation' intervention will receive a brochure from Stivoro, a Dutch organization for education about the risks of smoking, describing benefits of smoking cessation, how to prepare a quit attempt, how to prevent relapse, et cetera. Participants in the 'energy balance' intervention will receive a brochure about PA, including guidelines and a training schedule. Furthermore, they will receive four brochures about healthy diet from the Dutch Heart Foundation and the Dutch Nutrition Centre: 1) A brochure with the dietary guidelines of the Dutch Nutrition Centre promoting a varied diet, low in saturated fat and rich in fruits, vegetables and bread; 2) A leaflet describing products high in saturated fat and their low-fat alternatives; 3) A leaflet with the caloric values of the most common food products; 4) A brochure with recipes for healthy meals.

Incentives

Incentives will be handed out to all participants in the intervention group as well as those in the control group, to make participation more attractive and to avoid loss to follow-up. After 3 months, a t-shirt with the study logo will be sent. Along with the invitations for both follow-up measurements, a lottery ticket will be sent. Among the participants who attend the 2nd follow-up measurement (52 weeks), a heart rate measurement instrument

will be raffled. At the same time, a 3-day stay in a bungalow park can be won by the participant who best completes a slogan. At the end of the second follow-up measurement, a step counter will be handed out to all participants.

Quality assessment

To assess the quality of MI during the intervention, the Motivational Interviewing Treatment Integrity code (MITI) protocol will be applied to two face to face contacts of half of the counselors during the first three months of the intervention. For this purpose, each counselor will be asked to tape record 2 face to face contacts. The principal investigator will randomly choose a 10-minute lasting fragment from each tape, and make a transcript of the verbal communication on paper. Two independent MI-experts will code these fragments by using the MITI protocol (46). The coding provides two scores: a 'global score' and a 'behavior count'. The global scores refer to the entire verbal interaction between the participant and the counselor. A global score for MI spirit as well as for MI empathy will be assigned as a single number on a 7-point scale. The behavior count is a one-figure rating applied to the separate MI techniques, e.g. reflective listening and asking open questions. Any utterance may be assigned one of 6 primary behavior codes. After coding, the counselor will get feedback on his/ her performance of MI.

Measurements

Baseline data will be obtained from the PHS and the additional questionnaire. Six months after inclusion, a follow-up measurement will take place. Twelve months after inclusion, the second follow-up measurement will take place.

Primary outcome measures

Physical activity

The main outcome measure for PA is whether the participant has started to fulfill one or both of the public health recommendations for PA. If so, he is considered to have changed from physically inactive to physically active. On the PHS questionnaire, he will fill out how many days per week he usually is moderately physically active for more than 30 minutes. From this item, fulfilling the public health recommendation for moderate PA can be determined. Furthermore, he will be asked how many days during the last month he has performed vigorous physical activities that lasted long enough to make him sweat. By this item, fulfilling the public health recommendation for vigorous PA can be computed. Another outcome measure for PA is the frequency, duration and intensity of PA in leisure time. This will be assessed using the Short QUestionnaire to ASsess Health enhancing physical activity (SQUASH), which was shown to be a fairly reliable and valid questionnaire ($r_{Spearman}$ 0.58 and $r_{Spearman}$ 0.45 respectively) (47). The SQUASH was designed to measure four clusters of PA, i.e. commuting activities, household activities, activities at work and school, and leisure time activities. For the purpose of this study, only commuting activities and leisure time activities, i.e. walking, cycling, gardening, odd jobs, and sports will be measured, as these activities are considered relevant for the target group. The participant

will be asked to fill out how many days per week and how many minutes per day he usually spends on these physical activities, during a usual week within the past month. The level of exertion for each type of activity will have to be indicated as well. The level of exertion for sports, gardening, and odd jobs is classified as light, intermediate, and vigorous. The level of exertion for walking and cycling is classified as slow, intermediate, and fast. From the SQUASH, metabolic equivalents (METs) can be estimated. Light activities are rated as ≥ 2.0 to < 4.0 METs, moderate activities are rated as ≥ 4.0 to <6.5 METs, vigorous activities are rated as ≥ 6.5 METs (48). The cluster of items about household activities will be left out of the SQUASH questionnaire, as we expect these activities not to be major contributors to daily PA in this population of male construction workers. In addition, the SQUASH items about activities at work and school were not considered suitable for our population. The level of exertion, i.e. light, intermediate, or vigorous, of the daily activities at work will be assessed using a single question derived from the TNO questionnaire PA at work (49), which has not been tested for validity and reliability yet.

Dietary intake

Daily dietary intake will be assessed for the following food groups: wholegrain and white bread (slices), dinner portions (spoons), regular soft drinks and alcohol (glasses), *light* soft drinks (glasses), sweet and salty snacks (pieces), vegetables and fruits (pieces or portions), fish and crustaceans (portions). Of these food groups, average intake on days per week and slices/ spoons/ glasses/ pieces / portions per day during a usual week in the past month will be indicated. High intake of regular soft drinks, alcohol and snacks is considered as unhealthy dietary behavior, whereas high intake of light soft drinks, vegetables, fruits, and fish is considered as healthy dietary behavior. The questions about fruits and vegetables were derived from the short questionnaire for measuring fruit and vegetable intake, developed by Maastricht University (50). This questionnaire was shown to be sufficiently reproducible ($r_{Spearman}$ 0.79 after 1 year) and appeared to be suitable for ranking individuals according to their consumption of fruits and vegetables and according to changes in their consumption, at least in females. As we learned from the interviews, total daily food intake in this population is relatively high. Therefore, the items 'bread' and self-rated 'portions for dinner' were added to assess the daily 'amount' of food intake. All of these food groups may be targeted in the energy balance intervention, depending on the participants' actual diet.

Smoking

Current smoking status (smoker or non-smoker) will be assessed by a single item.

Biomedical variables

BMI (kg/m²), systolic and diastolic blood pressure (mmHg), HDL cholesterol, total cholesterol (mmol/l) and HbA1c (%) will be assessed by an occupational nurse at the PHS. First, weight will be measured on a digital balance, without shoes and jacket. After that,

blood pressure will be measured once, by manual inflation, while the worker is seated. In most OHSs, a Maxi Stabil 3 measuring instrument (Speidel & Keller) will be used for this purpose. Finally, for the determination of HDL cholesterol, total cholesterol, and HbA1c levels, venous blood will be drawn from the lower arm and transported to the laboratory for analysis. For each of these 3 measures 1.6 ml blood will be used. As described in the introduction, elevated BMI, blood pressure and cholesterol are indicators of CVD risk. HbA1c, a measure of hemoglobin glycosylation, is an indicator of the mean blood glucose level of the past 6-8 weeks (51). Elevated HbA1c was shown to be an independent risk factor for coronary heart disease in persons with and without diabetes (52).

Secondary outcome measures
Cardiorespiratory fitness
CRF will be measured in an indirect way, by means of a predictor rule that was developed by an international group of experts in the fields of epidemiology, fitness assessment and preventive medicine, and has been shown to be a reasonably accurate measure of VO_2max (53). Using this prediction rule, VO_2max is estimated from BMI, age, gender, resting heart rate (HR) and self reported data on habitual PA levels. The outcome of this prediction rule is indicative of a person's maximal workload expressed as METs; a measure for CRF. Resting HR is not assessed in the PHS and can neither be added for practical means. Therefore, it will be measured by the counselor at the first face to face encounter. At the follow-up measurement after 6 and 12 months HR will be measured again, only in the intervention group. For measuring resting HR a heart rate instrument (Polar S610, Polar Electro Oy, Finland) will be used. The participant will take off his shirt and lie down on examination bench. The Polar belt will be tied around his breast. The counselor will read the HR from the Polar watch, 10 seconds after it has reached the lowest frequency, and record this figure on the registration form.

Sedentary activities
In leisure time, the study population is relatively sedentary. Sedentary behavior is characterized by pursuits that require minimal amounts of energy, e.g. television watching and computer use. Several studies have shown that sedentary behavior is, independently from the PA level, a risk factor for CVD (54,55). Using the AQUA questionnaire, previously used by Slootmaker et al. (56), we will assess the days per week and minutes per day spent on television watching, computer use, sitting in a car or other sedentary activities in a usual week during the past month.

Stage of change
The 'stage of change' items in the questionnaire are based on the stages as defined in the PAPM. The stage of change for *eating less or healthier* as well as the stage of change for *becoming more physically active* will be measured using a single question with 5 outcome categories, of which the participant needs to choose the most appropriate. For PA, these categories are: "I have never thought about becoming more physically active"; "I have

thought about becoming more physically active, but I do not know (yet) whether I will do so"; "I have decided not to become more physically active"; "I have decided to become more physically active but I am not currently doing so (yet)"; "I think I am already physically active enough". The questions were derived from Wammes et al. (57), who applied the PAPM to a non-obese population in a study aimed at weight gain prevention, following Weinstein's staging algorithm. The validity and reliability of this questionnaire have not yet been tested.

Behavioral determinants

As described before, attitude, social influence and self-efficacy are important determinants of behavior (change) and will be addressed in the intervention. Therefore, attitude (on a 5-point Likert scale ranging from *very bad* to *very good*), self-efficacy (on a 5-point Likert scale ranging from *very difficult* to *very easy*) and social influence of partner, relatives, colleagues or friends (on a 5-point Likert scale ranging from *not at all* to *very much*) will be measured. The same determinants will be measured for *becoming more physically active*. The items about attitude and self-efficacy were derived from Oenema et al. (58).

Sickness absenteeism

Each participant will be asked to fill in 'total days absent from work' in the past 2 months. Since the difference between registered and reported sick leave was shown to increase with an increasing recall period, Severens et al. (2000) suggested a recall period of no more than 2 months (59). Therefore, besides the questionnaires at baseline, 6 and 12 months, an additional short questionnaire measuring sickness absenteeism only will be sent to all participants after 2, 4, 8 and 10 months. Participants will not only be asked to report their sickness absenteeism in general, but also their sickness absenteeism due to sports injury, as sports injuries may result form the intervention.

Cost-effectiveness

Next to investigating the effects of the intervention, the costs of the intervention will be compared to the effects. All costs for the development of the intervention, i.e. training and printing of brochures, as well as for the implementation of the intervention, i.e. (previously defined) reimbursements for participant's traveling expenses, counselor's face to face and telephone contacts and occupational nurses' health checkups, will be recorded by the principal investigator. Incremental costs of the intervention group compared to the control group will be divided by incremental effects for each of the biomedical effect measures, e.g. BMI, total cholesterol and systolic blood pressure, separately.

Process evaluation

Next to an effect evaluation, the process of the intervention will be evaluated in three ways. First, at post test the participants in the intervention group will be asked for their opinions about 1) the intervention as a whole; 2) the counselors' competence; 3) the visits

to the OHS, the telephone calls and the written materials; and 4) the effect of the intervention on their own behavior change. Second, by asking a random sample of the counselors to tape-record two of their conversations, the quality of MI will be assessed, as described before. Third, by means of forms filled out by the counselor after each conversation, the amount and duration of each conversation will be assessed, the main subject of each conversation, whether long-term goals have been achieved, et cetera.

Data analysis

On all outcome measures, intention-to-treat analyses will be performed. Both crude and adjusted linear and logistic regression analyses will be performed. In doing so, analysis of covariance will be conducted adjusting for the outcome variable measured at baseline. In the adjusted model, other potential confounders will be included as covariate, such as age and work activities. Furthermore, effect modification, e.g. by family history, will be checked. First of all, data will be analyzed for the whole intervention group, that is, irrespective of the intervention received. Secondly, subgroup analysis will be done among those having received the smoking or the energy balance intervention. As all participants will have to indicate at baseline which lifestyle behavior they prefer to change, the participants in each intervention subgroup will be compared to those in the control group having indicated the same type of intervention preference. Cost-effectiveness ratios will be calculated by dividing the difference between the mean total costs between the two study groups by the difference in the mean effects. For each outcome measure used in this evaluation, cost-effectiveness ratios will be presented graphically on a cost-effectiveness plane. To calculate the confidence intervals for the ratios, bootstrapping will be done. For all analyses, a significance of 0.05 will be applied. On the process evaluation, qualitative analyses will be performed.

Discussion

This lifestyle intervention was developed as a tool for prevention of CVD among those with an elevated risk. The content of the intervention is evidence-based and tailored to the target group. Furthermore, the intervention will exclusively be aimed at persons at risk for CVD, who may more likely be aware of the need to change behavior. Counseling will be performed by professionals experienced in face to face counseling of this target group. Based on the literature and interviews with relevant stakeholders we designed a structured counseling protocol, incorporating MI strategies. Counselors will raise awareness of the health problem and discuss determinants of behavior change, to facilitate the participant in increasing importance, ability and readiness to change, and in changing actual behavior. By applying the MITI, we will be able to report on the quality of MI in the intervention. The written information that will be given to the participants contains practical information and is easy to understand.

Several limitations of this study can however be mentioned. First, stress and other psychosocial problems will not primarily be addressed in the intervention, even though

these factors are positively related to CVD risk. The counselors were not trained in solving psychosocial problems. Stressful circumstances such as job strain, high work demands, and low job control that appear to be a barrier for behavior change will however be discussed. Secondly, the intervention does not take place at company level. Therefore, the workplace environment cannot be changed, even though the environment has been shown an important determinant of health behavior (39). Furthermore, in an individual-based intervention study participants may lack the support of other participants or their employer, and the suggested 'toolbox meeting' cannot be used as a medium for the intervention. Finally, in the PHS only a limited number of variables is measured. Therefore, CRF will be derived from an indirect instrument that may be less accurate in predicting VO_2max than a step test or treadmill test. For the same reason, waist circumference will not be assessed, even though abdominal obesity has been proven to be an important indicator for CVD risk (60,61).

Studying the effects of this intervention is important, as it aims at a serious and increasing health problem. This type of intervention has not been evaluated in this specific setting and in this target group yet. If proven effective, the employee will benefit from an improved lifestyle and a reduced CVD risk, and the employer may benefit from healthier workers and lower absenteeism. If proven cost-effective, in the future the OHSs in construction industry may implement this intervention on a larger scale.

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CHAPTER 4

Factors associated with non-participation and drop-out in a lifestyle intervention for workers with an elevated risk of cardiovascular disease

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Abstract

Background Non-response and drop-out are problems that are commonly encountered in health promotion trials. Understanding the health-related characteristics of non-participants and drop-outs and the reasons for non-participation and drop-out may be beneficial for future intervention trials.

Methods Male construction workers with an elevated risk of cardiovascular disease (CVD) were invited to participate in a lifestyle intervention study. In order to investigate the associations between participation and CVD risk factors, and drop-out and CVD risk factors, crude and multiple logistic regression analyzes were performed. The reasons for non-participation and drop-out were assessed qualitatively.

Results 20% of the workers who were invited decided to participate; 8.6% of the participants dropped out before the first follow-up measurement. The main reasons for non-participation were 'no interest', 'current (para-)medical treatment', and 'feeling healthy', and for drop-out they were 'lack of motivation', 'current (para-)medical treatment', and 'disappointment'. Participants were 3.8 years older, had a higher blood pressure, higher total cholesterol, and lower HDL cholesterol than non-participants, and were more likely to report 'tiredness and/or stress' and 'chest pain and/or shortness of breath'. After adjusting for age, most risk factors were not significantly associated with participation. Drop-outs were 4.6 years younger than those who completed the study. The prevalence of smoking was higher among non-participants and drop-outs.

Conclusions Participants had a worse CVD risk profile than non-participants, mainly because of the difference in age. Non-participants and drop-outs were younger and more likely to be smokers. The main reasons for non-participation and drop-out were health-related. Investigators in the field of health promotion should be encouraged to share comparable information.

Introduction

Hundreds of volunteers are usually needed for randomized controlled trials (RCTs) focusing on the promotion of a healthy lifestyle, and sufficient participants need to be recruited in order to find a statistically significant effect of the intervention. However, the first problem that is commonly encountered in the recruitment phase is low response, and prolonging the recruitment phase in order to achieve sufficient power is not always possible. A second problem in the recruitment phase is selection bias (1). Non-respondents may systematically differ from respondents in certain (health-related or socio-demographic) characteristics, and selection bias may impede generalization of the results to the target population. As soon as the recruitment phase has finished, a third problem arises, i.e. drop-out. In the vast majority of studies, a certain proportion of participants does not complete the study. The estimated number of drop-outs is usually taken into account in the power calculation. However, a point of concern is the possibility of selective drop-out (2-4), i.e. higher attrition in either the intervention group or the control group. Selective drop-out may attenuate or enhance the effects of the intervention.

Since non-response and drop-out may lead to bias, it is important to investigate the differences between participants and non-participants in socio-demographic and health-related characteristics. Previous research has shown that participants are relatively more often female and have a higher level of education (5,6). There is also a tendency for participants in health promotion trials to be slightly more overweight than non-participants (7,8). It would also be interesting to know the most common reasons for non-participation and drop-out, so that participation rates can be improved in future studies. In health promotion programs aimed at reducing the risk of cardiovascular disease (CVD) and diabetes, the main reasons for non-participation were ‘lack of time’, ‘financial constraints’ (8,9), ‘travel problems’ (10,11), ‘no interest’ (12), and perceptions of ‘being too old or too unwell’ (13). In some studies, reasons for drop-out have also been identified i.e. ‘health problems unrelated to the study’ (14-16), ‘lack of time’, and ‘dissatisfaction’ (17).

Several authors underline the importance of reporting participation rates, and the characteristics of participants as well as non-participants. These data have clear implications for the representativeness of the population, and consequently the generalizability of the results (18-20). A sub-study was performed within the Health under Construction study, to examine the characteristics of non-participants and drop-outs, as well as their reasons. In the Health under Construction study, the effectiveness of a six-month lifestyle intervention for male construction workers with an elevated CVD risk was evaluated. The intervention, provided by occupational physicians and nurses, consisted of individual counseling based on motivational interviewing, encouraging participants to stop smoking or to increase physical activity and/or improving their dietary behavior. Three face to face contacts with a duration of 45-60 minutes, and four telephone conversations, each lasting 15-30 minutes, were scheduled for each participant. The design and inclusion

criteria of the study have been described more extensively elsewhere (21). The study was commissioned by Arbouw, the Dutch national organization involved in monitoring and improving labor conditions and occupational health of workers in the construction industry. The Medical Ethics Committee of the VU University Medical Center approved the study protocol.

In this paper we describe: 1) recruitment, participation, and drop-out rates; 2) reasons for non-participation and drop-out; 3) differences in age and CVD risk-related characteristics between participants and non-participants, and between drop-outs and participants who completed the first follow-up measurement.

Methods

Invitation procedure

Each month, all Dutch occupational health services (OHSs) provide Arbouw with the results of the most recent Periodical Health Screenings (PHSs) of workers in the construction industry. The results include CVD risk-related variables, and these data were used to select workers who were at risk for CVD, by applying a predefined screening instrument. All eligible workers, i.e. those with an elevated risk according to the screening instrument, were invited by Arbouw to participate in the Health under Construction study. In order to guarantee anonymity, Arbouw coded all PHS data before sending them to the researchers.

Based on a power calculation, the minimum number of participants needed to detect a 10% difference between groups in meeting the Dutch guidelines for moderate intensity physical activity was 692. Anticipating a drop-out of 20%, 866 workers should have been included. Male construction workers, aged 18-55 years, with an elevated CVD risk, were invited to participate. For logistical reasons, only workers in certain predefined geographical areas in the Netherlands were invited. Due to a low response, after five months the inclusion criteria were adjusted. The maximum age was extended to 65 years, and to all male construction workers in the Netherlands with an elevated CVD risk. Each invited worker received a letter and a brochure explaining the study, describing the benefits (better health, two free health check-ups, and a chance to win a 3-day holiday), and the importance of improving future occupational health care. The safety of the study was emphasized, as well as the fact that the intervention would take place outside working hours at the nearest OHS. Included in the invitation were a 6-page questionnaire on lifestyle, absenteeism, medication use, and subjective health, and an informed consent form. By signing this consent form, the worker confirmed that he was aware of the 0.5 chance of randomization to the control group, and that he agreed to undergo the physical health check-ups and complete the follow-up questionnaires after 6 and 12 months.

Data-collection

The invited workers were asked to return the signed consent form and the questionnaire in the envelope that was provided, but also to send the consent form back even if they had decided *not* to participate, and to give their reasons for non-participation. Workers who did not respond to the first invitation within three weeks received a reminder, accompanied by the questionnaire and the consent form. Those who did not send the consent form back within a month after the second invitation were considered to be non-respondents. Drop-out was notified in one of four ways: by the worker himself, his wife, a counselor, or a medical assistant at the OHS. If a participant in the intervention group had dropped out without any explanation, he was not asked to give his reason, but he was asked by telephone to complete the follow-up questionnaire and to attend the follow up health check-up. During this telephone call, any misunderstandings were clarified, and some workers reconsidered their decision. In case of 'no show' at the follow-up health check-up, the participant was phoned to make a new appointment. Participants who did not return the follow-up questionnaire were phoned within a month by one of the researchers and asked to do so. Participants who did not attend the physical health check-up, did not send the questionnaire back, and did not respond to telephone calls, were defined as 'drop-outs without reason'. A participant who only attended the health check-up or only sent the questionnaire back was not considered as a drop-out. The procedure for clustering reasons for drop-out was comparable to that for clustering reasons for non-participation.

During the PHS, six biological CVD risk factors, i.e. body weight, systolic blood pressure (SBP), diastolic blood pressure (DBP), total cholesterol, HDL cholesterol, and hemoglobin A1c (HbA1c), were measured according to the PHS protocol. The PHS also included a questionnaire: Two items were related to heart problems, i.e. 'occasionally suffering from chest pain' and 'occasionally suffering from shortness of breath'. 'Chest pain and/or shortness of breath' was confirmed if one or both items were scored positively. Twelve items related to psychological risk factors, grouped in two clusters, i.e. 'tiredness', and 'ability to cope with work demands'. 'Tiredness and/or stress' was confirmed if more than 5 out of the 12 items were scored positively. Lifestyle-related CVD risk factors were also assessed by the questionnaire, i.e. smoking (yes/no), and not meeting the Dutch guidelines for moderate intensity physical activity (at least 5 days a week for a minimum of 30 minutes a day (22)) or for vigorous intensity physical activity (at least 3 days a week for a minimum of 20 minutes a day (23))'. Since type of work (administrative and supervisory tasks vs. construction tasks) can be regarded as a proxy for physical activity at work (little or none at all vs. a lot), type of work was also assessed.

Data analysis

We calculated the percentages of non-respondents, respondents who had agreed to participate, and respondents who had not (the latter will be referred to as 'non-participants-with-reason' [NPWR] in the remainder of this article). To make interpretation

easier we clustered reasons that were interrelated, based on common sense. Some NPWR gave more than one reason, and because all reasons were recorded, the total number of reasons exceeded the number of NPWR. For each cluster of reasons, we calculated the proportion of the total number of reasons. The procedure for clustering reasons for drop-out was comparable to that for clustering reasons for non-participation.

For both participants and non-participants, means and standard deviations were presented for the continuous variables: age, BMI, SBP, DBP, total cholesterol, HDL cholesterol, and HbA1c. Percentages were presented for the dichotomous variables: Smoking (yes/no), 'chest pain and/or shortness of breath' (yes/no), 'tiredness and/ or stress' (yes/no), 'meeting at least one of the two Dutch physical activity guidelines' (yes/no), and type of work (administrative and supervisory tasks vs. construction tasks). In order to investigate the association between each variable and participation, crude regression analyses were performed with participation as the dependent variable. Subsequently, a multiple logistic regression model was constructed to investigate the associations adjusted for other variables. A variable that had a p-value < 0.05 in the multiple regression model was considered to be significantly associated with participation. The model was built using a forward stepwise procedure, starting with the variable with the lowest p-value in the crude analysis, followed by the next lowest, and so on. Only variables with a p value <0.1 in the crude analysis were tested for association. To obtain further insight into the association between age and participation, three age groups were also defined (30-39, 40-49, and 50-65 years) and compared to a reference category (18-29 years), by calculating the Mantel Haenszel odds ratios (ORs). Identical analyses were performed with drop-out as the dependent variable.

