Karin Proper

Effectiveness of worksite physical activity counseling

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VRIJE UNIVERSITEIT

Effectiveness of worksite physical activity counseling

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Vrije Universiteit Amsterdam, op gezag van de rector magnificus prof.dr. T. Sminia, in het openbaar te verdedigen ten overstaan van de promotiecommissie van de faculteit der Geneeskunde op woensdag 29 oktober 2003 om 15.45 uur in de aula van de universiteit, De Boelelaan 1105

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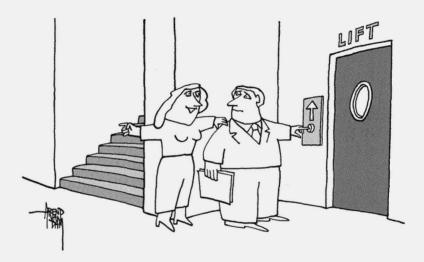
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Section 1

Introduction



Chapter 1

Introduction

A good health is an essential condition for a good performance of daily life activities. Human health is determined by biological factors that can not be influenced (i.e., genetics), and factors that are modifiable, such as lifestyle and environmental factors. As the latter, and in particular lifestyle, is controlled by the individual himself, one can partly control one's own health status. Consequently, the individual can reduce the risk for many chronic diseases himself.

Human lifestyle has changed considerably since pre-historic times. For example, men used to hunt and fish in order to survive, and thereby men were physically active at a high level of intensity. However, due to mechanization and automation, men became more and more physically inactive. In addition, the dietary habits have changed over time, which may be due to women's liberation. Currently, many women work outside the home and thereby have less time for doing the housekeeping and quickly scramble up a meal or visit a fast food restaurant, whereas they used to take the time to do the cooking.

Since lifestyle has changed over time, exposure to some important health-related risk factors has also changed over time. Lifestyle factors that play an important health-related role are physical activity, smoking, alcohol, and nutrition. This thesis will mainly focus on physical activity.

Physical activity: trends and consequences

Currently, the negative health impact of physical inactivity is no longer under debate. People who are physically inactive have a higher risk for many chronic diseases, such as cardiovascular disease,^{1,2} coronary heart disease,^{3,4} non-insulin-dependent diabetes mellitus,^{5,6} depression,⁷ and some types of cancer.⁸⁻¹⁰ Despite these negative health consequences, 55% of the Dutch population and 60% of the U.S. adults does not meet the recommended levels of moderate intensity physical activity (i.e., at least 30 minutes of moderate intensity physical activity recommendation (i.e., at least 20 minutes of vigorous intensity activities, at least 3 days per week).¹³⁻¹⁴

Closely related to physical inactivity is overweight, since weight gain is the result of a positive energy balance, i.e., energy intake (through food intake) exceeds energy expenditure (through physical activity). Continuous weight gain will in the short- or long-term lead to overweight ($25.0 \le BMI < 30.0 \text{ kg.m}^{-2}$) or even to severe overweight, i.e., obesity (BMI $\ge 30.0 \text{ kg.m}^{-2}$) which has serious health-related consequences, such as some cancers and cardiovascular diseases.¹⁵⁻¹⁶ The prevalence of (severe) overweight has been increasing dramatically throughout the world's population during the last few decades. In the Netherlands, the prevalence of overweight increased from 35% to 44% from 1990 to 2000.¹⁷ For obesity, the prevalence increased from 6% to 9%.^{17,18} In the U.S., during the last decade, the prevalence of overweight increased from 33% to 37%.¹⁹ For obesity, this increase was from 12% to 20%.¹⁹ Next to the individual health consequences, physical inactivity and obesity have major economic implications for society. In 1995, the direct costs of a lack of physical activity and obesity in the U.S. were 2.4% and 7%, respectively of the U.S. health care expenditures.²⁰ In West Europe, obesity-related costs have been estimated at 1-5% of the total health care expenditure.^{21,22} As to the implications for business, in the

U.K., it has been estimated that obesity and its consequences accounted for 18 million days of sickness absence in 1998, of which 418,000 days were directly attributable to obesity.²³ Thus, effective interventions are needed to optimize the balance between energy intake and expenditure. As low levels of physical activity seem to play a more dominant role in the development of obesity during the past decades compared to the energy intake,²⁴ interventions with the aim to increase physical activity levels is of particular relevance.

Intervention settings

The settings in which physical activity interventions are carried out, differ widely. For example, some settings such as schools and the workplace have particular relevance to different stages of life, whereas others are defined with reference to populations, such as people with a low socioeconomic status.²⁵ Below, only a limited number of the large array of settings for physical activity interventions will be described.

As physical inactivity in youth is an important public health concern, school settings are considered to be an effective infrastructure for promoting physical activity. In countries with a compulsory education law, all children and young people spend a large proportion of the day at school. Thus, the advantage of schools for physical activity promotion is that they provide direct access to almost the whole population of children.²⁵ From the viewpoint of the increasing prevalence of childhood obesity, interventions aimed at physical activity are recommended. A number of school-based physical activity interventions has shown encouraging results as to the prevention of obesity.²⁶

The primary health care setting is another setting for promoting physical activity. The general practitioner has a relatively high degree of contact with the general population, which makes it easier to influence the health-related behavior.²⁷ In 2000, the average number of visits to the general practitioner among the Dutch population was 4.1 per year, and of those who had once visited the general practitioner, the average number of visits was 5.5 per year.²⁸ Although physicians generally believe that most patients should benefit from increased levels of physical activity, they counsel their patients much less often about physical activity than about other risk behaviors, such as smoking.²⁹ Most cited reasons for this are time, reimbursement, perceived effectiveness, unclear exercise recommendations, and lack of training in behavioral counseling.³⁰ Nevertheless, some physical activity interventions have been introduced in the primary care setting, which have proved to be feasible and effective.^{31,32}

Further, during leisure time, people can visit a sports club, visit a park or other type of recreational area, which offer possibilities for physical activity. The environment has shown to be an important setting for performing physical activities. Several studies have provided evidence that the environment is an important determinant of physical activity.³³⁻³⁵ Changes in neighborhood structures and policies aimed at improving health-related behaviors, are therefore assumed to be promising.

Finally, worksites are convenient settings for physical activity promotion programs. The majority of adults spend a large proportion of their waking time at work.³⁶ The worksite thus provides the potential to reach a high percentage of the total adult population. In addition, it has been shown that, in 1996, 51% of the Dutch workers in the industry,

wholesale business, and services sit for a long time and 41% stand for a long time indicating that work is often associated with physical inactivity, which calls for compensation.³⁷

In the last few decades, companies in Western countries have increasingly become aware of the advantages of implementing health promotion, or specifically, physical activity interventions and have offered more often such interventions to their employees than before.³⁸ A survey in 1999 in the Netherlands has shown that more than a quarter of the employers conduct a health promotion policy, of which 18% is focused on improving physical activity.³⁹ There are several types of worksite interventions aimed at improving physical activity. For example, interventions can be divided according to the target group (e.g., all employees willing to participate versus those having health complaints), or the content (e.g., a (un)supervised fitness program with facilities in or outside the company, or an educational program). In addition, interventions can be group-based, like the more 'classical' fitness programs, or individual-based. In recent years, these individual-based programs have received increased attention because they are supposed to better meet the specific needs of the employee and thus have a greater potential. They are often based on theoretical models on changing behavior.

Theoretical models on changing behavior

The crucial question is how the (working) population can be stimulated to improve their physical activity behavior. Insight in the determinants of both the current physical activity behavior (why are people (in)active?) and the physical activity change (how do people become (in)active?) is relevant.

Several social psychological models exist for explaining behavior. Examples of determinant models that have been applied to several health-related behaviors are the Theory of Reasoned Action (TRA),^{40,41} the Social Cognitive Theory (SCT),⁴² the Theory of Planned Behavior (TPB), which is a more sophisticated revision of the TRA, and the Attitude - Social influence - self-Efficacy (ASE) model.^{43,44} According to the SCT, behavior is mostly determined by the expectations about the behavior concerned. According the TPB, behavior is best predicted by the intention to perform the behavior. The ASE model, which was derived from the TRA and the SCT, also states that behavior is determined by the intention to perform the behavior is determined by the intention to perform the behavior is determined by the intention to perform the behavior is determined by the intention to perform the behavior is determined by the intention to perform the behavior is determined by the intention to perform the behavior is determined by the intention to perform the behavior. The ASE model, which was derived from the transmittened by three factors: attitude, social influence and self-efficacy.

During the last few years, the TransTheoretical Model (TTM) has become popular.⁴⁵⁻⁴⁷ The TTM provides theoretical insights for explaining how and when people make their behavior changes over time. An important concept in the TTM is the 'stages of change' construct, suggesting that individuals attempting to change their behavior move through a series of stages. The following stages are distinguished: 1. precontemplation (not intending to change behavior), 2. contemplation (considering to change behavior), 3. preparation (making small changes in behavior), 4. action (actively engaging in behavior change), and 5. maintenance (sustaining the behavior change over time). People can progress to the next stage (e.g., moving from contemplation to preparation), but they can also regress to an earlier stage. An implication of the TTM is that people in different stages need different approaches in order to change their behavior. Thus, dependent on the stage of change, an

intervention should address different determinants to motivate the person to progress to the next stage. An example of an intervention based on the TTM is the Patient-centered Assessment and Counseling for Exercise and Nutrition (PACE) program.^{30,49} Using PACE materials, a counselor can address specifically those processes that help the individual to progress to the next stage, given his/her specific situation. Currently, PACE materials are available for the promotion of physical activity and healthful dietary habits. For physical activity, the PACE program has shown to be a feasible intervention.³² Moreover, it has shown short-term effectiveness on moderate intensity physical activity in a U.S. primary care setting.³¹ To our knowledge, no studies have been published to the effectiveness of the PACE program in the worksite setting.

Integrated model

Figure 1 presents an integration of the determinants and the stages of change of physical activity behavior, and a model describing the relationships between physical activity, fitness, and health.⁴⁹ This integrated model explains the relationships between the variables studied in this thesis.

The left part of the model indicates a reciprocal relationship between determinants of physical activity and the stage of change, showing that there is a direct influence of determinants on the stage of change and indicating that determinants differ per stage of change. Counseling subjects about physical activity, which concerns the main intervention under study in this thesis, can have a direct influence on the stage of change, but can also influence the determinants, which will probably lead to an improvement in the stage of change. Another component that can influence the stage of change either directly or indirectly (through a change in the determinants) concerns feedback. Feedback can involve both the own fitness/health status, and the actual performance of the physical activity behavior. It is assumed that small 'interventions' such as fitness- and health screenings, and the personalized feedback on test results as such, already produces an awareness of one's own behavior, and thereby can affect the determinants or the stage of change. For example, people might have a wrong idea about their own fitness or health profile, and as a consequence they think they do not have to change their physical activity behavior. The actual performance of physical activity can lead to a change in the determinants, such as attitude or self-efficacy of physical activity. If the feedback or the counseling is effective, the physical activity level can be improved. According to the model of Bouchard et al.49 (the middle part of the integrated model), an improved level of physical activity subsequently can lead to improved health-related fitness and improved health status. The right part of the model suggests that improved employee's health might also be beneficial for the company. If so, that is, if improved health will lead to less sick leave, for example, employers may benefit economically from their investment in worksite physical activity interventions.

Aim and outline of this thesis

The aim of this thesis is to describe the effectiveness of a particular worksite physical activity intervention involving individual counseling of workers using the PACE materials.

Section 2 "Effectiveness of worksite physical activity programs: Literature search", reviews the existing evidence of worksite physical activity programs on both individual (Chapter 2.1) and work-related (Chapter 2.2) outcome measures. Both reviews summarize the existing literature as to the effectiveness of worksite physical activity programs published from 1980 to 2000. Conclusions drawn in both reviews were based on a best evidence synthesis.

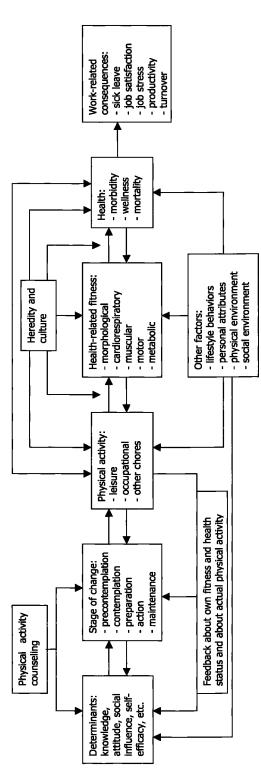
Section 3 "Effectiveness of feedback", describes the influence of personalized feedback on one's own fitness and health profile, after a battery of fitness- and health tests and a screening of the self-reported appraisal of stage of change.

Section 4 "Effectiveness of worksite physical activity counseling", describes the results of a randomized controlled trial (RCT) evaluating a physical activity counseling intervention in the worksite setting. Chapter 4.1 describes the effectiveness of the intervention on physical activity, fitness and health. Chapter 4.2 describes the effectiveness on sick leave. Chapter 4.3 presents the results of the cost-benefit and cost-effectiveness analysis that has been performed in order to conclude whether a company benefits from implementing an individual counseling program. Finally, Chapter 4.4 compares different statistical analyses using the same set of data as in Chapter 4.1.

Section 5 "Discussion and conclusions", addresses some practical and methodological issues as to worksite physical activity promotion (Chapter 5.1). After, the conclusions and recommendations for future research and practice of this thesis will be formulated (Chapter 5.2).



(1994) describing the relation between the physical activity counseling intervention concerned, the determinants of physical activity, the stages Figure 1. Model integrating determinants of physical activity behavior, the stages of physical activity change, and the model of Bouchard et al. of change regarding physical activity, the relation between physical activity and health, and probable (work-related) consequences.



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Section 2

Effectiveness of worksite physical activity programs: Literature search



Chapter 2.1

The effectiveness of worksite physical activity programs on physical activity, fitness, and health

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Abstract

Objective: To critically review the literature with respect to the effectiveness of worksite physical activity programs on physical activity, physical fitness, and health.

Data Sources: A search for relevant English-written papers published between 1980 and 2000 was conducted using MEDLINE, EMBASE, Sportdiscus, CINAHL, and Psychlit. The key words used involved a combination of concepts regarding type of study, study population, intervention, and outcome measure. In addition, a search was performed in our personal databases, as well as a reference search of the studies retrieved.

Study Selection: The following criteria for inclusion were used: 1) randomized, controlled trial or nonrandomized, controlled trial; 2) working population; 3) worksite intervention program to promote employees' physical activity or physical fitness; and 4) physical activity, physical fitness, or health-related outcomes.

Data Extraction: Two reviewers independently evaluated the quality of relevant studies using a predefined set of nine methodological criteria. Conclusions regarding the effectiveness of a worksite physical activity programs were based on a rating system consisting of five levels of evidence.

Data Synthesis: Fifteen randomized, controlled trials and 11 nonrandomized, controlled trials met the criteria for inclusion and were reviewed. Six randomized, controlled trials and none of the nonrandomized, controlled trials were of high methodological quality. Strong evidence was found for a positive effect of a worksite physical activity program on physical activity and musculoskeletal disorders. Limited evidence was found for a positive effect on fatigue. For physical fitness, general health, blood serum lipids, and blood pressure, inconclusive or no evidence was found for a positive effect.

Conclusions: To increase the level of physical activity and to reduce the risk of musculoskeletal disorders, we support implementation of worksite physical activity programs. For the other outcome measures, scientific evidence of the effectiveness of such a program is still limited or inconclusive, which is mainly the result of the small number of high-quality trials. Therefore, we recommend performing more randomized, controlled trials of high methodological quality, taking into account criteria such as randomization, blinding, and compliance.

The positive associations between physical activity and health are no longer subject to debate. People who are physically active at a sufficient level obtain a wide array of physical and mental health benefits compared with those who are not active.¹⁻⁸ However, because the majority of adults in developed countries are not physically active to a satisfactory degree, promoting physical activity is of great relevance.^{2,9-12} Based on the fact that most adults spend about eight hours a day at their workplace, offering physical activity programs at the workplace can be an efficient way to enhance adults' levels of activity. In the past few decades, programs aimed at increasing employees' physical activity or fitness have become popular in a wide variety of work settings.^{13,14} In the last 20 years, many studies were performed regarding the effectiveness of programs enhancing workers' physical activity or fitness levels.¹⁵⁻²⁶ Also, some reviews were conducted addressing the effectiveness of such programs.^{13,27-30} However, no systematic review on the effectiveness of worksite physical activity programs (WPAPs) on health-related benefits has been performed, with the exception of the meta-analysis by Dishman et al.¹³ Dishman et al.¹³ conducted a quantitative synthesis of the literature and concluded that WPAPs have a small, nonsignificant positive effect on physical activity or fitness.¹³ However, no other health-related components were evaluated in that review. The purpose of the present review is to systematically assess the effectiveness of WPAPs on physical activity, physical fitness, and health.

Methods

Study selection

The following three steps were taken to identify relevant studies published in the English language between 1980 and 2000: 1) a computerized search of MEDLINE, EMBASE, Sportdiscus, CINAHL, and Psychit; 2) a reference search of studies retrieved; and 3) a search in our personal databases. Table 1 presents the search strategy used. A study was included if 1) the study was a randomized, controlled trial (RCT) or a nonrandomized, controlled trial (NCT); 2) the study population involved a healthy working population; 3) the intervention was a worksite program aimed at enhancing levels of physical activity, exercise, and/or fitness; and 4) the outcome measure included physical activity, health-related fitness, or health.

Databases (hits)	Key words used
MEDLINE (n=266)	(intervention or evaluation or randomis* or randomiz* or control*
EMBASE (n=89)	or effect) and (workplace or worksite or work site or working place
Sportdiscus (n=263)	or worker or occupation or employer or employee or corporate or
CINAHL (n=44)	company or business or industry or industrial) and ((exercise or
Psychlit (n=75)	fitness or physical activity or sport) and (program or program)) and (physical activity or fitness or health or musculoskeletal or back or neck or shoulder or elbow or wrist or knee or upper extremity or lower extremity)
Personal databases	
(n=35)	
Limits	01/01/1980 to 26/05/2000; English language; human

 Table 1. Search strategy (databases, hits per database and keywords) used for literature search

Methodological quality and best evidence synthesis

Two reviewers (K.I.P. and M.K.) independently evaluated the methodological quality of the studies by using a criteria list based on the list of the Cochrane Collaboration Back Review Group.³¹ An item was scored positive in case of a satisfactory description and the use of adequate methods. Disagreements between the two reviewers were discussed during a meeting to achieve consensus. If they could not reach agreement, a third reviewer (A.J.B.) was consulted to achieve final judgment. To draw conclusions regarding the effectiveness, a rating system consisting of five levels of evidence (i.e., strong, moderate, limited, inconclusive, or no evidence) was applied, which was derived from several existing best evidence syntheses.^{30,32,33} For the description of the methodological quality criteria and the best evidence synthesis, we refer to Proper et al.,³⁰ who performed a systematic review of the effectiveness of WPAPs on work-related outcomes. Studies were considered to be of (relatively) high quality if more than 50% of the methodological criteria were scored positively. A WPAP was considered to have a positive effect in case of statistically significant results or a relevant effect size (i.e., ≥20% difference between study groups). By taking a relevant effect size into account next to statistical significance, the problem of a lack of statistical significant results due to a lack of statistical power is overcome. By categorizing studies according to a level of evidence, a hierarchical order of design and quality of the studies was created to draw conclusions as to the effectiveness of a WPAP on each outcome measure. For example, in case of two or more high-quality RCTs, conclusions were based on these RCTs only, leading to a conclusion of 'strong evidence' in case of consistent results or leading to 'inconclusive evidence' in case of inconsistent results, regardless of the results of any other study. However, in the case of only one or no high-quality RCTs, the conclusion of 'strong evidence' was not possible, and the conclusion had to be drawn on the basis of this single high quality RCT, eventually in combination with the results of available low-quality RCTs.

Results

Selected studies

The search identified a total of 772 publications. After reading the title or abstract, 693 publications were excluded. Common reasons for exclusion were the lack of comparison groups, the lack of relevant outcome measures, or an intervention not having its main focus on physical activity or fitness. In addition, 50 publications were excluded for not having met one of the inclusion criteria or because they could not be retrieved. Finally, 29 publications concerning 26 studies were selected, 15-26, 34-50 Tables 2 and 3 present characteristics of the relevant RCTs (n=15) and NCTs (n=11), respectively. Initially, the two reviewers disagreed on the methodological quality of 30 of the 223 items (13%). Cohen's κ was 0.72. Disagreement was mainly due to differences in the interpretation of the definition of the methodological quality items and to reading errors. As the two reviewers could reach complete agreement after a discussion session, the third reviewer was not consulted. Table 4 shows the methodological quality score of the studies reviewed. In general, the quality of the studies was poor: six RCTs were of high guality^{15,16,24,26,38,39} and none of the NCTs was of high quality. Common methodological limitations of the studies included a poor description of the randomization procedure or an inadequate randomization procedure, inappropriate blinding of the outcome assessor, and/or the absence of an analysis according to the intention-to-treat principle. For the NCTs, either the description or the rate of compliance with the program was also insufficient.

Effectiveness of worksite physical activity programs

The studies evaluated the effectiveness of a WPAP on at least one of the following outcome measures: physical activity, physical fitness, or health. Physical fitness was defined as health-related fitness, including cardiorespiratory fitness, muscle flexibility, muscle strength, and body weight and body composition. The health components evaluated were general health, fatigue, musculoskeletal disorders, blood pressure, and blood serum lipids (Table 5). Because the description and the outcomes of each study are given in Tables 2 or 3, we will focus only on the results of (high-quality) RCTs because they have more weight in the final conclusion regarding the effectiveness of WPAPs.

Physical activity

Five RCTs^{18,23,24,26,34} of which two were of high quality^{24,26} and three NCTs^{35,46,50} were identified. The first high-quality RCT²⁴ evaluated the effect of the WPAP at both the midpoint and at the end of the intervention and reported that participants had significantly increased their exercise behavior compared with the reference condition. The other high-quality RCT²⁶ showed a greater increase of energy expenditure in the intervention group compared with the reference and the diet group. Conclusion: there is strong evidence.

Study	Α	В	С	D	Ε	F	G	Н	I	Total
							_			score
RCTs		-					_			
Gerdle et al. ³⁸	-	+	+	+	-	+	-	+	+	6
Grønningäter et al. ¹⁵	-	+	+	+	-	+	-	+	+	6
Emmons et al. ²⁴	+	+	+	-	-	-	-	+	+	5
Gundewall et al. ³⁹	+	+	-	+	-	-	-	+	+	5
Kerr and Vos ¹⁶	+	-	-	+	-	+	-	+	+	5
Pritchard et al. ²⁶	-	+	-	+	-	+	-	+	+	5
Lee and White ²³	-	+	-	-	-	+	-	+	+	4
Halfon et al., ⁴⁰ Rosenfeld										
et al., ¹⁸ Ruskin et al. ⁴⁸	-	-	-	+	-	+	-	+	+	4
Härmä et al. ⁴²	-	+	+	-	-	+	-	+	-	4
Hilyer et al.44	-	+	-	+	-	-	-	+	+	4
Oja et al.45	-	+	-	+	-	+	-	+	-	4
Gamble et al. ²²	-	+	-	-	-	+	-	+	-	3
Grandjean et al. ²⁵	-	-	+	-	-	-	-	+	+	3
Oden et al. ¹⁷	-	+	-	-	-	-	-	+	-	2
Bassey et al. ³⁴	-	-	-	-	-	-	-	-	-	0
NCTs										
Skargren and Öberg ¹⁹	na	+	+	+	-	-	-	+	-	4
Wier et al. ⁵⁰	na	+	-	-	-	+	-	+	+	4
Blair et al. ³⁵	na	+	-	-	-	-	-	+	+	3
Cox et al., ²⁰ Shephard	na	-	-	+	-	-	-	+	+	3
and Cox ⁴⁹										
Fisher and Fisher ³⁶	na	+	-	-	-	-	-	+	-	2
Hartig and Henderson ⁴³	na	-	-	+	-	-	-	+	-	2
Genaidy et al. ³⁷	na	-	-	-	-	-	-	+	-	1
, Harrell et al. ⁴¹	na	+	-	-	-	-	-	-	-	1
Norris et al. ²¹	na	-	-	-	-	-	-	+	-	1
Ostwald ⁴⁶	na	-	-	+	-	-	-	-	-	1
Pavett et al.47	na	-	-	-	-	-	-	+	-	1

Table 4. Methodological quality of the randomized, controlled trials and the nonrandomized, controlled trials in terms of the effectiveness of worksite physical activity programs on physical activity, fitness and health (see Proper et al.³⁰ for description of criteria)

A, randomization procedure; B, similarity of study groups at baseline; C, eligibility criteria; D, drop-out rate; E, blinding of outcome assessor; F, compliance; G, intention-to-treat analysis; H, comparability of outcome assessment; I, follow-up measurement; na, not applicable; RCT, randomized, controlled trial; NCT, nonrandomized, controlled trial.

Cardiorespiratory fitness

Three high-quality RCTs,^{15,16,38} seven RCTs of low quality,^{17,23,25,34,42,45,48} and six NCTs,^{19,20,21,35,41,49,50} were identified. Of the high-quality RCTs, two^{15,16} showed a positive effect. Grønningsäter et al.¹⁵ showed a significantly greater increase in maximum oxygen consumption among the intervention group compared with the reference group. Kerr and Vos¹⁶ found significant differences in perceived fitness in favor of the intervention group. However, the remaining high-quality RCT³⁸ did not confirm these positive findings: no change in maximum oxygen consumption was seen for both study groups. Conclusion: there is inconclusive evidence.

Muscle flexibility

Four RCTs, all of low quality,^{22,23,44,48} and four NCTs^{20,37,41,43} were identified. Results of the RCTs were inconsistent. Hilyer et al.⁴⁴ showed a significant positive effect of the intervention on lower back and hamstring flexibility. In addition, Lee and White²³ showed relevant effect sizes in favor of the reference group at each posttest. The remaining RCTs^{22,48} did not find an effect on muscle flexibility. Conclusion: there is inconclusive evidence.

Muscle strength

One high-quality RCT,³⁹ three low-quality RCTs,^{22,42,48} and four NCTs^{19,20,37,41} were identified. The high-quality RCT³⁹ reported significantly increased muscle strength in the training group compared with the reference group. Of the low-quality RCTs, one⁴² showed a significant effect on abdominal muscle strength. Although Gamble et al.²² found significant changes in the experimental group, no significant differences between the intervention and reference group were found. In addition, Ruskin et al.⁴⁸ reported no effect of their physical activity program on handgrip strength. Conclusion: there is inconclusive evidence.

Body weight and body composition

Six RCTs,^{15,22,25,26,38,45} three of which were of high quality,^{15,26,38} and four NCTs^{20,36,46,49,50} evaluated the effectiveness on body weight. Two high-quality RCTs^{15,38} did not find an effect of the program on body weight, whereas Pritchard et al.²⁶ found a significant difference between groups in change of body weight. With the exception of the study of Grandjean et al.,²⁵ the remaining low-quality RCTs^{22,45} did not find an effect on body weight. Conclusion: there is inconclusive evidence.

Body composition was defined as the percentage of body fat and/or body mass index. One high-quality RCT,²⁶ five low-quality RCTs^{17,22,23,25,42} and four NCTs^{20,36,41,49,50} were identified evaluating body composition. Pritchard et al.²⁶ found significant changes in body mass index and total fat mass in favor of both the diet and the exercise group. Oden et al.¹⁷ reported a significant favorable effect of the exercise program, whereas no effect was found in the remaining four trials.^{22,23,25,42} Conclusion: there is inconclusive evidence.

General health

Three high-quality RCTs,^{15,16,38} one low-quality RCT,⁴² and three NCTs^{19,21,47} were identified. Although Grønningsäter et al.¹⁵ found a nonsignificant tendency toward a reduction in general health complaints in the intervention group compared with the reference group, effect sizes between the groups appeared to be relevant. In contrast, the remaining two high-quality RCTs showed no influence of the intervention on general health.^{16,38} Conclusion: there is inconclusive evidence.

Fatigue

Two RCTs, both of low quality,^{40,42} were identified. Härmä et al.⁴² showed relevant effect sizes in fatigue between the study groups. In addition, Halfon et al.⁴⁰ reported a significantly greater increase of mental and physical fatigue in the reference group compared with the intervention group. Conclusion: there is limited evidence.

Musculoskeletal disorders

Five RCTs^{15,38,39,42,44} and two NCTs^{19,43} were identified. Three RCTs were of high quality.^{15,38,39} Although Gerdle et al.³⁸ could not find statistically significant changes in prevalence or intensity of musculoskeletal complaints, effect sizes between the two groups in prevalence of low back pain were considered to be relevant. Grønningsäter et al.¹⁵ found a significant effect of the exercise intervention on both neck and back pain. Finally, Gundewall et al.³⁹ also observed a positive effect of the intervention on back pain. Conclusion: there is strong evidence.

Blood serum lipids

Four RCTs,^{15,23,25,45} one of them of high quality,¹⁵ and three NCTs^{36,46,50} were identified. None of the RCTs found either significant or relevant effect sizes in serum lipids between the study groups. Conclusion: there is no evidence.

Blood pressure

One RCT of high quality,¹⁵ one RCT of low quality,²³ and three NCTs^{21,36,46} were identified. Grønningsäter et al.¹⁵ showed no significant changes in systolic blood pressure. In addition, with the exception of a significant change in systolic blood pressure in favor of the exercise group after 24 weeks, the study of Lee and White²³ showed no significant changes in diastolic or systolic blood pressure between pretest and any of the follow-up measurements (12, 24, and 48 weeks). Conclusion: there is no evidence.

Outcome measure	Positive	No effect	Negative	Conclusion
(number of studies identified)	effect		effect	
Physical activity (n=8)	18, 24, 26,	23, 34, 46	-	strong evidence
	35, 50			
Cardiorespiratory fitness	15, 16, 17,	19, 23, 34,	-	inconclusive
(n≈16)	20/49, 21, 23,	38 , 42, 48		evidence
	25, 35, 41, 42,			
	45, 50			
Muscle flexibility (n=8)	20, 37, 41, 43,	22, 48	23	inconclusive
	44			evidence
Muscle strength (n=8)	19, 20, 37, 39 ,	22, 41, 48	-	inconclusive
	41, 42			evidence
Body weight (n=10)	25, 26 , 36, 46,	15 , 20/49,	-	inconclusive
	50	22, 38 , 45		evidence
Body composition (n=10)	17, 26 , 20/49,	22, 23, 25,	_ ·	inconclusive
	41, 50	36, 42		evidence
General health (n=7)	15 , 21	16 , 19, 38 ,	-	inconclusive
-		42, 47		evidence
Fatigue (n=2)	40, 42	-	-	limited evidence
Musculoskeletal disorders	15, 38, 39,	19, 44		strong evidence
(n≈7)	42, 43			
Blood serum lipids (n=7)	36, 50	15 , 23, 25,	-	no evidence
		36, 45, 46		
Blood pressure (n=5)	21	15 , 23, 36,	-	no evidence
		46		

Table 5. Studies demonstrating a positive, no effect, or a negative effect of the worksite physical activity program per outcome measure

Numbers listed refer to the reference numbers. High quality randomized, controlled trials are indicated by boldface type.

