PERFECTFIT @WORK

Effectiveness of blended web-based workplace health promotion programs

Tessa A. Kouwenhoven-Pasmooij

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Tessa Alexandra Kouwenhoven-Pasmooij

Colofon

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PERFECTFIT OP HET WERK
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	Prof. dr. ir. A. Burdorf
Overige leden:	Prof. dr. E.F.C. van Rossum
	Prof. dr. C.T.J. Hulshof
	Prof. dr. J.W. Roos-Hesselink
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CONTENT

Chapter 1

General Introduction

GENERAL INTRODUCTION

NON-COMMUNICABLE & CARDIOVASCULAR DISEASES

Non-communicable diseases (NCD) are the leading causes of premature deaths and morbidity all over the world, and have a large impact on quality of life (1, 2). Non-communicable diseases are non-infectious and non-transmissible diseases that may be caused by genetic or behavioural factors and generally have a slow progression and long duration (3). These include cardiovascular diseases (CVD), cancer, chronic respiratory diseases, and diabetes. Most of the NCD deaths are caused by CVD, mainly coronary heart disease, cerebrovascular disease and heart failure (4). Currently in Europe, 77% of the total burden of disease is attributable to NCD, the most significant being CVD and cancer (5). Although mortality due to CVD has decreased since 1970, its prevalence will keep increasing (6) with an expected 65% increase between 2011 and 2040 in the Netherlands (7), explaining the increased burden of disease. A similar rising trend is seen for related chronic health conditions that increase the risk of CVD, such as hypertension or obesity. For obesity, there has been an increase in the prevalence in western countries over the last 3 decades. In 2016, almost half of the Dutch adults were overweight and 16% were obese (8), representing close to triple the prevalence of 5.5% in 1990 (9).

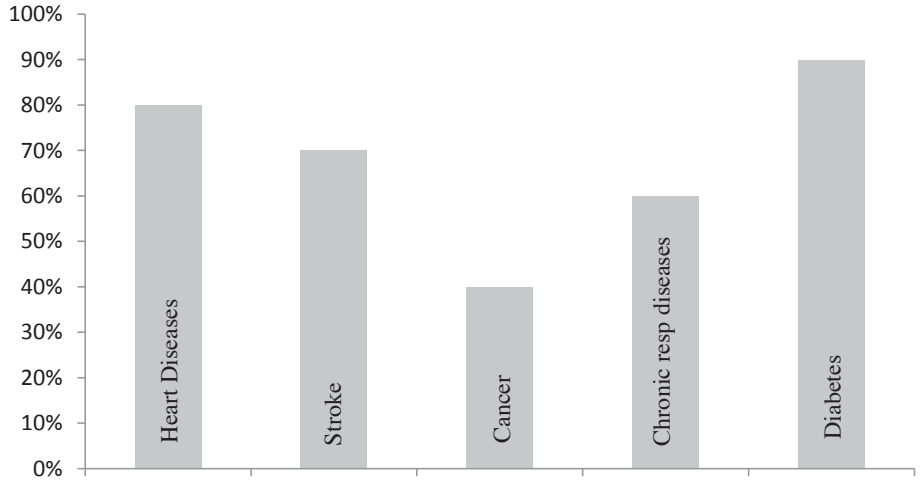
CARDIOVASCULAR DISEASES AND WORK

During their working lifespan, an increasing number of people is diagnosed with chronic health conditions. In addition, the number of individuals with multimorbidity is increasing (10). It is estimated that costs for CVD in the European Union are €210 billion a year, with €111 billion due to health care costs, and €99 billion due to productivity losses at work and the costs of informal care (1). CVD and related health conditions share many of the same modifiable risk factors, with large contributions of: physical activity, eating habits, smoking, alcohol consumption, and stress. These modifiable risk factors account for 80% of heart disease and 70% of stroke (Figure 1).

A majority of the western population does not meet the recommendations for healthy living (13, 14). According to the World Bank, preventive lifestyle measures could avoid more than half of the CVD burden (15). Thus, preventive health initiatives aimed at healthy lifestyle behaviour to decrease cardiovascular risks are beneficial to health and would improve sustainable employability of workers.

Having a CVD or a related health condition creates several challenges for employability in a number of ways at the individual and at the societal level. At the individual level

Figure 1. Percentage of non-communicable diseases caused by lifestyle factors.