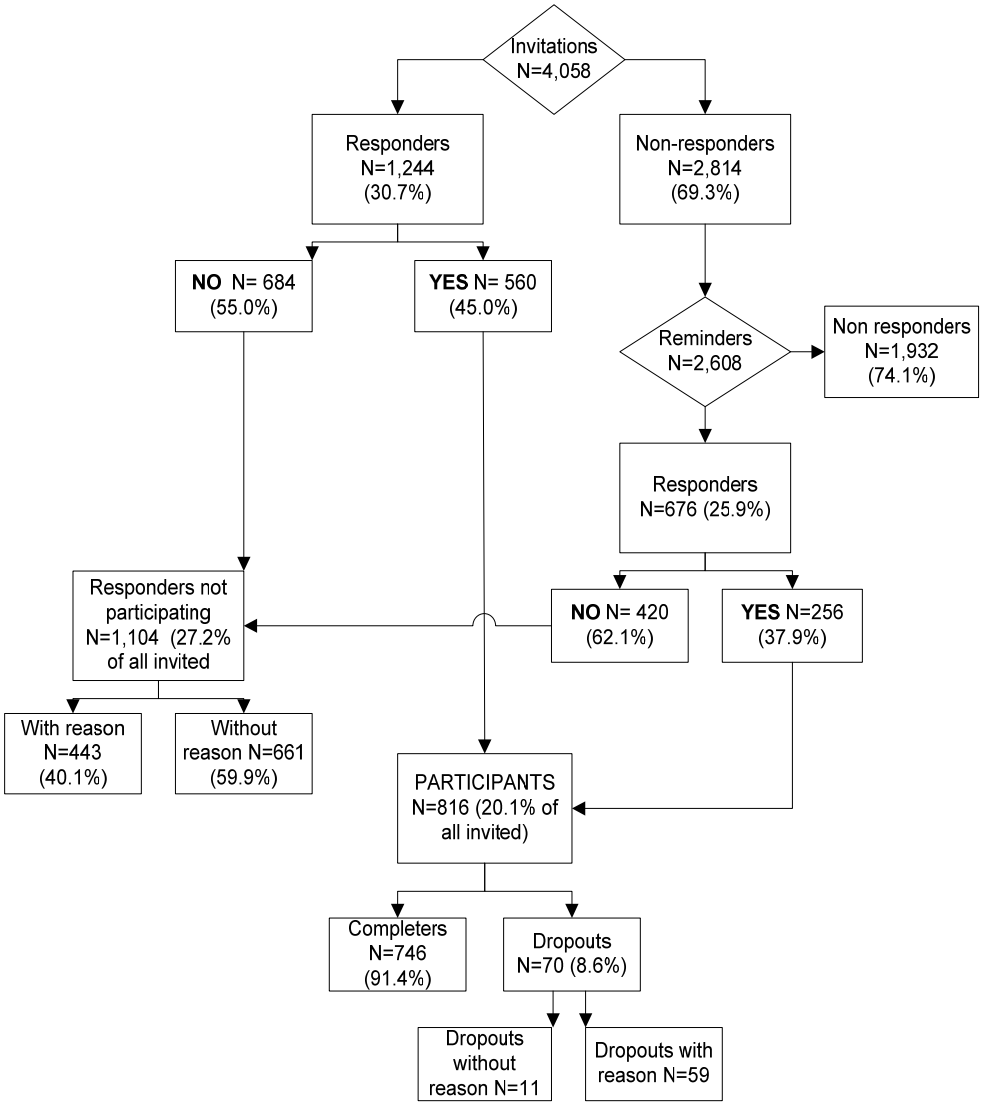
Results

Response and reasons

Figure 1 presents a flow-chart of inclusion and drop-out. Of the 4,058 invited workers who were invited, 30.7% sent the consent form back. Those who did not received a reminder, to which 25.9% responded. In total, 1,104 (27.2% of all workers invited) were unwilling to participate, 443 (40.1%) of whom gave one or more reasons. Of all the participants, 70 (8.6%) dropped out before the first follow-up measurement (47 (67.1%) were allocated to the intervention group), 59 of whom reported their reasons for drop-out.

Table 1 shows the reasons for non-participation and drop-out; the main reasons for both were 'not motivated' or 'not interested'. 'Having other health problems' and 'already receiving medical treatment' were also frequently mentioned by both NPWR and drop-outs. In most cases, it was not clear whether this treatment was aimed at CVD or at some other health problem. 'Feeling healthy', 'already adopted a healthier lifestyle', or 'the regular PHS is sufficient' were reasons that were only given by non-participants. Of the NPWR, 13 did not want to participate because they did not trust the OHS, and 42 stated that they were no longer working in the construction industry or would be leaving in the

Figure 1. Flow-chart of inclusion and drop-out.



near future, due to a change of job or retirement. The reason frequently reported by drop-outs in the intervention group was 'disappointment', mainly in the organization, e.g. due to a change of counselor or inaccurate planning of counseling appointments. The OHSs had failed to schedule the health check-ups for 8 participants, and because they had not sent their questionnaire back, they were considered as drop-outs.

Table 1. Reasons for non-participation and drop-out in the Health under Construction study.

Reasons	Cluster	NPWR		Drop-outs	
		(n)	(%)	(n)	(%)
Feeling healthy; already adopted/ starting to adopt a healthier lifestyle; regular PHS is sufficient	Health	88	19.0	-	-
Dissatisfied with the OHS or not trusting the project	Distrust	13	2.8	-	-
No interest; not motivated	Motivation	104	22.5	17	28.8
Other health problems/ currently receiving (para-) medical treatment	Treatment	96	20.8	11	18.6
Lack of time; expenses too high; travel distance too far	Time/ Money	84	18.2	9	15.3
Retired or working in a different branch	Work	42	9.1	2	3.4
Other, e.g. personal reasons	Other	35	7.6	3	5.1
Disappointed in organization e.g. due to counselor change	Disappointment	-	-	9	15.3
Follow-up measurements planned too late or not at all	Organization	-	-	8	13.6
Total reasons		462	100	59	100

NPWR: non-participants with reason. PHS: periodical health screening, OHS: occupational health service

Characteristics and associations

Table 2 presents the characteristics of participants and non-participants. The participants were older, had higher SBP, DBP and total cholesterol, and lower HDL cholesterol, and were less likely to smoke. With respect to type of work, fewer construction workers participated, compared to workers involved in administration and supervision. In the crude logistic regression models, the variables age, DBP, total cholesterol, HDL cholesterol, 'chest pain and/or shortness of breath', 'tiredness and/or stress', smoking, and type of work were significantly associated with participation. In the multiple logistic regression model, only age, smoking, type of work, and 'chest pain and/ or shortness of breath', remained statistically significant. SBP also appeared to be significantly associated with participation, although in the opposite direction to that in the crude model. Of all the variables, age appeared to have the strongest association with participation (OR 1.04; 95% confidence interval [CI] 1.03-1.05), and could be regarded as a confounder in the relationship between participation and most other variables.

Table 2 Characteristics of participants and non-participants in an individual lifestyle intervention trial for workers at risk for cardiovascular disease, and the associations with participation.

Variable	Participants		Non-participants		Crude	Multiple
	n	Mean (SD)	n	Mean (SD)	OR (95% CI)	OR (95% CI)
Age	816	46.08 (9.32)	3,240	42.24 (10.89)	1.04 (1.03;1.04)**	1.04 (1.03; 1.05)**
BMI (kg/m^2)	816	28.53 (3.61)	3,231	28.29 (4.12)	1.01 (1.00; 1.03)	-
SBP (mmHg)	816	142.13 (15.81)	3,231	141.48 (16.68)	1.00 (1.00; 1.01)	0.99 (0.99; 1.00)**
DBP (mmHg)	816	88.51 (9.68)	3,231	87.07 (10.10)	1.01 (1.01;1.02)**	-
Total cholesterol (mmol/l)	815	6.21 (0.94)	3,222	6.07(0.98)	1.16 (1.07;1.25)**	-
HDL cholesterol (mmol/l)	809	1.12 (0.21)	3,194	1.15 (0.22)	0.58 (0.41;0.84)**	-
HbA1c (%)	810	5.66 (0.40)	3,188	5.63 (0.44)	1.14 (0.96; 1.36)	-
	N	**%**	**n**	**%**	**OR (95% CI)**	**OR (95% CI)**
Smoking (% yes)	809	54.4	3,218	62.7	0.71 (0.61;0.83)**	0.66 (0.56; 0.78) **
Chest pain and/or shortness of breath (% yes)	809	32.5	3,210	28.0	1.24 (1.05; 1.46)*	1.21 (1.02; 1.44)**
Tiredness and/or stress (% yes)	812	35.7	3,205	30.5	1.27 (1.08;1.49)**	-
Fulfilling none of the PA guidelines (% yes)	798	40.7	3,180	40.2	1.02 (0.97; 1.20)	-
Type of work (% administrative/ supervisory tasks)	816	23.8	3,240	17.9	0.70 (0.58;0.84)**	0.70 (0.56; 0.78) **

*p<0.05. **p<0.01. SD: standard deviation; OR: odds ratio; CI: confidence interval; BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure; HDL: high density lipoprotein; HbA1c: hemoglobin A1c; PA: physical activity

The characteristics of drop-outs and non-drop-outs are presented in **Table 3.** Of all the drop-outs, 61.4% had been smokers, as opposed to 53.5% of the non-drop-outs. In both the crude and the multiple logistic regression model, only age was significantly associated with drop-out; drop-outs were significantly younger than non-drop-outs (OR 0.96; 95%CI 0.93-0.98). The ORs of participation and drop-out in the three different age groups are shown in **Table 4**.

Table 3 Characteristics of drop-outs and non-drop-outs in an individual lifestyle intervention trial for workers at risk for cardiovascular disease, and the associations with drop-out.

Variable	**Drop-outs**		**Non-drop-outs**		**Crude**	**Multiple**
	n	**Mean (SD)**	**n**	**Mean (SD)**	**OR (95% CI)**	**OR (95% CI)**
Age (years)	70	41.90 (9.79)	745	46.52 (9.12)	0.95 (0.93; 0.98) **	0.95 (0.93; 0.98) **
BMI (kg /m^2)	70	28.27 (3.84)	746	28.55 (3.59)	0.98 (0.91; 1.04)	-
SBP (mmHg)	70	142.13 (17.91)	746	142.16 (15.59)	1.00 (0.98; 1.02)	-
DBP (mmHg)	70	87.57 (10.92)	746	88.62 (9.55)	0.99 (0.96; 1.01)	-
Total cholesterol (mmol/l)	69	6.17 (0.90)	746	6.22 (0.94)	0.95 (0.73; 1.24)	-
HDL cholesterol (mmol/l)	69	1.14 (0.21)	741	1.12 (0.21)	1.67 (0.52; 5.37)	-
HbA1c (%)	69	5.62 (0.41)	742	5.67 (0.44)	0.79 (0.43; 1.47)	-
	n	**%**	**n**	**%**	**OR (95% CI)**	**OR (95% CI)**
Smoking (% yes)	69	61.4	740	53.5	1.44 (0.87; 2.39)	-
Chest pain and/or shortness of breath (% yes)	69	35.7	743	32.0	1.21 (0.72; 2.01)	-
Tiredness and/or stress (% yes)	70	34.3	746	35.8	0.94 (0.56; 1.57)	-
Fulfilling none of the PA guidelines (% yes)	67	41.4	731	40.4	1.13 (0.68; 1.87)	-
Type of work (% administrative/ supervisory tasks)	70	24.3	746	23.6	0.96 (0.54; 1.71)	-

**p<0.01. SD: standard deviation; OR: odds ratio; CI: confidence interval; BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure; HDL: high density lipoprotein; HbA1c: hemoglobin A1c; PA: physical activity.

Table 4 The odds ratios of participation and drop-out for three different age groups in a lifestyle intervention trial for workers at risk for cardiovascular disease.

Variable	Participation OR (95% CI)	Drop-out OR (95% CI)
Age 30-39 (reference age: 18-29)	1.64 (1.16 - 2.32) **	0.91 (0.38 - 2.21)
Age 40-49 (reference age: 18-29)	2.69 (1.98 - 3.66) **	0.45 (0.20 - 1.01)
Age 50-65 (reference age: 18-29)	3.30 (2.43 - 4.48) **	0.27 (0.11 - 0.63) **

**p<0.01. OR: odds ratio; CI: confidence interval.

Discussion

Of the workers who were invited, 20% participated in this lifestyle intervention trial. The reasons for non-participation were related to 'current (para-)medical treatment', 'feeling healthy', and 'no interest'. The participants were significantly older than the non-participants and, mainly related to this age difference, their CVD risk profile was worse than that of the non-participants. However, smoking was negatively related to participation, irrespective of age. Relatively few participants dropped out before the first follow-up measurement. The reasons given for drop-out were 'no interest', 'current (para-)medical treatment' and 'disappointed in the organization'. Drop-outs were generally younger and more likely to smoke, but their CVD risk profile did not differ significantly from that of the non-drop-outs.

Even though the Health under Construction study is not the only workplace lifestyle intervention study with a low participation rate (24,25), many other such intervention studies had a participation rate of far more than 20% of the target group (17,26-28). Sending invitations by post to the home address of individual workers, and not involving their employer or colleagues, may partly explain the low response in our study. Drop-out in our study remained lower than in several other workplace intervention studies involving lifestyle counseling (17,25,27).

Despite the fact that non-participants gave reasons such as 'feeling healthy', most of them still had high total cholesterol levels and/or high blood pressure. It is possible that their risk perception was inadequate. In several studies a substantial mismatch between actual and perceived risk has been found (29-32), partly caused by insufficient knowledge. In the invitations we sent, we could have specified and explained the individual risk profile. A second important reason for non-participation was 'already receiving (para-)medical treatment'. One way to address this issue would have been to explain, in the invitation letter or brochure, the possible additional positive effect of changes in lifestyle on their current (pharmacological) treatment. Finally, almost 10% of the workers who were invited appeared to have switched between various sectors of industry, or to have retired recently. This could not easily be avoided, and nor could lack of time, motivation, or external reasons. In conclusion, some, but not all of these problems might have been prevented. However, it is questionable whether participation rates could have been

increased in any way; there might have been underlying motives that were not known to us. Inevitably, we had to rely on the data reported by the participants themselves. Likewise, for drop-out, some but not all problems might have been prevented. Clearly, planning of counseling sessions and health check-ups should have been accurate to prevent disappointment and involuntary drop-out. For a considerable number of drop-outs 'time constraints' appeared to be a problem. By scheduling telephone contacts instead of face to face contacts, or by finding an OHS located more closely to their residence or workplace, we were able to solve this problem for some participants. Again, some of the abovementioned reasons may have been related to a lack of motivation.

Older workers were more willing to participate. Not surprisingly, when adjusting for age, the association between participation and some important CVD risk factors, e.g. total and HDL cholesterol, was no longer significant (33). Older workers were not only more likely to participate but also to complete the study, a finding that is in line with several other trials (26,34,35). However, the differences between drop-outs and non-drop-outs in CVD risk factors were only small. This is surprising, since the CVD risk-related variables would be expected to worsen with age. It should be noted that for some workers, drop-out or completion of the study may have been related to (a change in) lifestyle or CVD risk factors. Overall, there was a mismatch in age and CVD risk factors between participants and non-participants, as well as between drop-outs and non-drop-outs. Apparently, the lifestyle intervention was applied only to a sub-group of the target population.

A strength of the study is that we systematically studied the reasons for non-participation of more than 400 NPWR. Furthermore, because we obtained PHS data for all non-participants, we were able to analyze the differences in CVD risk factors between participants and non-participants, including the non-respondents. The information generated in this study may be beneficial for the development of future prevention trials. However, some limitations should also be mentioned. First of all, we did not know the reasons for non-participation of more than half of the workers who were invited. The reasons reported by the NPWR may not have been the same as those of the non-respondents. Secondly, the definition of drop-out may not have been accurate, because we expected that some drop-outs would complete the second follow-up measurement. Thirdly, not all of the results, and in particular, the data on population characteristics, can be generalized to other study populations.

In our study, the response rate was relatively low and only a subgroup of the target population participated and completed the study. Based on these findings, we would recommend that for future interventions investigators should 1) make a realistic calculation of the number of participants needed and the number of persons that need to be invited; 2) anticipate possible reasons for non-participation in a pilot study of the target population, and take into consideration our proposed solutions for stimulating

participation and preventing drop-out; 3) adjust the recruitment strategy in order to include the entire target population.

This is one of the few studies in which characteristics, as well as reasons for non-participation and drop-out, in a lifestyle intervention study were systematically investigated. We learned that an elevated CVD risk was positively associated with participation, but that this association was mainly due to age. Reasons for non-participation and drop-out were mainly related to perceived health, current treatment, and lack of motivation. In future studies, some of these problems could be anticipated, thereby increasing participation and completion rates. Investigators in the field of health promotion are encouraged to share comparable information, so that by learning from each other's experiences, intervention studies can be performed more efficiently and yield more valid results.

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CHAPTER 5

An individual-based lifestyle intervention for workers at risk for cardiovascular disease: A process evaluation

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Abstract

Purpose Evaluate counselors' adherence to an intervention protocol, counselors' competence, and the associations between three process indicators and body weight at follow-up in a 6-month individual-based lifestyle intervention for construction workers.

Design Process evaluation with qualitative and quantitative data.

Setting Occupational health service.

Subjects A total of 408 male construction workers with an elevated risk of cardiovascular disease received the intervention, and 27 occupational health professionals delivered the intervention.

Intervention Seven counseling sessions, the first during which four prescribed items had to be discussed. Motivational interviewing (MI) was used as a counseling technique.

Measures and Analysis The number of sessions and the items discussed were registered by the counselors. Adherence to MI was determined by expert scoring of transcripts of random segments of 19 counseling sessions. Counselors' competence was rated by participants and counselors separately. Associations between three process indicators and body weight at follow-up were determined by linear and logistic regression analyses.

Results Two-thirds of all participants attended five or more sessions, and 38.5% attended all seven sessions. In 90.2% of all cases, the counselor discussed all obligatory items in the first session. MI adherence was reached in one audio-taped fragment. Most (86.3%) of all participants agreed with the counselor being competent. Neither counselors' competence nor number of sessions or items discussed was significantly associated with body weight loss.

Conclusions Performing five sessions and discussing four prescribed items was feasible for the counselors, whereas performing MI was not. Still, participants were positive about the counselors' competence and willing to attend the intervention sessions. Investigators are encouraged to report the evaluation of their intervention process to improve future lifestyle interventions in research or in practice.

Purpose

At the end of a health promotion trial, investigators usually present the intervention effects as well as the intervention protocol. In practice, the intervention may not have been performed as intended. In such a case, the intervention effects cannot be purely explained by the predefined intervention protocol. The intervention process may influence the study outcomes and this has implications for the internal and external validity (1-3).

An intervention protocol may consist of one or more components, such as individual counseling, group sessions, and/or provision of brochures. These components should be delivered in the prescribed dosage and according to the predefined method. In some cases, however, the protocol is not precisely adhered to, owing to, for example, a lack of time, knowledge, or training. Mostly, it depends on the intervention provider to what extent and how the intervention components are being delivered, and it depends on the 'intervention recipient' to what extent the components are being received and used. One way to get insight into the intervention process is to evaluate specific process indicators relevant to the intervention (4-6).

Insight into the intervention process may provide explanations for the study outcomes. More specifically, when the relationship between the process indicators and the main study outcome is statistically analyzed, the influence of each indicator on the outcome of interest can be determined (7). Moreover, knowing the feasibility of an intervention for both intervention provider and user, and on which elements to focus to achieve the desired effect, may help improve development and implementation of future lifestyle interventions. Thus, a thorough process evaluation is an important component of a randomized controlled trial (RCT). According to the Consolidated Standards of Reporting Trials statement, the intervention of each RCT as it was actually administered should be reported in detail (8).

In the Health under Construction study, the effectiveness of a 6-month individual-based lifestyle intervention for male construction workers with an elevated risk of cardiovascular disease (CVD), aimed at changing physical activity and diet or smoking behavior was examined. The results of this study will be published in a separate article. The intervention protocol prescribed seven counseling sessions within six months. During the first contact, four items had to be discussed. Motivational interviewing (MI), a client-centered counseling strategy, had to be applied (9).

The relevance of this process evaluation is threefold: 1) provide a complete overview of the Health under Construction intervention; 2) contribute to the explanation for the intervention effects; and 3) provide recommendations for improvement of future lifestyle interventions. The goals of our process evaluation were to investigate: 1) the counselors' adherence to the intervention protocol; 2) the counselors' competence; and 3) the

associations between the process indicators ‘adherence’ and ‘competence’ and the main study outcome, body weight.

Methods

Subjects and intervention

The target population consisted of construction workers with an elevated risk of CVD who were invited based on the results of their periodic health risk appraisals. The counselors were occupational health service (OHS) professionals who were recruited by advertisement and word of mouth. The intervention protocol prescribed three face to face and four telephone contacts. Counselors had to schedule the sessions immediately after they had received the participants’ contact details from a research assistant. In the first session, the participant had to choose which topic he preferred to discuss during the entire intervention: energy balance or smoking. This choice was necessary to enable analysis of the intervention effects on body weight and lifestyle behavior in both groups separately. The intervention design has been described more extensively elsewhere (10). The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center.

Counselors

Counseling was performed by three occupational physicians, 22 occupational nurses, a nutritionist, and a social worker, varying in age between 28 and 59 years and all employed at one of the OHSs throughout the country. Of the 30 counselors who had been trained, three did not start the intervention due to a change of jobs (1), lack of time (1), or not being willing to comply with the protocol (1). Five counselors dropped out before they fully finished the interventions they had started, due to a change of jobs (2), lack of motivation (2), or illness (1).

Training

During a 2-day training, an MI expert explained theory, facilitated role playing, and gave personal feedback. Additionally, in this training, general lifestyle guidelines were taught by the principal investigator. The first group of 13 counselors participated in a pilot study, comprising one or two face to face contacts. After two months, in a follow-up training session, their experiences were discussed. Due to an expansion of the geographic area in which the study participants were recruited, after five months, another 17 counselors were hired for the project. The content of their 2-day training was adjusted to the experiences of the first training. Because of logistic constraints, there was no third training session.

Data collection

Adherence to intervention protocol

Adherence to the intervention protocol was assessed by measuring the number of sessions performed, number of items discussed, and quality of MI.

Number of sessions

The personal data of all participants as well as the date of each contact were recorded in an Access database (Microsoft Office Access 2003). Each session was reported to the principal investigator by the counselor by means of a registration form sent by e-mail. The maximum number of contacts was seven, and the minimum was five. The following variables were measured:

- Mean and median numbers of contacts per participant
- Percentage of participants who had five or more contacts
- Percentage of participants who had all seven contacts

Number of items

For each session, a registration form was provided on which the items to be discussed were indicated. This form had to be filled out by the counselor, after finishing the consultation. The first session was considered to lay the basis for the intervention. All of the items on the registration form of the first session could be considered as behavior change 'techniques'. They fit into the MI principles and might have facilitated the use of MI. The four items in the protocol were 1) discuss current health and lifestyle; 2) explore ambivalence on a 'decisional quadrant', by filling out advantages and disadvantages of current behavior and behavior change; 3) determine readiness, willingness, and ability to change on 10-point scales; and 4) specify short-term (four weeks) and long-term (six months) goals. The following variables were measured:

- Mean and median number of items discussed
- Percentages of first contacts during which all or none of the items were discussed

Quality of MI

The overall quality of MI in this study was determined by expert scoring of a number of fragments of conversations between counselor and participant. Ten counselors were asked to tape record two of their face to face contacts with different participants. Iris Groeneveld, MSc, and Saida Absalah, MSc, transcribed a randomly chosen 10-minute fragment from each tape. An independent MI expert coded these fragments by using the validated MI Treatment Integrity (MITI) code protocol (11, 12). Among others, the numbers of open and closed questions and MI-adherent and nonadherent statements were counted. Separate scores were given in different areas. In each audio taped fragment, the counselor was considered 'MI proficient' when the scores in four of those MI areas were at or above a cut-off value. The ratio of reflections vs. questions was determined, and a positive score was given if this ratio was ≥ 1. All statements that were not in accordance with MI were counted, and a positive score was assigned when one or none of these statements was made. A global score for MI 'spirit', based on cooperating, providing autonomy, and provoking, as well as for MI 'empathy', based on showing interest and understanding, was assigned as a single unit on a seven-point scale. Spirit and empathy scores were positive when the global score was ≥ 4. The counselors as a group

were considered to have counseled 'in the style of MI' when more than half of all transcribed fragments were categorized as such.

Competence
For measurement of the counselors' competence, both the opinions of the participants and those of the counselors themselves were determined.

Participants' opinions
After the intervention, each participant received a questionnaire and was asked to respond to the following statement by giving a score on a five-point scale (not agree at all [1] - fully agree [5]):

- The counselor was competent.

More specifically, the participants judged their counselor's competence regarding four counseling skills. Again, the statements were scored on a 5-point scale (not agree at all [1] - fully agree [5]), and were formulated as follows:

- The counselor listened well. (listening)
- The counselor supported in exploring abilities for changing lifestyle. (supporting)
- The counselor motivated. (motivating)
- The counselor provided useful information. (informing)

Counselors' opinions
After the intervention, all counselors filled out a questionnaire. Independent of the participants, they scored their own competence on the counseling skills listening, supporting, motivating, and informing (not agree at all [1] - fully agree [5]).

Another proxy for the counselors' perceived competence was the difficulty of performing three counseling skills. All of those skills were in accordance with the MI principles. On a 5-point scale (very difficult [1] - very easy [5]), the counselors responded to the question 'How difficult would you rate the following techniques?' regarding the following items:

- Asking open questions (asking)
- Summarizing what the participant just said (summarizing)
- Raising ambivalence on changing lifestyle (ambivalence)

Associations with body weight
At baseline and 6-month follow-up, all participants underwent a health check-up. Body weight was determined on a digital balance without shoes and jacket. Linear and logistic regression analyses were performed to determine the association between the process indicators number of sessions, number of items, and participants' opinion on overall competence and body weight (kg) at follow-up. For competence, the answering categories were dichotomized to define 'competent' (4 or 5 on the 5-point scale), and 'neutral' or 'not competent' (1 to 3 on the 5-point scale). Only the subgroup of participants who had

chosen the topic energy balance was selected. Baseline body weight (kg) and age (y) were defined as covariates in the regression model. Both variables were checked for effect modification.

Results

Adherence to intervention protocol

Number of sessions

The mean number of contacts per participant in the intervention group was five, and the median was six. Two-thirds (66.4%) of all participants had five or more contacts with their counselors; 157 participants (38.5%) had all seven contacts.

Number of items

The mean number of items discussed was 3.9, and the median was four. The counselors discussed the four obligatory items in 90.2% of all cases. Thus, in 9.8% of all first sessions, only some of the items (n=35) or none at all (n=2) were discussed.

Quality of MI

Because of a technical problem, one of 20 audio-taped fragments could not be coded. In **Table 1,** the results are presented. In seven audio fragments, the ratio of reflections vs. questions was ≥1. In four fragments, the number of statements not according to MI was ≤ 1. The mean score for spirit was 2.7 and the mean score for empathy was 3.1. Of all 19 fragments, one scored positive in all four domains. Thus, overall, counseling was not performed in the style of MI.

Table 1. Quality of MI in the Health under Construction study, as determined by application of the motivational interviewing treatment integrity code to 19 counseling fragments.

Item	Maximum score	Cut-off for MI	Average rating
Empathy (scale 0-6)	6	5	3.1
Spirit (scale 0-6)	6	5	2.7
Reflections: Questions (ratio)	2	1	0.7
MI nonadherent statements (n)	0	1	5.8

MI: motivational interviewing

Competence

Participants' opinions

A total of 301 participants (80.1% of all participants who had at least one counseling session) provided their opinions about their counselors' competence. One percent of participants fully disagreed, 1.0% disagreed, 11.8% neither agreed nor disagreed, 56.6% agreed, and 29.6% fully agreed that the counselor was competent. The participants' opinions about the counselors' competence in listening, supporting, motivating and informing are presented in **Table 2**.