Discussion

Effectiveness

The purpose of this review was to draw conclusions regarding the effectiveness of WPAPs on physical activity, physical fitness, and health. Our results indicate that the primary goal of such programs (i.e., enhancing general physical activity levels) is achieved. According to the model of Bouchard et al.,⁷ which describes the relationship between physical activity, fitness, and health, one would expect that this enhancement of physical activity would result in an improvement of cardiorespiratory fitness. However, no such evidence was found. One plausible explanation might be the fact that enhancement of cardiorespiratory fitness requires quite intensive physical activity (at least three times a week at 40 or 50 to 85% of maximum oxygen uptake reserve for at least 20 minutes),⁵¹ and it is likely that participants in WPAPs do not reach this frequency, intensity, and duration. Unfortunately, adherence to the programs was generally poorly reported in the studies, which made it impossible to verify this assumption.

Compared with the literature, our conclusions do not seem to be in line with those drawn by Dishman et al.,¹³ who concluded that WPAPs have a small, nonsignificant effect on physical activity. However, differences in conclusions are, in our opinion, the result of the different methods used for reviewing. For example, Dishman et al.¹³ performed a quantitative analysis, taking into account the methodological quality of the studies included, whereas we used a qualitative method. Also, the criteria used by Dishman et al.¹³ to evaluate the methodological quality of the studies were different from ours. Moreover, the types of interventions evaluated in the Dishman et al.¹³ review differed somewhat from those evaluated in the present review. In the present review, only worksite interventions with a primary focus on stimulating the level of physical activity or fitness were included, whereas Dishman et al.¹³ included programs with a more comprehensive training regimen as well. Thus, the methods used are of relevance in interpreting the conclusions.

Another important finding of this review is the strong evidence for the effectiveness of WPAPs on reducing musculoskeletal disorders. The literature regarding the associations between physical activity, physical fitness, and low back pain, for example, shows contradictory results. Videman et al.^{52,53} reported that physical activity seems to have a dual role, imposing a positive and negative influence on the spine. In addition, a recent review of epidemiological literature on the relationship between physical activity and musculoskeletal morbidity showed inconsistent results,⁵⁴ leaving the question of whether the promotion of physical activity could be an attractive additional preventive strategy in reducing musculoskeletal morbidity at the workplace unanswered. Although it is unclear how the structural changes and (musculoskeletal) symptoms are related,⁵⁵ this review indicates that the implementation of a WPAP may be a promising component of a strategy aimed at reducing or preventing musculoskeletal disorders.

With the exception of fatigue, we found no (conclusive) evidence that a WPAP has positive effects on other health-related outcomes. With respect to body weight or body composition, our findings seem to be in contrast with the pertinent literature.⁵⁶⁻⁵⁸ This contradiction may be explained by the fact that the populations in the studies we reviewed were generally

healthy, non-obese employees; therefore, benefits on body weight or body composition would presumably be small. Another plausible explanation for this contradiction can be attributed to the significant increases in physical activity due to WPAPs not being of sufficient magnitude to affect body weight and body composition.

Methodological quality of the studies

This review shows that the majority of the studies on the effectiveness of WPAPs had methodological shortcomings. Major problems included the lack of a sufficient description of the randomization procedure, blinding of the person performing the measurements, and absence of an intention-to-treat analysis. As several studies have provided empirical evidence that trials with inadequate methodological approaches or incomplete descriptions of procedures, particularly concerning concealment of treatment allocation and blinding, are associated with bias, 59-61 future investigators should pay attention to these aspects. Finally, it is worth mentioning that almost all of the studies applied self-reported data for the measurement of physical activity and health outcomes and therefore lacked the use of objective, more valid measures. If more objective instruments had been used, results regarding the effectiveness might have been different. However, because there was only one study³⁴ that applied an objective physical activity measure, we were not able to investigate a possible influence of such measure. Finally, particularly among the NCTs, the description of, or the rate of compliance with, the program was insufficient. In cases in which there was a lower compliance rate with the program than was prescribed, an underestimation of the results might have occurred. Thus, both from the employee's and the researcher's perspective, adherence to the intervention should be supported.

Conclusion

There is strong evidence for a positive effect of a WPAP on physical activity and musculoskeletal disorders, limited evidence for a positive effect on fatigue, and inconclusive or no evidence for a positive effect on cardiorespiratory fitness, muscle flexibility, muscle strength, body weight, body composition, general health, blood serum lipids, and blood pressure. The methodological quality of most studies evaluating the effectiveness of WPAPs is generally poor. Future studies should pay attention to the description and performance of the randomization, blinding of the outcome assessor, compliance, and intention-to-treat analysis.

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Table 2. Cha	Characteristics of the rai	Inni IIzen, wi	זרו הוובת הומוז ווו הרוווה ה		IIIYSICAI ALUVILY, I	ומורמה מווא ווכמומי
		Post-test/ follow-up	Study population; number used for analysis	Outcome measures and method of measurement	Adherence	Results
Emmons et al. ²⁴ (M=5)	 individually focused activities (2.5 years) reference: self- help programs on smoking cessation, nutrition and physical activity 	1.25 and 2.5 years	1.25 and 2.5 8762? (26 worksites of approximately 337) manufacturing workers; 2,055 included in analysis	1. physical activity: self- ? reported participation in regular exercise	₽.	significant effect [increase of 10.4% (interim) and 11.9% (end) (I) versus 2.4% and 1.7% (R)]
Gundewall et al.³ (M=5)	 back muscle strength, endurance and coordination exercises (13 months; 2-6 times per week, 20 min) 2. reference: no intervention 	13 months	78 nurses and nursing aides (1 man); 60 included in analysis	 strength: spring balance MSD: graphic rating scale for low back pain 	~	significant effects [strength: change of 20% (I) versus 10% (R)]
Pritchard et al. ²⁶ (M=5)	 exercise program: 12 months moderate, unsupervised aerobic exercise, diet unchanged (12 months, 3 times per week, 30 min) 2. diet program: reduction of dietary fat, activity unchanged 	12 months	66 workers from a business corporation; 58 included in analysis	 physical activity: energy expenditure (kcal) estimated from 3-day activity diaries body weight body composition: BMI and energy X-ray absorptiometry 	between 3 and 7 sessions per week	significant effects [energy expenditure: change of +14.6% (I) versus 6.5% (R); weight: -3.0% (I) versus +1.0% (R); BMI: - 4.4% (I) versus +1.0% (R)]

	significant effects [fitness: change of +10% (midtest) and +18% (posttest) (1) versus -2% and +1% (R); % body fat: change of -8% and - 14% (1) versus -3% and - 5% (R)]	significant effect on fitness (F(3.134)=9.3, p<0.0001); no significant effect on well-being ((F(3.135)=2.5, p<0.06)
		ce egular nts was during year
	1. fitness: VO _{2max} (graded treadmill test; Bruce protocol) 2. % body fat: 7 skin folds	 152 bank workers; 139 1. fttness: questionnaire average included in analysis 2. general health: attendan questionnaire on well-among n questionnaire on well-among participa being representing participa worn out and uptight 44 times worn out and uptight the first
	45 blue collar workers; 45 included in analysis	152 bank workers; 139 included in analysis
	24 weeks	12 months
monthly weight- monitoring sessions, following usual activity pattern	 aerobics, walking, 24 weeks jogging, bicycle ergometer (24 weeks, 3 times per week) reference: no intervention 	Kerr and Vos ¹⁶ 1. endurance, (M=5) strength and flexibility exercises (12 months, 1 time per week, 60 min) 2. reference: no intervention
	Oden et al. ¹⁷ (M=2)	Kerr and Vos ¹⁶ (M=5)

3. reference:

	significant effect on VO _{zmax} (p<0.001) and body weight (p<0.025); no significant effect on percentage of body fat and serum lipids	significant effect on fitness (4.5% net increase, p=0.02); no significant effect on body weight and serum lipids
	<i>۴</i> -	average compliance was 75-78% (active) and 92% (delayed active)
 Fatigue: questionnaire as to fatigue connected to the shift % body fat: skin fold number unknown 	 fitness: VO_{2max} (maximal graded treadmill test; Bruce protocol) body weight body fat: 7 skin folds serum lipids: total cholesterol, VLDL, LDL, HDL, triglycerides 	 fitness: VO_{2max}, submaximal HR, maximal cycle time [maximal treadmill test (walkers) and maximal bicycle test (cyclists)] body weight body weight serum lipids: total cholesterol, triglycerides, HDL
	37 female blue collar workers; 37 included in analysis	160 Finnish urban workers; 71 (first 10- week phase), 68 included in analysis (second 10-week phase)
	24 weeks	10 weeks
	 walking, jogging, cycling (24 weeks, 3 times per week, 20- 60 min) reference: no intervention 	 walking and cycling to and from work at self-selected speed (10 weeks, daily) reference: delayed active group
	Grandjean et al. ²⁵ (M=3)	Oja et al ⁴⁵ (M=4)

significant effect on leisure physical activity and fatigue; no significant effect on VO _{zmax} strength and flexibility	significant effect on flexibility [+15% (I) versus -10% (R)]; no significant effect on incidence of joint injuries	significant effect on maximum power output (((F(1:30)=8.29, p<0.001); relevant effect sizes in flexibility in favor of the reference group; no significant effect on physical activity, 5-minute
adherence rate was 90%	<i>د.</i>	average attendance of 9.6 of the 12 sessions
 physical activity: questionmaire about leisure time physical activity fitness: VO_{2max} (submaximal bicycle test; Åstrand protocol) factibility: sit and reach test strength: handgrip dynamometer fatigue: questionnaires including mental and physical fatigue 	 flexibility: sit and reach test, trunk rotation twist and touch, shoulder flexion and extension test, knee flexion and extension MSD: joint injuries 	 physical activity: questionnaire of 1-week activity recall fitnes: maximum power output, HR, resting, 5-minute recovery (bicycle test until HR reached 130
540 pharmaceutical workers; 232 included in analysis (VO _{2max}), 286 included in analysis (strength), 265 included in analysis (flexibility)	469 firefighters; 469 included in analysis	37 female university workers; 35 included in analysis
3 and 7 months	6 months	12, 24 and 48 weeks
 stretching, relaxation, muscular strength, aerobic exercise; 7 months, 5 times per week, 15 min) 2. reference: social games (7 months, 5 times per week, 15 min) 	 flexibility program (6 months, daily, 30 min) reference: no intervention 	 self-administered program of low- impact aerobic exercise and education (12 weeks, 2 or 3 sessions between weekly classes)
Halfon et al. ⁴⁰ Rosenfeld et al. ¹⁸ Ruskin et al. ⁴⁶ (M=4)	Hilyer et al ⁴⁴ (M=4)	Lee and White ²³ (M=4)

recovery, resting HR, percent of body fat, BMI, serum lipids, blood pressure	no significant effects on VO _{2mav} , health, body weight; relevant effect sizes in percentage of low back disorders [no change in the intervention group, but an increase in % low back in the reference group (from 22%-27%)]	no significant effects (strength: 25% and 15% improvement (1) versus 6% and 1% (R); flexibility: 27% (1) versus 10% (R); weight and % body fat: 0%-2% change in both groups)
	participation rate was 75±12%	attendance was at least 90% of the organized sessions
beats/min) 3. flexibility: sit and reach test 4. % body fat: 3 skin folds 5. BMI 6. serum lipids: total cholesterol/HDL, triglycerides, total cholesterol/HDL, ratio 7. blood pressure	 fitness: VO_{2max} (submaximal bicycle test; Åstrand protocol) general health: questionnaire about somatic and psychosomatic complaints MSD: questionnaire including nine anatomical regions body weight 	 strength: sit-up, standing broad jump flexibility: back and hamstring body weight % body fat: 4 skinfolds
	160 female home care workers; 77 included in analysis	24 ambulance workers; 14 included in analysis
	1 year	10 weeks
2. reference: wait-list group, invited to participate in a second 12-week exercise program	 coordination, strength, aerobic activities, stretching (1 year, 2 times per week, 60 min) reference: no intervention 	 flexibility, soccer, aerobic and strength exercises (10 weeks, 2 times per week, 1 hour [?]) reference: no intervention
	Gerdle et al.³ (M=6)	Gamble et al. ²² (M=3)

Bassey et al. ³⁴	Bassey et al. ³⁴ 1. unsupervised	12 and 24	12 and 24 580 factory workers; 59 1. physical activity:	1. physical activity:	one third had	no significant effects
(M=0)	walking program (12	weeks	included in analysis,	mechanical	nearly or fully	
	weeks, 5 times per		(pedometers); 56	pedometers, 24-h	achieved the	
	week, 20-40 min)		included in analysis (HR	body-borne tape	protocol	
	2. reference: no		records)	recorders	prescribed	
	intervention			2. fitness: HR (self-		
				paced walking test)		-
?, unclear or no	ot described specifically	y; BMI, bod)	/ mass index; HDL, high-	density lipoprotein; HR,	heart rate; (I), inte	?, unclear or not described specifically; BMI, body mass index; HDL, high-density lipoprotein; HR, heart rate; (I), intervention group; LDL, low-density
lipoprotein; M, I	Methodological quality	score; MSD,	musculoskeletal disorder:	;; (R), reference group;	VLDL, very low-den	ipoprotein; M, Methodological quality score; MSD, musculoskeletal disorders; (R), reference group; VLDL, very low-density lipoprotein; VO _{2max} , maximum
	:					

oxygen consumption.

Table 3. Ch	aracteristics of the non	randomized.	controlled trials in ter	Table 3 . Characteristics of the nonrandomized, controlled trials in terms of the effectiveness on physical activity, fitness and health	on physical activit	ty, fitness and health
Study	Intervention	Post-test/ follow-up	Study population; number used for analysis	Outcome measures and method of measurement	Adherence	Results
Wier et al. ⁵⁰ (M=4)	 physical exercise, individualized exercise prescription, short lecture (12 weeks, 3 times per week) reference: no intervention 	2-3 years	all (n=?) NASA- Johnson Space Center workers; 320 enrolled in intervention; 258 included in analyses	 physical activity: exercise habits questionnaire fitness: VO_{2max} (treadmill test; Bruce protocol) body weight & body fat: skin folds serum lipids: total cholesterol, HDL, triglycerides 	average compliance was 79%	significant effects (physical activity: F=16.66, df=3.222, p<0.001; fitness; +2.5 ml/kg/min in comply group versus -2.4 ml/kg/min in non-comply groups weight, % body fat, and serum lipids: groups changed at different rates over time. F=2.65, df=15.707, p<0.001)
Blair et al. ³⁵ (M=3)	 encouragement to initiate/maintain exercise, programs in exercise, smoking cessation, stress management, nutrition, weight control and blood pressure control (2 years) reference: health screen 	2 years	4,300 Johnson & Johnson Company workers (4 intervention companies (n=1,700); 3 reference companies (n=1,700); 2,147 included in analysis	 Physical activity: 3 methods of self-reported exercise: a. global self- estimate; b. vigorous exercise; c. (moderate, hard and very hard) activity of past 7 days 2. fitness: VO_{2ms} (submaximal bicycle test) 	~	significant effects (energy expenditure: increase of 104% (I) versus 33% (R); VO _{2max} increased 10.4% (I)

significant effects [flexibility: change of 7º (I) versus 3º (R); injuries: 25 injuries (I) versus 43 (R)]	significant effects of the combined program [strength improvement of 86% (dynamic), 59% (static back), 25% (static arm), 23% (static arm), 23% (static shoulder); flexiblifty: 11% (low back), 48% (trunk)]	significant effect of the aerobic program on general health; significant effect of the aerobic and anaerobic program on HR, diastolic and systolic blood pressure (in general for all outcome measures: both
<u>کہ ہ</u>	2 F	~
1. flexibility: knee extension 2. MSD (lower extremity injuries): weekly reviews	 strength: dynamic and static (procedure of Berger and Ayoub) flexibility: sit and reach test, trunk rotation test 	 fitness: HR (semi- automatic sphygmomanometer) and timed run (1.5-mile run) general health: general health: grochological
298 military infantry basic trainees; 262 included in analysis	28 manual handling operations workers; 28 included in analysis analysis	150 male police officers; 77 included in analysis
13 weeks	5 weeks	10 weeks
 addition of 3 hamstring stretching sessions reference: normal basic training program of stretching (13 weeks, daily) 	PRE: strength training, progressive resistance exercise (4 weeks, 4 times per week, 20 min) TFE: flexibility, strength training: progressive resistance exercise and trunk flexibility exercises (4 weeks, 4 times per weeks, 35 min) 1. PRE only 2. PRE and TFE 3. reference: no intervention	 aerobic training: road running (10 weeks, 3 times per week, approximately 30-40 min) anaerobic training: 2. anaerobic training (10 weeks, 3 times per
Hartig and Henderson ⁴³ (M=2)	Genaidy et al. ³⁷ (M=1)	Norris et al. ²¹ (M=1)

the aerobic and anaerobic group showed an improvement whereas the reference group remained stable)	significant differences of VO _{2max} in high adherents; significant decrease of strength in the reference group; flexibility and percentage of body fat improved in all categories, most in adherents; no significant effect on body weight	significant effect on fitness, general strength, flexibility and percentage of body fat; no significant effect on upper body strength [fitness: change of 21.5% (I) versus 13.4% (R); sit ups: 26.0% (I) versus 16.4% (R); flexibility: 8.3% (I) versus 7.4% (R); % fat: -5.6% (I) versus - 1.2% (R)]
	attendance of 2 or more classes per week (regular participants)	~ •
components of ill health 3. blood pressure	 fitness: VO_{2max} HR, test duration (Canadian Home Fitness Test) strength: handgrip dynamometer flexibility: sit and reach test body weight Se body fat: 4 skin folds 	 fitness: VO_{2max} (submaximal bicycle test; Åstrand protocol) astrength: maximal bench press, sit ups flexibility: sit and reach test % body fat: 3 skin folds
	1,858 assurance workers (1 test company [n=1281], 1 reference company [n=577]); 614 included in analysis (VO _{2max} HR, test duration); 534 included in analysis (handgrip, flexibility, body composition)	1,504 police trainees (25 sites); 1,504 included in analysis
	6 months	9 weeks
week, approximately 30 min) 3. reference: no formal training	 rhythmic calisthenics, jogging, ball games, lectures (6 months, 3 times per week, 30 min) 2. reference: no intervention 	Harrell et al. ⁴¹ 1. stretching and strengthening exercises, aerobic training (9 weeks, training (9 weeks, training (9 weeks, min) 2. reference: continued usual training
	Cox et al., ²⁰ Shephard and Cox ⁴⁹ (M=3)	Harrell et al. ⁴¹ (M=1)

ht ? significant effect on body tet weight, HDL, total ds: total cholesterol/HDL ratio and HDL, LDL, tratio and triglycerides; no significant effect on percentage of body fat, total cholesterol, ssure LDL and blood pressure	divity: self- ? significant differences in lorous) body weight in favor of the trices intervention ht program; no significant differences among the ds: in physical activity, total cholesterol, HDL, the ratio/HDL ratio, triglyceride levels and blood pressure
 body weight body fat serum lipids: total cholesterol, HDL, LDL, cholesterol/HDL ratio, triglyceride blood pressure 	 physical activity: self- reported (vigorous) exercise practices body weight blood pressure serum lipids: cholesterol, HDL, HDL/cholesterol ratio, triglycerides
65 college faculty, staff and administration workers; 65 included in analysis	experimental company: n=261 responded to survey; n=167 volunteered to participate in intervention; reference company: n=343 of n=536 responded to survey; 421 included in analysis
6 months	5 months
 1a. group activities: aerobic dance, exercise, weight training, swimming (6 months, 3 times per week, 45 min) 1b. individual 1b. individual 1b. individual 3b. individual 3b. individual 3c. reference: no intervention 	 mild: seminar, monthly newsletter on exercise and nutrition (3 months) moderate: further interpretation of test results, physical examination, maximal treadmill exercise test, access to exercise facility (3 months) intensive: individual explanation of test results, individual exercise prescription, organized, supervised,
Fisher and (M=2) (M=2)	Ostwald ⁴⁶ (M=1)

	aerobic exercises (12 weeks, 3 times per week) 4. reference: no intervention					
Skargren and Öberg ¹⁹ (M=4)	 strength and cardiovascular exercises (8 weeks, 2 times per week, 45 min) reference: no intervention 	before and after the two exercise periods	106 nurses and nursing aldes; included in analysis during exercise periods: 86 (questionnaire), 74 (VO _{2max}), 70 (strength); used for analysis during control periods: 78 (questionnaire), 58 (VO _{2max}), 55 (VO _{2max}), 55	 fitness: VO_{2max} (submaximal bicycle test; Åstrand protocol) strength: isokinetic dynamometer, knee flexion general health: guestionnaire about psychosomatic complaints MSD: questionnaire about symptoms in 7 areas 	regular participants attended at least 8 times	no significant effects in VO _{2max} or number of MSD or psychosomatic symptoms (VO _{2max} : change of 1.3 ml.kg ⁻¹ .min ⁻¹ [exercise periods] versus 0.7 ml.kg ⁻¹ .min ⁻¹ [reference periods]; MSD [n]: -0.4 [exercise periods] versus - 0.1 [reference periods]; a higher increase in strength during exercise periods [+11Nm] than during reference periods [-31Nm])
Pavett et al. ⁴⁷ (M=1)	 circuit weight training exercise (12 weeks, 3 times per week) reference: no intervention 	12 weeks	350 navy and marine corps men; 245 included in analysis	 general health: questionnalre consisting of a physical symptoms and a psychological distress scale 	~	no significant effect [change from 1.79 to 1.84 (I) versus a change from 1.95 to 1.84 (R)]
M: Methodoloc	gical quality score; pw.	: per week;	MSD: musculoskeletal	disorders; HR: heart rate;	BMI: body mass i	M: Methodological quality score; pw: per week; MSD: musculoskeletal disorders; HR: heart rate; BMI: body mass index; ?: unclear or not describe

ibed -. -. structure quality sure, pw. per week, much specifically; (1): intervention group; (R): reference group. 6

Chapter 2.2

Effectiveness of physical activity programs at worksites with respect to work-related outcomes

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Abstract

This paper systematically reviews the literature on the effectiveness of physical activity programs at worksites with respect to work-related outcomes. A computerized literature search, a reference search, and a manual search of personal databases were performed using the following inclusion criteria: randomized controlled or controlled trial, working population, worksite intervention program to promote physical activity or physical fitness, and work-related outcomes. The study quality was evaluated using nine methodological criteria. Conclusions were based on a 5-level rating system of evidence. Eight studies (4 randomized controlled trials and 4 controlled trials) were identified, but their methodological quality was generally poor. The outcomes were absenteeism, job satisfaction, job stress, productivity, and employee turnover. The evidence of an effect was limited for absenteeism, inconclusive for job satisfaction, job stress and employee turnover, and nil for productivity. The scientific evidence on the effectiveness of physical activity programs at worksites is still limited. Because of the few high quality randomized controlled trials, it is strongly suggested that this type of study be carried out. Future randomized controlled trials should pay special attention to the description of randomization, inclusion criteria, compliance, and analyses according to intention to treat.

Despite the promotion of a more physically active lifestyle, only a minority of adults is engaged in physical activity at a level sufficient to maintain or increase fitness and health.^{1,2} Because regular physical activity is associated with a decrease in risk factors for several chronic diseases,³⁻⁷ encouraging people to be (more) physically active is of major public health importance. In addition to the person-related benefits, employers may experience benefits from enhancing physical activity among their employees. Currently, corporations in western countries have become more and more aware of the importance of worksite programs aimed at increasing physical activity and fitness levels⁸ and have offered such programs to their employees far more often during the past 20 years than before.⁹ Both in practice and in the literature, physical activity programs, physical fitness programs, and exercise programs have been used rather interchangeably. Such an interchange is in fact undesired because of the different meanings of the constructs physical activity, physical fitness and exercise. In order to reduce confusion regarding these different constructs, we have chosen arbitrarily to apply one single term in this article for all programs that describe physical activity, physical fitness, or exercise at worksites, namely, physical activity programs at worksites. Thus, in this paper, we consistently apply this term, which includes any one of the three types of programs mentioned.

According to Jex & Heinisch,¹⁰ the primary rationale for implementing physical activity programs at worksites is that exercisers are healthier than nonexercisers, and therefore represent reduced health care costs for the company. Dishman et al.⁹ supports this rationale by stating that physical activity programs at worksites are aimed at increasing productivity and at reducing health care costs. Many studies, and some reviews, have addressed the effectiveness of physical activity programs at worksites.9,11-13 Two of these reviews11,13 described studies that investigated the impact of such interventions on both health-related and work-related outcomes, but failed to evaluate the internal validity of the studies. Two other reviews^{9,12} examined the methodological quality of the studies included. However, both of these reviews focused on health-related outcomes only. In conclusion, no review was found that evaluated the effectiveness of worksite physical activity programs on work-related outcomes while taking into account the methodological quality of each study. Therefore, the purpose of our review was to assess the effectiveness of physical activity programs at worksites on work-related outcomes systematically by applying several methodological quality criteria and using a rating system to determine the level of evidence as to effectiveness.

Methods

Literature search

The literature search included a computerized database search, a reference search, and a manual search in our personal database. The computerized literature search was conducted in Medline, Psychinfo, Sportdiscus, OSHrom, and Cisdoc. The key words used for the search were divided into four headings in accordance with the inclusion criteria given later in this paper. English, German, and Dutch publications from 1980 to 2000 were selected.

Subsequently, the reference and manual search results were examined for additional studies. The inclusion criteria were (i) randomized controlled trial (RCT) or controlled trial (CT), (ii) working population, (iii) worksite program intended to increase physical activity or fitness; and (iv) work-related outcomes. Criteria for exclusion were (i) physical activity programs at worksites aimed at secondary prevention of specific health complaints and (ii) comprehensive worksite health program in which physical activity or fitness was merely one of the many program components.

Methodological quality

Two reviewers (KP and BS) independently evaluated the studies identified by means of a list containing methodological criteria (table 1). These criteria were derived from methodological guidelines for systematic reviews developed by the Cochrane Collaboration Back Review Group.¹⁴ As these guidelines were developed to review randomized controlled trials in the field of therapies and secondary prevention for back pain, some criteria had to be omitted or adjusted for the purpose of this particular review.

As the first criterion (randomization procedure) is not applicable to studies without the randomization of subjects, controlled trials could reach a maximal quality score of 8 rather than 9. A positive score was given if there was a satisfactory description and adequate performance of each item concerned, according to the discretion of the reviewer. The reviewing process was planned so that a consensus meeting between the two reviewers would take place in order to solve disagreements, if such would arise. If no consensus could be reached during this meeting, a third reviewer should be consulted. Conclusions with regard to the effectiveness of physical activity programs at worksites on a certain outcome measure were drawn using a rating system as to levels of evidence. This rating system was based on several best-evidence syntheses applied in earlier comparable reviews.¹⁵⁻¹⁷ The following five levels of evidence were distinguished: (i) strong evidence: at least two randomized controlled trials of high quality with consistent results; (ii) moderate evidence: one randomized controlled trial of high quality and at least one randomized controlled trial of low quality or one randomized controlled trial of high quality and at least one controlled trial of high quality (for both situations, consistent results were required); (iii) limited evidence: one randomized controlled trial of high quality and at least one controlled trial of low quality or more than one randomized controlled trial of low quality or more than one controlled trial of high quality (for all situations, consistent results were required); (iv) inconclusive evidence: only one study or multiple controlled trials of low quality or contradictory results; and (v) no evidence: more than one study with the consistent result that no significant or relevant results were shown. A study was considered to be of high quality if more than 50% of the methodological criteria was scored positively. Otherwise, the study was considered to be of low quality. High and low quality are relative qualifications and have to be interpreted as relatively high and relatively low. The results of the studies were first examined for statistical significance. In case of no statistical significance, we checked whether the results were meaningful from an employer's perspective, defined as a 20% difference between study groups, in favor of physical activity programs at worksites.¹⁸ The results were considered to be consistent if at least 75% of the studies involved reported statistical

significance or were meaningful as already defined. In this process, a hierarchical order of design and quality was used for the studies. For example, for strong evidence to be the conclusion, only results of the identified randomized controlled trials that were of high quality were taken into account and evaluated for consistency.

Table 1. Criteria list for the methodological quality assessment of (randomized) controlled trials on the effectiveness of physical activity programs worksites and the definition of the criteria

Criterion	Definition
A Randomization	Positive if a random (unpredictable) assignment sequence of subjects to
procedure ^a	the study groups was used and if there was a clear description of the
	procedure and adequate performance of the randomization
B Similarity of	Positive if the study groups were similar at the beginning of the study
study groups	with regard to age and at least one of the relevant outcome measures; if
	differences existed between the groups, an adjusted analysis had to be performed
C Inclusion or	Positive if inclusion or exclusion criteria were specified
exclusion criteria	
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 Blinding	Positive if the person performing the assessments was blinded as to the
	assignment of subjects to the groups or if objective instruments were
	used; if questionnaires only were used, a negative score was given
F Compliance	Positive if the participants attended at least 75% of the prescribed
	frequency; if several adherent groups were distinguished, the high-
	frequency group had to attend at least 75% of the prescribed frequency
	to score positively
G Intention-to-	Positive if the intervention and reference subjects analysis were analyzed
treat	according to the group belonging to their (initial) assignment, irrespective
	of noncompliance and co-interventions
H Timing of	Positive if the timing of the outcome measurement was identical for all
outcome	the intervention and reference groups and for all important outcome
	assessments
I Follow-up	Positive if follow-up was 6 months or longer
^a Itom A is only and	licable for randomized controlled trials

^a Item A is only applicable for randomized controlled trials.

Results

The (computerized, reference, and manual) search identified 218 (193, 19, and 6, respectively) publications. Reading the title or abstracts or both resulted in the exclusion of 177 publications. After the whole text of the rest of the publications was read, another 20¹⁹⁻³⁸ had to be excluded. Most of the studies were excluded because they did not involve a physical activity program at a worksite or did not evaluate the effect on work-related outcomes. In addition, nine studies were excluded because of a lack of a reference group.³⁹⁻⁴⁷ Finally, 12 publications were selected.⁴⁸⁻⁵⁹ Three publications concerned the same randomized trial,^{52,56,57} and three others described one nonrandomized controlled trial.^{49,50,58} For that reason, eight studies were evaluated (4 randomized controlled trials and 4 controlled trials). The two reviewers reached initial total agreement on 72% of the studies. Cohen's kappa was 0.45 for this initial agreement. Interpretation errors were the main reason for discrepancies between the two reviewers. After some discussion, the two reviewers could not reach agreement concerning item C (table 1) for four studies. As a result, a third reviewer (VH) was consulted.