Table 2. Opinions of both participants and counselors about the counselor's performance of four counseling skills.

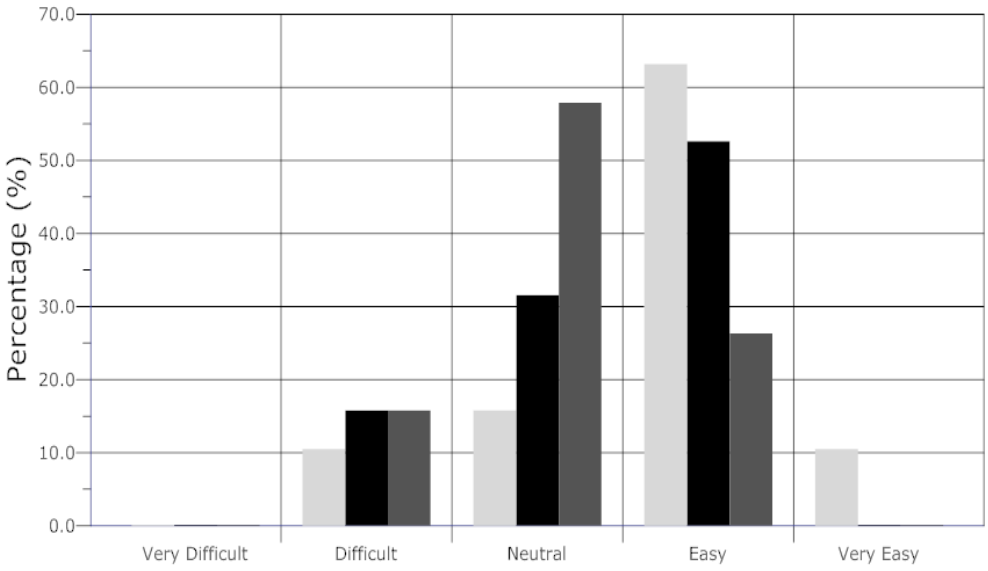
Counseling skill	Fully disagree (%)		Disagree (%)		Neutral (%)		Agree (%)		Fully agree (%)	
	P	C	P	C	P	C	P	C	P	C
Listening well	0.3	0	0	0	2.3	5.3	55.5	78.9	41.9	15.8
Supporting well	0.7	0	1.0	0	6.6	26.3	59.5	57.9	32.2	15.8
Motivating well	0.7	0	1.7	0	8.3	15.8	54.8	73.7	34.6	10.5
Informing well	1.0	0	0.7	0	7.6	31.6	58.5	52.6	32.2	15.8

P: participant; C: counselor

Counselors' opinions

Of the 19 counselors who provided their opinions, none (fully) disagreed with being competent in of any of the skills listening, supporting, motivating, and informing, as presented in **Table 2**. The opinions of counselors on the perceived difficulty of the techniques asking open questions, summarizing, and raising ambivalence are presented in **Figure 1.** Overall, asking open questions appeared to be easy or very easy for 73.7% (n=14) of the counselors. Summarizing and raising ambivalence were regarded as easy or very easy by 52.6% (n=10) and 26.3% (n=5) of the counselors, respectively.

Figure 1. Difficulty of three motivational interviewing techniques, as perceived by counselors.



Left bar (light grey): 'asking open questions'; middle bar (black): 'summarizing'; right bar (dark grey): 'raising ambivalence'.

Associations with body weight

The results of the regression analyses are presented in **Table 3.** Each process indicator is slightly positively related to body weight loss. The participants who (fully) agreed that their counselors were competent lost on average 1 kg more body weight than those who did not. None of the associations were statistically significant. There was no effect modification by age. Baseline body weight modified the effect of number of sessions on body weight at follow-up. The heaviest half of all participants (mean weight ≥ 93 kg) lost more body weight per session performed (β=-0.24, 95% confidence interval [CI] -0.60; 0.12), whereas the ones weighing less than 93 kg did not benefit from more sessions (β=0.19, 95%CI -0.15; 0.53).

Table 3. The influence of the process indicators on body weight (kg) at follow-up.

Process indicator	**n**	**β**	**95%CI**	**p**
Number of counseling sessions (n)	321	-0.01	-0.26; 0.24	0.93
Items discussed (n)	311	-0.15	-1.36; 1.06	0.81
Counselor competent (yes)	261	-1.03	-2.67; 0.61	0.22

CI: confidence interval

Discussion

The goals of this process evaluation were to investigate 1) to what extent the intervention protocol was adhered to; 2) the counselors' competence; and 3) the associations between the process indicators and body weight at follow-up. With respect to the first goal, we concluded that two-thirds of counselors scheduled five or more contacts, all four prescribed items were discussed in more than 90% of all first sessions, and the counselors were not MI proficient. With respect to the second goal, more than 90% of all participants (fully) agreed that their counselors were competent in listening, supporting, motivating and informing. For each of those skills, the counselors considered themselves as competent somewhat less often. Asking open questions was considered the easiest skill and raising ambivalence was regarded as the most difficult. The third goal resulted in the finding that the number of sessions, the number of items, or the counselors' competence as perceived by the participant was not significantly associated with body weight, although the association with competence was strongest and in the expected direction.

The number of sessions performed depended on both the counselors and the participants. In most cases, the fact that some participants had five or six sessions instead of seven may have been due to counselors' difficulties with planning all contacts within six months rather than to a lack of motivation of the participants. Nevertheless, the compliance rate of participants was fairly high and comparable to that of Wadden et al. (13) and Digenio et al. (14). Discussing the four predefined items in the first session appeared to be feasible for most counselors. A registration form containing a decisional quadrant that could be filled out with the client appeared to be a useful tool for inexperienced counselors.

Unfortunately, the counselors were not proficient in using MI. There may be several explanations: the duration of the training was only three days, the counselors did not have a practicing period before the actual study started, and they did not receive personal feedback during the intervention period. The latter would have been especially useful - personal feedback was proven to increase post training proficiency in an alcohol abuse intervention delivered by clinicians (15). In a study more related to ours, Brug et al. (2007) found that dieticians who had been trained in MI and received additional on-demand feedback and advice scored relatively high on the total number of reflections, empathy, and MI spirit as compared to the counselors in our study (16). Another factor that may have negatively influenced the delivery of MI in our study is the different counseling style that the counselors had been using during the past 5 to 30 years. They were used to discussing different topics, such as return-to-work or psychosocial problems, and counseling used to be less client-centered. Last, the scoring instrument should be considered. In our study, the MITI was used because since it sensitive, reliable, and more condensed and less complex than the original Motivational Interviewing Skill Code (12). Still, it appeared rather stringent. This was reflected in a study performed by Tollison et al. (2008) on the use of MI in a brief alcohol intervention. In their study, counselors were provided intensive MI training and weekly supervision during the whole intervention period, in which constructive feedback was provided. Still, they did not meet the criteria for proficiency in MI spirit, ratio of questions to reflections, and percentage of complex reflections (17). Altogether, the counselors in our study might have fulfilled the criteria for basic behavior change counseling, but not for MI (18).

The participants were strikingly positive about their counselor's competence, overall and in specific counseling skills. This might have been a reason for the high compliance. When compared with the participants' perceptions, the counselors slightly underestimated their competence. This may have been due to reporting bias - the evaluation forms were not anonymous to the investigator. Still, the majority of counselors considered themselves competent in listening, supporting, motivating, and supporting. Since listening and supporting are components of MI empathy, the counselors' opinions on these skills may be compared to the MITI results for empathy. These results appeared to be insufficient. The perceived difficulty of the skill asking open questions can also be compared to the results of the MITI. According to the MITI, only 29.8% of all questions were open questions, whereas 73.7% of all counselors indicated that this skill was easy or very easy. Thus, there is a discrepancy between subjective and objective MI competence. This inaccurate self-reflection could have resulted from the lack of feedback. This discrepancy has also been described by Miller et al, in a study on MI in an alcohol abuse project. Clinician self-reports of MI skillfulness were unrelated to proficiency levels in observed practice (15).

The relationship between body weight loss and frequency of sessions was investigated by Wadden et al. (2009), who found that the more sessions participants attended, the more

body weight was lost after one year. Although not significant in our study, a positive trend between the number of sessions and body weight was found as well, especially for the heavier half of the participants. Of all process indicators in our study, counselor competence had the strongest relation to body weight loss. As far as we know, this association has not been studied before. Important to note is that it is unclear whether a change in a process indicator is the cause or consequence of body weight loss. Unfortunately, we were not able to analyze the association between MI quality and body weight because MI quality was determined for only 10 counselors. However, as we know from previous studies, a better performance of MI is associated with larger intervention effects (19).

A strength of this study is that we provided a complete overview of the most important aspects of the process of this individual lifestyle counseling intervention. All sessions and items discussed were systematically registered, and opinions were provided by intervention providers and recipients. Furthermore, our study reveals valuable information for those planning to use MI as part of an intervention in research or practice. MI will probably be used in many future interventions, but evaluations of the quality of MI in lifestyle counseling are scarce. Also, in contrast to most other process evaluations, we described the link between the separate process indicators and a main outcome measure of the intervention study. In this way, light is shed on the contribution of each process indicator on the effect of the intervention. Limitations of the study include the following. Because of financial constraints, the MITI was applied to only 19 counseling fragments of 10 counselors. For determining overall MI quality, this number was sufficient. However, it was not possible to investigate the association between MI quality and intervention outcomes. Another drawback is that the questions that we asked to determine competence were not validated. Last, self-report can never be as accurate as objectively collected information.

For OHS professionals, it appears feasible to perform an individual-based lifestyle intervention for workers consisting of five sessions, and discussing a list of predefined items. The provided training, not followed by on-demand feedback, appeared insufficient to master the counseling method of MI. Construction workers with elevated CVD risk were willing to attend this intervention and had positive opinions about the counselors' competence. No associations between the process indicators and the intervention outcome were concluded. This study appeared valuable for providing insight into the feasibility and appreciation of the intervention process.

So what?

For developers of lifestyle interventions we suggest the following. The number of sessions to be scheduled should first be discussed with the intervention provider to check which number is feasible; a registration form containing prescribed items is recommended because it facilitates the conversation for the counselor, serves as a reminder for the

client (e.g. goals that were set), and makes registration of sessions and items easier for the investigator. Additionally, a longer training, a period of practicing MI, and personal feedback are recommended because the chances of achieving MI proficiency are increased. Furthermore, investigators are encouraged to systematically and thoroughly evaluate and report adherence to their intervention protocol. By learning from each other's experiences, flaws in future intervention protocols can be avoided.

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CHAPTER 6

Health under Construction: Short- and long-term effects on physical activity, diet, and smoking of a lifestyle intervention for construction workers at risk for cardiovascular disease

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Abstract

Objectives To evaluate the effects on physical activity (PA), diet, and smoking of a lifestyle intervention consisting of individual counseling among male workers in the construction industry with an elevated risk of cardiovascular disease (CVD).

Methods In a randomized controlled trial including 816 male blue- and white-collar workers in the construction industry with an elevated risk of CVD, usual care was compared to a 6-month lifestyle intervention. The intervention consisted of individual counseling using motivational interviewing techniques, and was delivered by an occupational physician or occupational nurse. In three face to face and four telephone contacts, the participant's risk profile, personal determinants, and barriers for behavior change were discussed, and personal goals were set. Participants chose to aim at either diet and PA, or smoking. Data were collected at baseline, six and 12 months by means of a questionnaire. For data analyses, linear and logistic regression analyses were performed.

Results The intervention had a statistically significant beneficial effect on snack intake (β -1.9, 95%CI -3.7; -0.02), fruit intake (β 1.7, 95%CI 0.6; 2.9), and smoking (OR 0.3, 95% CI 0.1; 0.7) at 6 months. The effect on snack intake was sustained until 12 months; 6 months after the intervention had ended (β -1.9, 95%CI -3.6; -0.2). The intervention effects on leisure time PA and metabolic equivalent-minutes were not statistically significant.

Conclusions Beneficial effects on smoking, fruit, and snack intake can be achieved by an individual-based lifestyle intervention among male construction workers with an elevated risk of CVD. Future research should be done on strategies to improve leisure time PA and on determinants of maintenance of changed behavior. Considering the rising prevalence of unhealthy lifestyle and CVD, especially in the aging population, implementation of this intervention in the occupational health care setting is recommended.

Introduction

In the Netherlands, among men aged younger than 65 years, a quarter of all deaths is due to cardiovascular diseases (CVD) (1). CVD may not only lead to premature death, but also to decreased physical functioning and lower quality of life (2). Important precursors of CVD are obesity, hypertension, and an abnormal blood lipid profile. These abnormalities are caused to a large extent by an unhealthy lifestyle, such as unhealthy diet (3), insufficient physical activity (PA) (4), and smoking (5). Irrespective of other CVD risk factors such as age, male gender, family history, or low job control (6), improving lifestyle will lower CVD risk. Effective lifestyle change strategies should be developed in order to prevent CVD.

Numerous trials have been performed among persons with an elevated CVD risk assessing the effectiveness of interventions aimed at changing lifestyle (7-9). Different strategies have been evaluated, among which providing advice, exercise classes, a prescribed diet, and individual counseling. Advice alone was proven to be less effective than individual counseling in achieving long-term behavior change among adults with an elevated CVD risk (8,9). Supervised exercise and diet alone may facilitate body weight loss (10), but long-term behavior change is less likely if not combined with more intensive diet and PA modification therapy (11), such as individual counseling. Nowadays, a frequently used counseling method is motivational interviewing (MI). MI was originally developed for changing addictive behaviors, but has also proven effective in lifestyle change (12,13). MI is a client-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence, and is based on the principle that behavior change occurs in stages (14). During MI, determinants are addressed that have consistently proven associated with behavior change, such as attitude and self-efficacy (15).

The workplace is an appropriate setting for investigating lifestyle interventions, since many adults of various socio-economic statuses, lifestyles, and risk profiles can be targeted at once. Moreover, in the working population, a lifestyle intervention will not only influence CVD risk. Improving diet and increasing PA may also lower absenteeism (16). Regular PA may increase work ability, due to its effects on cardio respiratory and musculoskeletal capacity, factors that normally decline with age (17). However, in most workplace lifestyle intervention studies, the sustenance of health effects, which is necessary for permanent CVD risk reduction, was not determined, as the final follow-up measurement took place directly after the intervention had ended (18,19). Recently, two workplace intervention studies were performed on the effectiveness of MI on lifestyle changes (20,21), showing that MI is more effective than providing health risk information only, and equally effective to group activities or computer-tailored advice. Again, in both studies, no long-term follow-up measurements took place.

In the Health under Construction study, we aimed to develop and evaluate a lifestyle intervention for construction workers with an elevated CVD risk in the Netherlands. In this

population, most workers are male and over 40 years of age. In 2008, the prevalence of overweight and obesity among male construction workers who attended a periodical health screening at the occupational health service was higher than in the total Dutch adult male population; 63.8% versus 52.3% (22). According to the Framingham risk score (23), 27.3% of male construction workers had a higher than moderate 10-year risk of coronary heart disease. In the Health under Construction study, we evaluated the short- and long-term effects on PA, diet, and smoking of a lifestyle intervention consisting of individual counseling using MI techniques among male workers in the construction industry with an elevated risk of CVD in the Netherlands.

Methods

Participants

All male construction workers aged 18-65 years, employed at different (>400) companies throughout the Netherlands, who had attended the voluntary periodical health screening at the occupational health service between January 2007 and February 2008 (59.4% of all invited), and who had an elevated risk for CVD (n= 4.058; 19.1% of all screened), were personally invited to the study. Elevated CVD risk was concluded if the worker's 10-year coronary heart disease risk was higher than moderate according to the Framingham risk score, and he additionally fulfilled at least one of the following criteria; body mass index (BMI) ≥ 30 kg/m^2; HbA1c ≥ 6.5%; consuming ≥ 35 glasses of alcohol per week; not meeting the PA guidelines; heart complaints; psychological complaints. The Medical Ethics Committee of the VU University Medical Center approved the study protocol. An extensive description of the study design is provided elsewhere (24).

Randomization, blinding, and sample size calculation.

The workers who consented to participate were pre-stratified for work type (blue-collar workers performing the construction work versus white-collar workers involved in administration and supervision), and individually randomized into the control or the intervention group, using Random Allocation Software (Version 1.0). After randomization, the research assistant notified each participant to which group he had been allocated. The investigator who performed the data analyses was blinded to the group allocation. Due to the study design, the intervention providers and participants could not be blinded. The sample size was based on PA; one of the main outcome measures of the study. To detect a 10% difference between the control and intervention group in the proportion of participants meeting none of both Dutch guidelines for moderate and vigorous intensity physical activity after 6 months, i.e. 38% in the control group and 28% in the intervention group, with a power of 80% and a 95% confidence interval (α=0.05), 692 persons were needed at the first follow-up measurement.

Intervention and control condition

Over a period of 6 months, each participant in the intervention group had three 45-60 minute face to face and four 15-30 minute telephone contacts with an occupational

physician or occupational nurse. This counselor applied a client-centered counseling style using MI techniques such as asking open questions, summarizing, listening, supporting, and raising ambivalence. In the first session, a stepwise protocol had to be followed. First, the participant's CVD risk profile was presented and his current health status was discussed. Second, the participant decided to aim at physical activity and diet, or smoking. Third, the participant was encouraged to indicate advantages and disadvantages of current and 'desired' behavior. Fourth, the participant was asked to indicate his willingness, readiness, and perceived confidence in his ability to change on 10-point scales. Last, the participant set long- and short-term goals, and formulated implementation intentions (25). In the following counseling sessions, progress and barriers were discussed. The participants in the control group received usual care, consisting of brief oral or written information from the occupational physician about their risk profile, based on the periodical health screening results. To all participants of both intervention and control group, brochures were provided containing information on PA, healthy eating, smoking cessation, and CVD.

Outcome measures

At baseline and after 6 and 12 months, a questionnaire on PA, diet, and smoking was filled out. For measuring PA, we used the fairly reliable ($r_{spearman}$ 0.58) and valid ($r_{spearman}$ 0.45) Short QUestionnaire to ASsess Health enhancing PA (SQUASH)(26). By means of this questionnaire, we determined the number of minutes per week spent on two domains of PA, i.e. leisure time PA (walking, cycling, doing odd jobs, gardening), and sports activities. In addition, the total weekly amount of energy expended due to the activities in those two domains was estimated, by multiplying the total number of minutes spent on each activity by its metabolic equivalent- (MET-) value (27) and summing all MET-minutes. With regard to diet, in line with the Short Questionnaire for Measuring Fruit and Vegetable Intake, the average weekly intake during the past month was determined for fruit (pieces) and vegetables (heated and raw; tablespoons). Moreover, consumption of alcohol (glasses), and snacks were assessed. The latter food group was defined as the sum of sweet (e.g. piece of pie), cold salty (e.g. handful of crisps), and warm salty snacks (e.g. piece of egg roll), eaten outside the regular meals. The food questionnaire was not validated but tested for face validity by an expert in nutrition and lifestyle change, and for comprehensibility by two construction workers. Current smoking status was defined as 'smoker' or 'non-smoker'. Furthermore, the participant was asked whether he had used nicotine replacement therapy or medication in case he had succeeded in smoking cessation. At baseline, the possible confounding variables age (years) and BMI were determined at the occupational health service. For determining BMI, body height (meters) without shoes was determined with the participant in standing position, his heels and head against the wall and his face in a horizontal plane. Body weight (kilograms) was measured without shoes and jacket, using a digital balance.

Data analyses

Data were analyzed using SPSS (Version 15.0, Chicago Ill). In the baseline questionnaire, all participants had indicated whether they would prefer to improve their dietary or PA behavior, or to quit smoking. Those who had indicated to prefer improving diet or PA (energy balance-related behaviors; EB) were analyzed separately from the ones who had indicated to prefer smoking cessation (SC). As a result of self selection, baseline differences between the intervention and control group may have arisen, possibly leading to confounding. Therefore, we checked for baseline differences between intervention and control group in age, BMI, smoking status and all of the outcome measures, within both the EB group and the SC group. To determine the effects at 6 months, linear and logistic regression analyses were done with the variable of interest as the outcome, and its baseline value, group allocation (intervention vs. control), and possible confounders as independent variables. The effects at 12 months were evaluated using the same method. In both the EB and SC group we checked for confounding by age and BMI, and for effect modification by variables that theoretically could modify the effect on the outcome measure of interest, i.e. age, BMI, smoking, work type, and marital status (partner/ no partner). Effect modification was concluded in case the p-value of the interaction term was <0.1. Only participants for whom data were present on all three time points were included in the analyses. Additionally, in order to assess the intervention effects among participants who had adhered to the protocol, linear and logistic regression analyses according to the 'per protocol' principle were done, for the effects at 6 and at 12 months. Of the intervention group, only those who had completed five or more counseling sessions on one of both topics (diet/ PA or smoking cessation) were included in the analyses. Of the control group, only those participants were included who had indicated *not* to have received lifestyle advice from any type of care provider, between baseline and 6 months.

Results

Baseline characteristics and confounding

In **Figure 1** the participant flow is presented. 288 Participants in the intervention group and 307 participants in the control group were included in the analyses. At baseline, in the EB group, 31.1% was a blue-collar worker and 69.9% was a white-collar worker, mean age was 47.4 years (standard deviation [SD] 8.8), mean BMI was 28.8 (SD 3.5), and 32.7% was a current smoker. BMI appeared to be a confounder for snack intake. For consistency reasons, all analyses in the EB group were adjusted for BMI. In the SC group, at baseline, 85.2% was a blue-collar worker and 14.8% was a white-collar worker, mean age and mean BMI were 46.8 (SD 8.9) and 27.8 (SD 3.2), respectively, and 100% was a current smoker. In the SC group, no confounding by age or BMI was concluded, thus no adjustments were made. No adverse events of the intervention were reported by any of the participants.

Physical activity

In **Table 1**, the values for leisure time PA, sports, and MET-minutes at baseline, 6 and 12 months, and the results of the linear regression analyses are presented, for the EB group

Figure 1. Flow diagram of the progress through the phases of the study

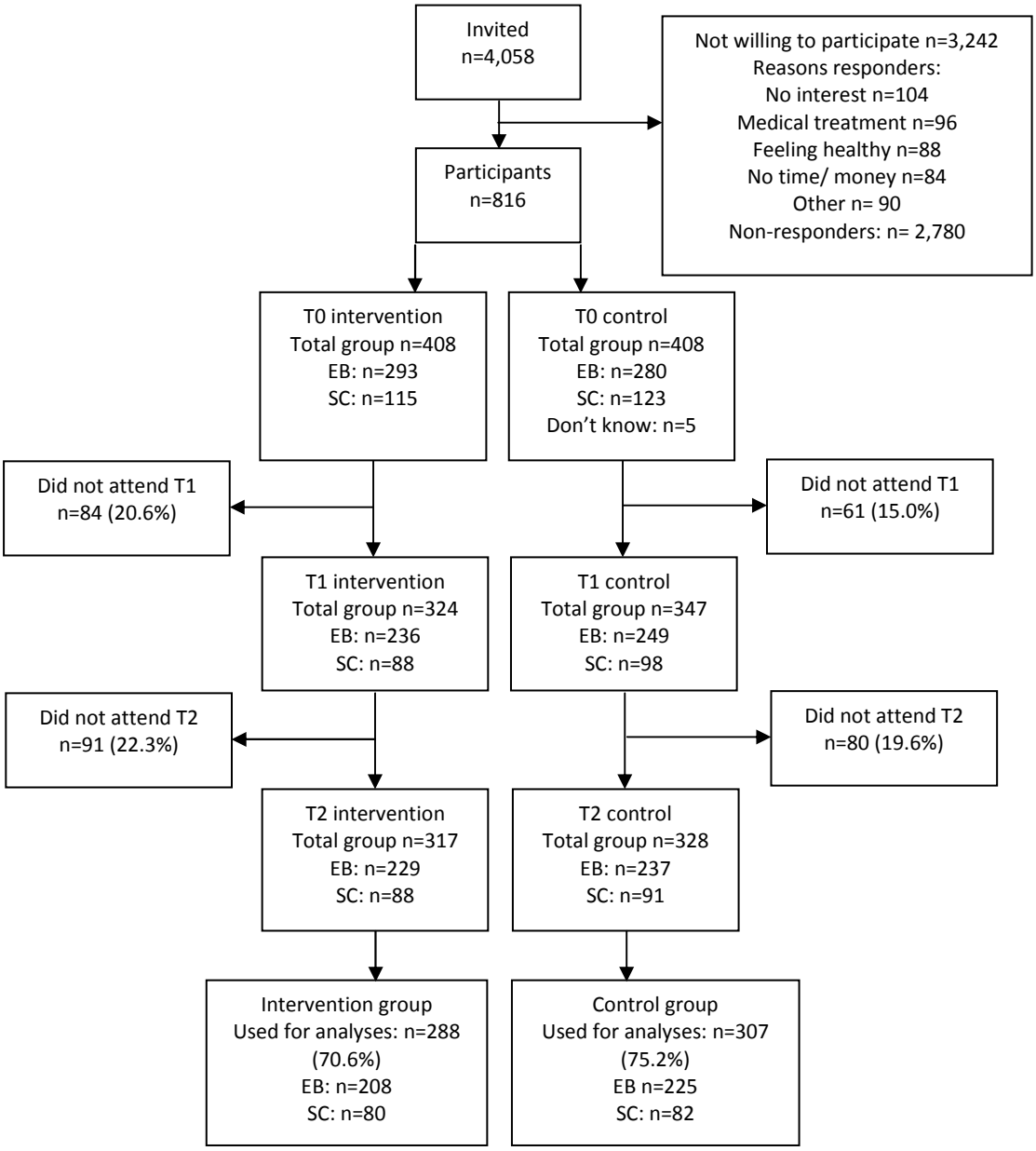

Table 1. Intervention effects in the energy balance subgroup, as determined by linear regression analysis, adjusted for body mass index.

	n	Baseline mean (SD)	6 months mean (SD)	β (95% CI) 6 months	12 months mean (SD)	β (95% CI) 12 months
Leisure time physical activity (minutes per week)						
Intervention	207	429.7 (390.0)	589.7 (464.2)	59.5 (-11.3; 130.3)	543.4 (462.5)	30.2 (-45.3; 105.8)
Control	222	466.0 (349.0)	552.8 (424.6)		529.4 (409.2)	
Sports activities (minutes per week)						
Intervention	207	95.1 (116.6)	107.3 (130.7)	10.1 (-9.6; 29.7)	109.9 (139.8)	2.2 (-19.0; 23.5)
Control	223	77.9 (126.8)	84.7 (139.0)		96.5 (143.3)	
Leisure time physical activity- and sports-related energy expenditure (MET-minutes per week)						
Intervention	206	2,130.5 (1,494.9)	2,852.4 (1,769.7)	226.5 (-81.6; 534.5)	2,678.6 (1,838.4)	132.2 (-177.7; 442.0)
Control	223	2,209.5 (1,543.8)	2,672.5 (2,060.1)		2,591.1 (1,899.0)	
Alcohol (glasses per week)						
Intervention	196	9.6 (9.9)	8.8 (9.1)	-1.3 (-2.7; 0.1)	8.8 (8.9)	-1.0 (-2.5; 0.4)
Control	213	9.6 (9.5)	10.2 (10.2)		9.9 (10.6)	
Snacks (pieces per week)						
Intervention	207	14.1 (11.2)	11.1 (11.1)	-1.9 (-3.7; -0.02)*	12.1 (9.2)	-1.9 (-3.6; -0.2)*
Control	220	13.1 (9.8)	12.6 (11.9)		13.6 (11.2)	
Fruit (pieces per week)						
Intervention	207	10.1 (6.9)	11.8 (8.1)	1.7 (0.6; 2.9)*	11.7 (8.3)	0.9 (-0.2; 2.1)
Control	221	10.8 (8.6)	10.7 (7.9)		11.3 (7.8)	
Vegetables (spoons per week)						
Intervention	207	17.0 (9.5)	18.0 (9.2)	0.9 (-0.6; 2.4)	17.5 (8.8)	0.04 (-1.4; 1.4)
Control	222	17.7 (10.3)	17.3 (8.3)		17.7 (8.8)	

* $p < 0.05$. SD: standard deviation; CI: confidence interval; MET: metabolic equivalent

only. No statistically significant intervention effects were found for any of those variables at 6 or 12 months, although the improvements in leisure time PA, sports, and MET-minutes at six months were largest in the intervention group. BMI was an effect modifier for leisure time PA at 6 months. The normal weight participants (BMI<25; n=52) in the intervention group decreased the time spent on leisure time PA (β -133.3, 95%CI -330.7; 64.1), whereas the overweight (BMI≥25; n=221) and obese (BMI≥30; n=156) participants increased their leisure time PA (β 68.9, 95%CI -29.6; 167.4 and β 104.6, 95%CI -15.7; 224.9). Age appeared to modify the 6- and 12-month effects of the intervention on leisure time PA as well. The intervention effect among participants aged 45 years and over (n=254) was larger than among the younger ones (n=175) at both 6 (β 88.8, 95%CI -10.1; 187.7 vs. β 21.0, 95%CI -76.6; 118.6) and 12 months (β 86.1, 95%CI -19.3; 191.5 vs. β -53.5, 95%CI -156.9; 49.9). In none of the BMI and age subgroups, statistically significant intervention effects were found.

Diet

In **Table 1**, the values for fruit, vegetables, alcohol and snacks at baseline, 6, and 12 months, and the results of the linear regression analyses are presented, for the EB group only. At 6 months, a statistically significant beneficial intervention effect was found for snack and fruit intake, and a borderline significant effect was found for alcohol. At 12 months, the intervention effect on snack intake was still statistically significant. Due to effect modification by age, the intervention effect appeared statistically significant among participants aged 18-44 (β -3.2, 95%CI -5.9; -0.5) only, but not among those aged 45 and over (β -1.1, 95%CI -3.2; 1.1). At 12 months, the effect on alcohol intake was modified by BMI. The normal weight participants significantly lowered their alcohol intake as a result of the intervention (β -3.8, 95%CI -7.6; -0.04), whereas the overweight and obese did not (β -0.8, 95%CI -2.9; 1.3 and β -0.4, 95%CI -2.7; 1.9).

Table 2. Intervention effects in the smoking cessation subgroup, as determined by logistic regression analysis.

	n	**Baseline (%)**	**6 months (%)**	**OR (95% CI) 6 months**	**12 months (%)**	**OR (95% CI) 12 months**
Smoking (%)						
Intervention	80	100	68.7	0.3 (0.1; 0.7)*	76.3	0.8 (0.4; 1.6)
Control	82	100	86.6		80.5	

* $p < 0.05$. OR: odds ratio; CI: confidence interval.

Smoking

In **Table 2,** the results of the logistic regression analyses in the SC group can be found. At 6 months, 25 persons (31.3%) in the intervention group had quit smoking, as opposed to 11 (13.4%) in the control group. The odds ratio (OR) of smoking was 0.3 (95%CI 0.1; 0.7). Nine (36%) persons in the intervention group who quit smoking had used nicotine replacement

therapy or medication, as opposed to 2 (18%) in the control group. The statistically significant effect was not sustained until 12 months follow-up (OR 0.8, 95%CI 0.4; 1.6). Age appeared a modifier of the intervention effect on smoking. The intervention was more effective among participants aged 45 years and over (n=100) than for the younger ones (n=62) at both 6 (OR 0.1, 95%CI 0.02; 0.5 vs. OR 0.7, 95%CI 0.2; 2.1) and 12 months (OR 0.4, 95%CI 0.1; 1.2 vs. OR 1.2, 95%CI 0.4; 3.8).

Per protocol analyses

According to the per protocol analyses, the differences between control and intervention group at both 6 and 12 months were larger than in the analyses of the study population as a whole. Again, the effect on fruit intake was statistically significant at 6 months (β 0.9; 95%CI 0.7; 3.1). Also, the effect on alcohol intake was statistically significant at 6 months (β -1.7, 95%CI -3.2; -0.1). The effect on snack intake was statistically significant at 6 months (β -2.6, 95%CI -4.5; -0.6) and at 12 months (β -3.2, 95%CI -5.0; -1.5). The effect on smoking was statistically significant at 6 months (OR 0.1, 95%CI 0.05; 0.3) as well as at 12 months (OR 0.4, 95%CI 0.2; 0.99).

Discussion

Findings

The aim of the study was to evaluate the effectiveness of a lifestyle intervention consisting of individual counseling using MI techniques for workers in the construction industry with an elevated risk of CVD. At 6 months, the intervention had a statistically significant beneficial effect on snack intake, fruit intake, and smoking. At 12 months, most of the initial improvements in the intervention group were still present, although the effects on smoking and fruit intake were no longer significant. At 12 months, i.e. 6 months after the intervention had ended, a significant effect was found on snack intake. Moreover, at 12 months, a statistically significant beneficial effect was found on alcohol consumption among the normal weight participants. No statistically significant intervention effects were found for time spent on leisure time PA and sports, or on MET-minutes per week. Work type did not modify any intervention effect, implying that the intervention is equally effective in blue- and white-collar workers.

Comparison to other studies

Physical activity had substantially increased in both the intervention and the control group at 6 months (+172 vs. + 94 minutes per week) and at 12 months (+129 vs. + 84 minutes per week), but the intervention effect was not significant. This is not in line with the reviews of Dugdill et al. (2008) and Conn et al. (2009), who concluded evidence for the effect of workplace counseling on PA (28,29). The lack of a significant intervention effect in our study may be related to the high levels of baseline PA at work, or due to the relatively large amount of time spent on doing ‘odd jobs’ outside working hours. The lack of a statistically significant effect on PA is unfortunate, since Ruzic et al. (2003) demonstrated that a high physical load at the workplace (or while doing odd jobs) did not induce positive

changes in aerobic capacity, strength, or flexibility of male workers aged 20-60 (30). Thus, in a future study, another strategy should be sought for stimulating engagement in leisure time PA among workers in the construction industry. With respect to diet, notable improvements were found in the intervention group. Pignone et al. (2003) also concluded that medium to high intensive interventions generally produced medium to large changes in dietary behavior, but they found no specific differences in effectiveness on fat or fruit and vegetable intake (31). In our study, especially the consumption of snacks was affected, possibly because participants realized that decreasing snack intake has a direct effect on losing body weight, which may have been their main goal. Finding a significant and equally large effect 6 months after the intervention has ended is important, since only long-term changes in behavior will lead to a sustained decrease of CVD risk. As to smoking, according to a recent Cochrane review, previous workplace individual counseling interventions aimed at smoking cessation resulted in quit rates between 6 and 21% in the intervention group (32). As compared to those studies, the short-term quit rate in the intervention group in our study was high. The relatively high frequency and long duration of contacts of the intervention in our study may have contributed to this result. Another factor that may have contributed to the high cessation rate was the fact that most counselors provided information on nicotine replacement therapy to those clients who were motivated to quit. A combination of counseling and medication use increases success rates, as stated by Fiore et al. (33).

Issues related to behavior change

Initial positive results at the short term and weakening of the effects at the longer term is a well-known phenomenon. Habitual behavior and convenience of the 'original' behavior may add to this effect. From this study we can conclude that it is vital to find out the determinants of *maintenance* of 'new' lifestyle behavior. As acknowledged by Pritchett et al. (2005), lifestyle modification often results in health improvements, but the challenge is to find out how to avoid relapse to old habits (34). If we know why some people maintain new behavior and others do not, tools for prevention of relapse may be developed. Possibly, short 3-monthly follow-up counseling sessions, either face to face or by telephone, may facilitate maintenance of behavior. As shown in the Finnish Diabetes Prevention Study, this strategy induced behavior change that was sustained at two years (9). Another issue which may be targeted in future research is the possible additive effect on environmental changes. During our intervention, behavioral determinants were discussed that could be changed by the participant himself, such as attitude and self-efficacy. However, behavior change is not only determined by personal factors, but also by the environment (35). When creating an environment in which the healthy choice is stimulated, such as healthy foods in the company restaurant, or the opportunity to visit a company fitness center (36), behavior change might be facilitated. Environmental changes are difficult to implement for blue-collar workers, who are physically active at work and usually work at different locations, but could be tested among white-collar workers in the construction industry.

Changes in the control group

Not only the intervention group improved certain lifestyle behaviors, the participants in the control group did so as well. This is not surprising, since they had just received the results of their periodical health screening and were notified of being at risk for CVD. The 'measurement effect', as described by Van Sluijs et al. (2006) may have been causal to the improvements in the control group found after 6 and 12 months (37). Also, the 'Hawthorne' effect, i.e. altering behavior because one is aware of being part of an experiment, may have played a role. Last, one should keep in mind that persons who are intrinsically motivated to change lifestyle will be more likely to participate in a lifestyle intervention trial than those who are not. Since these mechanisms apply to both the intervention and the control group, the intervention effects have probably not been distorted.

Limitations and strengths

Some limitations of this study should be mentioned. A well-known limitation is over- and underreporting of behavior. Since this 'misreporting' occurred in both groups, it has probably not introduced bias, although it may have attenuated the intervention effects. Another drawback is the fact that no validated questionnaire was used for measuring dietary intake. We had two reasons for doing so. First, we wanted the questionnaire to be completed by all participants, and considered the validated food frequency questionnaires too extensive for this purpose. Second, we aimed to determine the intervention effects on certain health-related food groups, and not on exact intake of grams or energy. Another limitation is the fact that participants were not blinded. In our study, the chance of contamination between groups was limited, since the workers were employed at more than 400 different companies and recruited and randomized individually. A limitation related to the study population may be selective participation and dropout. The participants were older and more likely to smoke than those who did not participate, and the drop-outs were younger and less likely to smoke than the participants (38). The differences between the target group and the study completers may slightly lower the generalizability of the results. Nevertheless, the age- and lifestyle-related characteristics of the drop-outs were equal in the intervention and the control group. Last, by analyzing the EB and SC group separately, the study may have become underpowered. Since, within the EB and SC groups, differences between intervention and control group were checked and adjusted for, no confounding will have occurred. This study also has numerous strengths. Compliance to the intervention was rather high, i.e. two-thirds of participants in the intervention group had five or more counseling sessions (39). Only few participants in the control group had received lifestyle advice from another care provider, thus the contrast between groups was large. Randomization was performed at the individual level, which is the preferred method since baseline differences between intervention and control group are least likely. With respect to the analyses, the participants in the EB group were analyzed separately from those in the SC group, in order to determine changes in the lifestyle behaviors that were actually aimed at. Furthermore, the study can be considered

as an effectiveness study as opposed to an efficacy study. Namely, counseling was conducted at the occupational health service and performed by an occupational health service professional instead of by the researchers themselves. As the results of this study reflect the intervention effectiveness in 'real life', decision makers will better be able to decide upon implementation. The most important strength is that we investigated the effects on CVD risk-related behaviors no less than 6 months after the intervention had ended. With this study, we generated knowledge on the effectiveness of a promising counseling strategy on behavior change among a population in which CVD risk will be rising in the following years.

Conclusions

We conclude that this lifestyle intervention for workers in the construction industry at risk for CVD had significant effects on snack and fruit intake and smoking at 6 months. The significant effects on snack intake were unchanged at the long term. Future studies should be done on strategies for changing leisure time PA, and on determinants of maintenance of changed behavior in this population. Considering the rising prevalence of unhealthy lifestyle and CVD, especially in the aging population, implementation of this intervention in the occupational health care setting is recommended.

What this study adds:

- Changing physical activity, dietary, and smoking behavior lowers the risk of cardiovascular disease, and may also have work-related benefits.
- Many workers in construction industry are aging and at risk of cardiovascular disease, and no strategies for sustained lifestyle change in this population are known.
- From a motivational interviewing-based lifestyle counseling intervention at the occupational health service, long-term improvements in diet can be achieved.
- Implementation of this intervention in the occupational health care setting is recommended.

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CHAPTER 7

Sustained body weight reduction by an individual-based lifestyle intervention for workers in the construction industry at risk for cardiovascular disease: Results of a randomized controlled trial

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Abstract

Objective To evaluate the effectiveness of a lifestyle intervention for male workers in the construction industry at risk of cardiovascular disease (CVD).

Methods In a randomized controlled trial performed in the Netherlands between 2007 and 2009, usual care was compared to 6 months of individual counseling using motivational interviewing techniques, delivered face to face and by telephone. Participants aimed at improving energy balance-related behavior or smoking cessation. Linear regression analyses were performed to determine the effects.

Results Body weight had significantly decreased at 6 (β=-1.9, 95% CI -2.6; -1.2) and 12 months (β=-1.8, 95%CI -2.8; -1.1). The intervention effects were also significant for diastolic blood pressure at 6 months (β=-1.7, 95% CI -3.3; -0.1). Among participants who had aimed at energy balance, the intervention had a significant favorable effect on body weight at 6 (β=-2.1, 95% CI -2.9; -1.3) and 12 months (β=-2.2, 95% CI -3.1; -1.3) and at HDL cholesterol (β=0.05, 95%CI 0.01; 0.10) and HbA1c (β=-0.06, 95%CI -0.12; -0.001) at 12 months, although there was no intervention effect on these variables over time.

Conclusion Individual-based counseling resulted in significant beneficial long-term effects on body weight. This is an important finding for occupational health, considering the rising prevalence of obesity and CVD.

Introduction

Cardiovascular disease (CVD) is the number one cause of death globally (1). The main precursors of CVD are smoking, obesity, hypertension, and a disturbed serum lipid profile (2,3). The latter three precursors are to a large extent influenced by an unhealthy diet (4-6) and insufficient physical activity (7-9). Smoking is an independent CVD risk factor, and also leads to hypertension and a disturbed serum lipid profile (10,11). Improving lifestyle is not only beneficial for health, but may also prevent absenteeism and high costs for the employer (12-14). Thus, a lifestyle intervention for workers at risk for CVD is considered potentially advantageous for workers as well as employers. Based on a systematic review of the literature, Groeneveld et al. (2010b) concluded strong evidence for an effect on body weight among workers with an elevated risk of CVD (15).

Three aspects need further investigation. First, data on the effectiveness of lifestyle interventions among workers in the construction industry, including both blue- and white-collar workers, are scarce. Most trials on diet and physical activity were aimed at white-collar workers only. Another gap to be filled in workplace lifestyle intervention research is related to the sustenance of changes in CVD risk factors. Not until an improved lifestyle is sustained over a longer term, the risk of CVD is permanently reduced. However, in most workplace lifestyle intervention studies, the final follow-up measurement took place directly after the intervention had ended (16-18). The last issue to be dealt with is which intervention strategy to use. Individual counseling was shown to be effective in numerous studies (19-21). A counseling style frequently used nowadays is motivational interviewing (MI) (22). Although originally developed for use in substance abuse therapy, in recent years it has been proven effective in several lifestyle intervention studies (23,24), although many studies on this topic were of poor quality (25). In the workplace intervention studies in which this counseling strategy was used (26,27) body weight was evaluated, but blood pressure and cholesterol were not.

In the Health under Construction study, we developed an individual-based lifestyle intervention for workers in the construction industry in the Netherlands with an elevated risk of CVD. In Dutch construction industry, most workers are male and over 40 years of age. In 2008, the prevalence of overweight and obesity among male workers in the construction industry who attended the periodical health screening at the occupational health service was higher than among the total Dutch adult male population; 63.8% versus 52.3% (28). Based on the Framingham risk score (29), more than a quarter of male workers in the construction industry had a higher than moderate 10-year risk of coronary heart disease. In the Health under Construction study, we investigated the effectiveness of the intervention on short- and long-term changes in lifestyle. Significant favorable effects were found for snack intake at 6 and 12 months, and for fruit intake at 6 months. Physical activity had substantially increased in both intervention and control group at 6 months (+172 vs. + 94 minutes per week) and at 12 months (+129 vs. + 84 minutes per week), although the intervention effect was not significant. Quit rates in the intervention vs.

control group were 31.1% vs. 13.4% at 6 months (OR for smoking 0.3, 95%CI 0.1; 0.7), and 23.7% vs. 19.5% at 12 months (OR 0.8, 95%CI 0.4; 1.6) (unpublished data). In the present article, we describe the short- and long-term effects of the Health under Construction study on body weight, blood pressure, cholesterol, and hemoglobin A1c (HbA1c).

Methods

Study population

Male workers in the construction industry aged 18-65 with an elevated risk of CVD were invited to the study, based on the results of their most recent periodical health screening. A worker was considered eligible for the study in case of a higher than moderate 10-year risk of coronary heart disease based on the Framingham risk score (29), and having one or more additional risk factors, i.e. body mass index (BMI) ≥ 30; HbA1c ≥ 6.5%; not meeting the physical activity guidelines; heart complaints; psychological complaints; alcohol intake ≥ 35 glasses per week. Of all male workers in the construction industry who underwent a periodical health screening between January 2007 and February 2008, 19.1% had an elevated CVD risk and was invited to participate. The Medical Ethics Committee of the VU University Medical Center approved the study protocol. The study design has been described extensively elsewhere (30).

Randomization, blinding and sample size

The workers who consented to participate were pre-stratified for work type (blue-collar workers performing the construction work versus white-collar workers involved in administration and supervision), and individually randomized into intervention or control group using Random Allocation Software (Version 1.0. Iran). This software randomly generated a list of numbers (0: control and 1: intervention). After randomization, the research assistant notified each participant to which group he had been allocated, and did not reveal the group allocation to the investigator responsible for data analysis. By asking the participants not to mention their group status during the follow-up measurements, we intended to blind the doctors' assistants who performed the measurements. Obviously, blinding of participants and intervention providers was impossible. Since physical activity was an important outcome measure of the study, the sample size was based on detecting a difference in the proportion of participants meeting none of both Dutch guidelines for moderate and vigorous intensity physical activity. To show a 10% difference between the intervention and the control group after 6 months, with a power of 80% and a 95% confidence interval (α=0.05), 692 persons were needed at the first follow-up measurement. To allow for 20% attrition, 866 persons were required at baseline.

Intervention and control condition

Participants in the control group received usual care, consisting of brief oral or written information from the occupational physician about their CVD risk profile. Over a period of 6 months, each participant in the intervention group had three 45-60 minute face to face and four 15-30 minute telephone contacts with an occupational physician or occupational

nurse. This counselor applied a client-centered counseling style using MI techniques such as asking open questions, summarizing, listening, supporting, and raising ambivalence (31). In the first session, after having discussed the CVD risk profile and current health status, the participant chose to discuss diet and/or physical activity, or smoking cessation. Then, pros and cons of behavior change, and willingness, readiness, and perceived confidence in the ability to change were discussed. Last, the participant set long- and short-term goals, and formulated implementation intentions. For example, a participant who chose to discuss energy balance-related behavior defined 'losing 5 kg of body weight' as a long-term goal and 'decreasing snack consumption' as a short-term goal. In subsequent sessions, progress and barriers were discussed and short-term goals could be adjusted. No specific weight loss advice was given.

Outcome measures

The outcome measures under study were body weight (kg), BMI (kg/m²), systolic and diastolic blood pressure (mmHg), HDL cholesterol (mmol/l), total cholesterol/HDL cholesterol ratio, and HbA1c (%). The periodical health screening served as the baseline measurement. The first and second follow-up measurements took place 6 and 12 months after inclusion. Body weight, without shoes and jacket, was measured on a digital balance. Body height, without shoes, was determined with the participant in standing position, his heels and head against the wall and his face in a horizontal plane. Blood pressure was measured once with the participant in seated position, by manual inflation using a Maxi Stabil 3 measuring instrument (Speidel & Keller, Jungingen, Germany). Two samples of non-fasting venous blood were collected; one of those was used for the determination of cholesterol, and the other sample was used for determining HbA1c. Cholesterol was analyzed by means of enzymatic colorimetric testing, using a Hitachi/ Modular analyzer. For the analysis of HbA1c, a Cobas Integra 800 analyzer was used (Roche Diagnostics GmbH, Mannheim, Germany). The variables that were checked for confounding or effect modification, i.e. age (years), smoking status (current smoker/ non-smoker), work type (blue-collar/white-collar), and having a first-degree family member who had a myocardial infarction or stroke before age 60 (family history: yes/no), were assessed by means of a questionnaire.

Statistical analyses

In the baseline questionnaire, all participants had indicated whether they would prefer to quit smoking or to improve their dietary or physical activity behavior. Based on these answers, a smoking cessation (SC) and an energy balance (EB) subgroup were defined. The latter included physical activity and diet, since both behaviors are necessary to achieve and maintain a healthy body weight (32,33). All outcome variables were checked for differences between control and intervention group at baseline, and their residuals were checked for normality. To determine the effects at 6 months, linear regression analyses were done with the variable of interest as the outcome, and its baseline value and group allocation as the independent variables. The effects at 12 months were evaluated using

the same procedure. For those analyses, only participants for whom data were present at all three time points were included. We checked for confounding by age, BMI, and smoking, and for effect modification by age, BMI, smoking, work type, and family history. Effect modification was concluded in case the p-value of the interaction term was <0.1. Besides, longitudinal analyses were done on all available data using the 'analysis of covariance combination approach', as described by Twisk et al. (34). Analyses were done for the study population as a whole as well as for the EB and SC subgroups separately. The subgroup in which a participant was analyzed was based on the preference he had indicated in the questionnaire. However, within the intervention group, of all participants who had 5 or more sessions, 15% switched between EB and SC or vice versa during the intervention. Therefore, additionally, 'per protocol' analyses were done, including only participants who had 5 or more counseling sessions on a single topic (SC or EB).

Results

In **Figure 1**, a flow diagram of the study population is presented. Between March 2007 and March 2008, 816 workers provided informed consent. Between September 2007 and March 2009, all follow-up measurements took place. 517 participants provided data on one or more variables at all three time points, and were used for analyses. No adverse events of the intervention were reported. In **Table 1**, the baseline characteristics of the study population are presented. The residuals of all variables were normally distributed. No significant differences were found between the control and intervention groups in any of the variables. Since BMI was a confounder in the intervention effects on some of the variables in the EB subgroup, all analyses in the total population as well as in the EB subgroup were adjusted for baseline BMI. In the SC group, no confounding was concluded, thus no adjustments were made.

Figure 1. Flow diagram of the progress through the phases of the Health under Construction study performed in the Netherlands (2007-2009).