The quality scores ranged from 3 to 7 for the randomized controlled trials and from 1 to 5 for the controlled trials (table 2). Two of the randomized controlled trials^{51,53} and one of the controlled trials⁵⁹ were, according to our rating system, of high quality. For the randomized controlled trials, most of the shortcomings were due to unclear descriptions of the randomization procedure and the inclusion criteria. For the controlled trials, a lack of a sufficient description of the inclusion criteria, dropouts, or the level of compliance with the intervention were common shortcomings. Moreover, with the exception of one study,⁵⁹ none of the trials had included an intention-to-treat analysis. The outcome measures of the studies were absenteeism from work, job satisfaction, job stress, productivity, and employee turnover.

Description of the studies

A description of the characteristics of each study is given in table 3.

Type of intervention

Of the four randomized controlled trials, three involved a combined program of aerobic, strength, and flexibility exercises.^{51-53,56,57} The other⁵⁵ focused on aerobic training only. Of the four controlled trials, the type of program differed somewhat. In the study reported by Cox et al.^{49,50} and Shephard et al.,⁵⁸ the main focus was on the development of cardiorespiratory fitness, while in the study of Skargren & Öberg⁵⁹ strength exercises were added to cardiovascular capacity exercises. In the study of Norris et al.,⁵⁴ two intervention programs were compared with a reference program, namely, an aerobic program and anaerobic program, which was aimed at improving muscle strength.

Study period

The study period of the four randomized controlled trials varied from 6 to 12 months, while that of the controlled trials lasted from 8 weeks to 1 year.

Study	Met	hodole	ogical	quality	y crite	rion ^a				Total score
	A	В	С	D	Ε	F	G	н	I	
Randomized controlled	trials									
Kerr & Vos, 1993 ⁵³	+	+	-	+	+	+	-	+	+	7
Grønningsäter et al., 1992 ⁵¹	-	+	+	+	-	+	-	+	+	6
Halfon et al., 1994 ⁵² ; Rosenfeld et al., 1989 ⁵⁶ ; Rosenfeld et al., 1990 ⁵⁷	-	-	-	+	+	-	-	+	+	4
Oden et al., 1989 ⁵⁵ Controlled trials	-	+	-	+	+	-	-	-	-	3
Skargren & Öberg, 1999 ⁵⁹	NA	+	+	+	-	-	+	+	-	5
Cox et al., 1981 ⁴⁹ ; Cox et al., 1987 ⁵⁰ ;	NA	+	-	-	+	-	-	+	+	4
Shephard et al., 1981 ⁵⁸										_
Blair et al., 1986 ⁴⁸	NA	+	-	-	+	-	-	-	+	3
Norris et al., 1990 ⁵⁴	NA	-		-	-	-		+	-	1

Table 2. Methodological quality of each study

^a See table 1 for the definitions of the criteria.

NA = not applicable.

Study population

Both blue- and white-collar workers were investigated in the studies. Two of the randomized controlled trials evaluated the effect of physical activity programs at worksites using white-collar employees,^{51,53} another randomized controlled trial used both white- and blue-collar employees,^{52,56,57} while the study of Oden et al.⁵⁵ investigated the effect using blue-collar subjects. Also, among the controlled trials, both blue- and white-collar employees were investigated. The types of employees studied in the controlled trials were employees working in insurance companies,^{49,50,58} nursing staff,⁵⁹ police officers⁵⁴ and school district employees.⁴⁸

Absenteeism from work

One high-quality randomized controlled trial,⁵³ one low quality randomized controlled trial,⁵⁷ and two controlled trials^{48-50,58} were identified that evaluated the effect on absenteeism from work. The randomized controlled trial of high quality⁵³ and one controlled trial⁴⁸ showed a statistically significant positive effect of the program on absenteeism from work. In the study of Kerr & Vos,⁵³ both experimental groups showed a decrease in the frequency of absenteeism, while the frequency of absenteeism in the reference groups increased. The other randomized controlled trial⁵⁷ did not show a change during the study period. Furthermore, both controlled trials reported a positive influence of the intervention on

absenteeism. On the basis of these findings, it was concluded that there is limited evidence for the effectiveness of worksite physical activity programs on absenteeism from work.

Job satisfaction

One randomized controlled trial of high quality,⁵¹ two randomized controlled trials of low quality,^{52,55,57} and one low-quality controlled trial^{49,50,58} were identified that investigated the effect of physical activity programs at worksites on job satisfaction. The trial of high quality⁵¹ reported a significant negative effect of the program on job satisfaction in that a decrease in job satisfaction was seen in the aerobic training group when it was compared with a stress management group and a reference group. In contrast, the study reported by Rosenfeld et al.⁵⁷ and Halfon et al.⁵² showed a positive effect of physical activity training in that the reference group reported significantly lower job satisfaction scores than the workers engaged in a physical activity program at their worksites. The third randomized controlled trial⁵⁵ did not find a statistically significant change in job satisfaction for either group during the study period. Finally, the only controlled trial^{49,50,58} did not show a significant effect for the intervention. Thus it was concluded that there is inconclusive evidence for the effectiveness of physical activity programs at worksites on job satisfaction.

Job stress

One high-quality randomized controlled trial,⁵¹ one low-quality randomized controlled trial,⁵⁵ and two controlled trials^{54,59} were identified that studied the effect of a physical activity program on job stress. The study of Grønningsäter et al.⁵¹ found no effect of the physical activity program on job stress. Although Oden et al.⁵⁵ could not find statistically significant differences in job stress, differences between the experimental and reference groups were evaluated as meaningful. The study of Norris et al.⁵⁴ showed significant improvements in self-reported measures of stress among the subjects participating in the aerobic and anaerobic training when compared with the reference group. In addition, the improvement of those engaged in aerobic training was greater than the effect of those engaged in anaerobic training. Finally, the study of Skargren & Öberg,⁵⁹ who evaluated the effect on organizational and psychosocial conditions and also physical work conditions, suggested that a physical activity program at work does not affect perceived work conditions, with one exception, namely, work planning. According to the results of the studies selected, we concluded that there was inconclusive evidence for an effect on job stress.

Productivity

Definitions of productivity in the studies included were (objective) self-efficiency, (perceived) work efficiency, quality yield, and net allowed hours. In addition, the method of measuring productivity differed among the studies in that some used subjective ratings,^{52,56} while others used objective measures of productivity.^{49,50,55,56,58} Rosenfeld et al.⁵⁶ evaluated the effectiveness on both objective and subjective measures of productivity. Two randomized controlled trials,^{52,55,56} both of low quality, evaluated the effect of a physical activity program at worksites on productivity. The study described by Halfon et al.⁵² and Rosenfeld et al.⁵⁶ found significantly higher ratings of perceived work efficiency in the physical activity group

than in the reference group. However, the objective measure of productivity, as reported by Rosenfeld et al.,⁵⁶ showed no change during the study period. The latter finding was supported by Oden et al.,⁵⁵ who also showed no statistically significant change in objectively measured productivity. The controlled study described by Cox et al.^{49,50} and by Shephard et al.,⁵⁸ also found no significant changes in productivity. Based on these findings, no evidence was found to indicate an effect of physical activity programs at worksites on productivity.

Employee turnover

Only one controlled trial was identified that had studied the effect on employee turnover.⁴⁹ This study⁴⁹ showed that both high and low adherents had significantly less employee turnover than the nonparticipants. But, due to a lack of (randomized) controlled studies, inconclusive evidence was concluded for the effectiveness of physical activity programs at worksites on employee turnover.

Discussion

Effectiveness

The purpose of this systematic review was to gain insight into the effectiveness of physical activity programs at worksites on work-related outcomes. Despite the shortcomings of most of the trials, the outcomes suggest that there is limited evidence for the effectiveness of physical activity programs at worksites on absenteeism from work. For absenteeism, two randomized controlled trials were retrieved; one of high quality and one of low quality. The randomized controlled trial of high quality reported positive results, in contrast to the second randomized controlled trial identified, which was of low quality. As studies with lower methodological quality are supposed to have biased findings, we highly value the (positive) result of the one high-quality randomized controlled trial. Consequently, we believe that physical activity programs at worksites may offer relevant benefits for business and corporations regarding absenteeism from work. In addition, the difference in the study population and the intervention of the reference group between the two randomized controlled trials in question may explain the contradictory findings. The (high quality) trial that reported a positive effect on absenteeism from work used white-collar bank employees, while, in the (low quality) trial without positive outcomes, the majority of the subjects were laborers. As a larger gain can be obtained with subjects not being physically active, it is expected that white-collar workers, performing hardly any physical activities during work, show greater benefits than blue-collar workers do.⁶⁰ The results of these two randomized controlled trials confirmed this dose-response relationship. Another explanation for the differences between the randomized controlled trials identified involves the program of the reference group. The trial that showed positive findings applied a reference group that did not take part in the fitness program and did not get any attention. In contrast, the study that did not find an effect used a reference group that received a social activity program and identical attention when compared with the physical activity group. This finding suggests a potential for a Hawthorne response, due to the less amount of attention the reference group received in comparison with the attention received by the intervention group.

We concluded that inconclusive evidence exists for the effect of physical activity programs at worksites on job satisfaction and job stress. Inconsistent results were the main reason behind this conclusion. In our opinion, the inconsistency of findings is largely due to variations in definition and the assessment of the outcomes or to the compliance with the program. With respect to the compliance, most of the studies failed to describe this aspect sufficiently so that we cannot determine the extent to which a positive effect can be expected for compliance. As the effectiveness of physical activity programs at worksites strongly depends upon compliance, future studies should pay attention to the description of the participation rate. Furthermore, it should be noted that most studies not having reported significant effects showed positive trends. It is noteworthy that 50% of the randomized controlled trials and the controlled trials used less than 100 subjects for their analyses, and therefore these studies may have lacked the statistical power needed to detect significant differences. Probably a larger sample would have resulted in significant effects. With regard to productivity, different results were found between the studies evaluating the effectiveness on subjective and objective measures. The only randomized controlled trial examining the effect on perceived productivity showed a positive effect, whereas the same trial, plus another randomized controlled trial, could not find a change in favor of physical activity programs at worksites with respect to objectively measured productivity. These contradictory findings suggest that the experience of workers with regard to their productivity does not necessarily reflect what they, in fact, produce. Another plausible explanation for this contradiction may be that the subjects involved in the studies using objective measures were mainly blue-collar workers, whose productivity is determined by machinery instead of by worker control. Thus it may be that an increase in physical activity will lead indeed to feelings of improved efficiency, while in fact productivity rates remain constant because of machinery control. Finally, inconclusive evidence was found for employee turnover, due to a lack of studies. Since a high employee turnover rate is very costly for the company, more high-quality research, preferably randomized controlled trials, should be conducted to determine whether physical activity programs at worksites prevent or reduce employee turnover.

Limitations of the studies

The methodological quality of the randomized controlled trials and the controlled trials included was poor overall. Most of the study shortcomings were due to a lack of, or unsatisfactory description of, randomization, intention-to-treat analysis, inclusion criteria, and compliance. It was stated in most studies that the employees were randomized into the intervention or reference group, without any mention of the randomization procedure or the person performing the randomization. As it remains unclear to the reader of these articles whether an adequate procedure was performed, bias may have existed.⁶¹ The randomization procedure was sufficiently described in only one study.⁵³

Another shortcoming included the compliance with the program, which in most cases was either described poorly or was found to be low according to our criteria.

Finally, with the exception of one controlled trial, none of the studies performed an intention-to-treat analysis. Absence of such an analysis may lead to bias since employees may drop out because of specific reasons that make them not comparable with the group that completes the study with respect to the outcome variables. Consequently, if dropouts are not taken into account, the effectiveness may be overestimated.

The aforementioned shortcomings are fully in line with the conclusions of Shephard,¹² who reported that most of the studies he reviewed suffered from low methodological quality, like small and biased samples or lack of appropriate control observations. Most of the studies identified did not randomize their subjects into an intervention or reference group. Taking into consideration that the nonrandomized studies included in this review often compared participants and nonparticipants, without controlling for baseline differences, personality, and other differences between these groups should not be ignored when the results are explained.^{11,62} Self-selection of participants into the intervention is a well known and very serious scientific shortcoming of nonrandomized studies evaluating the effects of physical activity programs at worksites. One should bear in mind, however, that employees who do not enjoy exercise, or who do not want to participate in a physical activity program at work, simply cannot be forced to do so.

Limitations of the review

As we excluded unpublished studies and abstracts, the possibility of publication bias cannot be ruled out. Small studies without significant differences in outcomes have a large chance of not being published.^{63,64} Thus taking into account the fact that unpublished studies probably more often have negative results, there may be a danger of an overrepresentation of positive effects of physical activity programs at worksites in this review. However, since the (published) studies identified in the review could often not prove statistically significant differences or meaningful results from an employer's standpoint, we consider the possibility of such an overestimation of positive effects to be small.

Another problem that cannot be ruled out is the possibility that not all relevant publications were identified. However, this risk is probably small since we used different search strategies and several different bibliographical databases.

Moreover, in a systematic review, the possibility of bias due to a restriction in language may exist, as publications with significant results are more often published in English than in other languages.^{63,65} Although we did not restrict this review to English-written studies only, the potential for such an overestimation of significant (positive) results still remains.

Methodological quality assessment

A meta-analysis (i.e., the statistically pooling of data) may provide more conclusive evidence about the effectiveness of physical activity programs at worksites than a qualitative analysis. Nevertheless, we decided to carry out a qualitative analysis and to perform a best-evidence synthesis and refrain from conducting a meta-analysis for two reasons. First, the methodological quality of the studies reviewed was rather poor, and, second, these studies were very heterogeneous in terms of context, design, and subjects. Although the rating system we applied is arbitrary, it is considered to be a suitable method for distinguishing objectively between different study designs (randomized controlled trials versus controlled trials) and to assess the methodological quality of studies (relatively high versus relatively low) in a reproducible manner. For example, strong or moderate evidence can only be concluded for outcomes from randomized controlled trials of high quality. The cutoff points used for categorizing a study as a high-quality study and for concluding consistent results were chosen arbitrarily. Theoretically, other conclusions could have been drawn if we had applied other cut-off points. However, raising or lowering the cut-off point by 10% would not have led to more or fewer high-quality randomized controlled trials; therefore the same conclusions would have been drawn and the results from this review can be considered not to be sensitive to a change in these cut-off points. And also, with this methodology, our results agreed with those of other systematic reviews.^{16,17}

In conclusion, there is limited evidence for the effectiveness of physical activity programs at worksites with respect to absenteeism from work and inconclusive evidence for effectiveness regarding job satisfaction, job stress, and employee turnover, and there is no evidence for effectiveness in respect to productivity. These conclusions are probably due to a lack of randomized controlled trials of high methodological quality. As many questions still remain unanswered, we strongly recommend that randomized controlled trials of high methodological quality programs at worksites with respect to work-related outcomes, although we realize that conducting such research in occupational settings is difficult.

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Study	Intervention	Posttest/	Study population	Outcome measures and their Results ^a	 Results[*]
		follow-up		assessment	
Randomized controlled trials	ials				
Grønningsäter et al.,	1. Aerobic exercise aimed at	10 weeks and	171 insurance company	Job satisfaction: questionnaire	Job satisfaction: -
1992 ⁵¹	improving physical capacity,	6 months	workers (92 men, 79	assessing comfort, challenge,	Job stress: 0
	strength, flexibility and relaxation;		women); age 25-67 years;	financial reward, relations with	
	10 weeks, 3 times per week, 55		72 used for the analysis	co-workers, resource adequacy,	
	minutes			and promotions	
	2. Cognitive behavioral stress			Job stress: questionnaire	
	management, lectures, group			assessing stress related to	
	discussion, self-study and home			workload, communication,	
	assignments; 10 weeks, 3 times			relocation, and leadership	
	per week, 55 minutes				
	3. Reference: no intervention				
Halfon et al., 1994 ⁵² ;	1. Regular physical exercise,	7 months	522 pharmaceutical	Absenteeism: (number of hours	Absenteeism: 0
Rosenfeld et al., 1989 ⁵⁶ ;	stretching, relaxation, strength,		workers (255 men, 267	absent due to iliness/ total	Job satisfaction: +
Rosenfeld et al., 1990 ⁵⁷	aerobic exercises; 7 months, 5		women); mean age 40	number of hours expected to	Productivity (i): +
	times per week; 15 minutes		years; 461? used for	work) x 100	Productivity (ii): 0
	Reference: social games; 7		analysis	Job satisfaction: questionnaire	
	months, 5 times per week; 15			Productivity: (i) self-reported	
	minutes			work efficiency (workload/work	
				fatigue) and (ii) objective self-	
				efficiency / [(actual time needed	
				to complete one defined unit x	
				the number of units	
				produced)/net assigned work-	
				time self-efficiency]	
Kerr & Vos, 1993 ⁵³	1. Exercise aimed at improving	12 months	152 bank workers	Absenteeism: absence time	Absenteeism: +
	endurance, strength, flexibility,		(gender?); mean age	registered in bank records	
	good body posture; 12 months, 1		37.6-39.4 years; 152 used		
	time per week, 60 minutes		for the analysis		
	2 Reference: no intervention				

Table 3. Detailed description of the randomized controlled trials and the controlled trials

Oden et al., 1989 ⁵⁵	 Aerobics, walk or jog, bicycle ergometer, aerobic dance; 24 weeks, 3 times per week Reference: no intervention 	24 weeks	45 blue-collar workers (9 men, 36 women); mean age 29.3 years (exercise group), 29.2 years (reference group); 45 used for the analysis	Job satisfaction: questionnaire Job stress: questionnaire Productivity: (1) net allowed hours (number of hours allowed for work on the product hours + the unplanned labor hours such as rework and repair of a product) and (11) quality yield (nerrentane of the product that	Job satisfaction: 0 Job stress: + Productivity (I): 0 Productivity (II): 0
<i>Controlled trials</i> Blair et al., 1986 ⁴⁶	 Weekly exercises and health education classes; 2 difference program cycles of a 10-week intervention phase Reference: participant group starting at a different time 	10 weeks (job satisfaction); 1 year (absenteeism)	12 136 school district workers (79% women (participants), 78% women (nonparticipants); mean age 42.7 years (participants), 41.0 years (nonparticipants), 1835?	passes inspection) Absenteeism: computer tape data from the district personnel office	Absenteeism: +
Cox et al., 1981 ⁴⁹ , Cox et al., 1987 ⁵⁰ ; Shephard et al., 1981 ⁵⁸	 Rhythmic calisthenics, jogging, ball games, lectures; 6 months, 3 times per week, 30 minutes Reference: no intervention 	6 months	used for the analysis yoo satisfaction), 10 806 used for the analysis (absenteeism) 534 of 1858 insurance compary workers completed all 3 physiological tests (234 men, 300 women); mean age (30.2-40.1 years; 1858 used for the analysis (absenteeism), 481 used for the analysis (job satisfaction)	Absenteelsm: collected for several months for several years Job satisfaction: questionnaire assessing type of work, supervision, pay, opportunities for promotion, and co-workers Productivity: average of quarterly departmental records Employee turnover: provided for individual departments along with an arbitrary assessment of	Absenteeism: + Job satisfaction: 0 Productivity: 0 Employee turn- over: +

Norris et al., 1990 ⁵⁴	 Aerobic training: road running: Weeks, 3 times per week, 45 minutes 	10 weeks	150 police officers (all men); age 20-50 years; 77 used for the analysis	productivity per department Job stress: questionnaire	Job stress: +
	 Anaerobic training: weight training to improve muscular strength; 10 weeks, 3 times per week, 35 minutes Reference: no intervention 				
Skargren & Öberg, 1999 ⁵⁹	 General strength and cardiovascular exercises; 8 weeks, 	8 weeks	106 nurses and nursing aides (84% women	Organizational or psychosocial work conditions: questionnaire	Organizational or psychosocial work
	2 times per week, 45 minutes per session		(participants); 86% women (participants),	measuring work climate, work content, work-pace, demands	conditions: 0 Physical work
	2. reference: no intervention		88% women (referents); mean age 35.8 years	on attention, work planning, job security, job constraints, and	conditions: 0
			(nonparticipants), 36.3	work-role aniloiguity Physical work conditions:	
			years (referents); 78 used for the analysis	questionnaire measuring heavy lifting, demanding work	
				positions, high work-pace, high demands on concentration and	
				precision, and mainly sitting	

a 0 = no effect; + = positive effect; - = negative effect.

Section 3

Effectiveness of feedback



Chapter 3.1

Short term effect of feedback on fitness and health measurements on self reported appraisal of the stage of change

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Abstract

Background: An individual's current status of physical activity and nutrition and readiness to change can be determined using PACE assessment forms. Practitioners have suggested that feedback on the fitness and health components, can produce a change in a subject's awareness of their behavior and thereby lead to a beneficial change in stage of behavior change.

Objective: To evaluate the short term effect of personalized feedback on fitness and health status on self reported appraisal of the stage of change.

Methods: A total of 299 civil servants were randomized to an intervention or a reference group. After having been tested for fitness and health, the intervention group received immediate feedback on their test results, whereas the reference group did not. PACE assessment forms were completed twice: before testing and after testing (reference group), or after testing and feedback (intervention group). The time interval between pre-and posttest was one hour. The influence of feedback was determined using a χ^2 test and an analysis of variance (ANOVA).

Results: On the basis of the χ^2 test, no significant effect of feedback was found on the stage of change of physical activity, nor on the stage of change with regard to nutrition. Analysis of variance result showed no significant effect on the raw PACE score as to physical activity, intake of fruit and vegetables and dietary fat. However, a significant effect was observed on the PACE score of 'calorie intake and weight management'. Subjects in the intervention group significantly more often regressed on their PACE score on this topic than the reference subjects.

Conclusions: Feedback at baseline on measurements of an intervention study can influence PACE scores and can be considered as a small but relevant start of the intervention itself.

The importance of regular physical activity is well established.¹ Research has shown significant benefits of regular activity in the prevention of cardiovascular diseases (CVD) and other chronic health problems,¹⁻⁶ Despite these benefits, more than 60% of the adult population is not physically active at a sufficient level, and a guarter of the adults in the United States are not active at all in their leisure time.^{1,7,8} Next to regular physical activity, the importance of healthy dietary habits has been emphasized in the prevention of many serious diseases such as cardiovascular diseases and some types of cancer.^{9,10} Still, most adults in Western countries do not the meet nutrition guidelines.¹¹⁻¹³ Furthermore, in both European countries and the United States, more than one third of the adults are overweight or obese.14-17 In addition, several studies have indicated that the prevalence of obesity has increased over the last few years,^{18,19} As the direct economic costs of treating obesity in the United States are estimated at over \$70 billion,²⁰ increasing the proportion of adults who are regularly active and have a healthy diet is a great public health challenge. The above mentioned is supported by Joyner,²¹ who stated that, in developed countries, inadequate physical activity and obesity are two of the major health threats. The current epidemic of being overweight is caused largely by an environment that promotes excessive food intake and discourages physical activity.²² Weight gain is the result of a positive energy balance, that is, energy intake (through food intake) exceeds energy expenditure (through physical activity). Minor changes in food intake or physical activity could have large effects on body weight and the prevalence of obesity in the population.²³ For interventions that promote physical activity and healthy dietary habits, adults are relatively easily accessible through the workplace. In the last few decades, many corporations have implemented health promotion programs to improve the fitness and health of their employees. However, the effectiveness of such programs is seriously hampered because target groups, in particular those with an unhealthy lifestyle who are not willing to change, are usually very hard to reach.

In the last few years, new individual-based approaches have been developed, focusing on the specific needs, motivations and barriers of the individual. One of the models describing the individual behavior or the individual's readiness to change behavior, is the transtheoretical model. This model suggests that individuals attempting to change their health behavior move through a series of stages²⁴ (a) precontemplation (not intending to change behavior); (b) contemplation (considering to change behavior); (c) preparation (making small changes in behavior); (d) action (actively engaging in behavior change); (e) maintenance (sustaining the behavior change over time). Integration of the transtheoretical model into health promotion interventions has appeared to be promising.²⁵ One of the interventions based on the stages of change model is the Patient-centered Assessment and Counseling for Exercise and Nutrition (PACE) program.^{26,27} Using the PACE assessment form, the individual's current status of physical activity and nutrition, and their readiness to change behavior can be determined. Hence, a counselor can address specifically those processes that help the individual to progress to the next stage, given his/her specific situation. Professionals conducting fitness and health tests often have the impression that personalized feedback on test results, already produces an awareness in the individual of their own behavior.

The hypothesis of this study is that personalized feedback on a person's fitness and health status leads to a change in their subjective appraisal of their stage of change as measured with the PACE assessment form, which is supposed to be more in correspondence with reality. It is expected that employees, who are not meeting the physical activity or dietary recommendations and who are not willing to become more physically active or adopt a more healthy diet (the precontemplators), may consider changing their behavior to achieve a better PACE score when they become aware of poor test results. Thus, the purpose of this study was to evaluate whether personalized feedback on fitness and health status given immediately after completing a fitness and health test protocol, affects a person's subjective appraisal of their stage of behavior change assessed by PACE scoring.

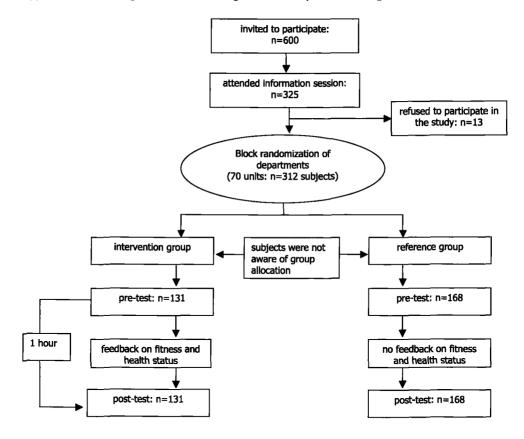


Figure 1. Flow chart of subjects in the trial

Methods

Study population

A total of 600 employees within three municipal services of a Dutch town were invited to participate. Inclusion criteria were: (a) being a municipal civil servant; (b) performing office work; (c) working at least 24 hours per week; (d) having a work contract lasting at least nine months after the measurements; (e) written informed consent. These criteria were set, because the recruited study population participated in a trial investigating the effectiveness of a PACE-type intervention lasting nine months. Results of that intervention will be reported in a separate paper. Participation was voluntary. Units (n=70), and thereby employees (n=312), were randomized to an intervention group or a reference group. A total of 299 subjects who met the criteria for inclusion were measured. Figure 1 presents a flow chart including the number of participants. The study protocol was approved by the medical ethics committee of the VU University Medical Center.

Randomization

The allocation schedule was made by a statistician, who was not involved in the project. Because of block randomization, the allocation schedule was drawn up before the baseline measurements. However, subjects were informed of the assignment after the baseline measurements. The assignment was carried out by the coordinator of the fitness and health tests, who did not perform any of the measurements. People who assisted with the tests were blinded to the allocation.

Pace assessment forms

PACE assessment forms were completed twice: (a) before the fitness and health tests, and (b) after the tests (reference group) or after the feedback given after the tests (intervention group). Subjects were not given the reason for completing the PACE forms twice. The time interval between the completion of the two PACE assessment forms was one hour. Each subject had to choose one out of eight statements that best fitted his/her current status of physical activity. According to the PACE counseling protocols, PACE assessment scores were classified into three stages of behavior change. PACE score 1 referred to the stage of precontemplation, PACE score 2-4 referred to the stage of contemplation/preparation, and PACE score 5-8 referred to the stage of action/maintenance. With respect to nutrition, each subject had to tick one out of four statements on three topics: (a) intake of fruit and vegetables; (b) dietary fat intake; (c) calorie intake and weight management. PACE score 1 referred to precontemplation, PACE score 2-3 referred to contemplation/preparation, and PACE score 4 to action/maintenance. All four PACE assessment forms have shown good short term reproducibility (weighted Kappa varied from 0.73 to 0.85; intraclass correlation coefficient varied from 0.76 to 0.89).

Fitness and health tests

The following variables were measured in all subjects: body weight, body height, waist and hip circumference, thickness of four skinfolds (biceps, triceps, suprailiac, and subscapular),

resting heart rate, diastolic and systolic blood pressure (BP) (NAIS blood pressure watch, type Fuzzy-logic, Tokyo, Japan), and total blood cholesterol (Reflotron, Boehringer Mannheim, Germany). Moreover, subjects who were not using beta-blockers, performed a submaximal exercise test on a cycle ergometer (Lifecycle 9500 HR, Life Fitness, USA) according to the Astrand protocol, by means of which the aerobic capacity (VO_{2max}) was estimated.²⁸ Subjects cycled for six minutes, except in case of a difference between the fifth and sixth heart rate frequency larger than five beats, subjects continued cycling for another minute. Waist and hip circumference, blood pressure and skinfold thickness were measured twice, and the means were calculated. After these measurements, intervention subjects received some additional measurements as part of the PACE-type intervention in which they were invited to participate for nine months. These additional measurements included: shoulder flexibility (stick with a scale division in centimeters), hand grip strength (grip strength dynamometer, Takei Scientific Instruments Co.), leg force (jump test using a springboard), hamstring flexibility (sit and reach test), heart function (electrocardiogram, Cardioperfect 4.1 st, The Netherlands) and lung function (peakflowmeter, Mini Wright, Clement Clarke). Body mass index was calculated as body weight (kg) divided by body height squared (m²). The percentage of body fat was calculated using the sum of the four skinfold thicknesses.²⁹

Feedback

Directly after testing, the intervention group consulted a sports doctor, who gave feedback in a standardized way on most of the test results, including waist circumference, percentage of body fat, diastolic and systolic blood pressure, total blood cholesterol, VO_{2max} , shoulder flexibility, hand grip strength, leg force, hamstring flexibility, and lung function. Test results on each of these variables were classified into two or more (not exceeding five) categories, which served as criteria on which the feedback was based. Thus, feedback was given in a standardized way using terms such as excellent, good, average, moderate, or bad, dependent on the number of categories. With respect to waist circumference and percentage of body fat, the criteria differed for men and women. For VO_{2max} , the criteria were dependent on both sex and age.

After standardized feedback, the sports doctor emphasized the role of regular physical activity and healthy dietary habits. Especially in the case of poor test results, the sports doctor encouraged subjects to improve their physical activity and dietary habits. Subjects in the reference group received neither their test results, nor feedback on these results. In case of extreme blood pressure values (diastolic ≥ 105 mm HG or systolic ≥ 180 mm HG) and/or total blood cholesterol levels (≥ 8.1 mmol.l⁻¹), a referral to a general practitioner was arranged. This was applied for both the intervention and reference group.

Analysis

Four groups indicating the pattern of change of behavior stage were distinguished. These groups were based on the classification used by Marcus et al.³⁰ and included: (a) stable sedentary (subjects who were in (pre)contemplation/preparation before and after the test); (b) stable active (subjects who were in action/maintenance at before and after the test); (c)

adopters (subjects who moved in a progressive pattern from (pre)contemplation/preparation to action); (d) relapsers (subjects who moved in a regressive pattern from action/maintenance back to (pre)contemplation/ preparation). Subsequently, a χ^2 test was conducted to examine the relationship between the pattern of change in behavior stage and the study group. In addition, of the raw PACE assessment scores, delta scores (post-test minus pre-test) were calculated, after which an analysis of variance (ANOVA) was performed using the delta score as the dependent variable, and the study group and sex as the independent variables. Alpha was set at 0.05. As people in the action/maintenance stage do not need to change behavior and were, for that reason, not the target group of the intervention, an additional subgroup analysis (analysis of variance) was conducted for the precontemplators and the contemplators/preparators only.