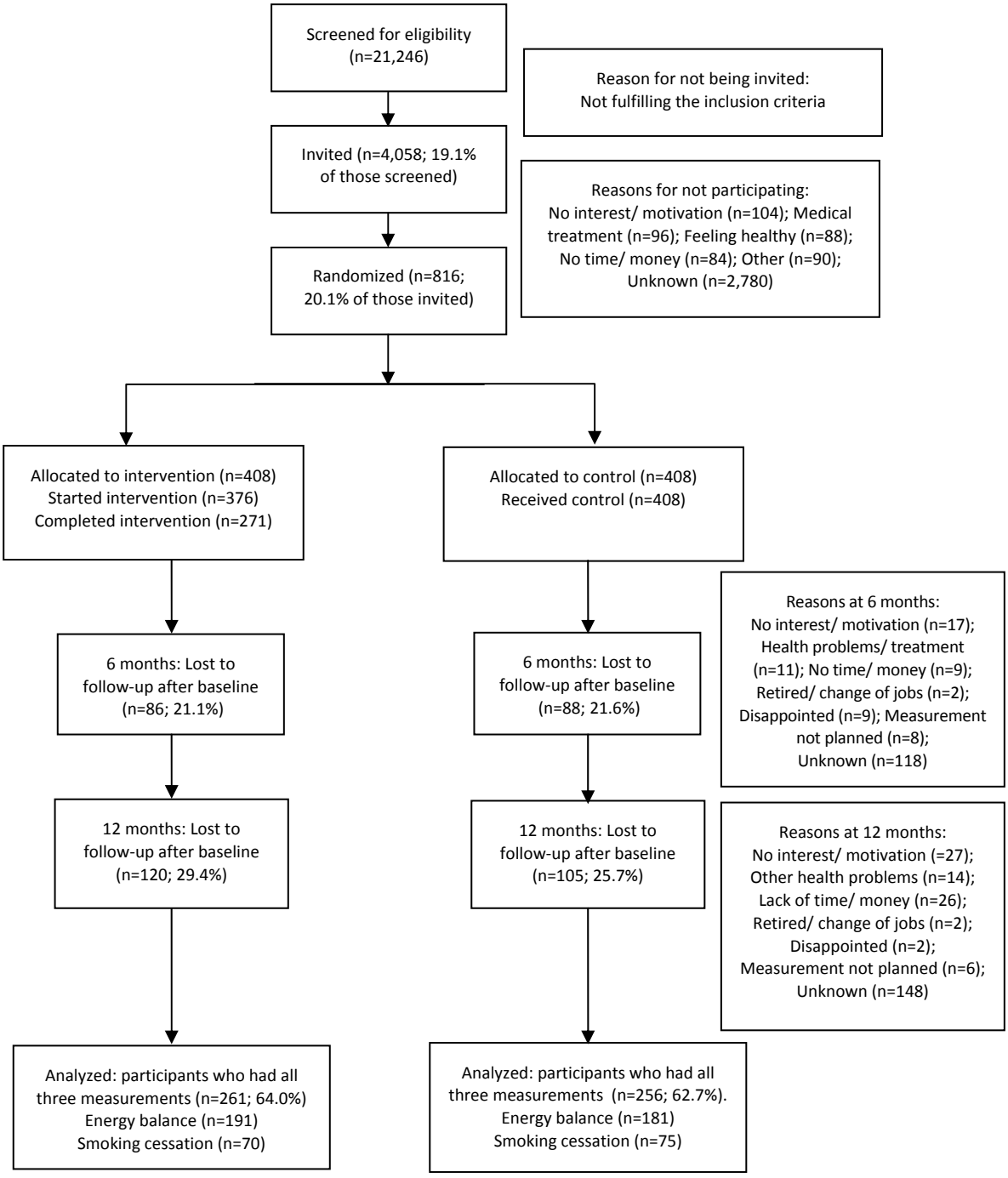

Table 1. Baseline characteristics of the total study population and of the EB and SC subgroups in the Health under Construction study, performed in the Netherlands (2007-2009).

Variable	Total		EB subgroup		SC subgroup	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Age (years)						
Intervention	261	46.9 (9.1)	191	46.5 (9.0)	70	48.1 (9.2)
Control	256	46.2 (8.8)	181	46.6 (9.0)	75	45.3 (8.5)
Body weight (kilograms)						
Intervention	261	93.1 (13.2)	191	94.5 (12.7)	70	89.3 (14.0)
Control	256	92.0 (12.8)	181	93.8 (12.7)	75	87.9 (12.1)
BMI (kg/m^2)						
Intervention	261	28.8 (3.5)	191	29.2 (3.5)	70	27.7 (3.3)
Control	256	28.2 (3.6)	181	28.6 (3.7)	75	27.4 (3.4)
	n	%	n	%	n	%
Smoking						
Intervention	259	53.3	189	36.0	70	100
Control	252	51.4	177	30.5	75	100
Family history of cardiovascular disease						
Intervention	260	31.2	191	32.5	69	27.5
Control	255	26.8	181	26.0	74	29.7
Blood pressure lowering medication						
Intervention	261	15.3	191	15.2	70	15.7
Control	255	13.6	180	15.6	75	9.3
Cholesterol lowering medication						
Intervention	260	9.2	190	6.8	70	15.7
Control	256	8.9	181	8.8	75	9.3
Blue-collar workers (proportion of total workers)						
Intervention	261	74.3	191	69.6	70	87.1
Control	256	73.7	181	70.2	75	82.7

EB: energy balance; SC: smoking cessation; SD: standard deviation; BMI: body mass index.

In **Table 2**, the results of the regression analyses in the study population as a whole are shown. At 6 and 12 months, body weight had significantly decreased as a result of the intervention. At 12 months, the intervention group had lost on average 0.9 kg, whereas the control group had gained 0.9 kg. The intervention effect on diastolic blood pressure was statistically significant at 6 months. At 6 and 12 months, the effect of the intervention on body weight was modified by baseline BMI. The largest intervention effect on body weight was found for the obese (BMI≥ 30, n=167; β=-2.9, 95%CI -4.3; -1.6 and β=-2.5;

95%CI -4.0; -1.0), at 6 and 12 months, respectively. Among the obese participants, the effect on HDL cholesterol was also statistically significant (β=0.06, 95%CI 0.00; 0.11). As to HDL cholesterol, only among the participants having no family history of CVD, HDL cholesterol had significantly increased at 6 months (n=366; β= 0.05, 95%CI 0.01; 0.10).

Table 2. Intervention effects at 6 and 12 months on precursors of cardiovascular disease, determined by linear regression analysis adjusted for baseline BMI, in the total study population of the Health under Construction study, performed in the Netherlands (2007-2009).

Variable	n	Baseline mean (SD)	6 months mean (SD)	β (95%CI) 6 months	12 months mean (SD)	β (95% CI) 12 months
Body weight (kg)						
Intervention	261	93.1 (13.2)	91.7 (13.1)	-1.9	92.2 (13.7)	-1.8
Control	256	92.0 (12.8)	92.6 (13.4)	(-2.6; -1.2)*	92.9 (13.6)	(-2.6; -1.1)*
BMI (kg/m^2)						
Intervention	261	28.8 (3.5)	28.3 (3.5)	-0.6	28.5 (3.7)	-0.6
Control	256	28.2 (3.6)	28.4 (3.8)	(-0.8; -0.3)*	28.5 (3.9)	(-0.8; -0.3)*
SBP (mmHg)						
Intervention	259	143.0 (15.8)	137.8 (16.0)	-2.2	138.1 (16.6)	-0.3
Control	257	141.0 (14.8)	138.9 (15.8)	(-4.6; 0.3)	137.2 (16.2)	(-2.8; 2.2)
DBP (mmHg)						
Intervention	259	89.1 (9.7)	85.2 (10.7)	-1.7	85.4 (10.2)	-0.4
Control	257	88.5 (9.4)	86.5 (9.4)	(-3.3; -0.1)*	85.3 (9.8)	(-1.9; 1.1)
HDL cholesterol (mmol/l)						
Intervention	256	1.13 (0.20)	1.21 (0.24)	0.03	1.20 (0.25)	0.03
Control	257	1.12 (0.21)	1.19 (0.25)	(-0.01; 0.06)	1.17 (0.26)	(-0.01; 0.07)
Cholesterol ratio						
Intervention	256	5.72 (1.14)	5.36 (1.21)	-0.11	5.53 (1.42)	-0.07
Control	257	5.71 (1.15)	5.45 (1.19)	(-0.29; 0.08)	5.58 (1.28)	(-0.28; 0.14)
HbA1c (%)						
Intervention	250	5.66 (0.41)	5.70 (0.39)	-0.004	5.74 (0.29)	-0.04
Control	255	5.66 (0.41)	5.70 (0.32)	(-0.06; 0.05)	5.78 (0.38)	(-0.09; 0.004)

*p<0.05. BMI: body mass index; SD: standard deviation; SBP: systolic blood pressure; DBP: diastolic blood pressure; HDL: high density lipoprotein; HbA1c: hemoglobin A1c.

The intervention effects in the EB subgroup are presented in **Table 3**. At 6 and 12 months, body weight had significantly decreased as a result of the intervention. At 12 months, the intervention group had lost on average 1.4 kg of body weight whereas the control group had gained 0.8 kg. Also, significant intervention effects were found at 12 months for HDL

cholesterol (+0.09 mmol/l in the intervention group as opposed to +0.04 mmol/l in the control group), and HbA1c (+0.07% vs. +0.13%). At 6 months, BMI modified the intervention effects on body weight, systolic blood pressure, and HDL cholesterol. For all three variables, the largest intervention effects were found among the obese; at 6 and 12 months the intervention group had lost 2.2 kg and 1.7 kg on average, respectively, and HDL cholesterol had risen by 0.10 and 0.09 mmol/l. The intervention effects on systolic blood pressure and HDL cholesterol were larger among the participants aged 45 and older than among the younger ones, although in none of the age groups the effects were statistically significant.

Table 3. Intervention effects at 6 and 12 months on precursors of cardiovascular disease, determined by linear regression analysis adjusted for baseline BMI, in the energy balance subgroup of the Health under Construction study, performed in the Netherlands (2007-2009).

Variable	Intervention (n)	Control (n)	β (95% CI) 6 months	β (95%CI) 12 months
Body weight (kg)	191	181	-2.1 (-2.9; -1.3)*	-2.2 (-3.1; -1.3)*
BMI (kg/m^2)	191	181	-0.6 (-0.9; -0.4)*	-0.7 (-0.9; -0.4)*
SBP (mmHg)	189	181	-1.4 (-4.3; 1.4)	0.1 (-2.9; 3.1)
DBP (mmHg)	189	181	-1.3 (-3.2; 0.5)	-0.2 (-2.1; 1.6)
HDL cholesterol (mmol/l)	188	181	0.02 (-0.02; 0.07)	0.05 (0.01; 0.10)*
Cholesterol ratio	188	181	-0.11 (-0.33; 0.10)	-0.22 (-0.46; 0.02)
HbA1c (%)	180	181	-0.02 (-0.07; 0.03)	-0.06 (-0.12; -0.001)*

*p<0.05. BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure; HDL: high density lipoprotein; HbA1c: hemoglobin A1c.

The intervention effects in the SC subgroup are presented in **Table 4**. Neither at 6 months nor at 12 months, significant intervention effects were found on any of the CVD precursors. Body weight increased by 0.7 kg in the control group and decreased by 0.7 kg in the intervention group.

As to the longitudinal analyses, the effects on body weight and BMI appeared significant over time, in the total study population (β = -1.8, 95%CI -2.8; -0.8 and β = -0.5, 95%CI -0.8; -0.2) as well as in the EB subgroup (β = -1.9, 95%CI -3.0; -0.7 and β = -0.6, 95%CI -0.9; -0.2). For HDL cholesterol (β = 0.01, 95%CI -0.05; 0.07) and HbA1c (β = 0.05, 95%CI -0.04; 0.14) in the EB subgroup, no significant intervention effects over time were found. According to the per protocol analyses, the intervention showed a statistically significant effect in the EB subgroup on body weight at both 6 (n=291; β= -2.5, 95%CI -3.4; -1.5) and 12 months (β = -2.5, 95%CI -3.5; -1.5), and on systolic blood pressure at 6 months (n=289; β= -3.2, 95%CI -6.3; -0.02). As a result of the intervention, HDL cholesterol had significantly increased and cholesterol ratio had significantly decreased at 12 months (n=288; β= 0.09, 95%CI 0.04; 0.14 and β= -0.30, 95%CI -0.56; -0.03 respectively).

Table 4. Intervention effects at 6 and 12 months on precursors of cardiovascular disease, determined by linear regression analysis adjusted for baseline BMI, in the smoking cessation subgroup of the Health under Construction study, performed in the Netherlands (2007-2009).

Variable	Intervention (n)	Control (n)	β (95% CI) 6 months	β (95%CI) 12 months
Body weight (kg)	70	75	-1.3 (-2.8; 0.1)	-0.9 (-2.4; 0.6)
BMI (kg/m^2)	70	75	-0.4 (-0.8; 0.1)	-0.3 (-0.8; 0.2)
SBP (mmHg)	70	75	-4.1 (-9.0; 0.9)	-0.9 (-6.1; 4.3)
DBP (mmHg)	70	75	-2.6 (-5.8; 0.5)	-0.8 (-3.6; 2.0)
HDL cholesterol (mmol/l)	68	75	0.04 (-0.03; 0.10)	-0.02 (-0.08; 0.05)
Cholesterol ratio	68	75	-0.06 (-0.40; 0.29)	0.34 (-0.08; 0.76)
HbA1c (%)	68	73	0.04 (-0.10; 0.17)	0.00 (-0.07; 0.08)

BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure; HDL: high density lipoprotein; HbA1c: hemoglobin A1c.

Discussion

Principal findings

We aimed to find out the short- and long-term effects of a 6-month lifestyle intervention among workers in the construction industry with an elevated risk of CVD. Among participants who had aimed at smoking cessation, no significant changes in CVD precursors were found. Among the participants who had focused at improving diet and physical activity, a 2 kg difference in body weight was concluded at 6 and 12 months. Significant intervention effects were also found for HDL cholesterol and HbA1c at 12 months when adjusting for the baseline value only, but when applying a longitudinal analysis technique, no significant effects over time were found.

Body weight loss

The effects on body weight in the present study are slightly larger than in several other worksite-based weight loss interventions, as shown in two meta-analyses. Anderson et al. (2009) concluded a net weight loss of 1.3 kg (35), and Verweij et al. (2010) found a net weight loss of 1.2 kg (36). However, in most studies included in these reviews, the time span between the end of the intervention and the last follow-up measurement was not mentioned. Leslie et al. (2002) specifically looked at maintenance of reduced body weight, and in contrast to our study, reported significant weight regain in the intervention groups (37). Among people involved in an intervention in which a prescribed diet or supervised exercise are offered, body weight regain is a common phenomenon. When inducing changes in habitual dietary and physical activity patterns, using a tailored method, long-term goals are easier to achieve and maintain. In our study we showed that, even without 'booster sessions', sustained body weight change can be achieved. In the SC group, as a result of the intervention, an increase in body weight was expected. Nevertheless, body weight in this subgroup remained stable, for which two reasons can be mentioned. First,

one third of participants in the SC intervention group started discussing physical activity or diet with the counselor at some point during the intervention (unpublished data). Second, despite a significantly higher smoking cessation rate in the intervention group than in the control group at six months, the majority (68.9%) had not quit smoking, and therefore no reason to gain body weight.

Clinical relevance

Not only statistical significance, also clinical relevance plays a role in the interpretation of the results of our study. Stevens et al. (2006) provided an extensive overview of opinions about defining body weight maintenance and clinical relevance (38). They stated that a change of 5% or greater from original body weight is considered potentially clinically relevant, and that weight maintenance should be defined as a weight change of <3%. According to this definition, in our study, 20.4% (n=39) of the EB intervention group achieved a clinically relevant body weight change at 6 months, and 18.8% (n=36) maintained this clinically relevant reduced body weight. In the control group, these percentages were 5.5% (n=10) and 2.8% (n=5). Still, Stevens et al. also emphasized that these cut-offs are somewhat arbitrary and that associations of weight change with health outcomes are generally continuous in nature. In the Diabetes Prevention Program, every kilogram of body weight lost was associated with a 16% reduction of diabetes risk (39). With respect to the clinical relevance of HDL cholesterol, each 0.03 mmol/l increase in HDL cholesterol was proven to reduce the risk of coronary heart disease by 2-3% (40). In our study, HDL cholesterol in the EB-group had increased by 0.05 mmol/l on the long term. Naturally, for participants who improved more than one outcome measure, the reduction in CVD risk will be larger.

Study limitations and strengths

Some limitations of the study should be mentioned. We did not measure central body fat, which is more strongly related to CVD than body weight (41). In our opinion, valid data on central body fat could only be obtained from waist circumference measurements performed by a trained observer, or by dual energy X-ray absorptiometry. A threat to external validity may be the fact that the participants were on average 3.8 years older than those who did not participate, and therefore had a significantly higher BMI, higher diastolic blood pressure, and lower HDL cholesterol at baseline. Moreover, the dropouts were on average 1.3 years younger than the participants used for data analyses (p=0.06). Nevertheless, more importantly, the difference in effects between the intervention and control group was not biased by differential dropout. Finally, counselors used MI techniques in the intervention, but they were not fully proficient in MI, as concluded from our evaluation of the practical execution of the intervention (31). If they would have been, the intervention might have been even more effective. Two methodological issues should be mentioned. First, the sample size calculation was based on detecting an effect on physical activity, and not on one of the outcome measures presented in this article. When aiming at a statistically significant difference between groups in body weight of 1.5 kg (35)

with a standard deviation of 5 (based on own data), a power of 80% and a 95% confidence interval, 467 participants would have been needed at 12 months, in the EB subgroup. However, these calculations, as all sample size calculations, heavily rely on assumptions. Another issue may be that we did not adjust for multiple testing. This approach is not uniformly acknowledged (42). Nevertheless, when applying a Bonferroni correction to our data, the effects on body weight at 6 and 12 months would still be statistically significant.

This study also has several strengths. The sample size was relatively large as compared to other individual-based intervention studies. Randomization was performed at the individual level, which is the preferred method as baseline differences between intervention and control group are least likely. Chances of cross-contamination between groups were minimal, as the participants were employed at different companies throughout the country. Moreover, the contrast between groups was large, since the compliance of participants in the intervention group was high. Last, the study can be considered as an effectiveness study as opposed to an efficacy study. Namely, counseling was conducted at the occupational health service, by an occupational physician or nurse. As the results of this study reflect the intervention effectiveness in 'real life', decision makers will better be able to decide upon implementation. Last, we investigated the effects on the most important CVD precursors not until 6 months after the intervention had ended.

Future research

The intervention is effective and feasible when performed by occupational physicians and nurses. It may be worthwhile to investigate this intervention in the primary care setting as well. Its efficacy could also be tested among workers in other occupational groups. Also, it would be interesting to find out the mechanisms that led to the changes in the CVD precursors presented in this article, by studying the actual contributions of diet, physical activity, and smoking.

Conclusion

This is the first study showing that an individual-based intervention using motivational interviewing techniques for workers in the construction industry can result in sustained beneficial changes in body weight. This is an important finding for occupational health, considering the rising prevalence of obesity and CVD in the aging male working population.

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CHAPTER 8

Cost-effectiveness and cost-benefit of a lifestyle intervention for workers in the construction industry at risk for cardiovascular disease.

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Abstract

Introduction An unhealthy lifestyle and obesity are associated with cardiovascular disease risk, but also with increased costs for society and employers. The aim of this study was to investigate the cost-effectiveness and cost-benefit of an individual-based lifestyle intervention for male workers in the construction industry with an elevated risk of CVD.

Methods In this randomized controlled trial among 573 workers, usual care was compared to a 6-month individual-based lifestyle intervention consisting of face to face and telephone counseling sessions. The time horizon of the study was 12 months. Body weight was measured at baseline, 6, and 12 months. At 6 and 12 months, data were collected on health care use and lifestyle-related out-of-pocket expenses. Self reported absenteeism was measured with 2-month intervals. Missing data were imputed using multiple imputations. The intervention effect on body weight was analyzed by linear regression analysis, and the 95% confidence intervals around the cost-differences were estimated with approximate bootstrap confidence (ABC) intervals. A cost-effectiveness analysis was performed from a societal perspective, in which all costs were divided by the intervention effect on body weight, in order to obtain an incremental cost-effectiveness ratio (ICER). Uncertainty around the ICER was estimated by bootstrapped cost-effect pairs, with 5,000 replications. As to the cost-benefit analysis from the employer's perspective, the incremental (intervention) costs were subtracted from the incremental (absenteeism) benefits.

Results A significant intervention effect on body weight was found, i.e. β -2.0 (95%CI -2.9; -1.1). The intervention costs were €605 per participant. In the intervention and control group, health care use costs were €212 vs. €279, out-of-pocket expenses were €390 vs. €333, and absenteeism costs were €3,302 vs. €3,604. The ICER was €145/kg weight loss. In case of a willingness to pay of €2,000, the probability of cost-effectiveness would be 0.95. The difference between intervention and control group in net employer costs was €254 (95%CI -1,070; 1,536).

Conclusion From a societal perspective, this individual-based lifestyle intervention was more effective and more expensive than usual care. The probability of cost-effectiveness depends on the societal willingness to pay. As the intervention costs were higher than the benefits of absenteeism, the intervention could not be regarded as cost-saving from an employer's perspective. Since the results were based on an imputed dataset, conclusions should be interpreted with caution.

Introduction

Worldwide, cardiovascular disease (CVD) is the number one cause of death (1). Important precursors of CVD are overweight and obesity, hypertension, and atherosclerosis. These abnormalities are caused to a large extent by an unhealthy lifestyle, i.e. an unhealthy diet (2) and insufficient physical activity (PA) (3). An unhealthy lifestyle and obesity not only affect health and health care expenditures (4-7), but may also have negative consequences for the employer. Insufficient PA is associated with poor work ability (8) and sickness absenteeism (9). Likewise, there is ample evidence that obesity is associated with decreased productivity, due to either presenteeism (10), absenteeism (11), or work disability (12, 13). Moreover, among obese workers, the incidence of workplace injuries is higher than among normal weight workers (14, 15). Thus, physical inactivity, obesity, and CVD are associated with elevated costs for health care, productivity loss, and work disability. Therefore, the necessity of developing and evaluating lifestyle interventions for workers is beyond doubt. Mixed effects of workplace lifestyle interventions have been achieved on lifestyle behaviors and body weight (16-20). It is difficult for employers or decision makers to decide upon implementation of a lifestyle intervention without insight into its costs and monetary benefits. Therefore, an economic evaluation is an important element of each lifestyle intervention trial.

An economic evaluation can comprise various types of analyses, such as a cost-effectiveness analysis, in which the incremental costs associated with an incremental change in a health outcome are determined, or a cost-benefit analysis, in which the incremental costs are subtracted from incremental monetary benefits (21). These analyses can be done from different perspectives, depending on the stakeholder responsible for the costs. In general, workplace lifestyle interventions are equally or more effective in improving health outcomes than usual care, but the costs borne by employers are usually higher (16, 22). Several workplace lifestyle interventions were shown to result in a net monetary gain for the employer, since they provided a positive return on investment through a reduction of productivity, and, for US employers, of health care costs (23). Thorough economic evaluations alongside high quality randomized controlled trials (RCTs) of workplace lifestyle interventions aimed at CVD risk reduction are scarce.

In the Health under Construction study, the effectiveness of an individual-based lifestyle intervention for workers in the construction industry with an elevated risk of CVD was investigated. A significant and sustained decrease in body weight was found (unpublished data). The current economic evaluation consisted of a cost-effectiveness analysis from the societal perspective, in which body weight was the outcome of interest. Also a cost-benefit analysis from the employer's perspective was performed. The time horizon of the economic evaluation was 12 months.

Methods

Study design and participants

Male workers in the construction industry aged 18-65 with an elevated risk of CVD, as based on a screening instrument adapted from the Framingham risk score (24), using the results of their periodical health screening (PHS), were invited to participate in the Health under Construction study. The workers who consented to participate were pre-stratified for work type (blue-collar workers performing the construction work versus white-collar workers involved in administration and supervision), and individually randomized into the control group or the intervention group by using Random Allocation Software (Version 1.0. Iran). The persons involved in data collection and data analysis were blinded to group allocation, whereas the participants and intervention providers were not. The design of the study and the characteristics of the study participants were published previously (25, 26). The Medical Ethics Committee of the VU University Medical Center approved the study protocol. In the baseline questionnaire, all participants had to indicate whether they preferred to improve PA or diet, or to quit smoking. Since the outcome of interest in the cost-effectiveness study was body weight, only workers who chose to aim at PA or diet were included in the analyses, i.e. two thirds of all participants. The participants in the control group received usual care, consisting of brief information from the occupational physician about their CVD risk profile. Participants in the intervention group received a 6-month intervention aimed at improving lifestyle.

Intervention

The intervention consisted of three 45-60 minute face to face counseling sessions at the nearest occupational health service (OHS), and four 15-30 minute telephone counseling sessions with an occupational physician or occupational nurse. All counselors received a 2- or 3-day training in motivational interviewing (MI). In the first counseling session, certain predefined items were discussed, including the participant's risk profile, the advantages and disadvantages of behavior change, his willingness, readiness, and perceived confidence in his ability to change, and personal short- and long-term goals. In subsequent sessions, progress and barriers were discussed and goals could be adjusted. All participants, in the intervention and the control group, received brochures on healthy lifestyle and CVD. Information on the process of the intervention, such as counselors' compliance, has been described elsewhere (27).

Health outcome

Body weight was measured at baseline, 6, and 12 months, by doctors' assistants at the OHS. Body weight was measured using a digital balance, with participants wearing no shoes and no jacket.

Resource use

In order to provide insight into all resources used, the number of counseling sessions for each participant was administrated by the counselors between baseline and 6 months. At

6 and 12 months, the number of visits to providers of primary care, specialist care, paramedical care and alternative care, the use of blood pressure or cholesterol lowering medication, and the purchases of all products associated with improving diet and physical activity, e.g. sports equipment, were reported by the participants by means of a questionnaire. Moreover, every two months, at 2, 4, 6, 8, 10, and 12 months, the participants filled in the number of days absent from work in the previous two months, a question that was adapted from the questionnaire of Koopmanschap et al. (28). The time frame of two months was chosen to minimize the risk of recall bias while limiting participant burden (29). At 6 months, the participants reported the number of hours taken off for visits to counseling sessions at the OHS.

Costs

Three cost categories were measured: direct health care costs, direct non-health care costs, and indirect non-health care costs. The direct health care costs included costs for the intervention and costs for other health care consumed. Intervention costs consisted of the costs for the trainer, for printing manuals, and for the face to face and telephone counseling sessions, according to prices paid. Also, a €15 reimbursement for the participants for each visit to a counseling session was included, as well as costs for the person who coordinated the counseling sessions, using the number of hours involved, valued as the gross salary including additional employers' costs such as premiums and holiday payments. Costs for visits to care providers were valued using Dutch standard costs (30). For the valuation of visits to care providers for whom standard cost prices were not available, prices according to professional organizations were used. Medication use was valued according to unit prices provided by the Royal Dutch Society for Pharmacy (31). All prices were adjusted to the year 2008, using consumer price indices (32). The direct non-health care costs, i.e. out-of-pocket costs for purchases associated with improving diet and PA, were self-reported by the participants. Indirect non-health care costs were costs associated with absenteeism. Data on the average gross year salaries for blue- and white-collar workers, including employer's costs, were provided by the Dutch Economic Institute for the construction industry. The costs associated with one working day of absenteeism were calculated by dividing the average gross year salary including additional employers' costs by the total amount of working days per year, i.e. 260. In the societal perspective, according to the equity principle, costs per working day were considered independent of work type and amounted to €229 per day. When calculating the average gross salary the proportions of white- and blue-collar workers in the study population, i.e. 0.32 vs. 0.68, were taken into account. However, for the cost-benefit analysis, which is conducted from an employer's perspective, the valuation of an absenteeism day was done according to work type, i.e. the costs for a working day of a white-collar worker were €264, and those for a working day of a blue-collar worker were €216.

Multiple imputations of missing values
All missing data on body weight, absenteeism, direct health care costs, direct non-health care costs, and indirect non-health care costs, were imputed using multiple imputations. Five different data sets were created in SPSS (version 17.0, Chicago, Ill) using Fully Conditional Specification and Predictive Mean Matching procedures. All available data on body weight at baseline, 6 and 12 months, group allocation, age, smoking status, absenteeism, and costs, were included in the imputation model. Thereafter the multiple datasets were analyzed as described below, using R (version 2.10.1) (33). Pooled estimates were computed following the rules as described by Rubin (34).

Main analyses
The main analyses were based on group allocation, regardless of adherence to the intervention. The intervention effect on body weight at 12 months was analyzed in SPSS (version 17.0, Chicago, Ill), using linear regression analysis, adjusted for baseline body weight. Outcomes with a p-value of <0.05 were considered statistically significant. The mean cost differences between intervention and control group were calculated for direct health care costs, direct non-health care costs, indirect non-health care costs, and total costs. The 95% confidence intervals of the cost differences were estimated with approximate bootstrap confidence (ABC) intervals (35). For the cost-effectiveness analysis, an incremental cost-effectiveness ratio (ICER) was estimated by dividing the difference in total costs between the intervention and control groups by the difference in effect on body weight. To graphically present uncertainty around the ratio, bootstrapped cost/ effect pairs, using 5,000 replications, were plotted in cost-effectiveness planes (36). A cost-effectiveness acceptability curve (CEAC) was estimated in order to provide insight into the probability that the intervention was cost-effective (y-axis) for a range of potential maximum amounts (x-axis) that a decision maker is willing to pay (37). At a probability of 0.95 or higher, the intervention can be regarded as cost-effective. For the cost-benefit analysis, the incremental costs of the intervention itself were subtracted from the incremental benefits associated with absenteeism. Confidence intervals of the cost differences were estimated by ABC intervals.

Sensitivity analyses
In order to test the robustness of the results, and to evaluate the cost-effectiveness and cost-benefit of the intervention considering different scenarios, several sensitivity analyses were performed: 1) A cost-effectiveness analysis, in which all absenteeism costs were multiplied by 0.8. An elasticity of 0.8 is frequently used, implying that a 100% loss of work time corresponds to an 80% reduction in productivity (38); 2) A cost-effectiveness and a cost-benefit analysis using a dataset in which all costs for occupational physicians were replaced by costs for occupational nurses. These analyses were done since we found that an intervention performed by an occupational nurse was equally effective in lowering body weight as an intervention performed by a - more expensive - occupational physician (unpublished data); 3) A cost-effectiveness and cost-benefit analysis including the

complete cases only. The 95% confidence intervals around the mean cost differences were estimated by using a bootstrap method with 5,000 replications.

Results

Of the 816 participants included in the Health under Construction study, 573 participants chose to aim at diet or PA, of whom 293 had been allocated to the intervention group and 280 to the control group. For 285 participants, at any time point, one or more variables were missing, which were mainly cost data. For those cases, the missing data were imputed. A participant flow is presented in **Figure 1.**

In **Table 1**, the baseline characteristics for the intervention and control group are presented as well as the differences between completers and non-completers, as derived from the original, unimputed database. Also, the differences between completers and non-completers in body weight at 12 months are presented. Non-completers were on average 3 years younger and had a 2 kg higher baseline body weight than completers. The difference in 12-month body weight between completers and non-completers was 2.7 kg in the intervention group and 3.7 kg in the control group.

Effectiveness

Linear regression analysis on the imputed datasets showed a statistically significant effect of the intervention on body weight (β -2.0, 95%CI -2.9; -1.2). From baseline to 12-month follow-up, the control group gained on average 1.0 kg, whereas the intervention group lost on average 1.1 kg of body weight.

Resource use

For the participants in the intervention group, the average number of counseling sessions was 5 (SD 2.3). As missing data on health care use were not imputed, the following data were derived from the unimputed dataset. Participants in the intervention group had on average 5.7 (SD 8.8) visits to a care provider, as opposed to 7.1 (SD 11.1) in the control group. This difference was mainly caused by the number of visits to the physiotherapist; 3.7 (SD 9.8) in the control group and 1.8 (SD 5.7) in the intervention group. In the intervention group, 29% used cholesterol or blood pressure lowering medication at some period during the 12 months, while in the intervention group this was 30%. In the intervention group, 69% bought one or more diet- or PA-related products, as compared to 64% in the control group. Of the complete cases, participants in the intervention and control group reported on average 12.3 (SD 29.7) and 9.1 (24.0) days of absenteeism, respectively, and 7.5% vs. 5.8% were absent from work for more than 3 months in total. In contrast, based on the imputed dataset, the average number of days absent from work was 14.4 in the intervention group, as opposed to 15.7 in the control group.

Figure 1. Flow diagram through the phases of the Health under Construction study.

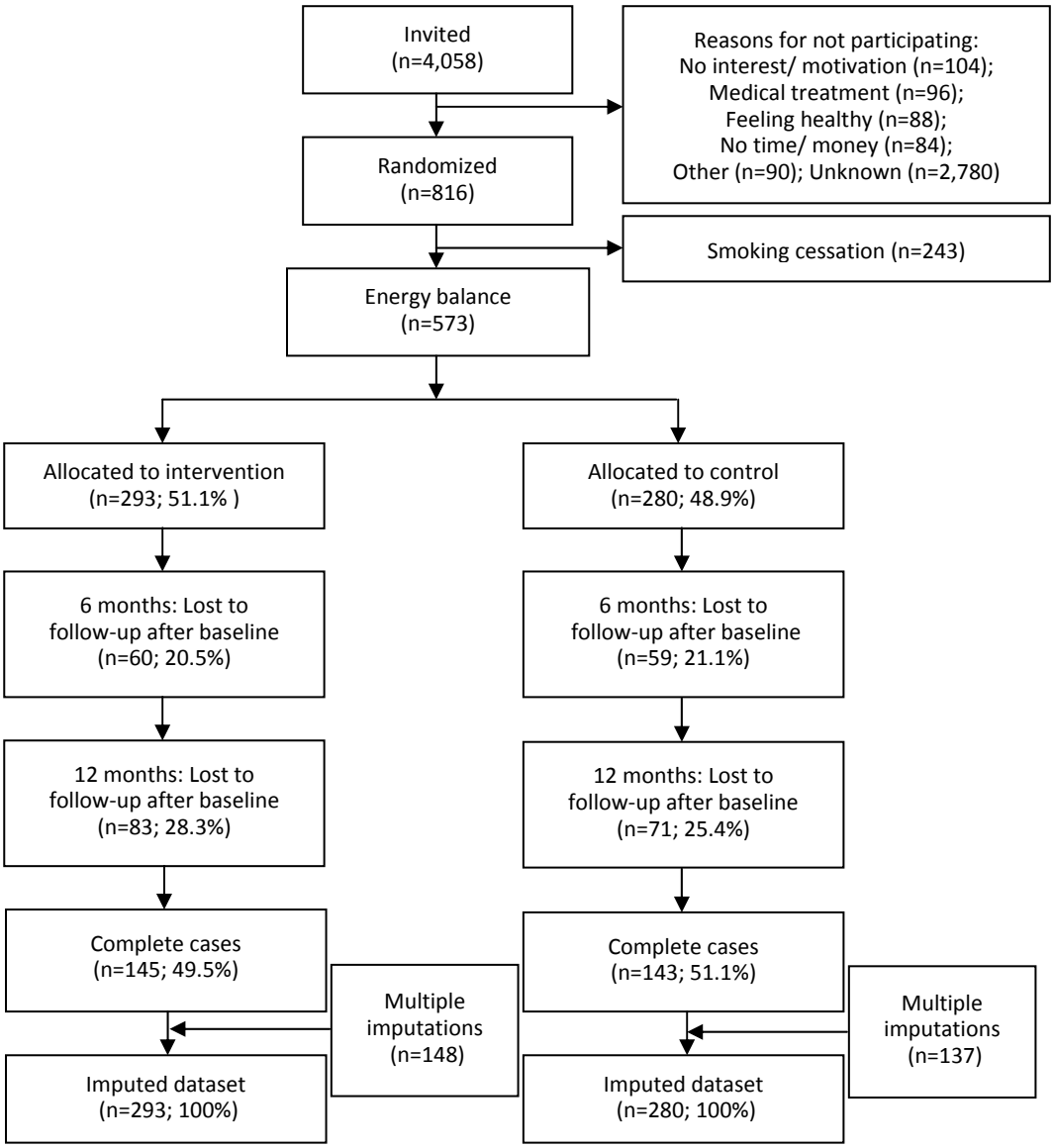


Table 1. Baseline characteristics and body weight at 12 months of participants in the intervention and control group in the economic evaluation of the Health under Construction study, in the original (unimputed) dataset.

Characteristic	Intervention group				Control group			
	All n; mean (SD)	Completers n; mean (SD)	Non-completers n; mean (SD)	Δ Incomplete-complete (95% CI)	All n; mean (SD)	Completers n; mean (SD)	Non-completers n; mean (SD)	Δ Incomplete-complete (95% CI)
Age (years)	293 46.0 (9.2)	145 47.6 (8.7)	148 44.5 (9.5)	-3.1 (-5.2; -1.0)*	280 46.7 (9.3)	143 48.3 (7.7)	137 45.1 (10.4)	-3.2 (-5.4; -1.0)*
Body weight (kg) baseline	293 95.3 (12.6)	145 94.1 (12.0)	148 96.5 (13.1)	2.4 (-0.5; 5.3)	280 93.8 (12.7)	143 93.0 (11.7)	137 94.5 (13.6)	1.5 (-1.5; 4.5)
Body weight (kg) 12 months	NA	145 92.5 (12.3)	65 95.2 (14.4)	2.7 (-1.1; 6.5)	NA	143 93.6 (12.1)	66 96.7 (15.0)	3.7 (-0.7; 7.0)
Characteristic	**n %**	**n %**	**n %**	**Δ Incomplete-complete (%)**	**n %**	**n %**	**n %**	**Δ Incomplete-complete (%)**
Blue-collar	293 71.7	145 70.3	148 73.0	2.7	280 66.9	143 67.8	137 76.6	8.8

*p<0.05. kg: kilogram; SD: standard deviation; CI: confidence interval

Table 3. Cost and effect differences, incremental cost-effectiveness ratios, and the distribution of cost/ effect pairs in the cost- effectiveness plane for the main analysis and three sensitivity analyses in the economic analysis of the Health under Construction study.

Analysis	Sample size (n)		Δ Costs	Δ Weight loss	ICER	Distribution CE plane (%)			
	Intervention	Control	€ (95% CI)	kg (95% CI)	€/kg	NE	SE	SW	NW
Main analysis	293	280	293 (-1,070; 1,646)	-2.0 (-2.9; -1.2)*	145	66.6	33.4	0	0
Elasticity 0.8[†]	293	280	353 (-747; 1,443)	-2.0 (-2.9; -1.2)*	175	73.7	26.3	0	0
Intervention provider[‡]	293	280	258 (-1,107; 1,601)	-2.0 (-2.9; -1.2)*	128	64.7	35.3	0	0
Complete cases	145	143	1,373 (-175; 2,834)	-2.1 (-3.1; -1.1)*	658	96.3	3.7	0	0

*p<0.05. CI: confidence interval; ICER: incremental cost-effectiveness ratio; CE: cost-effectiveness; NE: northeast; SE: southeast; SW: southwest; NW: northwest.
[†]Elasticity 0.8: 100% absenteeism is associated with 80% productivity loss. [‡] Intervention provider: all 3 occupational physicians are replaced by occupational nurses.

Costs

All average costs and cost differences are presented in **Table 2.** The mean intervention costs were €605 (SD 230) per intervention group participant. The direct health care costs, excluding the intervention costs, were significantly lower in the intervention group than in the control group. The total costs, i.e. direct health care, direct non-health care, and indirect non-health care costs, were higher in the intervention group than in the control group.

Table 2. Mean costs for each participant in the intervention and the control group, and the mean differences between groups at 12 months follow-up, in a multiply imputed dataset.

Cost category	**Intervention group n=293; € (SD)**	**Control group n=280; € (SD)**	**Mean difference € (95% CI)**
Direct health care	817 (409)	279 (370)	539 (472; 605)*
Intervention	605 (230)	0 (0)	605 (572; 629)*
Other health care	212 (313)	279 (370)	-67 (-126; -9.4)*
Direct non-health care	390 (508)	333 (534)	57 (-35; 146)
Indirect non-health care	3,302 (7,743)	3,604 (7,956)	-302 (-1,651; 1,021)
Total costs	4,508	4,215	293 (-1,084; 1,670)

*p<0.05. SD: standard deviation; CI: confidence interval

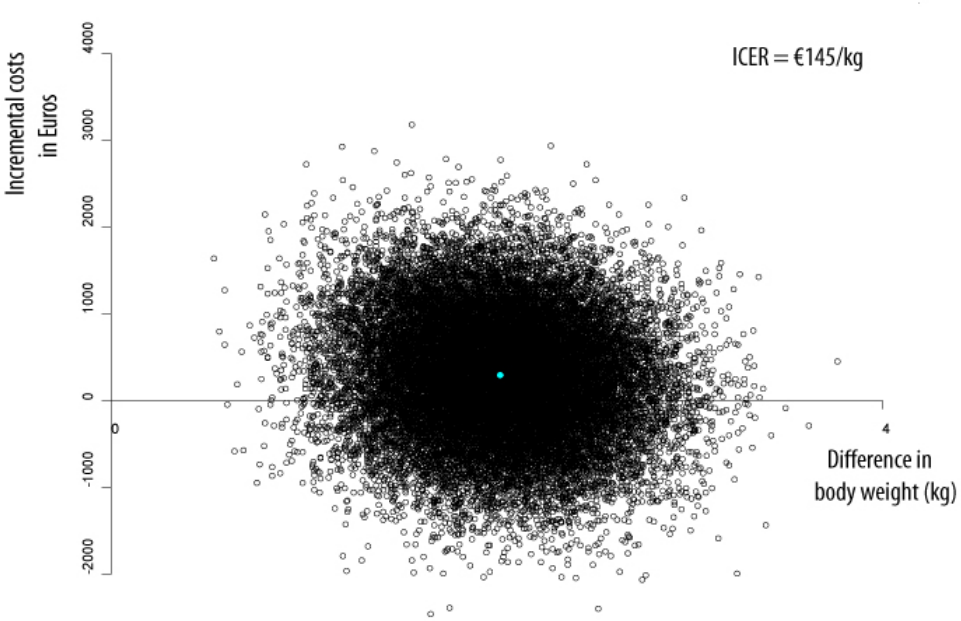
Cost-effectiveness

The ICER was €145/kg weight loss, implying that for one additional kg of body weight lost, the additional societal costs were €145. The uncertainty around this ICER was large, as shown in **Figure 2**. In this cost-effectiveness plane, 66.6% of the cost/effect pairs were in the northeast quadrant; in these cases, the intervention was more effective and more expensive than usual care, and 33.4% of the cost/effect pairs were in the southeast quadrant. In these cases, the intervention was more effective and less expensive than usual care. According to the CEAC, as presented in **Figure 3**, if society is not willing to have extra expenses to attain 1 kg extra weight loss, there is a probability of 0.33 that the intervention can be regarded as cost-effective. If society would be willing to pay €2,000, the probability would be higher than 0.95, and the intervention could be regarded as cost-effective.

Cost-benefit

Based on the imputed datasets, the employer had a net loss of €254 (95%CI -1,070; 1,536) as a result of the intervention. Again, the uncertainty around this amount was large, as indicated by the 95% confidence interval. The intervention can therefore not be regarded as cost-saving.

Figure 2. Cost-effectiveness plane for an individual-based lifestyle intervention aimed at body weight loss for workers in the construction industry with an elevated risk of cardiovascular disease.

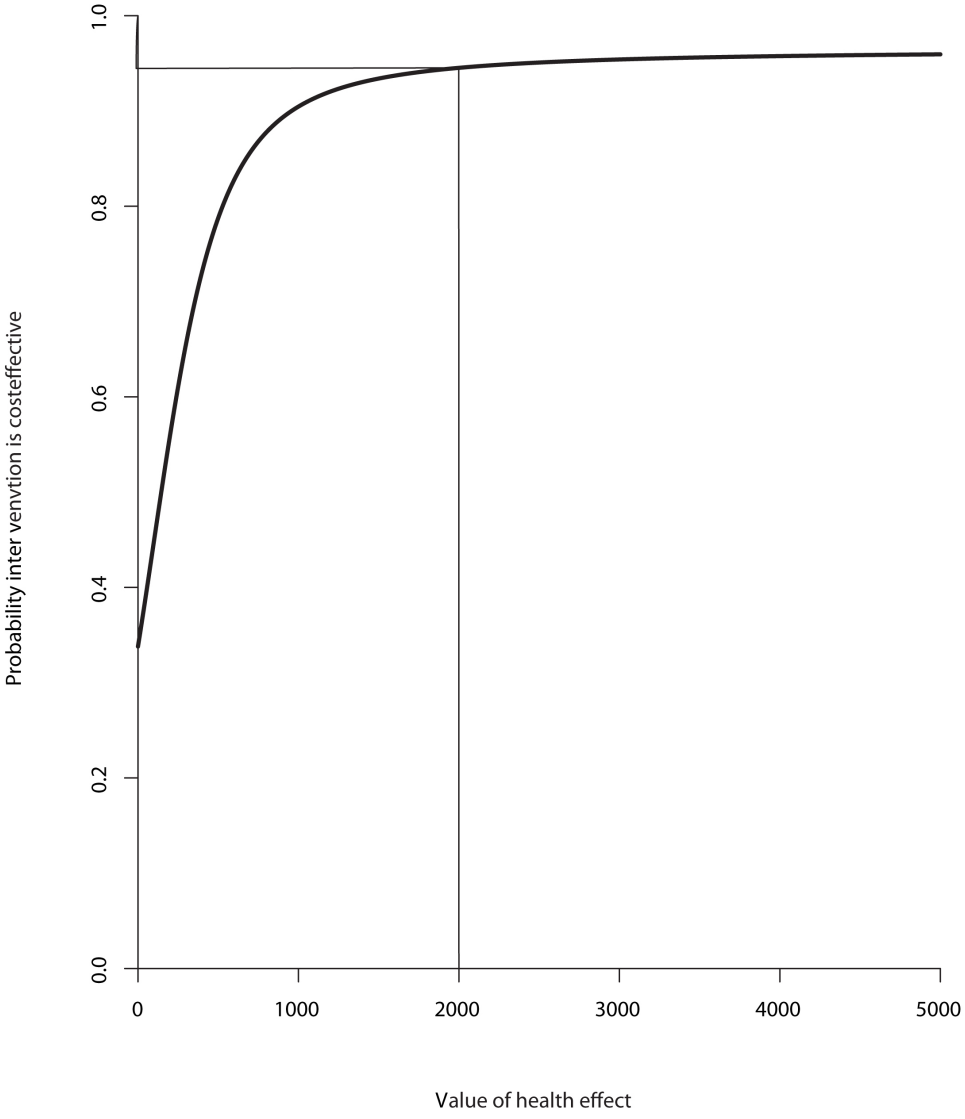


ICER: incremental cost-effectiveness ratio

Sensitivity analyses

All cost and effect differences and the ICERs of the main and sensitivity analyses are presented in **Table 3.** When applying an elasticity of 0.8, the ICER would be €175/kg weight loss. In case all occupational physicians would be replaced by occupational nurses, the ICER would be €128/kg weight loss. When only analyzing the complete cases, an ICER of €658/kg weight loss was found, which means that the society would have to invest €658 for one kg of additional body weight loss. As to the cost-benefit analysis, assuming the scenario of nurses instead of occupational physicians, the employer would have a monetary loss of €219 (95% CI -1,097; 1,501) per employee. The cost-benefit analysis on complete cases resulted in a monetary loss of €1,132 (95%CI -328; 2,601) for the employer.

Figure 3. Cost-effectiveness acceptability curve indicating the probability of cost-effectiveness for different values (€) of willingness to pay for an incremental kg of body weight loss.



Discussion

Main findings

The aim of this economic evaluation was to assess the cost-effectiveness and cost-benefit of an individual-based lifestyle intervention for workers in the construction industry with an elevated risk of CVD. The 6-month intervention had a significantly positive effect on body weight at 12 months follow-up. The intervention was more effective, but also more expensive than usual care. To attain one kg of body weight loss, as compared to usual care, would cost society €145. If society would be willing to pay €2,000, the intervention could be regarded as cost-effective. The cost-benefit analysis showed a monetary loss for the employer of €254 (95%CI -1,070; 1,536) per employee. Hence, the intervention did not appear cost-saving.

The intervention effect on body weight of 2 kg was larger than the effect of 1.2 (95%CI -0.7; 1.6) found by Verweij et al. (2010) in a meta-analysis of 9 workplace physical activity and dietary behavior intervention studies (20). The relatively large effect in our study may be related to the individual and client-centered approach**.** Not unexpectedly, due to this individual approach, and the number and duration of sessions, the intervention was relatively expensive. The costs for visits to other care providers and medication costs were significantly lower in the intervention group than in the control group, but did by far not offset intervention costs. When looking more closely to the data, we found that the direct health care costs were lower in the intervention group than in the control group only in the first six months of the evaluation period, i.e. during the intervention. However, between 6 and 12 months, there was no difference between groups in direct health care use anymore. In other studies, lasting reductions in health care use costs resulting from workplace lifestyle-related interventions have been described (39, 40). In those studies, the type of intervention and the health care resources included may have differed from our study. Furthermore, standard costs for health care differ considerably between countries, impairing comparability of studies (41). In our study, there was a non-significant reduction in absenteeism costs of €302 during the entire period, between baseline and 12 months. In general, absenteeism costs are skewed and therefore extremely large sample sizes are required to reach significance. Our study was underpowered to be certain about the observed change in absenteeism costs we found.

With respect to cost-effectiveness, most other workplace lifestyle cost-effectiveness studies only took the intervention costs into account (42, 43). If we would do so, one kg of body weight loss would cost €300, which is 10 times as much as in several other studies. An intervention of Rasu et al. (2010), consisting of tailored internet messages and two telephone calls for overweight workers, was equally effective but far less expensive than ours; 1 kg of body weight loss after 6 months could be achieved at the cost of US $25.92 (~€19.38) per participant (43). Whether this effect was sustained at the long term was not reported. In the British Counterweight study, on the effects of group and individual-based sessions among 642 overweight adults, the intervention led to a significant weight loss at

12 months of 3.0 kg, at the cost of UK £60 (~€45) per participant (42). In comparison to those studies, additional costs were included in our analyses to obtain a more realistic estimation of the overall societal costs associated with this intervention. One of the few comparable studies in which the cost-effectiveness for weight loss from a societal perspective was investigated was the study of Van Wier et al. (2010; unpublished data). From their individual-based lifestyle intervention delivered by internet, aimed at weight loss of Dutch overweight office workers, an ICER of €16/kg was concluded. This ICER seems more favorable than the one found in our study. Nonetheless, according to Van Wier et al. the probability that the internet intervention would be cost-effective at a willingness to pay of €1,000 was 0.8, whereas in our study this probability would be 0.9. Thus, not only the ICER but also the probability of cost-effectiveness should be considered in interpreting the results of an economic evaluation. With respect to cost-benefit studies, we found one study in which a comparable approach, a 9-month individual counseling intervention for Dutch civil servants, was investigated. In that study, the intervention costs were €430 per participant and the absenteeism-related monetary benefit was €125 per participant (22). These results are in line with our study; both workplace lifestyle intervention studies with a moderately long follow-up period resulted in a monetary loss for the employer, as the positive trend towards lower absenteeism costs in the intervention group did not outweigh the intervention costs. Pronk and Aldana (2001) concluded from the scientific literature that workplace health promotion intervention-induced decreases in absenteeism were usually modest, and that absenteeism reductions did not appear until the end of the evaluation period, after 1 - 4 years (44).

As said, the intervention was relatively expensive. Therefore, a cost-effectiveness analysis and a cost-benefit analysis were done assuming a strategy in which only the relatively inexpensive but equally competent occupational health professionals were deployed. Because of all 27 counselors, only three were occupational physicians and thus replaced for the analyses, the difference in ICERs between the main (€145/kg) and the sensitivity (€128/kg) analysis was only modest. Still, the results of these sensitivity analyses indicate the advantages of deploying less expensive care providers. Another sensitivity analysis concerned the valuation of absenteeism. When assuming an elasticity of 0.8, the societal costs associated with the intervention became higher because the absolute difference in absenteeism costs between intervention and control group decreased. If a lower elasticity than 0.8 would be applied, the difference in absenteeism costs would become even lower. It should be noted that for the Dutch construction industry, no data are available on elasticity. In fact, in each job type, a different elasticity might apply. In order to estimate the cost-benefit and cost-effectiveness of an intervention as accurate as possible, the elasticity that is applicable to the working population under study should be determined first.

Strikingly, there were substantial differences in mean absenteeism between the complete cases and the cases for which data were imputed. Among the complete cases,

absenteeism was highest in the intervention group, whereas after multiple imputations, total absenteeism was highest in the control group. Apparently, the participants in the control group who had incomplete data at certain time points were more likely to have a high absenteeism, or predictors of absenteeism, at one or more other time points. A possible predictor that might have led to an underestimation of absenteeism was body weight gain during the study, as can be seen in table 1. This underestimation may have been (partly) corrected for in the imputed datasets. When applying multiple imputations, it is assumed that data are missing at random; an assumption that may not necessarily hold true. Especially when large amounts of data are missing, multiple imputations may lead to flawed results. In our study, for half of all participants, one or more missing values had to be imputed. In order to make an accurate estimation of the cost-effectiveness of a study, non-completion should thus be prevented.