Results

Study population

With the exception of sex, there were no significant differences in demographic factors, test results and stage of change between the two study groups (tables 1 and 2). With respect to the current status of both physical activity and nutrition, only a minority of the subjects rated themselves as precontemplators. Three subjects, two of whom were in the reference group, received a referral to a general practitioner, because of extreme values of blood pressure or blood cholesterol.

	Whole group n=299	Interventio n group n=131	Reference group n=168	p value
sex (% women)	34.1	27.5	39.3	0.03
age (years)	44.1 (8.7)	44.6 (7.9)	43.6 (9.3)	0.33
body mass index (kg.m ⁻²)	25.8 (3.8)	25.9 (3.7)	25.7 (3.8)	0.66
body fat (%)	28.9 (6.5)	28.7 (6.6)	29.1 (6.5)	0.58
waist circumference (cm)	87.2 (12.3)	88.2 (11.1)	86.4 (13.2)	0.22
hip circumference (cm)	99.7 (6.9)	99.3 (7.1)	100.3 (6.6)	0.23
diastolic blood pressure (mm HG)	87.1 (8.8)	86.9 (8.5)	87.2 (9.0)	0.77
systolic blood pressure (mm HG)	139.8 (15.2)	139.7 (14.8)	140.0 (15.6)	0.86
total cholesterol (mmol. 1-1)	5.5 (1.0)	5.5 (1.0)	5.4 (1.0)	0.24
estimated VO _{2max} (I.min ⁻¹)	3.1 (0.8)	3.1 (0.8)	3.0 (0.8)	0.17
resting heart rate (beats.min ⁻¹)	71.3 (12.4)	71.8 (11.4)	70.7 (13.7)	0.47

Table 1. Baseline characteristics (demography, fitness and health status) of the study population

Values are mean(sd).

The p-value refers to the *t* test (for continuous data) or χ^2 test (for categorical data) to test for differences between the two study groups

Influence of feedback

Most of the subjects in the intervention and the reference group did not change with regard to stage of physical activity and nutrition behavior (table 3). Only a minority in both groups reported adopting a more physically active lifestyle or a healthier diet, or relapsing with regard to either. However, for calorie intake and weight management, a relatively large percentage of the intervention subjects (12%) reported a relapse. The x^2 test showed no significant differences between the study groups at the level of stage of behavior change, nor did a stratified analysis for men and women. The results of the analysis of variance, however, showed a significant difference in raw PACE score for calorie intake and weight management (p=0.002; table 4). The subgroup analysis, from which subjects in the action/maintenance stage were excluded, also showed a significant effect on calorie intake and weight management. Further, a separate analysis for men and women showed that the effect was mainly due to the men in our sample. It was shown that male intervention subjects significantly more often regressed on their PACE calorie intake and weight management score compared with male reference subjects, whereas no effect was seen among women. After having received feedback, 23% of the total intervention group, regressed on their PACE score on this topic. Of these, about half (53%) moved from action/maintenance to contemplation/preparation. In the reference group, only 7% regressed on their PACE score with regard to this topic.

	Interve	ention group	Referen	ce group
Stage	n	%	n	%
Physical activity:				
precontemplation	0	0.0	4	2.4
contemplation/preparation	60	45.8	70	41.7
action/maintenance	71	54.3	94	56.0
Fruit and vegetable intake:				
precontemplation	7	5.3	9	5.4
contemplation/preparation	67	51.1	84	50.0
action/maintenance	57	43.5	75	44.6
Dietary fat intake:				
precontemplation	24	18.3	32	19.0
contemplation/preparation	89	67.9	110	65.5
action/maintenance	18	13.7	26	15.5
Calorie intake and weight n	nanagem	ent:		
precontemplation	2	1.5	7	4.2
contemplation/preparation	77	58.8	101	60.1
action/maintenance	52	39.7	60	35.7

Table 2. Baseline distribution of stages of change by treatment group

Table 5. Heatment C	Progres		Stable		Regressed		
Baseline stage	I	R	I	R	I	R	
Physical activity:					_		
precontemplation	x	50.0%	x	50.0%	x	x	
		(n=2)		(n=2)			
contemplation/	15.0%	7.1%	85.0%	92.9%	x	x	
preparation	(n=9)	(n=5)	(n=51)	(n=65)			
action/maintenance	x	x	91.5%	88.3%	8.5%	11.7%	
			(n=65)	(n=83)	(n=6)	(n=11)	
Fruit and vegetable in	take:						
precontemplation	14.3%	x	87.7%	100.0%	x	x	
	(n=1)		(n=6)	(n=9)			
contemplation/	3.0	2.4%	97.0%	97.6%	x	x	
preparation	(n=2)	(n=2)	(n=65)	(n=82)			
action/maintenance	x	x	94.7%	92.0%	5.3%	8.0%	
			<u>(n=54)</u>	(n=69)	(n=3)	(n=6)	
Dietary fat intake:							
precontemplation	x	x	100.0%	100.0%	x	x	
			(n=24)	(n=32)			
contemplation/	x	2.7%	100.0%	97.3%	x	x	
preparation		(n=3)	(n=89)	(n=107)			
action/maintenance	х	х	72.2%	84.6%	27.8%	15.4%	
	_		(n=13)	(n=22)	(n=5)	<u>(n=4)</u>	
Dietary fat calorie inta	ke and weig	ht manage	ment:				
precontemplation	x	x	100.0%	100.0%	x	x	
			(n=2)	(n≂7)			
contemplation/	2.6%	2.0%	97.4%	98.0%	x	х	
preparation	(n=2)	(n=2)	(n=75)	(n =99)			
action/maintenance	x	x	69.2	88.3%	30.8%	11.7%	
			(n=36)	(n≂53)	(n=16)	(n=7)	

I= Intervention group, R= Reference group.

Discussion

The purpose of the present study was to evaluate whether instantaneous personalized feedback on fitness and health, affects the self reported appraisal of the stage of behavior change assessed by PACE forms. It was hypothesized that, after having been confronted with objective fitness and health status scores, a subject might change their subjective appraisal of their actual fitness and health profile. If so, they might change their self reported behavior stage. Our findings showed no significant effect at the level of behavior stage, for either physical activity, or nutrition. However, results of analysis of variance

showed that after consultation significantly more subjects in the intervention group regressed on their raw PACE score with respect to calorie intake and weight management, compared with the reference group. These findings suggest that personalized feedback does not immediately induce a change at the level of behavior stage, but does induce a change at a more sophisticated level, that is the raw PACE score.

The PACE assessment forms have shown to be of good short term test-retest reliability (weighted kappa, 0.73-0.85; intraclass correlation coefficient, 0.76-0.89). Thus, the effect shown on calorie intake and weight management was not due to the use of instruments that are not reliable.

A conceivable explanation for the effect of feedback on calorie intake and weight management is associated with the idea that a person has about his/her own body composition, in combination with the feedback given. In this study, feedback mainly concerned the results of the fitness and health tests. It could be the case that subjects had an initial self-image regarding their body composition that did not correspond to the actual values. If so, the objective information received by the intervention subjects may adjust this self image towards the real body composition. In its turn, this adjustment may result in a change in PACE score, indicating a more realistic appraisal of the respondent's stage. In practice, this may be an important mechanism, because subjects who consider themselves as being in the action/maintenance stage, probably think they do not need to change their behavior, whereas these rating themselves as contemplators are willing to improve their physical activity or dietary habits. Thus, feedback can induce a more appropriate staging of the respondent.

It is, the intriguing why we did not find an effect on the other topics assessed by PACE. With respect to physical activity, subjects received objective information about their aerobic capacity (VO_{2max}). In general, we think that most people do not know their VO_{2max} value, as a result of which a reference value is lacking, making it impossible to compare their subjective idea with the objective value. For intake of fruit and vegetables and dietary fat, no feedback was given specifically on the consumption of these food items. Thus, in contrast to body composition, the feedback on physical activity, and intake of fruit and vegetables and fat could not be translated directly into the categories available on the PACE forms. Moreover, for both fruit and vegetable intake and dietary fat intake, studies have shown discrepancies between the objective and subjective consumption indicating that most people are not aware of the fact that their behavior is unhealthy.³¹⁻³³ In practice, creating awareness of actual consumption of food must therefore be the first, essential step to changing behavior.³²

A few issues arise from our study. The first involves the study population. Although randomly allocated to an intervention or reference group, the sample consisted of a self selected population. Unfortunately, the recruitment of subjects in studies on the promotion of physical activity often leads to inclusion of a self-selected group of subjects. In general, workplace physical activity programs often recruit only 20% to 30% of the workforce, and these also tend to be more fit and more aware of health issues than non-participants.³⁴ Our study reached 50% (299/600) of the employees that were invited to participate, which is thus relatively large. Furthermore, it appeared that 61% of our study population did not

reach the moderate intensity physical activity recommendation.³⁵ Compared with 60% (winter) and 47% (summer) of the general Dutch population who do not reach this physical activity standard,³⁶ we conclude that our sample was similarly dominated by inactive people. However, as the sample included only a small percentage of precontemplators, we were not able to test the hypothesis that precontemplators in particular may consider changing their stage of behavior to the contemplator/preparator stage, after having been confronted with a potentially poor fitness and/or health status. Future research involving in particular precontemplators would thus be very interesting.

	Ia	Rª	p value ^b	Difference	95% CI
	mean (sd)	mean (sd)		in means	
	n=131	n=168		(I-R)	
physical activity	0.00 (1.07)	-0.07 (1.18)	0.67	0.07	-0.21; 0.32
fruit and vegetables intake	-0.04 (0.47)	0.01 (0.39)	0.32	-0.05	-0.15; 0.05
dietary fat intake	0.11 (0.61)	0.06 (0.50)	0.57	0.05	-0.09; 0.16
calorie intake and weight management	-0.18 (0.66)	0.05 (0.50)	<0.01	-0.22	-0.35; -0.08

Table 4. Treatment condition and PACE delta scores	(post-test minus pre-test)
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Values are mean (sd); 95% CI, 95% confidence interval.

^a I= Intervention group, R= Reference group; ^b the p value refers to the analysis of variance with the delta score as the dependent and study group and sex as the independent variables.

Secondly, for individual counseling based on a PACE assessment, it should be kept in mind that subjects may report better lifestyle habits than they actually have. For calorie intake and weight management, our findings support this type of 'misclassification'. Although doubt can be cast on the validity of PACE assessment forms, a more relevant question is whether it is possible for such an instrument to be valid when it relies on self reporting of a behavior that may not be accurately recalled.

Finally, the time interval between the completion of the two PACE assessment forms was short, namely one hour. For this reason, we can not exclude the possibility of a first measurement effect. As no detailed information was given about the aim of the completion of two PACE assessment forms, it may be that subjects merely repeat their baseline score. This would underestimate any effect of feedback. For our purpose, the one hour interval is suitable, as the main focus was to determine whether subjects would change their PACE score after having been confronted with the test results that are then directly related to their behavior. As we expected the influence of the feedback to be largest directly after having been confronted with the test results, the one-hour interval was essential. To change the actual behavior, a longer interval is needed. This was realized, so a PACE-type intervention lasting nine months (see methods section), was initiated directly after the baseline measurements.

To conclude, this study seems to support the notion of practitioners that feedback on measurements can in itself induce changes in PACE scores and a more realistic appraisal of

participants of their stage of change. Practitioners should therefore pay proper attention to feedback on measurements and fully use the potential of such feedback as the start of the intervention.

Conclusion

This study shows that personalized feedback on fitness and health status did not affect the PACE score on physical activity, intake of fruit and vegetables, and intake of dietary fat, but it did affect the PACE score on calorie intake and weight management. Subjects who received feedback appeared to regress on their behavioral stage with regard to this aspect more often than subjects without this feedback. Giving feedback on measurements at baseline of an intervention study can thus influence PACE scores and can be considered as a small, but relevant start of the intervention itself.

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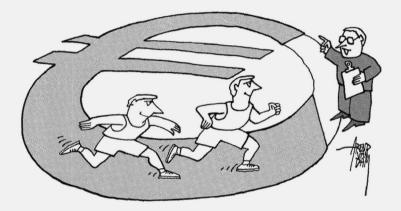
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Section 4

Effectiveness of worksite physical activity counseling



Chapter 4.1

Effect of individual counseling on physical activity, fitness and health. A randomized controlled trial in a workplace setting

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Abstract

Background: Physical inactivity and obesity are major public health problems. Our objective was to investigate the effectiveness of an individual counseling intervention at the workplace on physical activity fitness and health. Counseling content derived from the Patient-centered Assessment and Counseling for Exercise and Nutrition (PACE) program.

Methods: A total of 299 employees of three municipal services in the Dutch town of Enschede were randomly allocated into intervention (n=131) and control group (n=168). Over a 9-month period, intervention group subjects were offered seven counseling sessions. Counseling was based on the individual's stage of behavioral change using PACE physical activity and nutrition protocols. Subjects in both the intervention and control group received written information about several lifestyle factors. Primary outcome measures were physical activity (total energy expenditure, during sports activities, during physical activity leisure time other than sports, and meeting the moderate-intensity public health recommendations); cardiorespiratory fitness; and prevalence of musculoskeletal symptoms. Secondary outcome measures were body composition (body mass index [BMI], and percentage of body fat measured via skinfold thicknesses), blood pressure, and blood cholesterol.

Results: There were significant positive effects on total energy expenditure, physical activity during sports, cardiorespiratory fitness, percentage of body fat, and blood cholesterol. No effects were found for the proportion of subjects meeting the public health recommendation of moderate-intensity physical activity, physical activity during leisure time other than sports, prevalence of musculoskeletal symptoms, body mass index, and blood pressure.

Conclusions: Individual face-to-face counseling at the workplace based on PACE protocols positively influenced physical activity levels and some components of physical fitness. The implementation of workplace counseling programs for individuals should therefore be promoted.

The importance of physical activity in the prevention of chronic diseases is beyond doubt. Recent studies have shown associations between physical inactivity and major causes of mortality and morbidity.¹⁻⁴ However, the majority of the adult population in Western nations is still inactive or irregularly active.^{5,6} Obesity, another public health problem, is related to physical inactivity. During the past few decades, the prevalence of obesity has grown and is still increasing.⁷⁻⁹ Being overweight or obese is a risk factor for cardiovascular diseases, diabetes, and some types of cancer.¹⁰⁻¹⁴ Moreover, obesity has major economic implications for society. Obese employees are more often absent from work than non-obese colleagues; consequently, obesity has a negative influence on productivity.^{15,16}

Based on the trends mentioned above, strategies to increase physical activity and promote healthy dietary habits are of great importance. Interventions based on psychological constructs (e.g., the transtheoretical model [TTM])^{17,18} have been suggested as potentially effective. Using the concept of 'stages of change', the TTM aims to provide insight in how people make their behavioral changes over time. The following stages are distinguished: 1) precontemplation-not intending to change behavior; 2) contemplation-considering to change behavior; 3) preparation-making small changes in behavior; 4) action-actively engaging in behavior change; 5) maintenance--sustaining the behavior change over time. An example of an intervention based on the TTM is the Patient-centered Assessment and Counseling for Exercise and Nutrition (PACE) program.^{19,20} Based on the theory that people in different stages need correspondingly different approaches to change their behavior, PACE materials are developed to give tailored information for the stage of change and to motivate people toward the next stage. The PACE physical activity program has been shown to be a feasible and effective intervention in a clinical setting.^{21,22} To our knowledge, no studies have been published on the effectiveness of the combined physical activity and nutrition PACE program at the workplace. However, the PACE-type approach may be very promising in a workplace setting. For example, employees are typically busy, and a brief, individualized consultation may be what employees need. The aim of this study was to evaluate the effectiveness of a workplace individual-counseling program, using the PACE materials on physical activity, health-related fitness, and health.

Methods

Study design and study population

A randomized, controlled, single blind trial was conducted. Subjects were recruited from three municipal services in the Dutch town of Enschede. Inclusion criteria were 1) employment as civil servant; 2) work in office environment; 3) work \geq 24 hours a week at the local service; 4) contracted until the time of the post-test; 5) signed the informed consent form. All eligible employees were invited to attend an information session in which the content of the intervention and the study design were explained. Subjects who registered themselves for the information session and agreed to participate in the study were randomly allocated into the intervention and control group. The medical ethical committee of the VU Medical Center approved the study protocol.

Intervention

The intervention took place over 9 months (May 2000–January 2001). Active Living Papendal, a Dutch commercial company offering individual counseling to organizations, carried out the intervention. All subjects randomized into the intervention group were offered seven individual consultations, which were each 20 minutes in duration and given by a physiotherapist trained for using the PACE materials. Two counselors were involved, although one consulted with only ten subjects. Counseling focused primarily on the enhancement of the individual's level of physical activity and secondarily focused on the promotion of healthy nutrition habits. After having discussed physical activity and nutrition, subjects could also obtain counseling about other lifestyle factors, such as (work) stress, smoking, or musculoskeletal symptoms.

Based on the PACE assessment score, the stage of change regarding physical activity and nutrition was determined for each individual. Corresponding to the individual's stage of change, counseling took place using PACE protocols. There were three counseling protocols: one for the precontemplators, one for the contemplators/preparators, and one for those being in the action or maintenance stage. Moreover, during the first consultation, general written information about several lifestyle factors—physical activity, nutrition, alcohol, smoking, (work) stress, and ergonomics—was collected. During the second consultation, a plan was made to improve physical activity and nutrition behavior. The plan was further discussed during the remaining five consultations. Subjects in the control group received written information about lifestyle factors only. This information was the same as that handed out to the intervention group.

Measurements

Fitness tests, a questionnaire, and a structured interview were used to gather data on the outcome measures. Outcome assessments were performed before the intervention and directly after the completion of the last consultation of the last subject.

Primary outcome measures included 1) physical activity; 2) cardiorespiratory fitness; and (3) prevalence of musculoskeletal symptoms. Physical activity was assessed in three ways, First, physical activity was assessed by the moderate-intensity physical activity public health recommendations.²³ Each subject was asked the number of days a week over the past 2 weeks that he or she had participated in moderate-intensity physical activities for a total of ≥30 minutes a day.²⁴ According to Pate et al.,²³ moderate-intensity activities for the adult population are defined as activities at an intensity of 3 to 6 metabolic equivalents. Individuals reporting such activities ≥ 5 days a week were considered to be active. Second, total energy expenditure was calculated from the answers in a structured interview (7-day Physical Activity Recall [PAR]).25-27 The third physical activity outcome measure concerned the level of physical activity during sports (i.e., the sport index) and during other leisure-time pursuits (i.e., the leisure-time index), assessed by the Baecke questionnaire.^{28,29} The cardiorespiratory fitness measure was the mean heart rate in the last 2 minutes of the Åstrand bicycle test.^{30,31} In this test, subjects had to cycle at submaximal exertion for 6 minutes. At the post-test, subjects had to cycle at the same wattage and rotation speed as during the baseline measurement. Musculoskeletal symptoms were divided into low-back and upper-extremity

symptoms for prevalence over a 3-month period using a validated Dutch version³² of a Nordic questionnaire.³³

Secondary outcome measures were (1) body composition (i.e., body mass index [BMI] and percentage of body fat); (2) blood pressure; and (3) total blood cholesterol. The percentage of body fat was calculated from the sum of the thickness of four skinfolds: biceps, triceps, suprailiac, and subscapular.³⁴ Blood pressure and total cholesterol were assessed using a blood pressure watch (NAIS, Fuzzy-logic, Japan) and a reflotron (Boehringer Mannheim GmbH, Germany), respectively.

Randomization

For practical reasons, we ran the randomization program before baseline measurements. Because a larger loss to follow-up among the control subjects was expected, 45% of the subjects were allocated to the intervention group, and 55% to the control group. Block randomization for a total of 70 workplace units was conducted, given the anticipated influence of the intervention among colleagues at the same work unit. Moreover, randomization was performed within each municipal service (n=30, n=28, and n=12, respectively). This was done in order to achieve approximately equal numbers of intervention and control subjects in each municipal service.

Directly after completing the baseline measurements, subjects were assigned to the intervention or control group by the coordinator of the fitness and health tests, who did not perform any of the measurements. Those who assisted with the tests, as well as the person who administered the 7-day PAR, were blinded to allocation of subjects into groups.

Statistical analysis

The sample size calculation was based on observing an effect on the recommended moderate-intensity physical activity outcome measure, defined as an increase of 20% within the intervention group and an increase of 5% within the control group. For 90% power and a significance level of 5%, a sample size of \geq 95 employees per group was needed.

To estimate the effectiveness of the intervention, an analysis of covariance (ANCOVA) with baseline values as covariates, was applied. Linear regression analysis was used for continuous data, and logistic regression was used for dichotomous data. Variables that differed between the study groups at baseline ($p \le 0.20$), as well as a set of predefined variables (e.g., demographic factors, working unit, municipal service, health-profile-related variables), were checked for confounding. In order to determine whether subjects with a less favorable physical activity, fitness, or health profile showed greater benefits from the intervention, we checked for effect modification. Effect modification was defined as a significant (p < 0.10) interaction term between the study group and variable of interest. For the continuous data, paired *t*-tests were used to evaluate intra-group change.

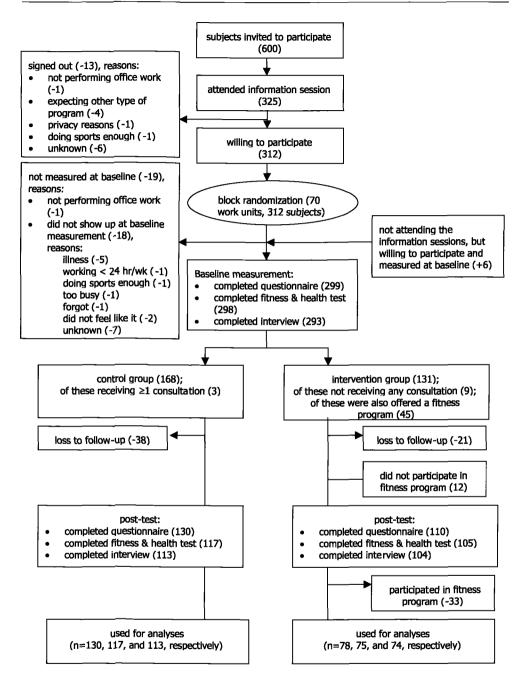


Figure 1. Flow diagram of subjects in the trial

Results

Subjects

The progress of participants through the various stages of the study is presented in figure 1. A total of 600 employees were invited to attend the information session. Of these eligible subjects, basement measurements were obtained for 299 who were randomly allocated into the intervention group (n=131) and control group (n=168). In the intervention group, the loss to follow-up was 16%, 19%, and 18% for the completion of the questionnaire, the fitness and health test, and the interview, respectively. Within the control group, the loss to follow-up was 23%, 30%, and 32% for the same items, respectively. The principal reasons for loss to follow-up were refusing to continue with the study and changing jobs.

Table 1 shows the demographic characteristics and outcome measure values at baseline and post-test for subjects with complete data for the variable of interest. Due to missing values at baseline or post-test, the number of subjects presented in table 1 differs by variable. There were no significant differences in demographic factors, physical activity, fitness, and health between subjects who withdrew from the study (n=59) and those who continued (n=240). As the differences between the study groups at baseline and the predefined variables did not confound the outcome of the trial (data not shown), the unadjusted analyses are presented.

Compliance

Two thirds of the intervention subjects attended six or seven consultations (n=32 and n=32, respectively). The average attendance frequency of all intervention subjects was 5.3.

Effectiveness on primary outcome measures

Linear regression analyses were acceptable in all situations because the residuals were uncorrelated and approximately normally distributed. There was no statistically significant effect on the proportion of subjects who met the recommendation of moderate-intensity physical activity (odds ratio [OR], 1.46; 95% confidence interval [CI], 0.76–2.79) (figure 2). In the intervention and control groups, 23% and 19%, respectively, changed from 'not active enough' to 'active'. With respect to total energy expenditure, a statistically significant effect was found in favor of the intervention group (table 2). The paired *t*-test showed that control subjects significantly decreased their total energy expenditure, whereas the intervention subjects showed a slight increase over time (table 3).

Similar results were found for the sport index. Sport activities in the control group declined by a statistically significant amount. These activities in the intervention group effectively did not change. In contrast, physical activities during leisure time apparently did not change for both groups. Regarding cardiorespiratory fitness, submaximal heart rate significantly declined (i.e., cardiorespiratory fitness improved) in the intervention group. In contrast, submaximal heart rate at a given power output increased among control subjects (table 3). The difference between the two study groups was statistically significant (table 2).

For the third primary outcome measure (i.e., prevalence of musculoskeletal symptoms), no effects were found for the lower back (OR, 1.15; 95% CI, 0.61–2.15) or the

upper extremities (OR, 0.73; 95% CI, 0.38–1.38) (figure 2). Finally, effect modification was found, which led to the conclusion that the higher the baseline energy expenditure level (measured by the 7-day PAR), the larger the effect of the intervention on physical activity (i.e., energy expenditure, sport index, and leisure time index).

	Inte	ervention gr	oup	Cont	rol group	
		Before	After		Before	After
Characteristics	n	mean (sd)	mean (sd)	n	mean (sd)	mean (sd)
mean age (years)	78	43.8 (8.3)	-	130	44.0 (9.4)	-
women (%)	78	25.6	-	130	38.5	-
higher educated (%)	78	66.6	-	130	64.6	-
active enough ^a (%)	76	48.7	42 .1	116	36.2	30.2
PACE score physical activity ^b	73	5.2 (1.7)	5.6 (1.7)	117	4.9 (1.7)	4.9 (1.8)
energy expenditure	c 0	1155.3	1219.5	444	11 78.8	1049.6
(kcal.day ⁻¹)	69	(394.1)	(505.8)	111	(693.9)	(342.6)
sport index ^{c,d}	71	3.0 (0.8)	2.9 (0.8)	118	2.6 (0.8)	2.5 (0.7)
leisure time index ^c	77	3.0 (0.6)	3.0 (0.6)	130	2.8 (0.6)	2.9 (0.6)
submaximal HR	70	135.1	132.9	102	135.6	138.0
(beats.min ⁻¹)	70	(10.5)	(12.6)	102	(11.5)	(14.7)
BMI (kg.m⁻²)	75	25.3 (3.3)	25.2 (3.2)	115	25.5 (3.3)	25.6 (3.5)
body fat (%)	75	27.9 (6.4)	26.5 (6.3)	117	28.8 (6.3)	28.2 (6.5)
diastolic BP (mmHG)	75	85.8 (8.3)	82.3 (9.2)	116	87.1 (9.3)	83.2 (9.2)
systolic BP (mmHG)	75	137.1	133.0	116	140.8	135.6
	/5	(13.7)	(14.5)	110	(15.5)	(15.0)
cholesterol (mmol.l ⁻¹)	75	5.5 (1.0)	5.3 (1.0)	117	5.3 (0.9)	5.3 (0.9)
low back symptoms (%)	78	50.0	47.4	130	49.2	44.2
upper extremity symptoms (%)	78	73.1	55.1	130	62.3	56.2

Table 1. Characte	ristics of study p	opulation before	and after intervention
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^a Performing \geq 30 minutes of moderate-intensity physical activities for \geq 5 days a week; ^b Index score ranged from 1 to 8: the higher the score, the more physically active; ^c Index score ranged from 1 to 5: the higher the index, the more physically active during sport or leisure time; ^d Study groups differed significantly at baseline (p=0.02).

BP, blood pressure; HR, heart rate; PACE, Patient-centered Assessment and Counseling for Exercise and Nutrition, sd, standard deviation.

Effectiveness on secondary outcome measures

ANCOVA results showed a statistically significant, positive effect of the intervention on the percentage of body fat and blood cholesterol (table 4). Although both groups showed significant declines in body fat, the intervention group showed a larger decrease compared to the control group. No significant effect on BMI was found. Further, both groups appeared to have significantly decreased their diastolic and systolic blood pressure (table 5), but no significant difference between the two groups was found (table 4). For all health profile related outcomes, an effect modification was found, which shows that the worse the baseline health profile (i.e., high BMI, blood pressure, and cholesterol), the more favorable the intervention effect.

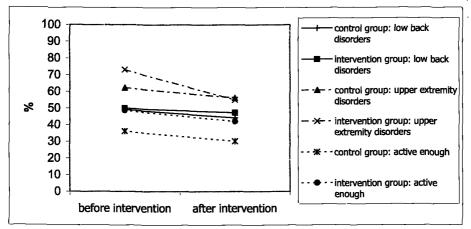


Figure 2. Percentages of musculoskeletal symptoms and recommendations of moderateintensity physical activity before and after intervention for each study group

Table 2. Results of (unadjusted) ANCOVA regarding	g intervention effectiveness on primary
outcomes measures	

Outcome variable	n	Beta (SE)	95% CI	р
energy expenditure (kcal.day ⁻¹)	180	176.18 (58.58) ^a	60.58; 291.78	0.003
sport index ^b	189	0.22 (0.08) ^a	0.07; 0.37	0.004
leisure time index ^b	207	0.06 (0.05) ^a	-0.04; 0.17	0.244
submaximal HR (beats.min ⁻¹)	172	-4.71 (1.35) ^c	-7.38; -2.05	0.001

^a A positive beta indicates a better energy expenditure and activity index of the intervention group compared to the reference group at post-test, given equal baseline values; ^b Index score ranged from 1 to 5: the higher the index, the more physically active during sport and leisure time; ^cA negative beta indicates a better cardiorespiratory fitness of the intervention group compared to the control group at post-test, given equal baseline values.

ANCOVA, analysis of covariance; CI, confidence interval; HR, heart rate; SE, standard error.

	Inte	rvention grou	p	Cont	rol group		Absolute
	n	mean (sd)	р	n	mean (sd)	P	difference
energy expenditure	69	64.24	0.281	111	-129.23	0.033	193.47
(kcal.day ⁻¹)		(490.87)			(630.38)		
sport index ^a	71	-0.01 (0.53)	0.867	118	-0.14 (0.54)	0.007	0.13
leisure time index ^a	77	0.05 (0.44)	0.339	118	0.02 (0.37)	0.482	0.03
submaximal HR	70	-2.24 (8.87)	0.039	102	2.47 (8.53)	0.004	4.71
(beats.min ⁻¹)		. ,					

^a Index score ranged from 1 to 5: the higher the index, the more physically active during sport and leisure time.

HR, heart rate; sd, standard deviation.

Table 4. Results of (unadjusted) ANCOVA regarding intervention effectiveness on secondary outcomes measures

Outcome variable	n	Beta (SE) ^a	95% CI	р
BMI (kg.m ⁻²)	190	-0.22 (0.13)	-0.47; 0.03	0.083
body fat (%)	192	-0.79 (0.32)	-1.43; -0.16	0.015
diastolic BP (mmHG)	191	-0.04 (1.00)	-2.01; 1.92	0.967
systolic BP (mmHG)	191	0.10 (1.50)	-2.85; 3.05	0.946
cholesterol (mmol.l ⁻¹)	192	-0.18 (0.09)	-0.36; -0.01	0.040

^a A negative beta indicates a lower body composition, blood pressure and cholesterol for the intervention group compared to the control group at post-test, given equal baseline values. ANCOVA, analysis of covariance; BMI, body mass index; BP, blood pressure; CI, confidence interval; SE, standard error.