Strengths & limitations

Several strengths of the study need to be mentioned. First, a full economic evaluation was performed within a study with a strong design, i.e. a randomized controlled trial. Second, the cost-effectiveness of the intervention was not assessed until 6 months after the intervention had ended. Third, sensitivity analyses were done to indicate the impact of a change in assumptions. All three strengths are proposed by Tompa et al. (2006) as quality indicators for economic evaluations of workplace interventions (45). Last, this trial can be regarded as pragmatic instead of exploratory, since the intervention took place within the OHS and was delivered by OHS professionals. A pragmatic trial is the preferred option for an economic evaluation, as it reflects the costs and effects that will be generated in 'real life' (46).

A first limitation concerns the fact that the economic evaluation was underpowered to detect differences in costs, as the sample size calculation was based on a clinical outcome. This is problematic since cost data usually follow a highly skewed distribution, implying a need for larger sample sizes in cost-effectiveness studies as compared to effectiveness studies (47). In the design of a trial, the sample size needed for the economic evaluation should already be determined, and sufficient time for recruitment should be planned. Another weakness may be the lack of data on presenteeism. We chose not to measure presenteeism, since it relies on self-report of a difficult concept (48), and there is no golden standard for measuring presenteeism yet (49). A major limitation is that non-completion was relatively large and partly selective. Hence, many imputations had to be done, part of which were probably not accurate since the missings may not have been completely at random.

Conclusion

In the Health under Construction study, the intervention was more effective but also more expensive than usual care, resulting in an ICER of €145/kg weight loss. Although the absenteeism costs were slightly lower in the intervention group, the intervention costs

were high, resulting in an average monetary loss for the employer of €254. Implementation of the intervention depends, among others, on the societal and employer's willingness to pay for an extra kg of body weight loss. By measuring absenteeism on the longer term, insight could be gained in possible future monetary benefits. As the results we found appeared after the imputation of missing data, these conclusions should be interpreted with caution.

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CHAPTER 9

General discussion

In this final chapter, we will summarize and discuss our findings, describe the public and occupational health context, and provide recommendations for research and practice.

Findings

First, we will address the three objectives as defined in **chapter 1.**

1) *To provide an overview of the evidence for the effectiveness of workplace lifestyle interventions on precursors of cardiovascular disease.*

In **chapter 2**, based on our systematic review, we found that there is strong evidence for the effectiveness of workplace lifestyle interventions on body fat. We also found evidence for effectiveness on body weight among workers with an elevated cardiovascular disease (CVD) risk. This finding supported our decision to aim our intervention at a population at risk for CVD. We recommended that in future studies, participants' compliance to the intervention and their lifestyle change achieved should be reported, in order to gain insight into the process that led to the intervention effects. In our own trial, we followed this recommendation, although we did not determine the mediating effect of lifestyle change on the changes in CVD precursors.

2) *To describe the design of the Health under Construction study, the characteristics of the participants, and the evaluation of the intervention process*

In **chapter 3**, we outlined the design of the Health under Construction study; a randomized controlled trial (RCT) in which usual care was compared to a lifestyle intervention. The intervention was developed based on the literature and the opinions of various stakeholders. It consisted of individual counseling in motivational interviewing (MI) style, aimed at improving lifestyle. In **chapter 4**, we showed that of all invited workers, 20% consented to participate. Frequently heard reasons not to participate were 'feeling healthy', and 'being ill or under treatment'. The participants were on average four years older, and therefore had a somewhat less favorable CVD risk profile than the non-participants. Likewise, study completers were four years older than dropouts. In **chapter 5,** it became clear that the participants who were allocated to the intervention group demonstrated a high compliance to the intervention, and their opinions on the counselors were positive. The counselors were compliant to the intervention protocol regarding the number of sessions and items discussed. However, they were not fully proficient in performing the counseling style, MI.

3) *To present the short- and long-term effects of the Health under Construction study on lifestyle and precursors of CVD, as well as an economic evaluation.*

As described in **chapters 6** and **7**, the intervention showed positive effects on several key outcome measures. In the energy balance intervention group, fruit intake had significantly

increased at 6 months, and snack intake had significantly decreased at 6 and 12 months. There were borderline significant effects on physical activity (PA) in leisure time in the energy balance intervention group. In the smoking cessation intervention group, at six months, 31.3% of participants reported to have quit smoking, as compared to 13.4% in the smoking cessation control group, although no significant effect was found at 12 months. Moreover, the intervention led to a significant and sustained body weight loss of 2 kg. Also, significant 12-month effects on high density lipoprotein (HDL) cholesterol and Hemoglobin A1c (HbA1c) were found, although the effects on these variables were not significant over time. In **chapter 8**, the intervention appeared more effective, but also more expensive than usual care. For one additional kg of body weight loss, the costs for society were €145. Without additional expenses, the probability of cost-effectiveness was 0.33. The net employer costs resulting from the intervention were €254 (95%CI -1,070; 1,536), hence the intervention cannot be regarded as cost-saving.

Methodological issues

Before heading on to the interpretation and reflections on the findings, some methodological issues should be discussed.

Strengths

The main strength is that we performed a randomized controlled trial, which is the preferred study design for investigating causal relations between determinants and outcomes. Second, the study population was relatively large. We included 816 participants; a number that was exceeded in only five out of 31 workplace lifestyle intervention studies in our systematic review. Third, the quality of the study was secured by a thorough development process and conscientious monitoring of both the intervention and the measurements. Fourth, we investigated all components of the study; i.e. design, participants, process, and effects, as recommended by the Word Health Organization (WHO). According to the WHO, a thorough evaluation of each workplace health promotion program is essential for deciding upon its implementation (1). Fifth, in contrast to many other lifestyle change interventions, we aimed at inducing sustained changes in daily behavior, instead of temporary changes by e.g. prescribing diet or organizing exercise classes during the intervention only. Last, this study took place in a relevant setting; an effective lifestyle intervention that is offered in the occupational setting will not only contribute to lower CVD risk, but indirectly also to sustained employability.

Limitations

A first limitation of the study is the use of subjective measurement instruments. Since we intended to compare behavior changes between groups; to measure certain sub-behaviors of diet and PA instead of total energy intake and energy expenditure; to minimize participant burden, and since time and resources were limited, we chose to use self-report to assess lifestyle (2). Nonetheless, if over- and underreporting would have

occurred, this would probably have been true for both groups. A second weakness of the study is its suboptimal external validity, which can be considered at two levels. First, when comparing the study completers to the invited workers, we found that they were older and less likely to be a smoker at baseline. Second, since in general only half of all workers in the construction industry attend the periodical health screening (PHS) that is offered by their occupational health service (OHS), a substantial number of workers was not invited for the study at all. Last, different datasets were used for evaluating the intervention effects. 517 participants attended all follow-up measurements at the OHS. A larger number of participants, 595, filled out all three questionnaires. In order to optimize the generalizability of the results and the chance of detecting a significant effect, we analyzed all 517 participants for chapter 7, and all 595 participants for chapter 6. Only for the economic evaluation, missing data were imputed, as cost data were missing for half of the cases. If for chapter 6 and 7 an imputed dataset was used, the results might have been slightly different. Still, the analyses on body weight in an imputed an unimputed dataset yielded almost the same results, as shown in chapter 7 and 8.

Interpretation and reflections

The abovementioned findings can better be interpreted by elaborating on the reach of the study and the effectiveness of the intervention. Also, we will reflect on certain important topics related to the intervention and the results.

Reach

All male workers in the Dutch construction industry, aged 18-65, with an elevated CVD risk as diagnosed during the PHS at the OHS between January 2007 and February 2008, were invited to the study. Only 20% participated, of which relatively few younger workers. As their age did not add to their CVD risk, based on the Framingham risk score, the main causes of their elevated CVD risk must have been derived from smoking, hypertension, or unfavorable cholesterol levels (3). Thus, an important subgroup of workers was underrepresented in the study. As the younger workers showed a larger intervention effect on snack intake than the older, the workers we missed could have benefited from the intervention. Also, the refusal of many smokers to participate is worrisome, as smoking is the main CVD risk factor. Altogether, in order to optimize participation, i.e. having a higher and non-selective response, it is worthwhile to improve the recruitment strategy. A socio-ecological approach, which implies involvement of the physical, social, and organizational environment, was previously shown advantageous in promoting lifestyle interventions (4;5). In the case of our intervention, the employer could promote the counseling trajectory during meetings at the workplace. Still, the actual recruitment of individuals should be done by the OHS, since selection of workers is based on PHS results. Another issue regarding (non-)selective response was the impossibility to invite the workers who did not attend the PHS; which accounted for 50% in 2007. Their lifestyle and health are unknown to us, but may have been related to their refusal to attend the PHS. Thus, increasing participation in a trajectory following the PHS is a second step, but

strategies to increase attendance to the PHS should be considered first. To enlarge the proportion of workers providing data on their CVD risk profile, we propose to offer the PHS, or an additional health checkup apart from the PHS, at the workplace instead of at the OHS. For example, a mobile unit could be used for this purpose. This might circumvent the problem of time constraints, as we described in chapter 4, and the workers may motivate each other to attend the health checkup. This approach appeared effective previously, in health checkups organized by a large OHS in the Netherlands (6). Another factor that needs to be mentioned when discussing the reach of this study is the proportion of participants who completed the study. The proportion of study completers was moderate, i.e. 73% filled in all three questionnaires and 63% attended all three follow-up measurements. Nevertheless, the compliance to the intervention was relatively high, which was positive, as the number of intervention sessions appeared associated to the intervention effect on body weight, although not significant.

Effectiveness

Positive intervention effects on lifestyle behavior were found, although moderate. Dietary and PA behavior is influenced by cognitive determinants as well as the physical and social environment (7;8). Some behavioral determinants were measured in our study, but the mediating effect on actual behavior was not analyzed. Still, we would like to mention a determinant that may not have been positively influenced by the intervention, or positively related to behavior. In our population of mainly blue-collar workers, the social influence on dietary behavior may have been positive but also negative. For example, vegetable intake may have been difficult to change because of a negative social influence of the spouse, as she usually prepares the meals. For vegetable intake, the worker would have benefited from a decrease in this influence. In contrast, for snack and fruit intake, social influence may have had a positive effect on behavior, and may have increased. This differential influence of the social environment in improving diet was reflected in the questionnaires. Between baseline and 6 months, for 27.6% (n=57) of the participants in the EB intervention group, social influence increased, whereas for an equal proportion (28.6%; n=59) it decreased (unpublished data). Regarding self-reported leisure time PA, a finding that struck us was the substantial increase in both groups. PA increased by almost 3 hours in the intervention group and by 1.5 hours in the control group. Between 6 and 12 months, this promising rise diminished in both groups, but the difference from baseline remained large. There is no clear explanation for the large increase in PA in the control group. Possibly, the PHS results or the measurements triggered participants to start becoming more physically active (9). Naturally, most participants were already intrinsically motivated to improve lifestyle; otherwise they would not have participated in the study. This positive attitude was reflected in the questionnaires; at baseline, the mean self-reported score for attitude towards changing PA was 4.0 on a 5-point Likert-scale (unpublished data). However, as there was a weight gain of 0.9 kg among the workers in the control group during the study, overreporting of PA should be kept in mind.

All in all, the intervention effects on most dietary and PA behaviors were modest. This could have partly been due to insufficient knowledge among the counselors and the participants. The first step in the counseling protocol was to increase knowledge and awareness of the CVD risk profile, but we think that insufficient attention was paid to increasing knowledge of how to change the various lifestyle behaviors. Also, as to PA, there may have been a lack of knowledge about the difference between PA at work and PA in leisure time, which was illustrated by the frequently mentioned barrier 'Already being physically active at work' (unpublished data). Since the physical workload in the construction industry usually does not substantially increase cardiorespiratory fitness (10), increasing aerobic PA in leisure time remains necessary to lower CVD risk. Still, overall, there was a trend in the direction of an improvement of energy balance-related behaviors. Therefore, an intervention effect on body weight was to be expected. Since snack intake significantly improved at the long term and PA did not, the effect on body weight was probably related this change in diet. The findings of Health under Construction were a confirmation of the conclusion of our systematic review that workers with an elevated CVD risk can loose body weight as a result of a lifestyle intervention. Overall, the conclusions of the systematic review would not change if the results of Health under Construction would be added. Last, one third of participants aimed at smoking cessation, which appeared doable on the short term, but relapse was common. This phenomenon was observed in many other studies (11). Nonetheless, some specific characteristics of blue-collar workers can be considered in interpreting this finding. In a study by Barbeau et al. (2004) , smoking was proven to be associated with job strain and low job control (12). In line with that, Sorensen et al. (2009) found that among blue-collar workers, smoking cessation was associated with decision latitude, and facilitated by encouragements of others to quit (13). In our study, encouragements were provided by the counselors during the intervention, but as soon as the encouragements stopped, relapse occurred.

Intervention method

As we stated in chapter 2, the stages of change principle was taken into account when designing the intervention. In the literature, the Transtheoretical Model (TTM) has frequently been criticized because the progression through stages is not always linear, and the time spans of six months are arbitrary and difficult for a respondent to indicate (14). We realized the weaknesses of the TTM, which supported our choice to use MI as a counseling technique. MI is based on several theories, and acknowledges the principle of the stages of change. However, progressing from precontemplation to maintenance of behaviour is regarded as a continuous process, and not as series of separate stages. Treasure and Smith (2001) phrased it as follows: 'readiness to change is rather fluid and can wax and wane within and between sessions' (15). Unfortunately, MI appeared difficult to adhere to for the counselors. Probably, a 2-3 day training was not sufficient, which confirms the observation of Miller et al. (2001). They stated that a 2-3 day training can increase the understanding of MI and acquire the basic skills, but to become proficient, personal feedback or a more advanced training is necessary (16). Although the counseling

style could not be regarded as MI, it was client-centered and most MI techniques were used. In any case, based on the study results, full MI proficiency was not necessary to achieve significant intervention effects. Still, in our opinion, a higher MI quality is preferable as it may improve the intervention effects. In order to equip all occupational nurses with MI skills, we would propose that MI is incorporated into the curriculum of the study for occupational nurses. In doing so, the occupational nurses will have a proper basis for counseling on lifestyle change, but possibly also for other consultations regarding e.g. return-to-work.

An issue that should also be considered is whether MI alone is sufficient to achieve behavior change. Many participants did not aim at lowering overall CVD risk per se, but at lowering body weight. However, based on our results and personal communication, the counselors did not have sufficient knowledge for adequate guidance in weight loss and prevention of weight regain. Therefore, we would also advice to integrate classes on diet and PA in relation to weight loss in the curriculum for occupational nurses, to enable counselors to provide adequate information in case a worker intends to loose weight (17;18). During the intervention, in addition to the provision of oral or written information, the counselor could provide tools such as calorie schemes, food diaries (19), and practical information about possibilities for PA in the neighborhood, such as cycling maps (20); all evidence-based methods to support weight loss and prevention of weight regain. The added value of providing practical information alongside MI was reflected in the study of Sorensen et al (2007); even though their intervention was less intense than ours - 4 telephone MI sessions and 12 tip sheets, tailored to construction workers - the effects on fruit intake and smoking were comparable to those in our study (21).

Importance of body weight loss

Altogether, the main finding of our study was a sustained weight loss of 2 kg, in a population with an average body weight of 93 kg, corresponding to a BMI of 28.5. We will reflect on meaning and relevance of this finding. There has been a debate on whether mortality linearly decreases with decreasing BMI, or whether it is actually lowest among the moderately overweight. During a 10-year follow-up period in a large cohort of German male construction workers, the risk of all cause mortality was indeed lowest between BMI 25.0 and 27.4 (22). In contrast, Adams et al. (2006) showed a linear increase in mortality from BMI 25 onwards in healthy men of which recalled weight at age 50 was used (23). In the German study, sensitivity analyses showed that mortality caused by CVD linearly increased with increasing BMI. In fact, for a BMI of 25, the hazard ratio of CVD mortality was 1.3 (95%CI 1.1; 1.6) as compared to a BMI of 20 (22). Consequently, the authors state that each decrease in BMI is beneficial for health. Not only weight loss, also weight stability is beneficial for lowering the risk of CVD mortality (24;25). In Dutch adult men, background weight gain is approximately 0.5 kg per year (26). The participants in the control group in our study gained almost twice this amount of body weight, i.e. 0.9 kg between baseline and 12 months. After retirement – which will be within 10 to 15 years in

our population - without intervening, workers will continue to gain weight. In fact, among workers who retire from active jobs, the average weight gain is usually higher than among those retiring from sedentary jobs (27). Unfortunately, despite a sustained decrease in snack intake, the participants in the intervention group also regained weight after 6 months, although at a slower rate than the control group. Part of the explanation may be that there was no effect on PA at 12 months. As PA is proven to prevent weight regain after weight loss (28), at the end of a weight loss intervention, PA should explicitly be discussed. Still, the best strategy to prevent weight regain and relapse into unhealthy behavior is probably to continue the intervention until old age.

Costs, medication, quality of life

As we concluded from the economic evaluation, this lifestyle intervention can only be regarded as cost-effective if the society is willing to pay € 2,000. This figure should be interpreted with caution, because of the numerous and partly selective missing data, and because resource use and absenteeism were self-reported. More importantly, for an economic evaluation, 1 year is a relatively short follow-up period (29). To determine future monetary costs and benefits, an economic evaluation should be done over a larger time period. We cannot make firm statements on future financial benefits, but we could bring up some expectations. First, by lifestyle modification, the costs associated with treatment of CVD and its precursors may be lowered. For example, by decreasing the proportion of workers being physically inactive, high annual costs associated with treating coronary artery disease and hypertension can be averted (30;31). Also, by adopting and maintaining a healthier lifestyle, costs associated with other chronic diseases, such as diabetes and cancer, will decrease (32). Inevitably, a proportion of individuals who improve lifestyle will eventually get CVD, diabetes, or cancer. However, if this event can be postponed, a number of years of elevated health care costs can be prevented (32).

Besides lifestyle modification, there is an other method to lower CVD risk, i.e. by using blood pressure and cholesterol lowering medication (33;34). Pharmacological treatment is usually offered in case lifestyle modification is insufficient, and certain critical values for blood pressure or cholesterol are exceeded (35-37). Data on the cost-effectiveness of both lifestyle modification and medication use during lifetime are currently lacking. Probably, the costs of lifelong generic medication (38) will outweigh the costs of a chronic lifestyle intervention consisting of yearly counseling sessions. With regard to diabetes, lifestyle modification had a more favorable cost: benefit ratio than treatment with the glucose-lowering medication metformin; in the Diabetes Prevention Program the overall costs of preventing a single case of diabetes during a 3-year period were US$ 4,301 for lifestyle vs. US$ 11,141 for metformin (39). Even if no financial benefits are obtained, lifestyle modification has advantages as compared to medication, such as preventing other chronic diseases at once, and assuring independence of daily medication and its possible side-effects. A major advantage of a lifestyle modification has frequently been mentioned in

this thesis; by being more physically active, and decreasing the risk of becoming obese, the costs associated with absenteeism and disability are likely to decrease (40;41).

To enable comparison of medical treatments or preventive measures, health related quality of life (HRQOL) is generally determined, and expressed as quality adjusted life years (QALYs). In the Netherlands, a ceiling ratio of willingness to pay for a QALY is established, which amounts to €20,000. We decided not to determine HRQOL, as the workers in our study population were expected to be already in the high end of the utility range, as noted by Van Wier et al. in a comparable study (2010; unpublished results). In the Diabetes Prevention Program, a generic HRQOL instrument showed significant improvements in HRQOL resulting from weight loss, irrespective of treatment modality, but only in persons with a BMI ≥35.0 (42). According to the review of Maciejewki et al. (2005), no evidence was found for an association between body weight loss and HRQOL when using a generic HRQOL instrument, but when using an obesity-specific HRQOL instrument, there was (43). Thus, if we would have applied an obesity-specific instrument we might have found an intervention effect on HRQOL. However, the disease-specific instruments cannot be used to compare HRQOL across studies.

Public and occupational health

Last, our findings will be put in the context of the public and occupational health policies in the Netherlands, and the lifestyle-related activities that are currently ongoing.

Public health and lifestyle

The Dutch population is aging: in 2040, 26% of citizens will be over 65, whereas currently this percentage is 15% (44). Considering the accompanying rise in chronic diseases, the costs of health care are increasing. Since the ratio of workers versus non-workers is decreasing, bearing these costs may become problematic. The Dutch National Institute for Public Health and the Environment noted that in order to keep health care within reach for each resident, the focus should shift from treatment to prevention (45). In the previous decade, several preventive measures have been initiated by the government, food industry, and nonprofit organizations; mainly aimed at creating an environment in which the healthy choice is made the easy choice. For example, the Healthy Choice Logo on food products facilitates choosing the relatively healthier food products. Also, municipalities intend to adjust the built environment so that recreational activities and PA among its inhabitants is stimulated. Not only is healthy behavior stimulated, some unhealthy behaviors are discouraged; as from 2008, there is a ban on smoking in cafeterias. These are all forms of primary prevention, also named a ‘population approach’, as it is aimed at the total population. In contrast, secondary prevention, or the ‘high risk approach’, is aimed at only a proportion of the population, namely those with an elevated risk of disease. This approach was applied in our study. As such an intervention is more personalized, each individual will benefit more than the individuals targeted using the

population approach. On the other hand, the high risk approach does not aim at the origin of the problem (46).

In the Netherlands, initiatives on the level of secondary prevention are stimulated as well. For example, individuals at risk of diabetes type 2 can be referred by their general practitioner (GP) to a lifestyle improvement trajectory, i.e. the 'beweegkuur', in which a lifestyle coach, physiotherapist and dietician are involved (47). This type of intervention fulfills the Dutch criteria for implementation and reimbursement by health insurers, as it is effective and essential (48), and cost-effectives on the longer term is expected. As our intervention is comparable to the 'beweegkuur', it is expected to fulfill these criteria as well. However, even if this type of intervention is reimbursed by the health insurer, all Dutch citizens are obliged by law to pay €165 to cover the first costs they make for health care utilization annually. As we learned, one of the reasons for workers not to participate in our study was related to costs. Remitting these €165, as postulated by the Ministry of Health, Welfare and Sports (49), seems a good idea to me, as long as lifestyle is demonstrable improving and maintained on the longer term.

Occupational health and lifestyle

In line with the abovementioned problems of aging, a decreasing workforce, and rising health care costs, the Ministry of Health, Welfare, and Sports noticed the need to stimulate sustained employability. On their request, the Dutch Socio-Economic Council investigated the possibilities for health promotion in the occupational setting (50). The Council recommended to focus on vitality and healthy lifestyle, for instance by offering lifestyle interventions to all workers, as long as these were voluntary. According to their report, only in case an unhealthy lifestyle would hamper the work ability of an employee, his employer should be able to intervene. The Labor Foundation raised this issue already before (51). I agree with their suggestion that, if interventions at the company level are implemented to create healthier working conditions, the workers should be involved in the development of these interventions. These interventions could include adjusting the availability and pricing of food products in the company restaurant, or offering fitness facilities. Besides, in my opinion, all workers should be offered a voluntary health screening, at least once or twice during their career. In case of an elevated CVD risk, they should be offered a lifestyle trajectory at the OHS or at the workplace. In order to facilitate the realization of the intended behavior change, the company's environment would need to stimulate the healthy choice. Not only would it be worthwhile to stimulate healthy behavior, but unhealthy behaviour could be discouraged, e.g. by applying a financial penalty. As smokers generate lower lifetime health care costs than non-smokers (52), it would not make sense to increase their health insurance premiums. However, as the employer pays for increased sickness absence - in 2003 to 2005 the number of sickness reports was 1.4 times higher in smokers as opposed to non-smokers (53) - the workers' salary could be adjusted.

In previous years, an increasing amount of OHSs and companies implemented health promotion activities. The companies' motives were not only related to sustained employability and absenteeism prevention, but they also considered it as good employment practice and part of their corporate social responsibility (50). A large banking company in the Netherlands developed a program in which all workers could participate in exercise classes, relaxation workshops, smoking cessation courses, and emailed nutrition advice. Some employers also decided to address the worker's lifestyle during the periodical performance interview (54). In my opinion, this measure is too directive, as it is unsolicited by the employee, and it might disturb the professional relation with the employer. It may even be regarded as offensive, and may not contribute to behaviour change. Moreover, as we found in our study, even if a worker knows about his risk status, client-centred individual counselling is necessary for making sustained changes in behaviour. Instead of addressing personal lifestyle during the performance interview, the employee could be asked for his opinions about the corporate lifestyle-related activities that are already implemented. Evidently, the opinions of the employees themselves are also important. According to a poll among the Dutch working population, 75% agreed that the employer was free to interfere with his workers' lifestyle, as long as the offered activities would be voluntary (54). Of the banking company employees, 87% agreed that the lifestyle program should be continued in the future. These percentages are promising, but must be interpreted with caution. In the interviews preceding our study, all workers were enthusiastic about a workplace lifestyle intervention (55). When the actual study started, only one fifth agreed to participate.

Personally, I propagate both a population approach as well as a high risk approach. As much as possible, those two approaches should be linked, because creating a healthy environment may facilitate bringing the intended lifestyle changes into practice. In the counseling sessions with workers at risk for CVD, the occupational physician or nurse could point to the company's lifestyle improvement activities, and to local or national initiatives, such as www.beweegmaatje.nl, a website through which a partner can be sought for leisure time physical activities. Another issue I would like to raise relates to the inclusion criteria for such an individual-based intervention. I suggest that workers who do not fulfill the criteria for an elevated CVD risk because they use blood pressure or cholesterol lowering medication, but who do have an unhealthy lifestyle, should be eligible for a lifestyle trajectory at the OHS as well. To enhance the successfulness of this strategy, the occupational health professional who starts this lifestyle trajectory should collaborate with the worker's general practitioner, as the ultimate aim is to improve an individual's health. The exchange of information between the OHS professional and other care providers might be facilitated by making the 'electronic patient dossier', an electronic tool for exchange of medical data, accessible to OHS professionals. Currently, communication or collaboration between the OP and GP is not yet common practice, which is partly due to feelings of distrust and status (55).