	Intervention group		Control group			Absolute	
	n	mean (sd)	P	n	mean (sd)	p	difference
BMI (kg.m ⁻²)	75	-0.08 (1.05)	0.488	115	0.13 (0.69)	0.040	0.21
body fat (%)	75	-1.39 (2.46)	0.000	117	-0.64 (1.99)	0.001	0.75
diastolic BP (mmHG)	75	-3.54 (7.72)	0.000	116	-3.86 (6.79)	0.000	0.32
systolic BP (mmHG)	75	-4.09 (10.12)	0.001	116	-5.18 (11.12)	0.000	1.09
cholesterol (mmol.l ⁻¹)	75	-0.21 (0.61)	0.004	117	0.01 (0.66)	0.933	0.22

Table 5. Results of paired t test regarding secondary outcome measures

BP, blood pressure; sd, standard deviation.

Discussion

Effectiveness and implications

The aim of this study was to evaluate the effectiveness of a workplace-based, individualcounseling program using PACE materials on physical activity, fitness, and health status indicators. We found a positive effect on physical activity, expressed as the total energy expenditure and as the sports index. In addition, a positive effect was found for cardiorespiratory fitness, percentage of body fat, and blood cholesterol. No effects were observed for changes in moderate-intensity physical activity (as defined in public health recommendations²³), physical activity leisure-time index, prevalence of musculoskeletal symptoms, BMI, and blood pressure.

These findings regarding physical activity partially confirm those of previous studies on the effectiveness of PACE interventions in the primary healthcare setting. Calfas et al.²¹ evaluated the effectiveness of the print-based version of PACE and concluded that physical activity counseling was effective on moderate-intensity physical activity among initially sedentary patients. Differences in study populations and counseling goals between our study and the Calfas et al.²¹ study may account for different results regarding the effect on moderate-intensity physical activity. In the Calfas et al.²¹ study, the counseling goal was to promote moderate-intensity physical activity. In our study, the majority of our study population wanted to improve their cardiorespiratory fitness; consequently, the counselor focused on vigorous activities. Another study evaluated the PACE+ computerized physical activity and nutrition program.³⁵ Preliminary results showed no significant effect for moderate- or vigorous-intensity physical activity. However, it appeared that subjects who set a goal to increase (moderate or vigorous) activity improved significantly more than those who did not target that behavior.

In addition, several other stage-based interventions in the workplace setting have been published, which overall suggest a positive effect. Marcus et al.³⁶ compared the effectiveness of a standard self-help exercise intervention with a self-help intervention tailored to the individual's stage of motivational readiness for exercise. Marcus et al.³⁶ found significant changes in motivational readiness for exercise that were significantly associated with changes in self-reported exercise measured using the 7-day PAR. Further, using a randomized, controlled trial design, Peterson and Aldana³⁷ concluded that stage-based, tailored messages are more effective at increasing short-term physical activity than generic messages or no information. In addition, Cardinal and Sachs³⁸ performed a randomized study in which three forms of mail-mediated, exercise-behavior- change strategies on weekly leisure-time exercise were compared. Although no significant interaction effects were found, it appeared that the intervention group, in which employees were encouraged to integrate more daily activities, showed a greater increase in activity than the control group.³⁸

In our study, inconsistent results were observed as to the significance of the physical activity outcome measures. Nevertheless, approximately the same trend was observed. With the exception of the leisure-time index, the control group showed a decrease in physical activity, whereas the intervention group remained practically stable and showed only a decrease in the proportion meeting the moderate-intensity physical activity recommendation.

Many studies have shown that physical activity increases in the summer in comparison with winter (e.g., Dannenberg et al.³⁹ and Matthews et al.⁴⁰). In the present study, the baseline measurement took place in April, whereas the post-test took place in January. The decrease seen in the control group could be the 'normal' decrease in the winter season. Thus, the intervention may have prevented the common seasonal decrease in winter.

Differences in physical activity results could be associated with 1) the instruments used and 2) the content of the counseling. The questionnaires and the 7-day PAR interview each measure a different type of activity. The sport index involves the amount of sport activities, including mainly vigorous-intensity activities, whereas the leisure-time index and the question as to the public health recommendation assesses moderate intensity activity. The interview included both moderate- and vigorous-intensity activities.

As to the content of counseling, the goal set by the majority of the intervention subjects was to improve cardiorespiratory fitness and to lose weight. As a consequence, the counselor mainly addressed activities needed to achieve the goal of vigorous-intensity activities instead of moderate-intensity activities. This may explain the changes seen in sport but not leisure activity.

In the intervention group, a significant improvement of cardiorespiratory fitness, percentage of body fat, blood pressure, and blood cholesterol was observed without a substantial change in physical activity. A small increase was seen only for energy expenditure, which might explain the improvement in cardiorespiratory fitness. We did not observe such an increase in the sport index, which might be insensitive for smaller changes in vigorous activities. This is a common, serious limitation of self-reported data compared to objective instruments, which are generally more accurate. The decrease in blood pressure, seen in both groups, might be due to artifact, that is, subjects had become accustomed to being measured. As to the percentage of body fat and blood cholesterol level, counseling content could have contributed to the decrease seen in the intervention group. As mentioned before, most subjects expressed losing weight as their goal. Moreover, the counselor was trained to focus on nutrition as well as physical activity.

The present study had several limitations. First, contamination may have occurred because both study groups were in the same municipal services. The possible influence of intervention group subjects on control group colleagues may have attenuated the intervention effects.

Second, it is worthwhile mentioning that because multiple outcomes were tested, statistical significance may be misleading. However, alpha was not adjusted for multiple testing. Instead, the actual p values, rather than significance versus non-significance, are presented so that the reader can determine the 'statistical importance' of each result according to his or her own standard. Moreover, no alpha adjustment was performed because we believed that the magnitude of the effect is more important than whether a relationship is significant, and the magnitude of the effect is not influenced by multiple testing.

Further, a problem in this study concerns the lack of inactive subjects not willing to change their activity behavior (i.e., the precontemplators). Since 26% of the Dutch adult population is considered to be precontemplator regarding physical activity⁴¹ and only 1% of our study population appeared to be precontemplators, we have to conclude that the representativeness of our results was limited to people who were at least in the stage of contemplation. Although we do not have data concerning the physical activity or fitness status of those who refused to attend the information session (n=275), it seems plausible that most precontemplators were among those not willing to participate in the present study.

Our findings are generally in agreement with the positive relationships among physical activity, fitness, and health. 42

The present study provides evidence that physical activity counseling has a positive effect on vigorous intensity physical activity (as shown by the sport index and the energy expenditure) and health-related fitness, including cardiorespiratory fitness and percentage of body fat. Consequently, to increase the proportion of employees who are physically active or fit, we recommend the implementation of physical activity counseling at the workplace. Moreover, based on the effect modification shown for the health-related outcomes, we recommend participation in physical activity counseling mainly for people with a less-favorable health profile. Even though persuading such individuals to participate in physical activity interventions is difficult, such participation results in the largest health-related benefits compared to people with better health profiles.

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Chapter 4.2

Worksite health promotion using individual counseling and the effectiveness on sick leave. Results of a randomized controlled trial

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Abstract

Objectives: To investigate the effectiveness of a worksite health promotion program by individual counseling on sick leave.

Methods: Three municipal services of Enschede, The Netherlands, participated in this trial. A total of 299 civil servants were measured at baseline and were randomized by cluster into the intervention (n=131) or the control group (n=168). During nine months, subjects in the intervention group received a total of seven consultations, particularly aimed at increasing their physical activity level and improving their dietary habits. Both the intervention and the control subjects received written information as to several lifestyle factors. Sick leave data regarding the nine month intervention period (from May until January) were collected from each municipal service's Personnel Department. In addition, sick leave data concerning the nine month period pre- and post intervention were collected. Sick leave data were analyzed using multilevel analysis.

Results: For both groups, the mean sick leave rate during the intervention increased compared to before the intervention. After the intervention period, the control group increased even more (from 22.9 to 27.6 days), whereas the intervention group slightly decreased (from 21.5 to 20.5 days). Median values of sick leave rate decreased for both groups. No statistically significant intervention effect was found. In both groups, the mean sick leave frequency slightly decreased over time (intervention effects were not significant).

Conclusions: The present study showed no significant effect of individual counseling on sick leave. Continued research investigating the effectiveness of this individual counseling program on several health-related outcomes is useful to clarify the trend observed in sick leave.

During the past few decades, both in the US and in European countries worksite health promotion programs have increasingly been implemented.^{1,2} Main factors addressed in such programs involve physical activity or fitness, and nutrition. Although reasons for implementation may differ between organizations, offering a health promotion program to employees is generally based on the assumption that it produces benefits to the individual and the organisation.¹ It is suggested that such programs will improve health and thereby will contribute to a decrease in sick leave. Although there is indeed some evidence that physical activity or fitness programs at the worksite are beneficial for the employer in terms of reduced sick leave, strong evidence is still lacking due to the methodological shortcomings of the studies performed and inconsistencies found between the studies.^{3,4}

A promising intervention strategy to promote healthful behavior concerns individual counseling. Individualized programs address the actual individual behavior and thereby meet the specific needs of the individual. For this reason, individual counseling is suggested to be more effective than group-based programs. An example of a tailored intervention is the Patient-centered Assessment and Counseling for Exercise and Nutrition (PACE),^{5,6} which is based on the transtheoretical model (TTM).^{7,8} The TTM is based on the assumption that people make behavioral changes by passing through various stages, namely: 1) precontemplation (not intending to change behavior); 2) contemplation (considering to change behavior); 3) preparation (making small changes in behavior); 4) action (actively engaging in behavior change); 5) maintenance (sustaining the behavior change over time). By using PACE physical activity and nutrition materials together, a comprehensive health promotion program is provided. The PACE physical activity intervention was developed for primary health care and has, in this setting, proven to be effective in increasing the level of physical activity at the short-term.⁹

We studied an intervention using PACE physical activity and nutrition materials at the worksite. This PACE-type intervention at the worksite has shown to be effective on energy expenditure, physical activity during sports and cardiorespiratory fitness.¹⁰ Our hypothesis is that persistent regular physical activity improves the health status, thereby leading to less illness, and as a consequence to reduced sick leave. Many studies have shown associations between physical activity and a reduced risk for several chronic diseases.¹¹⁻¹³ Since chronic diseases cause in particular long-term sick leave, one might expect to find effects of a physical activity intervention on long-term sick leave, rather than on short spells of sick leave. Some studies that evaluate the effectiveness of a worksite physical activity program indeed have shown more pronounced effects on long-term sick leave than on short-term.^{14,15} However, another recent randomized trial could not confirm these findings.¹⁶ Thus, evidence for the effectiveness of a worksite physical activity program on (the type of) sick leave still remains obscure. The aim of the present paper is to describe the effectiveness of the PACE-type intervention on sick leave.

Material and methods

Study population

Three municipal services of a Dutch town, Enschede, that decided to implement the individual-based intervention, participated in the study. Employees meeting the inclusion criteria were invited to attend an information session, during which the content of the intervention as well as the design of the study was explained. The inclusion criteria were: 1) being a civil servant; 2) being a white-collar worker; 3) having a contract for at least 24 hours a week; 4) having a contract until the moment of post-test.

Randomization

Randomization took place within each municipal service at the level of work unit, given the anticipated contamination of the intervention among colleagues working within the same unit. An unequal number of subjects in the intervention versus the control group (45% versus 55%, respectively) was arranged, as a larger loss to follow-up was expected among control subjects compared to intervention subjects. Although, for practical reasons, the allocation schedule had to be arranged before the baseline measurements, subjects were informed about the group assignment after the baseline measurements. The study protocol was approved by the medical ethical committee of the VU University Medical Center.

Interventions

During nine months (from May 2000 until January 2001), all intervention subjects were offered a maximum of seven consultations. Consultation was done by a physiotherapist, who was trained for the use of the PACE protocols. Each consultation took place during working time and was 20 minutes in duration. The counseling was primarily focused at increasing the level of physical activity, and secondarily at improving the dietary habits. If there was time left and only at the specific request of the employee, other topics such as job stress and musculoskeletal symptoms could be addressed. During the first two consultations, PACE physical activity and nutrition materials were used in order to set up a plan to improve the concerned behavior. Moreover, during the first consultation, intervention subjects received written information about several lifestyle factors (i.e., physical activity, nutrition, smoking, job stress, and musculoskeletal symptoms). During the remaining five consultations, the physical activity and nutrition plan was discussed and, if necessary, adjusted.

Subjects in the control group only received the written information about lifestyle factors. This information was given directly after baseline measurements and was exactly the same as the intervention subjects received during the first consultation.

Data collection

After having signed the written informed consent, all participating employees were measured. Employees were measured again directly after the intervention. Measurements consisted of a questionnaire, fitness and health tests, and a structured interview. The questionnaire involved demographic factors, physical activity behavior, health status, and work(stress)-related factors. In the fitness and health tests, the following parameters were

measured: body height, body weight, blood pressure, total blood cholesterol, waist and hip circumference, and thickness of four skin folds (i.e., biceps, triceps, suprailiac, and subscapular). In addition, a submaximal bicycle test was performed in order to estimate the maximum aerobic capacity.^{17,18} The structured interview involved physical activities performed in the past seven days.^{19,20} Further, sick leave data were obtained from each municipal service's Personnel Department. In the records, absences due to holidays and pregnancy were excluded. For the analyses, sick leave data from three periods of the same nine months (i.e., from May until January) were used: before (1999/2000), during (2000/2001) and after the intervention (2001/2002).

The outcome measures were: 1) sick leave rate, and 2) frequency of sick leave. Sick leave rate was defined as the total number of sick leave days during the nine month period of concern. In case of partial work disability, one was considered to be absent from work through illness. Sick leave frequency concerned the number of newly reported cases of sick leave during each period from May until January. An episode of sick leave was defined as a period of sick leave preceded and followed by a period of at least one day at work.²¹

Data analysis

The statistical analysis was based on the intention-to-treat principle. To study the course of the effectiveness of the intervention on sick leave, longitudinal data analysis was used correcting for sick leave before the intervention, with both sick leave during and sick leave after the intervention as the outcome measure. Because there were two outcome measures for each subject (i.e., sick leave during and after the intervention period), and because of the cluster randomization, multilevel analysis²² was used. In doing so, we first checked whether there was a random intercept by stepwise adding the level of respondent, work unit, and service at the constant variable. After, we checked if there was a random slope for the same three levels. Based on the 'final' model, we checked for confounding. Both crude and adjusted analyses were carried out. In the crude analysis, the independent variables were group allocation, time, and sick leave before the intervention. In the adjusted analysis, age, gender, education, smoking, physical activity, 23,24 physical fitness (i.e., average heart rate during last two minutes of bicycle test), and (work)stress-related variables (i.e., emotional exhaustion, depersonalization, feelings of competence (Dutch version of the Maslach Burnout Inventory)²⁵ were added as possible confounders. In case of a change of the effect size of more than 10%, the variable was considered to be a confounder. Further, effect modification was checked for the following variables: time, age, gender, and sick leave before the intervention. Effect modification was defined as a significant (p<0.10) interaction term between group allocation and the variable concerned. In case of missing values concerning the possible confounding variables, data were imputed taking the average (for continuous data), or the most frequent category (for nominal or ordinal data).

Subjects who terminated employment at the municipal service, and intervention subjects who participated in a coinciding supervised fitness program given by the counselor involved in this project, were excluded from the analyses.

Results

Study population

A total of 600 civil servants were invited to attend an information session during which the intervention and the study protocol was explained. Of these, 325 attended this session, After the session, 13 persons refused to participate in the study. Based on the 312 remaining employees, cluster randomization of work units (70 work units) took place. During baseline measurements, six employees showed up who did not attend the information session and who were willing to participate. Also, 18 employees who attended the information session and who did not sign themselves out for participation, did not show up during baseline measurements. Further, one employee willing to participate had to be excluded, because he did not meet one of the inclusion criteria. Thus, 299 employees meeting the criteria for inclusion were measured at baseline and were assigned to the intervention (n=131), or the control group (n=168). During the intervention two subjects (one in each study group) stopped working at the municipal service. Another eleven subjects terminated employment after the intervention (intervention group: n=3; control group: n=8). Further, 33 intervention subjects who were offered to participate in the coinciding supervised fitness program and who indeed participated at least once, were excluded from the analyses in order to evaluate merely the effect of the individual counseling intervention. The majority of the subjects were highly educated (table 1). Though not statistically significant (p>0.05), there were relatively more women in the control group compared to the intervention group (38.9% versus 27.8%). At baseline, there were no differences between the intervention and control group with respect to sick leave. In addition, there were no differences in sick leave between employees who stopped working and those who continued working at the municipal service.

	Intervention group	Control group
	(n=97)	(n=167)
gender (% female)	27.8	38.9
age (years) ^a	43.8 (8.1)	43.7 (9.3)
high educated (%)	63.9	62.7
absence rate (days) ^a	17.2 (42.1)	15.2 (41.0)
absence rate (days) ^b	5.0	4.0
absence frequency (times) ^a	1.3 (1.5)	1.3 (1.4)
absence frequency (times) ^b	1.0	1.0
prevalence of absence (%)	63.9	62.9

Table 1. Baseline data of the demographic factors and outcome measures

^a Mean (standard deviation); ^b median.

Note. There were no significant differences between the study groups.

Compliance

Of the intervention subjects (n=97), the majority (79.4%) attended five (n=13), six (n=32) or seven (n=32) consultations. Nine intervention subjects did not attend any consultation for several reasons (e.g., lack of time, privacy reasons or forgotten). Next to physical activity and nutrition, 18% of the intervention subjects reported that the counselor had also addressed job stress. For musculoskeletal disorders, this was 14%.

 Table 2. Mean and median values of sick leave rate (in days) in the period before, during and after the intervention per study group

	Before	During	After
mean (standard deviation) sick leave rate			
intervention group	17.2 (42.1)	21.5 (53.9)	20.5 (52.3)
control group	15.2 (41.0)	22.9 (56.4)	27.6 (62.4)
median sick leave rate			
intervention group	5.0	4.0	2.0
control group	4.0	4.0	2.0

Effectiveness on sick leave

For both groups, the mean sick leave rate increased during the intervention, compared to before the intervention (table 2). The control group showed an increase from 15.2 to 22.9 days, while the intervention group increased from 17.2. to 21.5 days. In the period after the intervention period, the control group increased further (from 22.9 to 27.6 days), whereas the intervention group slightly decreased in mean sick leave rate (from 21.5 to 20.5 days). As to the median values of sick leave rate, both groups decreased (table 2). The intervention group decreased from 5.0 days (before) to 4.0 days (during) and to 2.0 days (after). The control group first remained stable (median days of sick leave: 4.0), after which the median value decreased to 2.0 (period after the intervention). Frequency of sick leave showed a slight decrease over time for both groups. The mean sick leave frequency of the intervention group decreased from 1.3 to 1.1 to 1.0 times during the nine months period of concern. For the control group, this was 1.3, 1.2, and 1.1, respectively.

Multilevel analyses showed neither a statistically significant effect for sick leave rate, nor for frequency of sick leave (table 3). The adjusted analyses did not change the results (table 3). For sick leave rate, a significant interaction was found between the group allocation and sick leave rate in the period before the intervention: the less days of sick leave before the intervention, the larger the effect size in favor of the intervention. For frequency of sick leave, no effect modification was observed.

	Crude 'difference' ^a (SE)	95% confidence interval	Adjusted 'difference' (SE)	95% confidence interval
rate	-5.10 (4.97)	-14.84; 4.63	-6.09 (4.82) ^b	-15.53; 3.36
frequency	-0.13 (0.12)	-0.37; 0.11	-0.10 (0.12) ^c	-0.34; 0.15

Table 3. Results of the multilevel analyses to determine the effectiveness on sick leave rate and frequency

^a differences (and standard errors) between the intervention and control group analyzed with multilevel analysis; negative difference is in favor of the Intervention group; ^b adjusted for: gender, smoking, and depersonalization; ^c adjusted for: age, physical activity during sports and physical activity during leisure time other than sports.

Discussion

The purpose of this study was to investigate the effect of individual counseling at the worksite on sick leave. For companies, reduction of sick leave is often an important effect expectation of such program.

It appeared that almost two third of all workers had been absent during the nine months period before the intervention. Therefore, one might expect some potential for a decrease in sick leave. However, we did not observe such a decrease. Instead, during the intervention the mean sick leave rate increased for both groups. However, a decreasing trend was observed in the median value of sick leave rate. The different trends observed in mean and median values of sick leave rate was due to a change in the long-term sick leave. During the intervention period, in both groups, more subjects had been absent because of long-term illness compared to the period before the intervention period. After the intervention period, in the intervention group, a reduction was seen in long-term sick leave, resulting in a decrease in the mean sick leave rate.

At the start of the intervention, a large firework disaster occurred in Enschede, which might explain the overall increase of mean sick leave rate during the intervention period. This disaster ended in 22 deaths and ruined an entire neighborhood (about 1500 damaged houses), even leading to a parliamentary inquiry. In particular, one municipal service was involved in this disaster due to the permits provided for the firework storage and the responsibility for providing accommodation for those who had become homeless. Despite this interference, which may have influenced the effect of the counseling to some extent, results are considered to be relevant. Although during the intervention, this service showed a larger increase in mean sick leave rate compared to the other two services, no significant interaction was observed between municipal service and the effect on sick leave. Moreover, we applied a randomized controlled trial design at the level of work units within each municipal service, which resulted in an equal distribution of work units of the service in question over the intervention group and control group. In addition, it is well-known that a randomized controlled trial design controls for factors outside one's own control.

The individual counseling concerned has shown to have a favorable effect on physical activity and fitness at the short-term. Health, defined as musculoskeletal symptoms was not influenced statistically significant by the counseling intervention.¹⁰ Based on the assumed positive relationship between physical activity, fitness and health,²⁶ it is expected that on the longer term health will improve also, with a subsequent lowering effect on sick leave. Therefore, it is interesting to study whether effects on physical activity will persist, since a longer period of regular physical activity is needed to reach more pronounced health, and thereby sick leave effects. In addition, with reference to the effect modification shown in this study, it might be interesting to further study different groups of employees (e.g., employees who have been absent for a long-term versus those who have hardly been absent through illness).

As far as we know, no studies have been published yet to the effectiveness of a worksite physical activity or lifestyle counseling program based on the transtheoretical model on sick leave. However, several studies have evaluated other types of worksite physical activity programs on sick leave. Two reviews summarized the available evidence on the effectiveness of worksite physical activity programs and both concluded only limited evidence for a positive effect on sick leave due to methodological shortcomings of most studies.^{3,4} Therefore, high quality (randomized controlled) studies evaluating the effectiveness on sick leave of worksite health promotion or physical activity programs on sick leave are needed, and in particular those using an individual-based approach. In addition, future research as to the effectiveness of different types of worksite physical activity programs, e.g., group-based versus individual-based interventions, is useful in order to determine whether the evidence can be explained by the type of program.

Some methodological issues of the present trial need to be addressed. First, as is common in sick leave data, the data were not normally distributed and were skewed to the right: the majority of the employees was either not absent or absent for only a few days, while a few persons were absent because of illness for a long time and thereby largely contributing to a high mean of the total number of sick leave days. Because of the skewed data distribution, we also presented the median. Although a nonparametric test may seem suitable also, we decided to conduct a multilevel analyses. This was acceptable since the model assumptions were tested and fulfilled. The residuals were uncorrelated and normally distributed due to the fact that we performed an analysis of covariance, taking sick leave during and after the intervention period as the outcome variable and adjusting for the sick leave data of the period before the intervention.

Secondly, randomization took place at the level of work unit, instead of the individual level. Although randomization by individual is commonly preferred, cluster randomization is sometimes desirable. In our study, randomization by unit of workers avoided contamination between employees working within the same unit receiving different interventions. Moreover, randomization by work unit was expected to enhance the compliance as colleagues might stimulate each other. Nevertheless, the use of cluster randomization can threaten the validity of standard procedures commonly used in comparative trials to assess the effect of an intervention.²⁷ A third methodological issue concerns the power of the study to detect a statistically significant effect on sick leave. At the start of the project, we

performed a power analysis. However, the power analysis was based on finding an effect on physical activity, which was our primary outcome measure. Based on our hypothesis (mentioned in the Introduction) and the fact that sick leave is a relevant issue for the company, we analyzed the effect on sick leave too. Sick leave data are not normally distributed, but skewed and have large standard deviations. As a consequence, a large sample size is required, which is not feasible in many studies, and especially in randomized controlled studies evaluating workplace physical activity or health promotion programs. This means that the statistical non-significance found might be caused by a power-problem. Nevertheless, our results still give a good impression of the effect of the counseling intervention on sick leave. Although we recognize the importance of statistical significance, we like to emphasize that conclusions should not be based on statistical significance alone, but also on the effect size.

In conclusion, no statistically significant intervention effects were found for rate or frequency of sick leave. Although median values of sick leave rate decreased for both groups, after the intervention, a difference of average sick leave rate (six days) was observed between the two groups in favor of the intervention. To clarify the sick leave trends observed, continued research evaluating the effectiveness of the individual counseling intervention of concern is recommended.

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Chapter 4.3

Cost-benefit and cost-effectiveness analysis of a worksite physical activity counseling program

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Submitted

Abstract

The present study evaluated the impact of worksite physical activity counseling by means of a cost-benefit and a cost-effectiveness analysis.

299 civil servants were randomly assigned to an intervention (n=131) or a control group (n=168). The intervention period was nine months. Intervention costs were compared to the monetary benefits due to a reduction in sick leave. In addition, intervention costs minus the monetary benefits due to sick leave reduction were compared to effects: percentage meeting the moderate intensity physical activity public health recommendation, energy expenditure, cardiorespiratory fitness, and upper extremity symptoms.

The intervention costs were \in 429.9 per participant. The benefits due to sick leave during the nine-month intervention period were \in 125.2 leading to net total costs of the intervention of \in 304.7. During the same nine-month period in the year after the intervention, the benefits due to sick leave were \in 635.2. No statistically significant differences in costs and benefits were found between the two groups. As to the cost-effectiveness, an improvement in energy expenditure and cardiorespiratory fitness was observed to be gained at higher costs. The point estimates of the cost-effectiveness ratios were \in 5.2 (without imputation of effect data) and \in 2.7 (with imputation of effect data) per extra kilocalorie energy expenditure per day, and \in 234.9 (without imputation of effect data) and \in 45.9 (with imputation of effect data) per beat per minute decrease in submaximal heart rate.

Although a positive trend was observed, this study does not provide a financial reason for implementation of a worksite physical activity counseling intervention.

Physical inactivity and its consequences are of major concern for Western society. Physical inactivity is associated with an increased risk for many chronic diseases, such as cardiovascular disease^{1,2} and some types of cancer.³⁻⁵ Another consequence of physical inactivity is overweight, since weight is caused by a dysbalance between energy expenditure (physical activity) and energy intake (nutrition). During the last decades, the prevalence of overweight and obesity has increased dramatically. Currently, in the Netherlands, the prevalence of obesity is approximately 10%, whereas in the UK and the US, this percentage is even the twofold.⁶⁻⁹ The consequences for both public health and economic impact are enormous. In Europe, obesity-related costs have been estimated at 1-5% of the total health care expenditure.¹⁰⁻¹² Besides, employees having overweight or obesity appear to be more often absent from work as a consequence of which a loss of productivity occurs.¹³⁻¹⁵ In the UK, it is estimated that in 1998 there were over 18 million days of sickness absence from work attributable to obesity (418,000 days) and its consequences (17.6 million days), which is assumed to be an underestimate rather than an overestimate.⁹ In addition, significant positive associations have been observed between (moderate and vigorous) physical activity and productivity, and between obesity and absenteeism-related decrements in productivity (16). Furthermore, a study among Norwegian nurses' aides showed an association between regular leisure-time physical activity and reduced risk of sick leaves of more than 14 days, compared to those who did not perform regular physical activities.¹⁷

Despite the well-documented benefits, 60% of the US adult population and 55% of the Dutch adults is not physically active enough according to the public health moderate intensity physical activity recommendation.¹⁸⁻²⁰ Moreover, in 2000, 27% of the US adults performed no leisure time physical activity at all.¹⁸

Employers in Western countries have invested increasingly in worksite physical activity programs as well as comprehensive health promotion intervention.²¹ Potential benefits assumed by the employers vary considerably and are among others improved health, reduced sick leave, improved productivity and/or company image. Although the effectiveness of worksite health promotion interventions has been studied, limited evidence is available about the efficiency, i.e., the financial impact of such programs for companies. Therefore, Harris and colleagues²² recommended to perform more research on the financial impact of such interventions. Insight in the efficiency of a worksite health promotion intervention can be used to support decision-making of the employer.

The aim of this paper was to evaluate the efficiency of a worksite physical activity counseling intervention by means of a cost-benefit and a cost-effectiveness analysis.

Methods

Study population

Subjects were recruited from three municipal services of a Dutch town, Enschede. Criteria for inclusion were: 1) being a civil servant; 2) performing office work; 3) working for at least 24 hours a week at the local municipal service of Enschede; 4) having a contract until at least the moment of the post-test. Further, an informed consent form had to be signed before the

baseline measurements. The study protocol was approved by the Medical Ethical Committee of VU University Medical Center.

Interventions

A randomized controlled trial was conducted. For more detailed information as to the study design, we refer to another paper.²³ After baseline measurements, subjects who volunteered to participate, were randomly assigned to the intervention (n=131) or the control group (n=168). During nine months, i.e., from May 2000 until January 2001, all intervention subjects were offered a maximum of seven consultations. The consultations took place during working time and were approximately 20 minutes in duration. Counseling was mainly aimed at the promotion of physical activity and healthful dietary habits. This was done using standardized protocols on the basis of the individual's stage of behavior change.^{24,25} The stage of behavior change was determined during baseline measurements and was checked during the first consultation. Both subjects in the intervention group and those in the control group received general written information about the following lifestyle factors: physical activity, nutrition, alcohol, smoking, (work) stress, and musculoskeletal symptoms. The control group, however, did not receive the counseling intervention.

Outcome measures

Outcome measures were sick leave, physical activity, fitness, and musculoskeletal symptoms. Measurements took place two weeks before the first consultation (April 2000) and directly after the nine-month intervention (January 2001). Sick leave (excluding absence due to holidays and pregnancy) was measured using the records from each municipal service's Personnel Department. Data from the same nine-month period (May-January) in the year before (1999/2000), during (2000/2001) and after the intervention period (2001/2002) were collected. Physical activity was made operational in two ways: 1) by meeting the moderate intensity physical activity public health recommendation (20) and 2) by assessing the total energy expenditure. Subjects who reported to have participated in moderate intensity physical activities for a cumulative minimum of 30 minutes a day, for five or more days a week, were considered to be active. Total energy expenditure was assessed using a structured interview (7-day Physical Activity Recall (PAR)),26-28 and was expressed as kilocalories per day, which was adjusted for body weight. Fitness was expressed as cardiorespiratory fitness and was measured using a submaximal bicycle test.^{29,30} To evaluate the change in cardiorespiratory fitness, the average heart rate during last two minutes of cycling was used as a measure, i.e., the submaximal heart rate. As to musculoskeletal symptoms, upper extremity symptoms were chosen because of a high prevalence in the study population. The three-month prevalence of upper extremity symptoms was assessed using a validated Dutch version of the Nordic questionnaire.^{31,32}

Economic evaluation

A cost-benefit analysis was performed to compare the intervention costs with the monetary benefits due to sick leave reduction. For the remaining outcome measures (i.e., moderate

intensity physical activity recommendation, energy expenditure, cardiorespiratory fitness and upper extremity symptoms), a cost-effectiveness ratio was calculated.

The company perspective was used as the basis for the economic evaluation. This means that only costs relevant for the company (i.e., the municipal services) were considered, notably costs of the intervention and costs due to productivity loss of the subjects. Costs of the intervention included costs that were directly related to the implementation of the individual counseling program. These costs were the amounts of money that the three municipal services would have had to pay for the intervention without interference of the study, and without the costs of the control group. These costs included the development and management of the program, the information session, the consultation with the sports physician who gave feedback about test results, the written information, and the individual counseling intervention given by the counselor. For the intervention group, the costs of the fitness- and health tests (pre- and post-tests) were also included, since these tests were part of the intervention offered. The intervention costs were calculated using the market price that had to be paid by the company. We considered also costs due to the estimated time spent by employees of the Personnel Department while arranging the time schedules for the information sessions, the fitness- and health tests, and the individual counseling. Table 1 presents the costs for the intervention group. Monetary benefits of the intervention included reduction of costs due to sick leave. Both the time spent by the Personnel Department employees and the benefits due to reduced sick leave were valued using the mean salary costs of the civil servants working in the municipal services concerned. Salary costs include the gross salary, the employer's social benefits, and the vacation allowance. The mean salary costs of the civil servants was €41,105.- per year. To calculate these costs per day, the costs per year were divided by 12, and subsequently divided by 30.7, which is the average number of calendar days per month for the period May until January. Thus, the mean salary costs per calendar day was €111.58 based on a production elasticity of working time of 1.0.

Cost-benefit analysis

For the cost-benefit analysis, the costs of the monetary benefits due to reduced sick leave were calculated for the intervention period (from May 2000 until January 2001). Subsequently, the single expenditures of the intervention (i.e., intervention costs and the costs due to the time spent by the Personnel Department) were compared to the monetary benefits of sick leave reduction during the intervention period. For the same nine-month period after the intervention (from May 2001 until January 2002), the difference in monetary benefits due to sick leave reduction between the intervention group and the control group was calculated. Because of the gap of three months between the two nine-month periods (February 2001 - April 2001), no comparison was made between the benefits in the year after the intervention and the intervention costs. Moreover, the intervention costs were already taken into account in the former analysis.

Cost-effectiveness analyses

To calculate the cost-effectiveness ratios, incremental costs of the intervention group compared to the control group were divided by incremental effects for each of the effect measures separately. In this analysis, we used total costs by summing costs of the intervention and sick leave. Thus, in our cost-effectiveness analyses, all costs and monetary benefits were put in the numerator and compared to the effect in the nominator. For the cost-effectiveness analysis, benefits due to a reduction in sick leave during the intervention period were taken only, in order to evaluate the differences in costs and effects in the same period, (i.e., from May 2000 until January 2001).

Statistical analysis

Unadjusted differences between the two study groups are presented, as the confounders were shown to hardly influence the results.²³ For the cost-benefit analysis, the differences between the intervention group and the control group in mean intervention costs and in mean benefits due to sick leave reduction were compared using bias-corrected and accelerated bootstrapping using 2000 as the number of replications.³³ In doing so, 95% confidence intervals were computed. Bootstrapping is a suitable method for the analyses of cost data, as cost data are usually highly skewed and bootstrapping does not make any assumptions on the distribution of the data as is done with the traditional statistical methods, such as a Student's t-test.³³ For the cost-effectiveness analyses, mean effects per study group were calculated using the delta score (posttest minus pretest). Subsequently, cost-effectiveness ratios were calculated by dividing the difference in the mean total costs (i.e., including monetary benefits due to sick leave) between the two study groups, by the difference in the mean effects. Confidence intervals for the cost-effectiveness ratios were calculated again with bootstrapping, using the bias-corrected percentile method with 5000 replications. For each outcome measure used in this evaluation, cost-effectiveness ratios were plotted on a cost-effectiveness plane.³⁴ The cost-effectiveness plane consists of four quadrants with a horizontal axis indicating the effectiveness of the intervention and the vertical axis indicating the costs.

Sensitivity analysis

Three sensitivity analyses were conducted. 1) For the Netherlands, an elasticity measure between labor time and labor production was estimated to be 0.8, which means that a reduction of 100% in labor time results in a decrease of 80% in production.³⁵ In this paper, results were based on an elasticity of 0.8. The sensitivity analysis was conducted to compare the results with an elasticity of 0.5 and 1.0. 2) Because of loss-to-follow-up, there were missing values in the effect measures, but not in the cost measures. As a consequence, for the analyses, we could not use cost data of subjects with missing effect measures, as a result of which the power of the economic evaluation decreased. Moreover, the mean total costs taken into account differed per effect measure due to different missing values per effect measure. Therefore, to enhance the power and to have equal costs per effect measure, a sensitivity analysis was performed imputing data as to the effect measures. Imputation was done by the 'last value carried forward' method, implying the baseline value.

3) A sensitivity analysis was performed to investigate the impact on the results when also including costs of participants associated with the loss of working time, and thereby loss of productivity due to the time spent to the information session, the fitness- and health tests, and the visits to the counselor itself. In the main analyses, these costs were not taken into account, since almost all intervention subjects reported to have compensated this in their own time, and thereby these costs were not for the account of the municipal service.

Results

Study population

A total of 299 subjects were measured at baseline and were randomized into the intervention group (n=131) or the control group (n=168). Sick leave data were only missing for those who terminated employment at the municipal service during the period from the start of the intervention until January 2002. In the nine-month period during the intervention, one subject in the intervention group and one subject in the control group terminated employment. After the intervention period (from February 2001 until January 2002), another 11 subjects stopped working at the municipal service (n=3 in intervention group; n=8 in control group). Within the intervention group, complete data were available for 76 (physical activity public health recommendation), 69 (energy expenditure), 70 (submaximal heart rate), and 78 (upper extremity symptoms) subjects. For the control group, complete data were available of 116, 111, 102, and 130 subjects, respectively. Within the control group, it appeared that the subjects who did not complete one of the follow-up measurements (i.e., questionnaire, interview or fitness test) differed from those who did complete these measurements in that the drop-outs had, on average, more days of sick leave in the nine-month period before, during, and after the intervention. This was not the case for the intervention group: no differences in sick leave data were observed between the drop-outs and those who continued in the study.

Intervention costs	Euro
costs for implementation of the intervention ^a	41,907.1
costs due to time spent by Personnel Department	223.2
total costs for 98 intervention employees	42,130.3
total costs per intervention employee	429.9

Table 1. Costs of intervention (in euro) for 98 intervention persons

^a based on the market price to be paid by the municipal service.

Cost-benefit analysis

The intervention costs were \in 429.9 per participant (table 1). Table 2 shows the mean intervention costs and sick leave costs per employee during the intervention period. No statistically significant differences in either total costs or sick leave costs were found between the two study groups. During the intervention period, the intervention group had lower costs due to sick leave (mean difference: \in -125.2, 95%CI: \in -1,385.6 - \in 1,061.6). The mean total

costs during the intervention were higher in the intervention group compared to the control group (mean difference: \in 304.7; 95% CI: \in -1,028.7 - \in 1,419.0). In the year after the intervention, the benefits due to a reduction in sick leave increased further. The mean difference in sick leave costs between the two study groups after the intervention period was \in -635.2 (95% CI: \in -1,882.6 - \in 814.3) in favor of the intervention.

Effects of the intervention

In table 3, the mean effects of the counseling on the outcome measures are presented. For a more detailed presentation of the effects, we refer to another paper.²³ A significant positive intervention effect was observed for energy expenditure. The intervention subjects expended more kilocalories per day, whereas the subjects in the control group decreased in their energy expenditure. For cardiorespiratory fitness, the same positive phenomenon was observed. The intervention subjects improved in their fitness level (i.e., decreased their submaximal heart rate), in contrast with the subjects in the control group, who deteriorated at the submaximal bicycle test. There was no significant effect on the proportion of subjects meeting the moderate intensity physical activity public health recommendation. The proportion of subjects that met this recommendation decreased from 48.7% to 42.1% in the intervention group and from 36.2% to 30.2% in the control group. Further, although the prevalence of upper extremity symptoms decreased more in the intervention group than in the control group (17.9% versus 6.2%), no statistically significant effect was found.

Cost-effectiveness analyses

Figures 1 to 4 show the cost-effectiveness planes for each outcome measure. Except for the number of participants meeting the public health physical activity recommendation, most of the incremental cost/effect pairs of the other outcomes were in the north-east quadrant (90%, 96%, and 77% for energy expenditure, submaximal heart rate, and upper extremity symptoms, respectively) indicating positive effects at higher costs for the counseling intervention compared to the control condition. In particular for energy expenditure and cardiorespiratory fitness, the planes clearly indicate that the counseling was more effective than the control condition as no or hardly any points are in the west quadrants (1% and 0%, respectively). The point estimate of the cost-effectiveness ratio for energy expenditure is €5.2 (95%CI €-4.9 - €27.4) per extra kcal.day⁻¹ per employee (table 3). For cardiorespiratory fitness, the ratio is €234.9 (95%CI €-10.0 - €829.6) per beat per minute decrease in submaximal heart rate (table 3). For the public health physical activity recommendation, most of the incremental cost/effect pairs were distributed in the south-east (39%) and the south-west (38%) quadrants. Moreover, the points considerably cross the origin of the plane, indicating that the counseling intervention was neither more costly nor more effective on the public health physical activity recommendation.

	Before the intervention (May 1999 - January 2000)	rvention nuary 2000)	During the intervention (May 2000 - January 2001)	tervention 'anuary 200∶	()	After the intervention (May 2001 - January 2002)	ervention January 20((Z(
	Intervention	Control	Intervention	Control		Intervention Control	Control	
	group n=97	group n=167	group n=97	group n=167	Difference (95% CI) ^b	group n=94	group n=159	Difference (95% CI) ^b
average total days								
of sick leave	17.2	15.2	21.5	22.9	1.4	20.5	27.6	7.1
intervention costs			429.9 ^c	0.0	429.9 ^c		,	ı
sick leave costs			1,915.0	2,040.2	-125.2	1,829.9	2,465.1	-635.2
			(4,813.5)	(5,030.8)	(-1,385.6;	(4,666.3)	(5,568.0)	(-1,882.6; 814.3)
					1,061.6)			
total costs			2,344.9°	2,040.2	304.7			
				(5,030.8)	(-1,028.7;			
					1,419.0)			

working time of 0.8.³⁵, ^b differences in sick leave costs between the two study groups (95% CI= 95% confidence interval obtained by bias corrected and accelerated bootstrapping); a negative difference indicates a positive balance: less costs in the intervention costs than in the control group; ^c no standard deviation or 95% confidence intervals could be calculated, since these costs were the same for all intervention subjects.

	Without im	mputatio	nputation of effect data	data		With imp	utation o	With imputation of effect data	R	
	Intervention	tion	Control group	lroup		Intervention	tion	Control group	dno	
	group					group				
Outcome measure	Mean	Mean	Mean	Mean	Ratio ^a	Mean	Mean	Mean	Mean	Ratio ^a
	costs	effects	costs	effects	(95% CI)	costs	effects	costs	effects	(95% CI)
	(ps)	(ps)	(ps)	(ps)		(ps)	(ps)	(ps)	(ps)	
Meeting public health 2,507.6	2,507.6	-6.6	1,946.9	-6.0	-1,029.9	2,381.4	-5.3	2,136.5	-4.5	-316.4
recommendation (%) (5,298.3) (0.6)	(5,298.3)	(0.6)	(5,200.0) (0.5)	(0.5)	(-36,535.4 ;	(4,884.2) (0.5)	(0.5)	(5,215.6) (0.5)	(0.5)	(-52,773.8 ;
					-591.1)					-77.1)
Energy expenditure	2,582.6	64.2	1,577.8 -129.2	-129.2	5.2	2,416.0 48.2	48.2	2,050.4	-86.4	2.7
(kcal.day ⁻¹)	(5,545.4) (490.9)	(490.9)	(4,442.3)	(630.4)	(4,442.3) (630.4) (-4,9 ; 27.4)	(4,932.4) (425.2)	(425.2)	(5,044.3) (518.3)	(518.3)	(-9.1; 27.8)
Submaximal heart	2,222.8	-2.2	1,118.4	2.5	234.9	2,112.5	-1.7	1,963.3	1.6	45.9
rate (beats.min ⁻¹)	(4,786.1) (8.9)	(8.9)	(3,352.1)	(8.5)	(-10.0 ; 826.6)	(4,291.5) (7.7)	(7.7)	(4,805.5) (6.9)	(6.9)	(-313.9; 573.1)
Upper extremity	2,461.2	-17.9	1,829.2	-6.2	53.6	2,364.9	-14.6	2,040.2	4.8	33.2
symptoms (%)	(5,237.1) ((0.5)	(4,938.6) (0.5)	(0.5)	(-100.9; 809.4)	(4,834.7) (0.5)	(0.5)	(5,030.8) (0.5)	(0.5)	(-166.8;609.2)

Table 3. Mean costs, effects and cost-effectiveness ratios for the physical activity public health recommendation, energy expenditure,

^a a positive cost-effectiveness ratio indicates the amount of money to be paid to achieve a positive intervention effect.

Sensitivity analysis

Use of an elasticity measure of 0.5 resulted in lower cost-effectiveness ratios compared to 0.8 (ratios: -939.8, 4.0, 181.1, and 47.2 for meeting the public health recommendation, energy expenditure, submaximal heart rate, and upper extremity symptoms, respectively). Analogously, using an elasticity measure of 1.0 resulted in higher cost-effectiveness ratios (ratios: -1,090.0, 5.9, 270.8, 57.9, respectively). It would be expected that the lower the elasticity, the higher the cost-effectiveness ratios, and thereby less favorable, due to more costs because of less savings of sick leave reduction. However, the 'unexpected' trend observed was caused by the missing values in the control group including subjects with a long sick leave duration. As a consequence, particularly for energy expenditure and submaximal heart rate, the costs of the control group decreased substantially, namely from 2,040.2 to 1,557.8 and 1,118.4, respectively (tables 2 and 3), and were thereby abrupt lower than the sick leave costs in the intervention group. Only for submaximal heart rate, the costeffectiveness ratio changed from statistically non-significance with a production elasticity of labor time of 0.8 to a statistically significant cost-effectiveness ratio using an elasticity measure of 0.5 (€181.1; 95% CI €25.0 - €585.5) in favor of the counseling, because with a lower elasticity, the confidence interval becomes narrower. For the other analyses, the use of an elasticity measure of 0.5 or 1.0 had no impact as to the statistical significance of the outcome of the economic evaluation.

Results of the imputation of the effect data are also presented in table 3 (right part). The effect measures within each study group were slightly smaller and conclusions as to the effectiveness of the counseling remained the same when having imputed data compared to without imputation. The costs in the study groups were approximately the same for each outcome measure (table 3). However, as there still were a few missings per outcome (e.g., caused by the fact that some subjects were not able to perform the submaximal bicycle test), costs varied slightly per outcome measure. Further, as (almost) all costs were taken into account (i.e., including those who had been sick for a long time), mean total costs of the control group increased. As a consequence, the difference in costs between the two groups decreased, which resulted in lower cost-effectiveness ratios compared to without imputation. For example, the ratios after imputation of effect data for energy expenditure and submaximal heart rate were 2.7 and 45.9, respectively versus 5.2 and 234.9, respectively (table 3). Confidence intervals of the cost-effectiveness ratios were still very large and not statistically significant. Contrary to the analyses without data imputation, the use of an elasticity measure of 0.5 resulted in a larger difference in costs between the groups compared to an elasticity measure of 0.8, leading to higher cost-effectiveness ratios. Use of an elasticity measure of 1.0 led to lower ratios.

Including the costs due to the time spent by the employees on attendance of the information session, tests, and the counseling (\in 73.0 ± \in 16.6) did not influence the outcome of the cost-effectiveness.

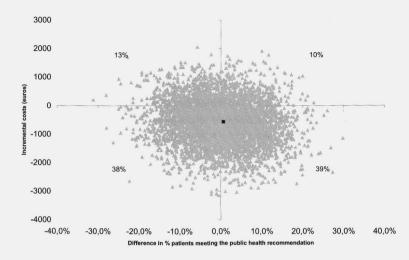


Figure 1. Cost-effectiveness plane for the physical activity public health recommendation (point estimate: -1,029.9; 95% CI: -36,535.4 - -591.1).

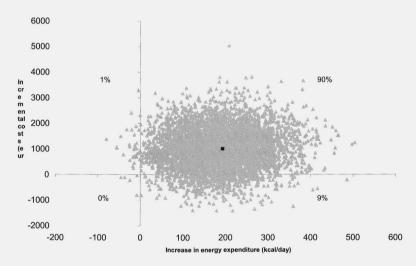


Figure 2. Cost-effectiveness plane for energy expenditure (point estimate: 5.2; 95% CI: - 4.9 - 27.4).

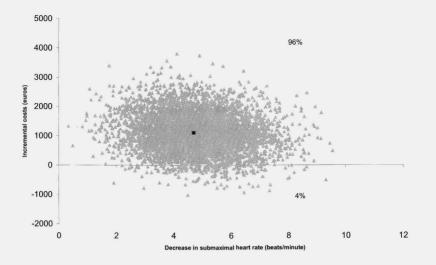
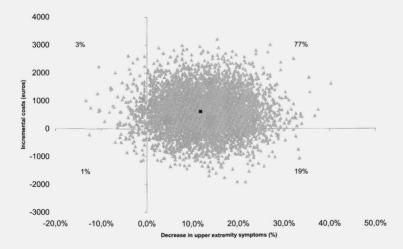
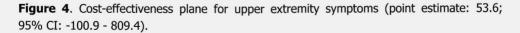


Figure 3. Cost-effectiveness plane for submaximal heart rate (point estimate: 234.9; 95% CI: -10.0 - 826.6).





Discussion

As to the cost-benefit analysis, no evidence was found for significant cost savings. Because there was an increasing trend in sick leave (costs) in the control group, the counseling intervention might reveal significant positive net benefits in the longer term. Although not statistically significant, the difference between the intervention group and the control group in sick leave costs was quite large and might be considered as relevant from the employer's perspective. As is common in economic evaluations, the trial is underpowered to find statistical significant differences in costs between the groups since cost data are skewed. Relatively few subjects were responsible for a relatively large proportion of costs, which will lead to wide confidence intervals of the differences, and in case of a small numbers, tentative conclusions. Even though we dealt with the skewed data by bootstrapping, this does not improve the power of the study.

With respect to the cost-effectiveness, our findings showed an improvement in energy expenditure and cardiorespiratory fitness in the intervention group to be gained at higher costs. Based on an elasticity measure of 0.8, the cost-effectiveness ratios were 5.2 euro and 234.9 euro per extra kilocalorie energy expenditure per day and decrease in beat per minute of the submaximal heart rate per employee, respectively. However, due to the very large (non statistically significant) confidence intervals, we can not say with certainty that this is the amount of money to be invested in order to achieve improved energy expenditure and fitness levels. Moreover, there were some other uncertainties, which we tried to overcome in the sensitivity analyses. Because of a selective group of missing values as to the outcome measures, namely those who has been sick for a long time, results should be interpreted with caution. Without taking into account the costs of the persons who were missing at the outcome measures, the mean costs in the control group decreased substantially, and were thereby much lower than the costs for the intervention group. Thus, the use of an elasticity measure of 0.5 led to a larger decrease in costs in the intervention group than in the control group, leading to a smaller difference in costs between the two groups compared to an elasticity measure of 0.8. This resulted in a lower cost-effectiveness ratio compared to an elasticity of 0.8.

Despite the counterarguments for imputing data, e.g., imputed data are not real and may thereby misrepresent the effect, we decided to impute data of the effect measures for the purpose of the economic evaluation. Notably, missing values in effect measures will lead to missing values of the cost data, because cost data of patients without effect measures cannot be used in the cost-effectiveness analysis. Moreover, generally, the power of an economic evaluation is low. Missing data will even more decrease the statistical power. Therefore, by imputing data as to the effect measures under the condition that the effect measure will not (substantially) change, the power of the cost differences will be increased. We imputed data by the 'last value carried forward' method, which appeared to be conservative since the effect measures hardly changed, or even became somewhat smaller. From table 3, it could be seen that the ratios were more favorable for the counseling intervention, though still large confidence intervals were observed. Hence, the conclusion must be that effects on energy expenditure and cardiorespiratory fitness can be gained, but at a certain price. What price this exactly is, we can not say. Still, it is dependent on the (culture of) a company what amount of money an employer is willing to pay for each extra kilocalorie energy expenditure per day per employee or decrease of the submaximal heart rate. And probably, other arguments than health-related effects will play a role in the decision-making for implementation of a worksite physical activity counseling intervention. It is quite conceivable that the most relevant argument for an employer concerns the net benefit based on the personnel's productivity. Although no positive cost-benefit balance was shown for the intervention period, considering the benefits due to sick leave in the year after the intervention, it might be that, after a longer term, the employer benefits from its investment. However, this study does not provide such evidence yet.

A few comments should be made with respect to the analyses performed. Firstly, for the cost-effectiveness analyses, we calculated ratios and presented cost-effectiveness planes. It should be mentioned that the ratio should be interpreted together with the costeffectiveness planes. The cost-effectiveness plane may even give more information. For example, a positive cost-effectiveness ratio can indicate that the intervention is more effective and more costly or it can imply an ineffective, but cheaper intervention. In addition, the ratio does not indicate the magnitude of the effects or the costs. A cost-effectiveness plane, in contrast, clearly indicates whether and how much the intervention is more or less effective (shown on the horizontal axis) and more or less costly (shown on the vertical axis). In our study, it appeared that the cost-effectiveness ratio's using an elasticity of 0.5, 0.8 and 1.0 were statistically significant for the physical activity public health recommendation. However, looking at the cost-effectiveness plane, all point estimates were distributed around the intersection of the horizontal and vertical axis indicating no differences between the two groups for either the costs or the effectiveness.

Secondly, the cost-benefit analysis presented in this study actually concerns a partial cost-benefit analysis. In a full cost-benefit analysis, all costs and all health-related effects are expressed in monetary units. In our analysis, we refrained from valuing the health effects, because of the difficulties associated with the valuing. Therefore, we decided to conduct a cost-effectiveness analysis in addition to a cost-benefit analysis. In doing so, all costs and benefits of the intervention were compared to the health-related effects. As sick leave can be valued and because it can be considered as benefits to the intervention, it was subtracted from the costs.

Further, there are several other potential benefits for the company, which were not included in our study, such as reduced employee turnover, productivity, commitment to the company, or improved corporate image. Most of these benefits are hard to measure and value, as a consequence of which we did not include these potential benefits. Though an economic evaluation is a useful tool for companies to decide whether or not they benefit from implementation of a worksite physical activity program, other benefits that are hard to determine should be weighed in the decision as well.

Except for costs due to sick leave, no costs for the control condition were taken into account. However, the control group received a small 'intervention' existing of the written information about lifestyle factors, pre- and post-tests and the attendance to the information session. These costs were not taken into account since they were offered for the purpose of

the study only. This small intervention might have had a small health-related effect thereby weakening the observed effects of the intervention.

The health care costs, such as costs due to medical consumption or therapy, were not taken into account, since these costs were not for the account of the municipal service. Based on the fact that the study population is a 'healthy' working population, who do not frequently make use of health care, we assume these costs have been low. Moreover, retrospective self-reports of the medical consumption and therapies indicated no substantial differences between the two groups. Based on the above mentioned, we believe our results would not have been influenced when having included these costs.

Our results cannot easily be compared to the results of other studies evaluating the cost-benefits and cost-effectiveness of similar interventions, because of a lack of similar studies. Most studies evaluated the economic impact of comprehensive health promotion programs instead of programs primarily aimed at improving physical activity. Moreover, the majority of the reviews on the economic outcomes of worksite health promotion programs are based on studies from the United States. In the United States, the employer is responsible for the medical costs, which is not the case in the Netherlands. Hence, an employer in the United States will benefit from reduced health care costs, a Dutch employer will not.

Most of the reviews published, suggest a positive economic impact of worksite health promotion programs, with a reduction in absenteeism being an important component.³⁶⁻³⁸ Further, Shephard³⁹ estimated the immediate return to be as much as \$2 to \$5 per U.S. dollar invested. He suggested in his review of worksite fitness programs that, despite the limitations of many studies, exercise (particularly in the context of general health promotion) is both cost-effective and results in net benefits. Similar to Shephard,³⁹ a few studies have estimated the benefits and overall suggested a positive return on investment of worksite health promotion programs. For example, Golaszewksi et al.⁴⁰ estimated a benefit-to-cost ratio of U.S. \$3.4 for a worksite health promotion program. Additionally, Ozminkowski et al.⁴¹ estimated the return on investment of a health promotion program between U.S. \$4.65 and U.S. \$4.73 saved per dollar spent on the program.

Finally, it should be noted that different methods were applied in the studies mentioned to assess the cost-effectiveness of worksite health promotion programs. As no standardized methodology is available for the analysis of costs and cost-effectiveness of worksite physical activity programs, we strongly recommend to formulate standardized methods regarding how to assess the cost-effectiveness of such programs.

In conclusion, our findings showed no statistically significant cost-benefits of the worksite physical activity counseling intervention. Further, our results showed that the counseling had a positive effect on energy expenditure and cardiorespiratory fitness, gained at higher costs. This study thus provides no arguments to implement a physical activity program at the worksite on the basis of short-term cost-benefits only. However, other aspects, such as long-term productivity, improved employee commitment, or corporate image may play a role in the decision whether or not to implement such a program.

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Chapter 4.4

Evaluation of the results of a randomized controlled trial: How to define changes between baseline and follow-up

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Abstract

The most common way to evaluate the effect of an intervention is to compare the intervention and non-intervention group regarding the change in the outcome variable between baseline and follow-up. However, there are many different ways to define 'changes'. The purpose of this paper was to demonstrate how different definitions of change used in the analysis can influence the results of a study. A randomized controlled trial was used as an example. The results of the analyses showed that for continuous outcome variables 'analysis of covariance' seems to be the most appropriate, because it corrects for the phenomenon of regression to the mean. For dichotomous outcome variables on the other hand, multinomial logistic regression analysis with all possible changes over time as outcome seems to be the most appropriate, especially because of its straightforward interpretation. It is important to realize that a different definition of change can lead to (totally) different results in the evaluation of the effect of an intervention.

Randomized (controlled) trials are considered to be the golden standard in order to evaluate the effect of a certain intervention.¹ In a randomized controlled trial, the population under study is randomly divided into an intervention group and a non-intervention or reference group (e.g. a placebo group or a group with 'usual' care, etc.). The groups are then measured after a certain period of time to investigate the differences between the groups in the outcome variable. In most randomized controlled trials, also a baseline measurement is performed. With the information gathered in this baseline measurement, it is possible to compare the changes in the outcome variable between the intervention and the reference group. Although this procedure looks guite straightforward, the definition of change can be rather complicated. In fact, from the beginning of the '60s there is an ongoing debate how to define change.²⁵ When evaluating the 'controlled trial literature', surprisingly, in most research situations, the absolute change between a baseline measurement and a follow-up measurement is calculated and this absolute change in a certain outcome variable is compared between the groups of interest. However, there are many alternative ways available to define changes between a baseline and a follow-up measurement,⁶ and because of that there are many alternative ways available to evaluate the results of a (randomized) trial. The purpose of this study was to demonstrate how different definitions of change used in the analysis can influence the results of a study. Furthermore, the purpose was to give some recommendations how to analyze data from randomized trials. The randomized trial, which is used as an example in this paper, was designed to evaluate the effect of an individual counseling program at the worksite to improve physical activity and to enhance healthy dietary changes.

Methods

The randomized trial

The trial used as an example in this paper was described in detail elsewhere.⁷ In brief, 299 civil servants working within three municipal services of a Dutch town, Enschede, were randomized into an intervention or a reference group. All subjects randomized into the intervention group were offered seven consultations, each 20 minutes in duration. The intervention period was nine months and counseling was primarily focused on the enhancement of the individual's level of physical activity using standardized protocols.^{8,9}

Subjects in the reference group received no individual counseling. Directly after baseline measurements, they received only written information about several lifestyle factors. This information was equal to that handed out to the intervention group.

Despite a few missing observations for some of the outcome variables, for the present example data are available for 75 subjects in the intervention group and 118 subjects in the reference group. The difference between the two groups is caused by the fact that 33 subjects of the intervention group (non-randomly) participated in a coinciding supervised fitness program. They were excluded from the analyzes in order to evaluate merely the effect of the individual counseling intervention. The results of the analysis including these 33 subjects were, however, comparable to the results presented here.

Outcome variables

Outcome variables were assessed before the intervention and directly after the completion of the last consultation. In principle, the trial had three primary outcome variables (physical activity, cardiorespiratory fitness, and prevalence of musculoskeletal symptoms) and three secondary outcomes (body composition, i.e., the percentage of body fat and the body mass index, blood pressure and serum cholesterol). To make the example not too extensive, we selected two continuous outcome variables (i.e., physical activity levels and total serum cholesterol), and two dichotomous outcome variables (i.e., proportion of subjects being active according to the moderate intensity physical activity public health recommendation,¹⁰ and existence of upper extremity complaints). The two continuous outcome variables were selected because of differences between the groups at baseline.

Physical activity levels were assessed by the Baecke questionnaire.^{11,12} With this questionnaire, both the physical activities during sport (i.e., the sport index) and during leisure time (i.e., the leisure time index) were measured. Both were combined into one physical activity index. Total serum cholesterol was assessed using a reflotron (Boehringer Mannheim GmbH, Germany) and expressed in mmol/l.

The proportion of subjects being active (according to the moderate intensity physical activity recommendation of 'being active enough') was assessed by asking a simple question considering the number of days a week in the past two weeks the subject had participated in moderate intensity physical activities for a total of 30 minutes a day.¹³ In case of having performed such activities for at least five days a week, one was considered to be active. Upper extremity complaints were determined using a validated Dutch version of the Nordic questionnaire, assessing the prevalence in the last three months,^{14,15} and were dichotomized into 'no complaints' versus 'one or more complaints'.