In conclusion, the government, OHSs, employers, and employees all recognize the need of lifestyle-related health promotion, and many initiatives have been taken so far. However, most were not systematic, relatively small-scale, and not evidence-based. The results of the Health under Construction study contribute to the knowledge of the feasibility and effectiveness of lifestyle interventions for workers at risk for CVD.

Recommendations

From the discussion of the study results, several recommendations can be extracted. We advise to implement this intervention within the OHS, as usual care for workers in the construction industry with an elevated risk of CVD. Before doing so, our recommendations for creating circumstances necessary to start and execute an optimized the intervention should be taken into account.

Preparation

- The organization responsible for the education of occupational nurses should incorporate MI into the curriculum, as well as education on how to guide weight loss and maintenance;
- Within the first months after the 2-3 day MI training, an MI trainer should offer the occupational nurses personal feedback;
- OHSs should organize health checkups, that are promoted by the employers, and executed at the OHS or using a mobile unit stationed at the workplace;
- Based on the PHS results, OHS professionals should make a personal risk profile for each worker at risk for CVD, as in our study.

Action

- The OHSs should invite each worker at risk of CVD for a first 45-minute counseling session, comparable to the first session in our study, using the risk profile and registration form;
- A worker who decides to proceed, should set goals and start with the subsequent counseling sessions, led by a trained occupational nurse;
- During the intervention, for workers who prefer to loose weight, the occupational nurse should provide sufficient information on how to loose weight and maintain weight loss, and on the association of weight loss and maintenance with both diet and PA.

Evaluation

Last, for enlarging the knowledge on the (cost-) effectiveness of Health under Construction, we suggest investigators to:

- Analyze the mediating effects of behavioral determinants on behavior change, and of behavior change on CVD precursors, using data from the current study;

- Analyze the costs and effects of this intervention on a longer term, either by following our study population, or in a separate study;
- Investigate the feasibility and effectiveness of this individual-based intervention in other branches, with and without environmental changes at company level.

Conclusions

This well-appreciated and partly feasible intervention led to sustained improvements in diet and body weight. At 12 months, the intervention was more effective but also more expensive than usual care. Nevertheless, a workplace intervention that is effective in making sustained changes in lifestyle and health is of high relevance for occupational health, as it may contribute to sustained employability in this aging population. Therefore, after incorporating our suggestions for improvement, we recommend implementation of this intervention.

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SUMMARY

The aim of this thesis was to describe the development and evaluation of an individual-based lifestyle intervention among workers in the construction industry with an elevated risk of cardiovascular disease (CVD). In **chapter 1**, an introduction to this topic was provided. CVD is a chronic and degenerative disease, of which the risk is strongly influenced by lifestyle behaviors such as diet, physical activity, and smoking. There is evidence for the effectiveness of individual-based interventions aimed at lifestyle behavior change among workers. In the construction industry, the proportion of workers who are overweight or at risk of CVD is relatively large, and no guideline for CVD risk reduction yet exists. In this study, the feasibility and (cost-) effectiveness of a lifestyle intervention in the construction industry was investigated. In this thesis, the following objectives were addressed:

1) To provide an overview of the evidence for the effectiveness of workplace lifestyle interventions on precursors of CVD;
2) To describe the design of the Health under Construction study, the characteristics of the participants, and the evaluation of the intervention process;
3) To present the short- and long-term effects of the Health under Construction study on lifestyle and precursors of CVD, as well as an economic evaluation.

Chapter 2 concerned a systematic literature review on the effectiveness of workplace lifestyle interventions. To the 31 studies that fulfilled the inclusion criteria, a best-evidence system was applied, taking into account the quality of the study and the consistency of effects. Strong evidence was found for a positive effect of workplace lifestyle interventions on body fat, one of the strongest predictors of CVD risk. Among populations with an elevated risk of CVD, there was strong evidence for a positive effect on body weight as well. Due to inconsistencies in results between studies, there was no evidence for the effectiveness of workplace lifestyle interventions on blood pressure, cholesterol, triglycerides, and HbA1c. Populations with an elevated risk of CVD seemed to benefit more from lifestyle interventions than populations not at risk, and supervised exercise interventions appeared less effective than group or individual counseling. For future intervention studies we recommend to report participants' compliance with the intervention and the lifestyle changes achieved, in order to gain better insight into the mechanisms that led to the intervention effects.

In **chapter 3**, the design of Health under Construction study was thoroughly described. Health under Construction is a randomized controlled trial for male workers in the construction industry, both those involved in construction activities and in administration, supervision, and management, with an elevated risk of CVD, in which usual care is compared to an individual-based lifestyle intervention. The intervention was based on opinions of employers, employees, and occupational physicians, and on a literature search on the current evidence for the effectiveness of lifestyle interventions. The intervention

consisted of three face to face and four telephone contacts with an occupational physician or nurse, on either improving diet or physical activity behavior, or smoking cessation. The counselors followed a stepwise protocol and used motivational interviewing as a counseling style. Measurements took place at baseline, 6, and 12 months. By means of questionnaires, data were collected on e.g. lifestyle behavior and absenteeism. Doctors' assistants measured body weight, HDL and total cholesterol, systolic and diastolic blood pressure, and HbA1c.

In **chapter 4**, we provided insight into the factors associated with non-participation and dropout in the Health under Construction study. To examine the associations between (non-) participation and CVD risk factors, and the associations between (non-)dropout and CVD risk factors, we used crude and multiple logistic regression models. By means of questionnaires, the reasons for non-participation and dropout were assessed. The participants, i.e. 20% of all invited, had a worse CVD risk profile than non-participants with respect to blood pressure, cholesterol, tiredness and/or stress, and chest pain and/or shortness of breath. The worse CVD risk profile was mainly explained by the difference in age; participants were 3.8 years older than non-participants. Dropouts were 4.6 years younger than those who completed the study, and more likely to smoke. Thus, the study completers were on average older and less likely to be a smoker at baseline than those invited. The main reasons for non-participation were 'no interest', 'current (para-)medical treatment', and 'feeling healthy', and for dropout the main reason was a lack of motivation.

In **chapter 5,** we evaluated the practical execution of the intervention, as well as the opinions of the counselors and participants. The adherence of the 27 counselors to the intervention protocol was determined by registration of the number of sessions and items discussed, and by measuring the quality of motivational interviewing using expert scoring of random segments of 19 counseling sessions. Counselors' competence was rated by participants and counselors separately. Associations between three process indicators and body weight loss between baseline and 6 months were determined using linear regression analyses. Two-thirds of all participants attended five or more sessions, and 38.5% attended all seven sessions. In 90.2% of all cases, the counselor discussed all obligatory items in the first session. Adherence to motivational interviewing was reached in only one audio taped fragment. 86.3 Percent of all participants agreed with the counselor being competent. Neither perceived counselors' competence, nor number of sessions or items discussed, was significantly associated with body weight loss.

In **chapter 6,** the effects of the intervention on lifestyle behaviors were described. Complete data were available for 595 participants. Participants who had chosen to aim at diet and physical activity (energy balance) were analyzed separately from the ones who aimed at smoking cessation. Effect sizes were determined by linear and logistic regression analyses in which the baseline value was added as a covariate. In the energy balance

subgroup, the intervention had a significant beneficial effect on snack intake (pieces per week: β -1.9, 95%CI -3.7; -0.02) and fruit intake (pieces per week: β 1.7, 95%CI 0.6; 2.9) at 6 months. The effect on snack intake remained significant at 12 months (β -1.9, 95%CI -3.6; -0.2). At 6 months, 31.3% of participants had quit smoking, as compared to 13.4% in the control group (OR for smoking 0.3, 95%CI 0.1; 0.7), but this effect was not sustained until 12 months (OR 0.8, 95%CI 0.4; 1.6). Both control and intervention group participants substantially increased their leisure time physical activity by almost 1.5 and 2.5 hours per week respectively.

In **chapter 7**, we described the intervention effects on precursors of CVD, i.e. the biological risk factors. Complete data were available for 517 participants. The intervention had significant effects at 6 months on body weight (β -1.9, 95%CI -2.6; -1.2) and diastolic blood pressure (β -1.7, 95%CI -3.3; -0.1). The effect on body weight effect was sustained until 12 months (β -1.8, 95%CI -2.6; -1.1). Among participants who had aimed at energy balance, the intervention had a significant effect on body weight at 6 (β -2.1, 95%CI -2.9; -1.3) and 12 months (β -2.2, 95%CI -3.1; -1.3), and on HDL cholesterol (β 0.05, 95%CI 0.01; 0.10) and HbA1c (β,-0.06, 95%CI -0.12; -0.001) at 12 months. The effects on HDL cholesterol and HbA1c over time, as determined by longitudinal analysis, were not significant. On average, the obese participants achieved the largest improvements in body weight, blood pressure, and HDL cholesterol. Among participants who had aimed at smoking cessation, the intervention had no significant effects; beneficial changes in blood pressure and cholesterol were found in both groups, and even body weight decreased in the intervention group.

In **chapter 8**, the cost-effectiveness from the societal perspective, and the cost-benefit from the employer's perspective were described. We included only those participants who had chosen to aim at energy balance, i.e. 573. All missing data were imputed by multiple imputations. For the cost-effectiveness analyses, all costs for the intervention, health care use participants purchases related to lifestyle, and absenteeism were totaled and divided by the incremental effect on body weight. For the cost-benefit analysis, the costs for the intervention were subtracted from the incremental benefits associated with absenteeism. An incremental cost-effectiveness ratio was calculated, of which the uncertainty was estimated by bootstrapping cost/ effect pairs. The intervention was more effective but also more expensive than usual care. For one additional kg of body weight loss, the costs for the society would be €145. In case of a willingness to pay of €2,000, the probability of cost-effectiveness would be 0.95. The net employer costs resulting from the intervention were €254 (95%CI; -1,070; 1,536); thus the intervention cannot be regarded as cost-saving.

In **chapter 9**, we summarized and discussed our findings, outlined the strengths and limitations of our study, described the public and occupational health context, and provided recommendations for research and practice. In conclusion, this systematically

developed, well-appreciated, and partly feasible intervention led to sustained improvements in diet and body weight. The results can be generalized to the older male workers in the construction industry with an elevated risk of CVD, both the ones involved in construction activities and those in supervision and management. At 12 months, the intervention was more effective but also more expensive than usual care. Still, a workplace intervention that is effective in making sustained changes in lifestyle and health is of high relevance for occupational health, as it may contribute to sustained employability in this aging population. Therefore, after incorporating our suggestions for improvement, we recommend implementation of this intervention.

SAMENVATTING

Dit proefschrift is gewijd aan 'Bouwen aan Gezondheid': een onderzoek naar de effectiviteit van een leefstijlinterventie voor werknemers in de bouwnijverheid met een verhoogd risico op hart- en vaatziekten (HVZ). In **hoofdstuk 1** wordt een introductie gegeven op het onderwerp. Het risico op HVZ wordt voor een groot deel bepaald door leefstijlfactoren zoals voeding, fysieke activiteit en roken. Meer bewegen, gezonder eten en stoppen met roken heeft een grote invloed op ziekte en sterfte als gevolg van HVZ. Om mensen te helpen hun leefstijl te veranderen moet worden gericht op de voorspellers (determinanten) van hun gedrag, en rekening gehouden met hun persoonlijke situatie. In de bouwnijverheid in Nederland is het aantal werknemers met een ongezonde leefstijl, overgewicht of een verhoogd risico op HVZ relatief hoog, zoals blijkt uit de resultaten van de periodieke medische onderzoeken die worden uitgevoerd op de arbodienst. Voorafgaand aan dit promotieonderzoek was er onvoldoende kennis over hoe de arbodienst kan bijdragen aan de verbetering van leefstijl van deze werknemers. In dit promotietraject is de uitvoerbaarheid en (kosten-) effectiviteit van een leefstijlinterventie voor deze doelgroep onderzocht.

Voor **hoofdstuk 2** deden we een literatuurstudie naar het effect van leefstijlprogramma's (interventies) voor werknemers op de uitkomstmaten lichaamsgewicht, body mass index (BMI; kg/m^2), lichaamsvet, totaal cholesterol en HDL cholesterol (het ' goede' cholesterol), bloeddruk, en HbA1c (een maat voor suikergehalte in het bloed). Na een systematische zoektocht in elektronische databases vonden we 32 geschikte artikelen over dit onderwerp. Om conclusies te trekken over het bewijs voor de effectiviteit van de beschreven interventies werd voor iedere uitkomstmaat afzonderlijk gekeken in hoeveel studies er een significant effect was. Daarbij werd rekening gehouden met de kwaliteit van iedere studie. Uit deze literatuurstudie bleek dat er sterk bewijs was voor een positief effect op lichaamsvet. Bij werknemers die al een verhoogd risico op HVZ hadden, was ook sterk bewijs voor een positief effect op lichaamsgewicht. Ook waren er aanwijzingen dat 'bewegen onder begeleiding' minder effectief was dan individuele of groepsgewijze gesprekken over het veranderen van leefstijl. We weten nu voor ons eigen onderzoek dat we gewichtsverlies kunnen verwachten, en dat persoonlijke gesprekken de beste manier zijn om dit te bereiken. Om beter te begrijpen hoe interventie-effecten op deze uitkomstmaten tot stand komen, raden we toekomstige onderzoekers aan om in hun artikelen te vermelden in welke mate werknemers de interventie hebben gevolgd, en welke leefstijlveranderingen ze daarmee bereikt hebben.

In **hoofdstuk 3** is de opzet van het onderzoek uitgebreid beschreven. Bouwen aan Gezondheid is een gerandomiseerde, gecontroleerde studie naar het effect van een leefstijlinterventie. De doelgroep wordt gevormd door mannelijke werknemers in de bouwnijverheid; zowel de timmermannen en stratenmakers als het administratief en leidinggevend personeel. De gebruikelijke zorg voor werknemers met een verhoogd risico op HVZ bestaat, in de meeste gevallen, uit een kort leefstijladvies van de bedrijfsarts. In Bouwen aan Gezondheid werd deze gebruikelijke zorg vergeleken met een op het individu

gerichte leefstijlinterventie. Bij de ontwikkeling van de interventie is rekening gehouden met de wensen van werknemers, werkgevers en bedrijfsartsen, en met de bestaande kennis uit de literatuur. De interventie duurde zes maanden en bestond uit drie persoonlijke gesprekken op de arbodienst en vier telefoongesprekken, met een getrainde consulent; een bedrijfsarts of arboverpleegkundige. De deelnemer bepaalde of hij zich wilde richten op gezonder eten en meer bewegen, of op stoppen met roken. In het eerste gesprek werden onder meer zijn risicoprofiel, de persoonlijke voor- en nadelen van gedragsverandering, zijn motivatie om te veranderen, en persoonlijke doelen besproken. De consulenten gebruikten 'motiverende gespreksvoering'; een gesprekstechniek waarin door middel van, onder andere, open vragen wordt geprobeerd om de deelnemer te laten nadenken en verwoorden wat hij zelf wil en kan veranderen. Aan het begin van het onderzoek (nulmeting) en na 6 en 12 maanden werden gewicht, bloeddruk, cholesterol en HbA1c gemeten op de arbodienst. Daarnaast vulden de werknemers vragenlijsten in over onder andere leefstijl en ziekteverzuim.

In **hoofdstuk 4** zijn de redenen om niet deel te nemen aan het onderzoek en de redenen om de vervolgmeting na 6 maanden niet te ondergaan (gedefinieerd als uitval) beschreven. Van de 4.058 genodigde werknemers besloten er 816 (20%) om deel te nemen aan het onderzoek. Daarvan vielen 70 werknemers (8.6%) uit. De belangrijkste redenen om niet deel te nemen waren 'ik heb geen interesse', 'ik ben al onder behandeling bij een arts' en 'ik voel me gezond'. De belangrijkste reden om te stoppen was een gebrek aan motivatie. Daarnaast zijn verschillen tussen deelnemers en niet-deelnemers, en tussen uitvallers en niet-uitvallers bepaald door middel van statistische regressieanalyses. Deelnemers bleken gemiddeld bijna vier jaar ouder en hadden daardoor een iets hoger HVZ risico dan niet-deelnemers. Uitvallers waren bijna vijf jaar jonger dan deelnemers die niet uitvielen, en onder de uitvallers waren relatief meer rokers. Voor de interpretatie van onze eigen resultaten zijn deze bevindingen belangrijk, omdat we hierdoor weten dat de effecten van onze interventie niet gelden voor de hele doelgroep maar voornamelijk voor de wat oudere werknemers. Voor toekomstige studies is deze kennis belangrijk omdat men kan anticiperen op redenen om niet deel te nemen, bijvoorbeeld bij het bepalen van een wervingsstrategie.

Hoofdstuk 5 gaat over de uitvoering van de interventie en de mening van consulenten en deelnemers. Het aantal gesprekken dat de consulenten voerden en het aantal onderwerpen dat besproken werd, werd vastgesteld op basis van registratieformulieren. De kwaliteit van de gesprekstechniek werd bepaald door fragmenten van de gesprekken op te nemen en te coderen. De competentie van de consulenten werd bepaald door middel van vragenlijsten. Door middel van regressieanalyses werd de associatie tussen deze 'procesindicatoren' en een belangrijke uitkomstmaat, gewichtsverlies, bepaald. Tweederde van de deelnemers voerde vijf of meer gesprekken, en éénderde voerde alle zeven gesprekken. In meer dan 90% van de gevallen besprak de consulent alle verplichte onderwerpen. Slechts één op de 10 consulenten hield zich volledig aan alle regels van

motiverende gespreksvoering. Desalniettemin betitelde 86% van de deelnemers de consulent als competent. Geen van de procesindicatoren was significant geassocieerd met gewichtsverlies, al leek het erop dat werknemers die hun consulent als zeer competent beoordeelden ook het meeste succes hadden bij het afvallen. Uit de procesevaluatie concluderen we dat onze uitkomsten in de meeste gevallen het gevolg zijn van vijf gesprekken, met een matige kwaliteit van de voorgenomen gesprekstechniek. Voor toekomstige interventies raden we aan een langere training en feedback op de motiverende gespreksvoering te verzorgen.

In **hoofdstuk 6** zijn de effecten op leefstijl beschreven. Voor de analyses werden alleen de gegevens gebruikt van de 595 deelnemers die op alle meetmomenten de vragenlijst hadden ingevuld. Door middel van regressieanalyses, waarin werd gecorrigeerd voor de waarde van de uitkomstmaat op de nulmeting, werden de effecten bepaald. In de groep die had gekozen om voeding- en beweeggedrag te veranderen (tweederde van de totale studiepopulatie), werd in de analyses ook gecorrigeerd voor BMI. Na 6 maanden aten de werknemers in de interventiegroep in vergelijking met de controlegroep 2 snacks per week minder en 1.7 stuks fruit per week meer; beide statistisch significante effecten. Na 12 maanden was het effect op snacks nog steeds statistisch significant. Er was geen significant effect van de interventie op de tijd die besteed werd aan bewegen in de vrije tijd, maar er was wel een toename te zien ten opzichte van de nulmeting in zowel de controlegroep (1.5 uur per week meer beweging) als de interventiegroep (2.5 uur per week meer beweging). Van de deelnemers die zich hadden voorgenomen om te stoppen met roken was na 6 maanden in de interventiegroep 31.3% gestopt, tegenover 13.4% in de controle groep; een statistisch significant effect. Echter, na 12 maanden was een groot deel van de werknemers die gestopt waren teruggevallen. Met deze interventie kan dus een blijvend effect behaald worden op de consumptie van snacks. Er moet meer onderzoek gedaan worden naar hoe veranderd gedrag kan worden volgehouden op langere termijn.

In **hoofdstuk 7** werden de effecten op gewicht, BMI, bloeddruk, cholesterol en HbA1c beschreven. 517 deelnemers hadden alle drie de metingen ondergaan. Op de gegevens van deze groep werden regressieanalyses gedaan, waarin werd gecorrigeerd voor de waarde op de nulmeting. Van de deelnemers die zich specifiek hadden gericht op voeding en bewegen was het gemiddelde lichaamsgewicht op de nulmeting 93 kg. In deze groep werd een statistisch significant effect op lichaamsgewicht bereikt: na 12 maanden was de interventiegroep gemiddeld 1.4 kg afgevallen en de controlegroep was 0.8 kg aangekomen. Er was na 12 maanden ook een significant positief effect op HDL cholesterol en HbA1c. Echter, in een ‘longitudinale’ regressieanalyse, waarbij rekening werd gehouden met de verandering over de tijd, bleek dat de effecten op HDL cholesterol en HbA1c niet significant waren. De werknemers die obees (BMI≥ 30) waren op de nulmeting hadden het meeste baat bij de interventie. Bij deelnemers die hadden gericht op roken waren lichte verbeteringen te zien op cholesterol en bloeddruk, en zelfs op

lichaamsgewicht, maar er waren geen significante effecten van de interventie. Er kan met deze interventie dus een significant en blijvend effect op gewichtsverlies worden bereikt van 2 kg. Dit is een groter effect dan in de meeste vergelijkbare studies.

Voor **hoofdstuk 8** zijn een kosteneffectiviteit-analyse en een kostenbaten-analyse gedaan. Alleen de werknemers die zich hadden gericht op voeding en bewegen zijn hierin meegenomen. De kosteneffectiviteit analyse is gedaan vanuit een 'maatschappelijk' perspectief: alle kosten die mogelijk samenhangen met de interventie, waaronder kosten voor gezondheidszorg en verminderd ziekteverzuim, zijn hiervoor opgeteld en gedeeld door het interventie effect op gewichtsverlies. De kostenbaten-analyse is gedaan vanuit het perspectief van de werkgever, waarbij de kosten van de interventie zijn afgetrokken van de baten van verminderd ziekteverzuim. De interventie kostte gemiddeld €605 per persoon. Daarentegen waren de kosten voor het gebruik van gezondheidszorg iets (maar niet significant) lager in de interventiegroep dan in de controlegroep. Er was geen effect van de interventie op ziekteverzuim. We concludeerden dat de interventie effectiever maar ook duurder was dan de gebruikelijke zorg. Voor een extra kilo gewichtsverlies waren de totale maatschappelijke kosten gemiddeld €145. Pas als de maatschappij bereid is om €2,000 of meer te betalen voor een kilo gewichtsverlies, kan deze interventie als kosteneffectief beschouwd worden. De kosten voor de werkgever waren gemiddeld €254 voor iedere werknemer; dus de interventie was niet kostenbesparend. In vervolgstudies zouden het ziekteverzuim en de kosten op langere termijn gemeten moeten worden om een beter beeld te krijgen van de economische gevolgen van deze interventie.

In **hoofdstuk 9** vatten we de resultaten samen en bespraken we de sterkte en zwakke punten van het onderzoek. Ook benadrukten we het belang van de studie en deden we aanbevelingen voor onderzoek en praktijk. In conclusie, deze systematisch ontwikkelde, matig uitgevoerde, maar goed gewaardeerde interventie leidde tot blijvende verbeteringen in voeding en lichaamsgewicht. De resultaten gelden voor de iets oudere mannelijke werknemers in de bouwnijverheid met een verhoogd risico op hart- en vaatziekten. Een belangrijke bevinding was dat de effecten 6 maanden na afloop van de interventie nog aanwezig waren. Dat duidt erop dat de deelnemers structurele veranderingen hebben doorgevoerd in hun dagelijks leven; een voorwaarde voor verlaging van het risico op HVZ op de langere termijn. Na 12 maanden was de interventie effectiever maar ook duurder dan de gebruikelijke zorg. Desalniettemin, een interventie die leidt tot aanhoudende verbeteringen in leefstijl en gezondheid van werknemers is zeer relevant voor werkgevers en de maatschappij, omdat deze mogelijk bijdraagt aan duurzame inzetbaarheid; momenteel een speerpunt in onze vergrijzende populatie. We raden aan om de interventie te optimaliseren door onze suggesties ter verbetering ter harte te nemen, en vervolgens de interventie te implementeren binnen de bedrijfsgezondheids-zorg.

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ABOUT THE AUTHOR

Iris Frieda Groeneveld was born in Leiden, the Netherlands, on the 3rd of May 1980, as a daughter of Ymte Groeneveld and Henriëtte Groeneveld-Mennega. After graduating from the gymnasium at the Bonaventura College, in 1998, she moved to Amsterdam. She was fascinated by biology in general and the human body in particular, and therefore decided to study medical biology, at the VU University in Amsterdam. After finishing her internship and the department of experimental therapies at the Dutch Cancer Institute, she obtained her master's degree in 2002. She considered research on diseases on a molecular level interesting but not satisfying, and therefore she decided to study health sciences, again at the VU University. During her internship, she determined the nutritional status of school children in Quetzaltenango, Guatemala, at the Center for Studies of Sensory Impairment, Aging, and Metabolism (CESSIAM). There she became interested in nutrition, overweight, and the causes and consequences of an unhealthy lifestyle. She received her master's degree in 2005. Subsequently, in 2006, she started a PhD project at the EMGO+ Institute for Health and Care Research of the VU Medical Center in Amsterdam, at the department of Public and Occupational Health, under the supervision of Karin Proper, Allard van der Beek, and Willem van Mechelen. Between 2006 and 2010, she developed and evaluated a lifestyle intervention for workers in the construction industry at risk for cardiovascular disease. Meanwhile, she completed the master course on epidemiology at the EMGO+ Institute. After finishing her PhD thesis, she worked at the Universidad Europea, department of Physiology, in Madrid, exploring physical activity and quality of life of children with cystic fibrosis. From Januari 2011, she will be employed at the Coronel Institute of Occupational Health/ Academic Medical Center, University of Amsterdam, investigating methods to facilitate return-to-work among cancer survivors. She strives to continue working as a researcher.

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