Definition of change between baseline and follow-up measurements

For the continuous outcome variables the following analyzes were performed to evaluate the effect of the intervention: 1) Absolute change, i.e., a linear regression analysis with the difference between the follow-up measurement and the baseline measurement as outcome variable; 2) Analysis of covariance, i.e., a linear regression analysis in which the follow-up measurement is used as outcome variable and in which the baseline measurement is used as covariate; 3) Residual 'change' analysis, which contains two steps. First a linear regression analysis is performed between the follow-up measurement (as outcome variable) and the baseline measurement. Secondly, the difference between the observed value at the follow-up measurement and the predicted value by the regression analysis in the first step is used as outcome variable in the analysis to evaluate the effect of the intervention.¹⁶

For dichotomous outcome variables two ways to define changes are compared to each other: 1) absolute change and 2) analysis of covariance. The effect of the intervention was analyzed by either simple or multinomial logistic regression analysis. The fact that multinomial logistic regression has to be used has to do with the fact that the change in a dichotomous outcome variable leads to a categorical outcome variable with four categories. For instance, for the proportion of subjects who are active, the following four categories can be distinguished: 1) active at baseline and follow-up; 2) not active at baseline and follow-up; 3) active at baseline, but not at the follow-up; 4) not active at baseline, but active at followup. Because the intervention was aiming on either increase of physical activity or maintaining to be active, or to decrease upper extremity complaints or maintenance of no complaints, in the analysis only three groups are considered (for physical activity: more/stable active, less active and stable inactive and for upper extremity complaints: less/stable no complaints, more complaints and stable complaints). For the analysis of covariance for the dichotomous outcomes, logistic regression analysis was used.

All analyses were performed with SPSS 10.0.

	Interventio	n group	Control gro	up
	Baseline	Follow-up	Baseline	Follow-up
physical activity index	6.0 (1.1)	6.0 (1.0)	5.4 (1.1)	5.3 (1.1)
total serum	5.5 (1.0)	5.3 (1.0)	5.3 (0.9)	5.3 (0.9)
cholesterol(mmol/l)				
physical activity				
stable active	30.3%		18.1%	
increase	11.8%		12.1%	
decrease	18.4%		18.1%	
stable inactive	39.5%		51.7%	
upper extremity complaints				
stable no complaints	21.8%		27.7%	
less complaints	23.1%		16.2%	
increase in complaints	5.0%		10.0%	
stable complaints	50.0%		46.2%	

Table 1. Descriptive information^a of the variables used in the presented example

^a for the continuous variables, mean and standard deviations are given and for the categorical variables the proportion of subjects in the different categories.

Results

Table 1 shows the descriptives of the variables used in the present example. For both physical activity and serum cholesterol the baseline value in the intervention group is slightly higher than in the reference group (p<0.01 and p=0.13 respectively; the difference at baseline was one of the reasons for selecting the continuous outcome variables in the example). For both dichotomous outcome variables, the majority of the subjects remain stable in both the intervention and the reference group.

Table 2 shows the results of the linear regression analysis evaluating the effect of the counseling intervention regarding total physical activity and total serum cholesterol using several methods of defining change. For both physical activity and serum cholesterol all methods indicate a positive effect of the intervention. However, both the magnitudes of the effects and the corresponding p-values differ between the methods. For instance, for physical activity the absolute change indicates a weaker effect than the analysis of

covariance and the method of residual change. Furthermore, the effect of the intervention evaluated by the absolute change in physical activity was not significant, while the effect evaluated by analysis of covariance and residual change was highly significant.

For serum cholesterol just the opposite is true, i.e., the absolute change indicates a stronger effect than the analysis of covariance and the method of residual change, although the differences are not as obvious as for physical activity.

Table 2. Effect of an individual counseling program at the worksite regarding the physical activity index and serum cholesterol levels evaluated with different methods of defining change

	Regression coefficient	Standard error	p-value
Physical activity index			
absolute change	0.145	0.106	0.172
analysis of covariance	0.276	0.101	0.007
residual change	0.261	0.098	0.009
Total serum cholesterol			
absolute change	-0.216	0.094	0.023
analysis of covariance	-0.182	0.088	0.040
residual change	-0.181	0.088	0.040

Table 3. Effect (odds ratios, 95% confidence intervals [CI] and p-values) of an individual counseling program at the worksite regarding the proportion of subjects being active and the proportions of subjects with upper extremity complaints evaluated with different methods of defining change

		Odds ratio	95% CI	p-value
Physical activity				
absolute change	more/stable active ^a			
	less active	0.73	0.38 - 1.67	0.455
	stable inactive	0.55	0.29 - 1.05	0.069
analysis of covariance		0.68	0.36 - 1.31	0.250
Upper extremity complaints				
absolute change	less/no complaints ^a			
-	more complaints	0.44	0.14 - 1.41	0.166
	stable complaints	0.67	0.34 - 1.31	0.242
analysis of covariance		0.73	0.38 - 1.38	0.332

^a reference category.

Table 3 shows the results of the analyses evaluating the effect of the counseling intervention on the two dichotomous outcome variables. Although none of the relationships reached statistical significance, for both outcome variables the counseling intervention has a positive effect. Furthermore, the result of the analysis of covariance seems to be a sort of average of the results obtained from the multinomial logistic regression analysis.

Discussion

In this paper several methods to define changes between subsequent measurements are compared to each other in an analysis to evaluate the effect of a worksite counseling intervention. From the presented results it is obvious that the choice for a specific method to define changes influences the answer to the research question.

Continuous outcome variables

It is important to realize that the interpretation of the results is different. For physical activity, the results of the analysis of the absolute change can be interpreted in such a way that the intervention group showed a 0.145 higher increase in physical activity compared to the reference group. The results of the analysis of covariance indicate that given an equal (or average) baseline value, the value at the follow-up measurement is 0.276 points higher for the intervention group compared to the reference group. The analysis of the residual change has more or less the same interpretation as the analysis of covariance, although this is slightly more difficult to understand. The general idea behind the analysis of covariance and the analysis of residual change is that these methods correct for the phenomenon of regression to the mean.¹⁷⁻²⁴ The consequence of regression to the mean is that, just by chance, the change between baseline and follow-up is related to the initial value.

The difference in results regarding physical activity has to do with the fact that the two groups differ at baseline in their physical activity levels. In fact the intervention group was more active at baseline compared to the reference group. Compared to the intervention group, the reference group is, therefore, more likely (just by chance) to increase their physical activity levels. As a result of this, the analysis of absolute change is 'biased' by regression to the mean. A similar (but opposite) phenomenon occurs for the effect of the intervention on total serum cholesterol.

So, although the interpretation of the absolute difference is probably the most straightforward, possible differences at baseline between the groups to be compared are not taken into account. However, when there are no differences in baseline values between the two groups to be compared, all three methods will lead to the same results. Some researchers argue that the best way to define changes, correcting for the phenomenon of regression to the mean, is a combination of the analysis of covariance and the analysis of absolute change. They suggest analyzing the absolute change correcting for the baseline value. However, this approach is mathematically exactly the same as the analysis of covariance.⁶

Dichotomous outcome variables

Like for the situation with a continuous outcome variable, the interpretation of the results obtained from the multinomial logistic regression analysis is different than the interpretation of the results from the logistic analysis of covariance. For instance, for the upper extremity complaints, the analysis of covariance showed that given an equal (or average) score at baseline, the odds of having 'one or more' upper extremity complaints at the second measurement for the intervention group is 0.73 times the odds of having 'one or more' upper extremity complaints at the second measurement for the intervention group is 0.73 times the odds of having 'one or more' upper extremity complaints at the second measurement for the reference group. The

interpretation of the results of the multinomial logistic regression analysis is more straightforward, i.e., it is equal to 'standard' logistic regression analysis. Besides this, it also provides more information, because for each of the possible changes that can occur, separate 'effects' are estimated.

For dichotomous outcome variables, also the phenomenon of regression to the mean can occur, and analysis of covariance assumes to correct for this. However, this correction is slightly more complicated than for continuous outcome variables. This is due to the fact that the outcome variable is the natural logarithm of the odds of having 'one or more' upper extremity complaints at the follow-up measurement, while the dichotomous variable at baseline is used as covariate.

Sophisticated analysis

This paper is limited to a trial in which only one follow-up measurement was performed. When there is more than one follow-up measurement, and the aim of the study is to analyze the differences in development in a certain outcome variable between two or more groups, sophisticated longitudinal statistical techniques are available, such as random coefficient analysis (multilevel analysis), modeling of covariance structures or generalized estimating equations.²⁵⁻²⁷

Floor and ceiling effects

In the present example the outcome variables did not show any 'floors' or 'ceilings'. This problem often occurs when questionnaires are used to measure certain characteristics of the subjects under study. Suppose that for instance pain reduction is the (continuous) outcome variable of a certain trial and that pain is scored from 1 (indicating no pain) to 10 (extremely heavy pain). For a person with a baseline level of pain equal to 2, the amount of pain reduction can only be one unit, while for a person with a baseline pain level of 8, the maximum amount of pain reduction can be 7. In those situations it is fairly obvious that the evaluation of the absolute change is problematic. Using the analysis of covariance or the residual change score is slightly better, but not optimal. In these kind of situations it is recommended to use a change score which is relative to the maximum change which can be achieved.⁶

Recommendation

Although in most studies the absolute change between a baseline measurement and a followup measurement is used to evaluate the effect of certain intervention, in many situations this is not the most appropriate way. It is, however, difficult to give a straightforward advice regarding the definition of change that should be used in a longitudinal study with two measurements. The choice for a particular method greatly depends on the characteristics of the outcome variable. However, when a continuous outcome variable is involved and there are no anticipated 'ceiling' or 'floor' effects, the analysis of residual change or analysis of covariance is recommended, because both techniques correct (if necessary) for the phenomenon of regression to the mean. Although these two techniques both produce almost the same results, the analysis of covariance is preferred, because the regression coefficients are somewhat easier to interpret. When there are anticipated 'ceiling' or 'floor' effects, they should be taken into account.

When changes in a dichotomous outcome variable are analyzed, multinomial logistic regression analysis of the categorical variable is probably preferable to (logistic) analysis of covariance, especially because multinomial logistic regression provides more information and the interpretation of the results is fairly straightforward.

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Section 5

Discussion and Conclusions



Chapter 5.1

General Discussion

The purpose of this thesis was to describe the effectiveness of worksite physical activity programs with a particular focus on the effectiveness of a counseling intervention. For the latter, a randomized controlled trial was conducted. In the first part of this chapter, the main findings of that trial will be summarized. In order to consider the results of the trial in a wider context, results will be compared to the literature. Although a randomized controlled trial is a common and accepted method to investigate the effectiveness of an intervention, there are some methodological drawbacks in conducting such a study design in the worksite setting. In the second part of this chapter, some of these drawbacks will be discussed. Moreover, the results presented in this thesis undoubtedly will raise questions for occupational health care and public health care. Therefore, in the final part of this chapter, the implications of the findings for business and society will be discussed.

Main findings

The model as described in the Introduction (Chapter 1) is presented in this chapter again, indicating the variables that have been evaluated in the randomized controlled trial and whether or not these variables have been influenced by the intervention.

The effects on physical activity, fitness, and health

The evidence for the effectiveness of the physical activity counseling intervention on healthrelated outcomes was described in Chapter 4.1. For physical activity, there was a positive effect for total energy expenditure and sport activities. This effect was mainly due to a decrease in physical activity in the control group, instead of increased levels of physical activity among the intervention group. It was concluded that the intervention was effective as it prevented the seasonal decrease of physical activity during winter time. No effect was found on the proportion of participants meeting the public health physical activity recommendation and physical activities during leisure time other than sports. These two physical activity measures involve moderate-intensity activities rather than vigorous-intensity activities. Hence, we concluded that the counseling intervention particularly induced vigorous-intensity physical activity. This conclusion was supported by the effect observed on one aspect of cardiorespiratory fitness, i.e., submaximal heart rate. Intervention subjects improved their submaximal heart rate, whereas the control subjects deteriorated their submaximal exercise performance. Both groups showed a small decrease in reported low back pain and upper extremity symptoms. However, no intervention effect was found.

For the secondary outcomes, significant positive intervention effects were found on the percentage of body fat and blood cholesterol. However, the effect sizes were rather small. Further, no significant effects were found on the body mass index and on blood pressure.

In conclusion, the findings of the randomized controlled trial suggest that worksite physical activity counseling is effective for some part of the integrated model, namely vigorous-intensity physical activity, percentage of body fat, submaximal heart rate, and blood cholesterol. Follow-up measurements are needed to assess possible other health effects in the longer term.

The effects on sick leave

Both groups showed an increase in the average number of sick leave days during the ninemonth intervention period compared to the nine-month period one year before the intervention. Median values remained stable (control group), or decreased from five to four days (intervention group). After the intervention period, the control group continued increasing in the average number of sick leave days, whereas the intervention group returned to baseline level. As median values decreased in both groups (from four to two days) in the nine-month one year after the intervention. It appeared that the difference in sick leave days was mainly due to few subjects who were absent because of illness for a (very) long time. Further, both groups showed a slight decrease in the frequency and prevalence of sick leave over time with no significant or relevant differences between the two groups. In conclusion, no effect of the intervention on sick leave could be demonstrated.

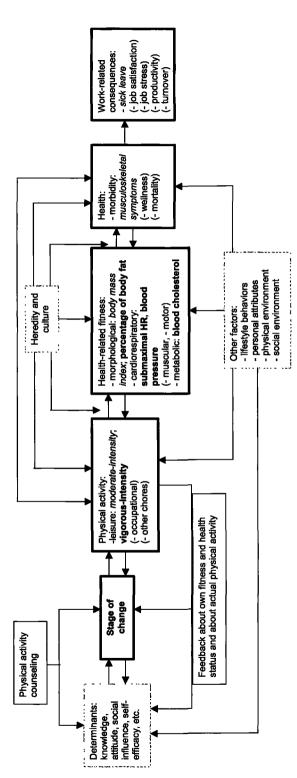
The cost-benefit and cost-effectiveness analysis

During the nine-month intervention period, the mean intervention costs were higher in the intervention group compared to the control group (\in 304.7). During the same nine-month period in the year after the intervention, the benefits due to sick leave were \in 635.2. No statistically significant differences in costs and benefits were found between the two groups. As to the cost-effectiveness ratio, no statistically significant cost-effectiveness ratios were found. It was concluded that the positive effects on energy expenditure and submaximal heart rate could only be gained at a certain price: \in 5.2 per extra kilocalorie per day, and \in 234.9 per beat per minute decrease in submaximal heart rate.

Comparison with the literature

Below, our findings as to the effectiveness of the individual counseling program (Section 4) will be compared to other studies that evaluated worksite individual-based physical activity interventions. To draw a (cautious) conclusion about what type of program should be promoted in order to achieve certain effects, the overall evidence for the effectiveness of individual-based programs, including our results, will be compared to the available evidence for the effectiveness of group-based physical activity interventions at the worksite. Next to the studies in the reviews (Section 2), recently published studies were added from a new literature search using the same key words as applied for the reviews, and additional key words to identify worksite stage of change-based interventions in particular.

Figure 1. Integrated model (see Introduction of this thesis) applied to the outcome measures evaluated in this thesis. Blocks presented in **bold** have been evaluated in our study; variables presented **bold** were positively influenced by the counseling; for the variables presented in italics, no statistically significant positive effect was observed; variables that are in parentheses have not been evaluated in our study, but were presented in the model in the Introduction.



Individual-based programs

For physical activity, our results are supported by other trials that evaluated the effectiveness of a stage of change-based physical activity intervention at the worksite,¹⁻³ all suggesting a positive effect on physical activity. In addition, our review (Chapter 2.1) concluded a 'strong evidence' for a positive effect on physical activity, which was mainly based on two high quality randomized trials that evaluated an individually focused program.^{4,5} In contrast, a recently published study evaluating a worksite tailored program did not show an effect on aerobic physical activities (e.g., walking, swimming, bicycling); only an effect was shown on strengthening and flexibility activities.⁶ Based on the above mentioned findings, individual-based worksite physical activity interventions, whether or not applying the stage of change construct, overall suggest a positive effect on physical activity. No clear distinction could, however, be made as to the effectiveness on moderate- versus vigorous-intensity activities, as was done in our study.

For cardiorespiratory fitness, our study showed favorable intervention effects (Chapter 4.1). Of the randomized trials included in the review (Chapter 2.1) that studied the effectiveness of an individual-based intervention, two out of the three showed favorable intervention effects as well.⁷⁻⁹ Overall, a worksite individual-based program seems to positively influence cardiorespiratory fitness.

As to body composition, blood pressure and blood cholesterol, we recommend more high quality randomized studies evaluating the effects of individualized programs. Our study found a positive effect on the percentage of body fat and blood cholesterol (Chapter 4.1). However, no effect was observed for body mass index and blood pressure. As to the effect on body mass index, our results are supported by Campbell et al.⁶ who also reported no effect of a tailored program on body mass index. Of the studies reviewed (Chapter 2.1), the only high quality trial did observe significant effects on body weight and body composition.⁵ For blood pressure and blood cholesterol, no high quality trials evaluating individual-based physical activity programs were identified. Overall, the low quality trials under review (Chapter 2.1) did not observe intervention effects on blood pressure and blood cholesterol.^{7,8} In summary, the effectiveness of individual-based programs on body composition, blood pressure, and blood cholesterol, still remain obscure, due to a lack of high quality trials and inconsistent findings in the few relevant studies available.

Our study did neither find relevant differences nor a statistically significant effect on musculoskeletal symptoms in favor of the intervention group. Our results were supported by the randomized trial of Horneij et al.,¹⁰ showing no effect of an individually designed physical training program on neck, shoulder, or low back pain. There were no high quality trials that evaluated the effectiveness of individual-based programs on musculoskeletal symptoms included in the review (Chapter 2.1). As a consequence, to date, based on the few trials, there is no evidence for a positive influence of individual-based worksite physical activity programs on musculoskeletal symptoms.

For sick leave, our study did not show an effect on sick leave (Chapter 4.2). As far as we know, no studies have been published yet evaluating the effectiveness of a similar program on sick leave. Therefore, we are not able to conclude a positive effect of an individual-based program on sick leave. As sick leave, and in particular the costs associated

with employee's absence from work, is a relevant aspect for companies for decision-making as regards implementation of worksite physical activity programs, more high quality research is needed evaluating individual-based approaches on sick leave.

Individual-based versus group-based programs

Of the studies reviewed (Chapter 2.1), only one randomized study evaluated a group-based aerobic training program, which did not find an effect on physical activity.¹¹ Thus, to date, for improving physical activity, there is more evidence for a positive effect of an individual-based program compared to a group-based program.

For cardiorespiratory fitness, the conclusion of 'inconclusive evidence' drawn in the review as described in Chapter 2.1 was based on high quality trials that evaluated fitness programs using group-based training sessions.¹²⁻¹⁴ For group-based programs, there is inconsistency as to the results found in high quality trials. For individual-based programs, on the other hand, there was consistency for a positive effect. Therefore, based on the available evidence, a preference can be pronounced for the individual-based approach compared to group-based interventions.

For musculoskeletal symptoms, it seems that group-based interventions are more effective compared to individual-based interventions. The review (Chapter 2.1) concluded 'strong evidence', which was based on the three high quality randomized trials identified, evaluating group-based programs, showing positive effects on musculoskeletal symptoms.¹³⁻¹⁵

Overall, based on the trials identified in the review (Chapter 2.1) no evidence for a positive effect of group-based interventions on body composition, blood pressure, and blood cholesterol is concluded. For body composition, four low quality trials were identified evaluating group-based interventions,¹⁶⁻¹⁹ of which only one observed an effect.¹⁶ In addition, for blood pressure and blood cholesterol, the very few trials^{13,19} identified, did not show an effect. Based on the existing evidence, it seems that worksite physical activity programs, whether or not individual-based, do not have the potential to influence these outcome measures, especially for blood pressure and blood serum lipids. However, taking into account the integrated model, a positive influence on blood pressure and blood serum lipids may not be ruled out. More high quality research is therefore needed evaluating the effectiveness of worksite physical activity programs and investigating the reason why no evidence could yet be demonstrated. Possibly, a longer term is needed to demonstrate such effects.

Finally, the review described in Chapter 2.2 concluded 'limited evidence' for a positive effect on sick leave, which was mainly caused by the positive findings of the only high quality trial identified, evaluating a group-based in-company fitness program.¹² In contrast, a recently published study,²⁰ in which a worksite group-based exercise training program was evaluated, did not observe an effect on sick leave. To date, neither individually oriented programs, nor interventions applying a group-based approach, seem to show (clear) evidence for a positive effect on sick leave.

The conclusions as to the effectiveness of individual-based versus group-based interventions are summarized in table 1. In summary, implementation of a worksite individual-based program seems to be more appropriate than a group-based intervention in order to achieve improved physical activity and cardiorespiratory fitness (excluding blood pressure) levels. For the effectiveness on the prevalence of musculoskeletal symptoms, the opposite seems to be justified. The more pronounced positive effect of a group-based program compared to an individual-based program might be explained by the type of activities induced by the program. On the one hand, group-based programs frequently include a combination of cardiorespiratory fitness, strength and flexibility exercises. Based on the hypothesis that improved strength and flexibility might prevent musculoskeletal symptoms, group-based programs are more effective. On the other hand, application of an individual approach might rather lead to increased levels of physical activity and cardiorespiratory fitness compared to a group-based intervention, since the activities performed are selected by the person himself, which might lead to a higher adherence to the activities planned. In addition, the activities concerned in individual-based interventions do not necessarily include activities that improve strength or flexibility. For the remaining outcome measures described, no clear distinction in the existing evidence for the effectiveness can be made between the different approaches.

	Individual-based program	Group-based program
Physical activity	+	0?
Cardiorespiratory fitness	+	?
Musculoskeletal symptoms	0	+
Body composition	?	0?
Blood pressure	0	0?
Blood cholesterol	?	0
Sick leave	0?	?

Table 1. Summary of the effectiveness of individual-based and group-based worksite

 physical activity programs on different outcome measures

+: evidence for a positive effect; 0: no evidence for a positive effect; +?: studies suggest evidence for a positive effect, however, more high quality research is needed to support this; 0?: studies suggest no evidence for a positive effect, however, more high quality research is needed to support this; ?: inconclusive evidence due to inconsistent results.

Methodological issues

To study the effectiveness of an intervention, a randomized controlled trial is a widely accepted method. The major advantage of the use of such a design is the similarity of the study groups, thereby reducing the influence of possible confounding effects. However, performing a randomized controlled trial in order to evaluate physical activity interventions at the worksite also has some drawbacks.

In the reviews (Section 2), the methodological quality of the studies included was evaluated by a criteria list consisting of nine items. According to these criteria, our own trial (Section 4) would reach a score a 8. Thus, our study is considered as a 'high quality' randomized controlled trial. Considering that this score is substantially higher than those included in the reviews, it should be mentioned that we, of course, were aware of the criteria on beforehand since we had applied them in order to assess the quality of the studies included in the reviews. Below, the most important items will be discussed.

Randomization

Despite randomization, there were relatively more women in the control group than in the intervention group. Though the randomization procedure was not completely successful in the sense that exactly comparable groups were achieved, we believe the impact of this difference to be small. For all analyses, we checked whether variables, like gender, were confounders or effect modifiers. If so, the variable was included in the adjusted (regression) model. However, results of the crude and the adjusted analyses, in which gender was added as a covariate, did not influence the outcome of the trial. Moreover, no effect modification was observed for gender.

Compliance

In general, the effectiveness of an intervention is largely dependent on the compliance to the program. For physical activity interventions, this involves the adherence rate to the program. Generally, the adherence to worksite physical activity programs is rather low (see tables 2 and 3, Chapter 2.1). In addition, a study to the long-term (from 1995 to 2000) participation rate of an in-company fitness program in the Netherlands has shown an average adherence rate of 8-9 times per three months.²¹ In our study, two third of the intervention subjects visited the counselor at least six times out of the seven consultations that were offered to them, which was rather high. Companies that decide to implement a physical activity program with the rationale of achieving benefits for either the individual or the company should thus put much effort in achieving a high adherence rate, and thereby increase the chance to achieve the benefits assumed. Examples of such effort are support from management, reminders sent to the employees, or incentives.

Selection bias

The total drop out rate during the study period, i.e., from baseline to follow-up measurements, was less than 30%. However, it should be mentioned that the initial withdrawal was rather high. Of the potential 600 participants, a total of 299 volunteered and participated in the study. Thus, about 50% of the potential study population was not reached. High initial withdrawal is a common problem encountered in randomized controlled trials at the worksite, and in particular in those studies that evaluate physical activity interventions. As people simply cannot be forced to participate in a program, selection bias is inevitable. Since we do not have demographic, lifestyle or health-related data of the non-participants, we cannot evaluate the extent of this bias. However, the relatively inactive or

unfit persons tend to nonparticipation in physical activity programs. Thus, our results are rather an underestimation than an overestimation.

Content of the intervention

Due to the use of an individual approach, in which the consultation differs for each individual in order to meet the needs of the individual, it is hardly possible to describe the content of the consultations in detail. This is valid for both the consultations with the counselor (Section 4) and the consultation with the sports physician, who gave feedback on one of the three the test results (Section 3). For both types of counseling, the way of counseling was standardized as much as possible. The counselor was instructed to address at least physical activity and nutrition in each consultation. Also, standardized forms (PACE) were applied during the first two consultations in order to set up a plan to improve the physical activity and nutrition behavior. As to the feedback given, this was standardized using reference values. Nevertheless, the precise way in which the counselor or the sports physician (further) conducted the counseling remains obscure. Future studies are useful to get insight in the impact of the feedback, the counseling, and to get insight in what consultation strategies are (most) effective.

Co-intervention: the Enschede firework disaster

Right at the start of the counseling intervention, a large firework disaster took place in Enschede, which is considered a severe co-intervention. The firework disaster ended in 22 deaths and ruined a whole neighborhood (about 1500 damaged houses). Furthermore, it led to a parliamentary inquiry. The firework disaster had an enormous impact on one of the three the municipal services included in our study, since this service was involved with the permits provided for the firework storage. This service was also responsible for the accommodation that had to be arranged for those who had become homeless. The firework disaster may thus have influenced the possible effects of the counseling intervention. For example, it may have contributed to the increase of sick leave during the intervention period in both the control and the intervention group. In addition, the effect observed on physical activity, which was due to a decrease in the control group, could also have been attributed to the firework disaster instead of, or together with the common seasonal decrease during winter. Although the impact of the firework disaster cannot be ignored, the study results are considered to be relevant due to the use of a randomized controlled trial design, which controls for factors unforeseen.

Statistical methods used

The effectiveness of an intervention can be evaluated using different statistical analysis methods. In our trial, analysis of covariance was used, which is a regression analysis with the follow-up measurement as the outcome variable and the baseline measurement as one of the predictors. Another method to evaluate the effectiveness of an intervention is an analysis of variance, which is based on the absolute difference in change between the two study groups. Although the conclusions would be the same, results of Chapter 4.4 obviously showed that effect sizes and the corresponding p-values differ between the methods. As

analyses of covariance corrects for the phenomenon of regression to the mean, this method is preferable, in spite of the fact that the interpretation of the results derived from the absolute difference is more straightforward. However, for dichotomous variables, the interpretation of a multinomial regression analysis provides much more information compared to the (logistic) analysis of covariance. As a consequence, the multinomial regression analysis is recommended. Nevertheless, although we did not analyze the dichotomous variables using a multinomial logistic regression analysis, the conclusions as to the effectiveness of the counseling intervention remain unchanged. Moreover, the baseline and follow-up measurement values were presented, as well as the actual p values, so that the reader can interpret the results himself.

External validity

In comparison with the total Dutch worker population, the participants of our study were more likely to be male, were older, higher educated and less physically active according to the current moderate-intensity public health physical activity recommendation. Our study population consisted of 34% women (Dutch worker population: 40%), 63% highly educated persons (Dutch worker population: 28%) with an average age of 44 years (Dutch worker population: 38 years) and 39% met the current public health physical activity recommendation (Dutch worker population: 46%).^{22,23} Regarding the stage of behavior change as to physical activity, our study population included less precontemplators (1%) compared to the general (i.e., working and non working) Dutch population (26%).²⁴ We therefore conclude that our study population concerns a selective sample and results may not be generalized widely.

Implications for business

The present study showed a positive effect of a worksite physical activity counseling intervention on vigorous intensity physical activity, cardiorespiratory fitness expressed by a decrease in the submaximal heart rate, percentage of body fat, and blood cholesterol. Based on the integrated model presented in the Introduction (Chapter 1), it was hypothesized that an employer benefits from a fit workforce in the short- or the long-term, for example manifested by reduced absenteeism. This, however, could not be confirmed in our study.

Another potential effect from physically active, physically fit, or healthy employees for the company, concerns the so-called 'presenteeism', which, for instance, refers to a higher productivity. Although 'presenteeism' was not evaluated in this thesis, according to the integrated model, the possibility of a positive effect on productivity may not be ruled out.

Furthermore, the increase of the aging (working) population in the Netherlands, and the fact that physical activity is inversely related to age,²² makes worksite physical activity counseling an attractive way to maintain a well-employable workforce. In addition, aging is associated with an increased risk for many chronic diseases and associated absenteeism, and thereby a lower productivity level. It is likely that older employees will rather participate in an individualized program, in which they can select the physical activities themselves, than in

a group-based fitness program. Therefore, individual counseling might be more appropriate. In conclusion, from different points of view, promotion of a worksite physical activity counseling program may be attractive for business.

Considering the major costs for business that are attributable to absence from work through illness, the cost-benefit and cost-effectiveness analysis as described in Chapter 4.3 address a relevant issue. From the employers' perspective, it is understandable that a favorable return on investment or a favorable cost-effectiveness ratio facilitates decisionmaking on implementation of a worksite physical activity intervention. Our results, however, did not show statistically significant benefits or a statistically significant cost-effectiveness ratio for physical activity, fitness or upper extremity symptoms. It should be considered that lack of statistical significance might be due to a lack of power, which is a common problem in cost-effectiveness analyses.²⁵ As there usually is a large variation in the cost data compared to 'clinical' effect measures, the sample size required for an economic evaluation is very large.²⁶ Because the sample size calculation in most trials, including our trial, is based on finding a 'clinical' effect, trials usually are underpowered for an economic evaluation. For the time being, it is concluded that the effects observed can only be obtained at a certain price. Thus, no financial argument can yet be given for implementation of worksite physical activity counseling. However, as described in the preceding paragraph, there are other assumed benefits, which have not been evaluated in our trial. In addition, other non-financial aspects, e.g., improved corporate image or job commitment, may play a role in the decision-making of the implementation of worksite physical activity (counseling) programs. In our opinion, these should all be taken into account.

Further, it is worthwhile mentioning that despite our study did not provide evidence for a (significant) cost-effectiveness, the existing literature as to worksite physical activity, or comprehensive health promotion programs in general shows positive cost-effectiveness findings thereby promoting worksite physical activity or health promotion programs.

A better cost-effectiveness ratio could probably be achieved by a specific (target-) population approach. The question that arises is whether one should counsel those persons, who are already active, and for whom relatively small effects can be gained. It is suggested that the lower the baseline physical activity status, the greater the health benefit associated with increased physical activity.²⁷ Based on our findings, it is plausible that more pronounced health-related effects can be expected when focusing on those persons who are at high behavioral risk, e.g., the least active, least fit, and least healthy persons. Analogously, the highest cost savings can be expected in such a group. A program can, for instance, be focused on those having musculoskeletal symptoms or on subjects having a 'high' risk for cardiovascular diseases. Ozminkowski et al.,²⁹ for instance, supported this hypothesis by showing a better return on investment when focusing on high risk populations for poor health or high medical expenditures compared to the whole population.

Counseling in groups instead of an individual-based approach can also positively influence the economic outcome of the counseling intervention. Although an individualized program has the major advantage of meeting the personal behavior, needs and so on, a group-based counseling approach will often be associated with lower costs. To maintain the advantage of individual-based approach, groups could be formed on the basis of the current physical activity behavior and the intention to change the behavior. Such a group-based counseling approach might lead to similar effects with lower costs when compared to purely individual-based counseling. Future research is recommended evaluating such approach.

The group-based counseling approach as proposed here differs from the group-based programs that have been evaluated in the first part of this Chapter ('individual-based versus group-based programs'). Based on the available evidence as to the effectiveness of worksite physical activity programs, we were not able to take a strong position for either an individual-based or a group-based approach with the exception of the effects on physical activity and musculoskeletal symptoms. Thus, the question of whether a company should or should not implement a physical activity program and if so, what type of program they should implement, cannot unambiguously be answered yet. A comparison of the effectiveness of both options is needed for such an advice.

Implications for society

Physical inactivity and the consequences of inactivity, e.g., (severe) overweight also have an economic impact for the society since this group has higher health care expenditures. As a consequence, physical activity should be stimulated from a societal perspective too in order to prevent an increase of people being overweight. As a worksite physical activity program has the advantage to reach a large proportion of the adult population, and has the potential to improve levels of physical activity, implementation of programs at the worksite should be promoted also to reduce the negative consequences of physical inactivity on the level of the society as a whole. Since different 'authorities', i.e., society, business, and the individual himself, may benefit from a physically active population, it is reasonable that costs of health promotion are shared. Therefore, worksite physical activity programs can be stimulated by subsidies, so that the investment is not on the account of the company only. After all, both society and business may, in either the short-term or the long-term, expect positive effects of an active, fit, and consequently healthy population. In the (decision-making of) implementation of the worksite physical activity programs, occupational health physicians, and/or staff department of the company, may play an important role.

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Chapter 5.2

Conclusions and Recommendations

Conclusions

Based on the current trends in Western society as to physical activity and (severe) overweight and the negative consequences for both public health and occupational health, prevention of physical inactivity and (severe) overweight is of great relevance. For that, worksite health promotion programs aimed at optimizing the balance between energy expenditure and energy intake by increasing the physical activity level are recommended. The conclusions of the studies presented in this thesis are:

- Based on the literature, strong evidence was found for a positive effect of worksite physical activity programs on physical activity and musculoskeletal symptoms and limited evidence for a positive effect on fatigue and absenteeism from work.
- Based on the literature, no or inconclusive evidence was found for a positive effect of worksite physical activity programs on cardiorespiratory fitness, muscle flexibility, muscle strength, body weight, body composition, general health, blood serum lipids, blood pressure, job satisfaction, job stress, productivity and employee turnover. More high quality randomized studies are needed.
- Personalized feedback on the fitness and health status can influence the subjective appraisal of one's own stage of behavior change and thereby can be considered as a small, but relevant start of the intervention itself.
- The worksite physical activity counseling intervention positively influenced vigorousintensity physical activity, submaximal heart rate, percentage of body fat, and blood cholesterol.
- The worksite physical activity counseling intervention did not influence other healthrelated outcome measures, such as moderate-intensity physical activity, body mass index, blood pressure, and musculoskeletal symptoms.
- The worksite physical activity counseling intervention did not have a significant effect on sick leave.
- The worksite physical activity counseling intervention did neither show significant differences between costs and benefits, nor a statistically significant cost-effectiveness ratio. The positive effects on physical activity and fitness could only be gained at higher costs.
- For continuous outcome variables 'analysis of covariance' seems to be the most appropriate statistical method, because it corrects for the phenomenon of regression to the mean. For dichotomous outcome variables, multinomial logistic regression analysis with all possible changes over time as outcome seems to be the most appropriate.

Recommendations for future research

Although this thesis improves insight in the effectiveness of physical activity programs in the worksite setting, some questions remain unanswered and some other questions have been raised. Thus, the following recommendations for future research are made:

- To evaluate the long-term effects of an individual counseling intervention in order to determine whether the change in physical activity behavior and fitness level will continue and thereby achieve more pronounced health benefits and possibly associated workrelated consequences, such as reduced sick leave.
- To perform more randomized controlled trials evaluating the effectiveness of similar interventions to support our findings. Outcome measures should include person-related consequences, e.g., physical activity, fitness and health, as well as work-related consequences, e.g., sick leave.
- To compare the effectiveness of different types of worksite physical activity programs. In
 particular, studies that compare the effectiveness of an individual-based intervention
 versus a group-based intervention are needed.
- To evaluate whether a worksite physical activity counseling intervention is effective among the least active group, since it is generally suggested that more pronounced effects are obtained among persons being inactive or not regularly active.
- To evaluate the optimal content of a counseling intervention (what aspects of the counseling, which consultation strategies and approaches are most effective?).
- To further analyze (e.g., using LISREL) the relationships between the variables described in the integrated model presented in this thesis.
- To evaluate the costs and effectiveness of group-based counseling, possibly in comparison with an individual-based counseling approach.

Recommendations for practice

- To enhance physical activity or cardiorespiratory fitness levels, individual-based worksite physical activity programs appear to be more attractive for business than group-based programs. For the prevention of musculoskeletal symptoms, group-based are preferable to individual-based worksite physical activity programs.
- In the decision-making of the implementation of worksite physical activity (counseling) programs, business should take into account non-financial aspects, such as improved corporate image or job commitment, next to the cost-benefit argument.
- From a cost-effectiveness point of view, it seems important to focus physical activity
 programs on risk groups within the company rather than implement programs for all
 workers, including those who are fit already. Special attention should be given to
 methods to enhance participation among those who are the least physically active.
- Companies are an attractive setting to promote physical activity. Both business and society can gain from implementation of physical activity programs in this setting. Government should consider to support company-based physical activity programs

financially to facilitate a wide implementation, also in smaller companies, which often have with limited financial resources.

Summary

This thesis deals with the effectiveness of worksite physical activity programs (WPAP). WPAPs are implemented on the basis of certain rationales. These rationales are rather diverse and can involve improving and/or maintaining the fitness and health status of the workforce, but can also involve work-related advantages, such as a reduction of sick leave. However, the effectiveness of a WPAP often remains unclear. The aim of this thesis was to evaluate the effectiveness of WPAPs, and in particular the effectiveness of an individual based counseling program. In this thesis, the following questions have been dealt with:

- 1. What can be found in the literature about the effectiveness of WPAPs?
- 2. Does personalized feedback on the fitness and health profile affect the subjective appraisal of the own behavior and the intention to change the behavior?
- 3. What is the effectiveness, the cost-benefit, and the cost-effectiveness of an individualbased counseling WPAP?

The first part (*Section 1*) of this thesis concerns the introduction. Based on the trends and consequences of physical (in)activity, it becomes clear that the promotion of physical activity is needed. Promotion of physical activity can take place through various settings, among which the workplace, the focus of this thesis. Besides, in the introduction a few theoretical models are presented, which can be applied to several health-related behaviors, including physical activity. Based on these models, an integrated model is formed. This integrated model indicates how and which variables are related to being or becoming physically active or not, as well as the consequences associated with that. The integrated model has been applied to the studies, described in the sections 2,3 and 4.

The second part (*Section 2*: Chapters 2.1 and 2.2) of this thesis summarizes the literature concerning the effectiveness of WPAPs. Relevant studies were identified by a search in several databases. Some criteria were used to include a study in the review. Only (randomized) controlled trials, evaluating the effectiveness of a WPAP, primarily aimed at enhancing levels of physical activity, exercise, and/or fitness, were included. The quality of the included studies was evaluated using a predefined set of methodological criteria. Conclusions regarding the effectiveness were based on a rating system consisting of levels of evidence.

Chapter 2.1 describes the results of the review as to the effectiveness of WPAPs on physical activity, fitness, and health-related variables. 772 publications were initially identified, of which 26 studies (15 randomized controlled trials, 11 controlled trials) were finally selected. Based on a best evidence synthesis, strong evidence for a positive effect on physical activity and musculoskeletal disorders was concluded. Further, there was limited evidence for a positive effect on fatigue. For the remaining fitness- and health-related outcome measures, inconclusive or no evidence was found for a positive effect of a WPAP. This was due to inconsistency in the findings of the studies, or was caused by a lack of high quality studies.

Chapter 2.2 summarizes the literature as to the effectiveness of WPAPs on workrelated outcome measures, namely absenteeism from work, job satisfaction, job stress, productivity, and employee turnover. Out of the 218 identified studies, only eight studies met the inclusion criteria. The methodological quality of these eight studies was generally poor, as a consequence of which only limited evidence was concluded for a positive effect on absenteeism from work. For the remaining work-related outcome measures, inconclusive or no evidence was found.

The results of these two reviews show that the evidence for the effectiveness of WPAPs is still limited, partly due to lack of randomized controlled trials of high methodological quality. Such studies are therefore recommended.

The third part of the thesis (*Section 3*: Chapter 3.1) deals with the earlier mentioned second research question. Some practitioners suggest that not only the physical activity intervention, but also the fitness and health measurements as such, and particularly the feedback received regarding these measurements, can already produce a change. As the real fitness and health status can be different from one's own appraisal, objective information about the fitness and health profile may produce a change in awareness of the own behavior, which is more consistent with reality. As a consequence of this changed perception, the intention to change the behavior may also change.

This chapter describes the results of the effectiveness of feedback as to the objective fitness and health profile on the subjective appraisal of the behavior and the intention to change the behavior, or: the stage of change. In doing so, the same study population was used as in Section 4 (described below in more detail). Directly after testing, the intervention group consulted a sports physician, who gave feedback in a standardized way on most of the fitness and health test results. The control group received neither feedback by the sports physician, nor the test results. No statistically significant effect was found of feedback on the stage of change. However, for the raw scores a significant effect was found on one of the three nutrition topics: 'calorie intake and weight management'. Persons having received feedback, intervention subjects were less positive about their calorie intake and weight. These results suggest that feedback indeed can produce a change in the subjective appraisal of one's own behavior and can therefore be considered as a small intervention in itself.

For the fourth part (*Section 4*: Chapters 4.1 to 4.4), a randomized controlled trial was conducted among three municipal services of Enschede's local authority. A total of 600 employees were approached, of which 299 were willing to participate in the study. Of these, 131 and 168 employees were randomized into the intervention group and the control group, respectively. During nine months (from May 2000 to January 2001), all intervention subjects were offered seven consultations, each of 20 minutes in duration. Counseling focused primarily on the enhancement of the individual's level of physical activity and secondarily on the promotion of healthy nutrition habits. This was done using standardized protocols, which took into account the stage of change. Before the start of the intervention and after the intervention, measurements took place, existing of a questionnaire, fitness tests, and an interview. Moreover, sick leave data were obtained from each municipal service's Personnel Department.

Chapter 4.1 presents the results of the worksite physical activity counseling program on individual-related outcome measures, namely physical activity, fitness and health. There were significant positive effects on total energy expenditure, physical activity during sports, cardiorespiratory fitness, percentage of body fat, and blood cholesterol. No effect was found for the proportion of subjects meeting the public health recommendation of moderateintensity physical activity, which states that every adult has to perform moderate-intensity physical activities for a total of at least 30 minutes a day for five or more days of the week. In addition, no effects were found for physical activity during leisure time other than sports, prevalence of musculoskeletal symptoms, body mass index, and blood pressure.

In *Chapter 4.2*, the effectiveness of the counseling intervention on sick leave is described. Both study groups showed an increase in the mean sick leave rate during the intervention compared to before the intervention. In the same period in the year after the intervention, the control group increased even more, whereas the intervention group slightly decreased in the mean sick leave rate. Statistical analyses showed an average difference in mean sick leave rate of six days, in favor of the intervention group. In both groups, the mean sick leave frequency slightly decreased over time. Results of multilevel analyses showed no statistically significant intervention effect.

Chapter 4.3 describes the cost-benefit and the cost-effectiveness of the counseling intervention. The intervention costs were \leq 429,90 per participant. The benefits due to sick leave reduction during the nine-month intervention period were \leq 125.20, leading to net total costs of the intervention of \leq 304.70 per participant. In the year after the intervention, the mean sick leave rate increased in the control group against a slight decrease in the intervention group. As a consequence, the benefits of the intervention became larger. No statistically significant differences in costs and benefits were found between the two groups. As to the cost-effectiveness, an improvement in energy expenditure and cardiorespiratory fitness was observed to be gained at higher costs.

Chapter 4.4 presents the effectiveness of the counseling intervention using two different statistical analysis techniques. The first statistical analysis method is based on testing the difference between the study groups in the absolute change, i.e., a linear regression analysis with the difference between the follow-up measurement and the baseline measurement as outcome variable. The second method, an analysis of covariance, concerns a linear regression analysis in which the follow-up measurement is used as outcome variable and in which the baseline measurement is used as covariate. It appeared that conclusions as to the intervention effect can differ per statistical analysis method. The results of the analyses showed that for continuous outcome variables 'analysis of covariance' seems to be the most appropriate, because it corrects for the phenomenon of regression to the mean. For dichotomous outcome variables on the other hand, multinomial logistic regression analysis with all possible changes over time as outcome seems to be the most appropriate, especially because of its straightforward interpretation.

Finally, in the last part, *Section 5* (Chapters 5.1 and 5.2), all findings of the above mentioned studies are summarize and integrated in the model presented in the introduction. The results of the randomized controlled trial, described in Section 4, are thereby placed in a wider

context. In doing so, a distinction was made between the effectiveness of individual-based versus group-based WPAPs. It was concluded that for enhancing physical activity or cardiorespiratory fitness levels, individual-based WPAPs appeared to be preferable to group-based programs. For the prevention of musculoskeletal symptoms, group-based were considered to be preferable to individual-based worksite physical activity programs. In order to even better interpret the results described in Section 4, some methodological issues were described.

Chapter 5.1 describes implications for both business and society. With this, the interests for and the responsibility of the different authorities have been discussed.

Chapter 5.2 finishes this thesis with recommendations for future research and for practice.

Samenvatting

Dit proefschrift gaat over de effectiviteit van bewegingstimuleringsprogramma's via het werk, oftewel bedrijfsbewegingsprogramma's (bbp's). Bbp's worden geïmplementeerd met bepaalde beweegredenen. Deze beweegredenen zijn zeer divers en kunnen betrekking hebben op het verbeteren en/of behouden van de fitheid of gezondheid van het personeel, maar kunnen ook op bedrijfsgerelateerde voordelen betrekking hebben, zoals een reductie van het ziekteverzuim. Ondanks deze beweegredenen blijft de daadwerkelijke effectiviteit van een bbp vaak onduidelijk. Doel van dit proefschrift is het evalueren van de effectiviteit van bbp's, en in het bijzonder van een individu-gericht counseling programma. In dit proefschrift zijn de volgende drie vraagstellingen behandeld:

- 1. Wat is er in de literatuur bekend over de effectiviteit van bbp's?
- 2. Heeft het geven van persoonlijke feedback over fitheid en gezondheid reeds een effect op het bewustzijn over het eigen gedrag en de bereidheid dat gedrag te veranderen?
- 3. Wat zijn het effect, de kosten-baten, en de kosten-effectiviteit van een individu-gericht counseling programma ter bevordering van lichamelijke activiteit?

Het eerste deel (*Sectie 1*) van dit proefschrift betreft de inleiding. Uit beschreven trends en de gevolgen van lichamelijke (in)activiteit wordt duidelijk dat bewegingsstimulering gewenst is. Bewegingsstimulering kan in verschillende settings plaatsvinden, waaronder de werkplek. Dit proefschrift richt zich op deze setting. Ook is er in de inleiding een aantal modellen beschreven, die toegepast kunnen worden bij het stimuleren van gezond gedrag in het algemeen, maar die ook bruikbaar zijn voor het stimuleren van meer lichaamsbeweging. Op basis van bestaande modellen is in de inleiding een geïntegreerd model gepresenteerd. Dit model geeft aan hoe en welke variabelen van invloed zijn op het al dan niet lichamelijk actief zijn en de daarmee gepaard gaande gevolgen. Het geïntegreerde model is toegepast op de onderzoeken die beschreven zijn in de secties 2, 3 en 4.

Het tweede deel (*Sectie 2*: Hoofdstukken 2.1 en 2.2) van dit proefschrift geeft een overzicht van de literatuur over de effectiviteit van bbp's. Hiertoe is in verschillende databases gezocht naar geschikte literatuur. Voor de uiteindelijke selectie in de literatuurstudie is een aantal criteria gesteld. Zo zijn alleen (gerandomiseerde) gecontroleerde onderzoeken geselecteerd. Bovendien zijn alleen onderzoeken ingesloten die het effect van een bbp hadden onderzocht, dat vooral gericht was op het stimuleren van de lichamelijke activiteit en fitheid. De kwaliteit van de geselecteerde onderzoeken is beoordeeld aan de hand van vooraf gestelde methodologische kwaliteitscriteria. Met behulp van beslisregels over de sterkte van het bewijs is vervolgens voor elke uitkomstmaat een conclusie getrokken over de effectiviteit van bbp's.

Hoofdstuk 2.1 beschrijft het resultaat van de literatuurstudie naar de effectiviteit van bbp's op individuele uitkomstmaten, te weten: lichamelijke activiteit, fitheid en gezondheid. Van de aanvankelijk 772 geïdentificeerde publicaties zijn uiteindelijk 26 onderzoeken, waarvan 15 gerandomiseerde gecontroleerde onderzoeken, geschikt bevonden en opgenomen in de literatuurstudie. Op basis van de beslisregels is geconcludeerd dat er een sterk bewijs is voor een gunstig effect van bbp's op de mate van lichamelijke activiteit en klachten aan het bewegingsapparaat. Verder is er een beperkt bewijs voor een positief effect

op vermoeidheid gevonden. Voor de overige fitheids- en gezondheidsvariabelen kon geen conclusie getrokken worden of is er geen bewijs gevonden voor een positief effect. Dit is veroorzaakt door inconsistentie in de bevindingen van de verschillende onderzoeken of door een gebrek aan onderzoeken van goede kwaliteit.

Hoofdstuk 2.2 geeft een samenvatting van de literatuur over het effect van bbp's op werkgerelateerde uitkomstmaten: ziekteverzuim, werktevredenheid, werkstress, productiviteit en personeelsverloop. Van de 218 aanvankelijk geïdentificeerde publicaties bleken slechts acht onderzoeken te voldoen aan de inclusiecriteria. De methodologische kwaliteit van de acht onderzoeken was over het algemeen laag, waardoor niet meer dan een beperkt bewijs voor een positief effect op ziekteverzuim kon worden geconcludeerd. Voor de overige werkgerelateerde uitkomstmaten kon geen conclusie getrokken worden, of werd geen bewijs gevonden voor een positief effect.

De resultaten van de twee literatuurstudies laten zien dat het bewijs voor de effectiviteit van bbp's vooralsnog beperkt is, mede als gevolg van een gebrek aan gerandomiseerde onderzoeken van goede kwaliteit. Dergelijke onderzoeken zijn dus aanbevolen.

Het derde deel (Sectie 3: Hoofdstuk 3.1) behandelt de eerder genoemde tweede vraagstelling. Sommige praktijkbeoefenaars menen dat niet alleen een beweeginterventie, maar ook de metingen, en vooral de feedback die men krijgt over het eigen fitheids- en gezondheidsprofiel, al bepaalde veranderingen teweeg kunnen brengen. De objectieve fitheid en gezondheid kan namelijk verschillend zijn van de eigen subjectieve indruk hierover. Informatie over de objectieve fitheid en gezondheid kan dus tot een verandering van het bewustzijn over het eigen gedrag leiden, die meer in overeenstemming is met de werkelijkheid. Als gevolg van deze veranderde perceptie, kan de bereidheid tot een verandering van het gedrag ook wijzigen. Dit hoofdstuk beschrijft de resultaten van het effect van feedback over de objectief gemeten fitheid en gezondheid op de eigen inschatting van het gedrag en de intentie dit gedrag te veranderen, oftewel de gedragsveranderingfase. Hiervoor is dezelfde onderzoeksgroep gebruikt als in Sectie 4 (hieronder uitvoeriger beschreven). De interventiegroep kreeg na afloop van de metingen een persoonlijk gesprek met een sportarts die feedback over de testresultaten gaf. De controlegroep, daarentegen, kreeg feedback noch testresultaten. De gegeven feedback bleek geen statistisch significant effect te hebben op de gedragsveranderingfase. Echter, op de oorspronkelijke scores was wel een significant effect zichtbaar voor één van de drie voedingsaspecten, namelijk energiebalans. Personen die feedback hadden gekregen waren 'verslechterd' in hun score ten opzichte van de controlegroep: zij waren minder positief geworden over hun gewicht en energie-inname. Deze resultaten suggereren dus dat feedback inderdaad tot een verandering in de eigen perceptie van het gedrag kan leiden. Feedback kan derhalve als een geringe interventie beschouwd worden.

Voor het vierde deel (*Sectie 4*: Hoofdstukken 4.1 tot en met Hoofdstuk 4.4) is een gerandomiseerd gecontroleerd onderzoek uitgevoerd onder drie diensten van de gemeente Enschede. Van de 600 benaderde kantoorwerknemers waren 299 bereid deel te nemen aan

het onderzoek. Hiervan zijn door middel van cluster randomisatie, 131 en 168 werknemers willekeuria ingedeeld in de interventiegroep respectievelijk de controlegroep. Iedereen in de interventiegroep kreeg gedurende negen maanden (van mei 2000 tot en met januari 2001) zeven consultgesprekken van 20 minuten aangeboden. Tijdens deze consultgesprekken is ten eerste aandacht besteed aan het stimuleren van voldoende beweging en ten tweede aan het stimuleren van gezonde voeding. Dit is gedaan aan de hand van gestandaardiseerde protocollen die rekening houden met de gedragsveranderingfase. Voor de start van de interventie en na afloop van het laatste consult vonden metingen plaats, bestaande uit een aezondheidstesten. Daarnaast ziin vragenlijst, een interview en fitheidsen ziekteverzuimregistraties verzameld over de periode van het jaar voor de interventie (mei 1999) tot en met een jaar na afloop van de interventie (januari 2002).

Hoofdstuk 4.1 presenteert de resultaten van de counseling interventie op individuele uitkomstmaten, te weten lichamelijke activiteit, fitheid en gezondheid. Er werd een gunstig statistisch significant effect gevonden van de interventie op het energieverbruik, de mate van lichamelijke activiteit tijdens sport, de cardiorespiratoire fitheid, het percentage lichaamsvet en het bloedcholesterolgehalte. Er kon echter geen statistisch significant effect aangetoond worden op het percentage werknemers dat voldeed aan de Nederlandse Norm voor Gezond Bewegen, die stelt dat iedere volwassene tenminste vijf dagen per week minstens een half uur matig intensief lichamelijk actief moet zijn. Ook werd geen effect gevonden op de mate van lichamelijke activiteiten tijdens de vrije tijd (behalve sport), klachten aan het bewegingsapparaat, de quetelet-index en de bloeddruk.

In *Hoofdstuk 4.2* wordt het effect van de interventie op ziekteverzuim besproken. De beide onderzoeksgroepen lieten een toename zien in de gemiddelde verzuimduur in de periode tijdens de interventie, ten opzichte van diezelfde periode in het jaar voordat de interventie startte. In het jaar na de interventie was de gemiddelde verzuimduur bij de interventiegroep licht gedaald, terwijl dit bij de controlegroep bleef stijgen. Uit de analyse bleek een gemiddeld verschil tussen de twee groepen van ruim zes verzuimdagen. De verzuimfrequentie daalde iets over de tijd in de beide groepen. Resultaten van een multilevel analyse toonden echter geen statistisch significante effecten aan.

Hoofdstuk 4.3 beschrijft de kosten-baten en de kosten-effectiviteit van het counseling programma. De interventiekosten bedroegen €429,90 per deelnemer. In de periode tijdens de interventie bedroegen de baten als gevolg van een daling in het ziekteverzuim €125,20. Hierdoor kwamen de interventiekosten in diezelfde periode neer op een bedrag van €304,70 per deelnemer. In het jaar volgend op de interventie steeg de gemiddelde verzuimduur in de controlegroep, tegen een lichte daling van het verzuim in de interventiegroep. Als gevolg hiervan werden de baten groter. Er werd over geen van de perioden een significant verschil gevonden in de kosten en baten tussen de twee groepen. Wat betreft de kosten-effectiviteit werd geconcludeerd dat er voor een bepaalde prijs effecten te bereiken zijn op het energieverbruik en de fitheid.

Hoofdstuk 4.4 presenteert de effectiviteit van het counseling programma aan de hand van twee verschillende analysetechnieken. De eerste analysetechniek is gebaseerd op het toetsen van het verschil in de verandering (nameting minus de voormeting) tussen de twee groepen. De tweede methode, de covariantie analyse, toetst het verschil tussen de twee groepen op de nameting, waarbij gecorrigeerd wordt voor gegevens verzameld tijdens de voormeting. Het bleek dat conclusies over het effect van de interventie kunnen verschillen per analyse methode. Een covariantie analyse methode lijkt al met al de meest geschikte methode voor het analyseren van continue gegevens, omdat deze corrigeert voor regressie naar het gemiddelde. Voor dichotome uitkomstmaten daarentegen, lijkt de eerste aanpak de meest aangewezen analysetechniek, omdat de resultaten ervan makkelijk te interpreteren zijn en meer informatie geven over de veranderingen die optreden.

Tot slot worden in het laatste deel, *Sectie 5* (Hoofdstukken 5.1 en 5.2) alle bevindingen van de hiervoor beschreven onderzoeken samengevat en in één model geïntegreerd. De resultaten van het onderzoek bij de gemeente Enschede worden daarmee geplaatst in een bredere context. Hierbij is tevens een onderscheid gemaakt tussen de effectiviteit van individuele versus groepsgewijze bbp's. De conclusie was dat individuele programma's de voorkeur verdienen voor het bereiken van een toename van de lichamelijke activiteit en cardiorespiratoire fitheid. Voor de preventie van klachten aan het bewegingsapparaat lijken groepsgewijze bbp's eerder een geschikte aanpak. Om de resultaten van het hoofdstuk beschreven in sectie 4 nog beter te kunnen interpreteren zijn nog enkele methodologische aspecten behandeld.

Hoofdstuk 5.1 beschrijft een aantal implicaties voor zowel het bedrijfsleven als voor de maatschappij. Hierbij zijn de belangen voor en de verantwoordelijkheid van de verschillende partijen aan de orde gesteld.

Hoofdstuk 5.2 sluit af met aanbevelingen voor toekomstig onderzoek alsmede voor de praktijk.

Dankwoord

Het is gelukt: het boekje is af! Terwijl ik dit zo opschrijf - heel bewust gebruikmakende van het uitroepteken - zou je denken dat het een zware bevalling is geweest. Nou, ik kan julie verzekeren dat dat ook het geval is geweest. Hoe vaak heb ik wel niet gedacht: "had ik maar...", "ach, waarom zou ik überhaupt nog...?", "dat stuk gooi ik er gewoon uit". Maar goed, aan alles komt een einde, dus ook aan dit promotie-onderzoek. En hoe tegenstrijdig ook, één van de redenen waarom ik tegen dit deel van het boekje op zie, dat daadwerkelijk het laatst geschreven is, is dat ik er stiekem toch een beetje moeite mee heb het af te sluiten. Want naast de moeilijke perioden, zijn er zeer waardevolle momenten geweest, die duidelijk de overhand hebben gehad. En hieronder wil ik dan ook graag de personen bedanken op wie ik gedurende het hele traject kon rekenen en die er voor mij een hele leuke en leerzame tijd van hebben gemaakt.

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Dan kom ik nu bij de wetenschappelijk begeleiding.

Allard, mijn copromotor. Ik begin met jou, omdat jij mede de oorzaak bent geweest dat ik aan dit traject begonnen ben. Tijdens het congres (PREMUS) in Helsinki heb je me aan het denken weten te zetten. Dank je wel, en dat meen ik! Daarnaast wil ik je bedanken voor de enorme inzet die je hebt getoond, met name bij de start van het project waarbij alle protocollen in 'no time' opgesteld moesten worden, en jij niet terugdeinsde voor het werken op een zaterdag of je vrije dag. Met die inzet ging je ook de discussies met me aan. Al die vragen die je me stelde omdat je ôf het goed wilde begrijpen, ôf omdat je het mij wilde laten uitleggen om te checken of ik het zelf wel snapte. Wat de reden precies was, ik weet het nog niet, maar ik heb er veel aan gehad.

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About the author

Karin Ingeborg Proper was born on the 20th of January 1972 in Vaassen, the Netherlands. She completed her Higher General Secondary Education (H.A.V.O.) at the Katholiek Veluws College in Apeldoorn in 1989 and finished two years of pre-university education (V.W.O.) afterwards. She started the Physical Education Academy in Groningen in 1991. In 1992, she completed both the V.W.O and the propaedeutic year of the Physical Education Academy. In the same year, she started her study Human Movement Science at the University of Groningen with a specialization in Work & Health. During her study, in 1996, she moved to Solna, Sweden, for an additional research project of six months at the National Institute for Working Life. Hereafter, she started her final paper at TNO Prevention and Health in Leiden, where she was involved in a randomized controlled trial studying the effectiveness of Cesar Therapy in chronic low back pain patients. In 1997, she completed her study Human Movement Science, and continued to work at TNO Work and Employment in Hoofddorp. She was involved in several projects, but the main area concerned physical (in)activity among workers. In 2000, she started her PhD project presented in this thesis, which was a collaboration between TNO Work and Employment and the EMGO Institute. Since finishing her dissertation, she continued to work as a researcher at TNO Work and Employment in the field of Physical Activity, Health and Work.

De meerderheid van de volwassen bevolking beweegt te weinig en de gevolgen daarvan zijn aanzienlijk. Mensen die voldoende bewegen hebben een verlaagd risico op een groot aantal chronische ziekten ten opzichte van degenen die niet voldoende bewegen. De werkplek is een geschikte setting voor het stimuleren van bewegen. Inmiddels lopen bij een aantal bedrijven programma's die het bewegen moeten bevorderen. De beweegredenen voor implementatie van dergelijke programma's zijn divers en variëren van het verbeteren en/of behouden van de fitheid of gezondheid van het personeel tot het reduceren van het ziekteverzuim. De effectiviteit van dergelijke programma's blijft echter vaak nog onduidelijk. Het proefschrift behandelt de effectiviteit van bedrijfsbewegingsprogramma's, met specifieke aandacht voor de effectiviteit van een individu-gericht counseling programma.



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