Heart disease: 80%of heart disease is caused by lifestyle factors
Stroke: 70% of stroke is caused by lifestyle factors
Cancer: 40% of all cancer is caused by lifestyle factors
Chronic respiratory diseases: 60% of chronic respiratory disease is caused by lifestyle factors
Diabetes: 90% of Type 2 diabetes is caused by lifestyle factors
Adapted from World Health Organisation (11, 12)

it may lead to problems in: being productive at work, remaining productive at work, and getting and maintaining work (16, 17). At the societal level, CVD imposes substantial productivity costs when assessing absenteeism, presenteeism, early retirement, and premature mortality (18). Workers with cardiovascular risk factors, such as poorly controlled diabetes, smoking, drug and alcohol abuse, sleep deprivation, and obesity, are shown to be more likely to be involved in occupational injuries (12). Obesity not only increases the risk of CVD, but also increases the risk of numerous health conditions which are unfavorable for well-being and work performance, including low quality of life (6), sleep apnea (19), arthritis (20), and depression (21). At the workplace, obesity is associated with a higher frequency and longer duration of sickness absence (22, 23), and with an increased risk of exit from paid employment via disability benefit (24). Vice versa to CVD or related health conditions decreasing work performance, being unemployed showed a decreased perceived health (25). This illustrates the need to postpone the onset of CVD and related health conditions, and to decrease morbidity, in order to optimise both health, wellbeing, and work performance.

WORKPLACE HEALTH PROMOTION PROGRAMS

There are considerable health benefits at all ages, for both men and women, in increasing physical activity, improving diet, stopping smoking, reducing alcohol, and balancing stress and relaxation. Despite these benefits, solely knowledge about risk factors and potential consequences of our actions is not enough for individuals to change health behaviour and control personal health (26, 27). Lifestyle behaviour change also requires motivational and volitional processes (28, 29). There is evidence that improved health and vitality among workers contribute to increased productivity at work (30-32). A sense of health is multifactorial, including dimensions such as physical and mental wellness, social well-being, and function, balanced by resilience and self-direction (33, 34). The workplace is an ideal setting for improving health behaviour, because the labour force participation level exceeds 65% in all EU countries (35). Although it is important to note that CVD and related health conditions are the result of complex interactions between many factors, including lifestyle behaviours, environment, and genes, personalised interventions at the worksite have the potential to prevent and reduce health risks and thus improve productivity at work.

The attention for workplace health promotion programs has grown (36, 37), and organisations offer programs to their employees more frequently (38), since these are promising for well-being and sustainable employability of workers. Recent systematic reviews conclude that these programs, if appropriately designed, contribute to health, reduction of absenteeism, increased productivity and a better work culture (39-42), and may lead to a positive "return on investment" (43). Effective elements of these health programs are the selection of high-risk populations, multifactorial approach to health, interventions that are based on work-related and behavioural theories, web-based health screening with feedback influencing future behaviour, and advice from a physician in combination with individual counseling. Despite the advantages of a broad reach and easy accessibility (44), eHealth-only approaches tend to suffer from high attrition and dropout rates (45), which should be prevented if aiming for a sustainable lifestyle change. Apart from eHealth, face-to-face coaching can be an important component in lifestyle behaviour programs. Motivational interviewing is a suitable coaching technique for improving CVD risk factors (46, 47). A recent review suggested that such face-to-face coaching may help intensify the effect of eHealth technologies (48).

Since there is no "one size fits all-solution", the chances for pro-actively finding a *perfect fit* between individual behaviour and content of intervention could be provided by a personalised approach. A specific approach to this in medicine is called P4 Medicine: Personalised, Predictive, Preventive, Participatory (49). Although mutual benefits for individual and organisation could be increased by blending eHealth and non-eHealth components for a more personalised approach and for optimal effectiveness, good qual-

ity studies in randomised controlled setting are lacking (42). Insight in the effectiveness of so-called blended workplace health promotion programs in employees at increased CVD risk is needed, providing guidance for future implementation towards sustainable employability by health risk reduction.

THIS THESIS

Staying vital in work is increasingly challenging, since CVD and related health conditions have an earlier onset of age, the number of employees with CVD risk factors or morbidity is increasing, and the retirement age is rising. To facilitate sustainable vitality for longer working lives, the aim of this thesis is to gain insight into the determinants of leaving paid employment in employees with cardiovascular disease, and into the effectiveness and the quality of implementation of blended workplace health promotion programs in employees at increased cardiovascular risk.

Two research questions will be answered in this thesis:

1. What is the impact of work-related factors on exit from paid employment via disability, unemployment, and early retirement, in employees with a cardiovascular disease?
2. What is the effectiveness of blended workplace health promotion programs?

DATASETS USED IN THIS THESIS

SHARE. Data from the Survey of Health, Ageing, and Retirement in Europe (SHARE) were used to study the impact of work-related factors on exit from paid employment via different exit routes, in employees with a cardiovascular disease (chapter 2). SHARE started in 2004 aiming to gain insight into ageing and how it affects individuals in the diverse cultural settings of Europe (50, 51). For the study described in chapter 2, three waves of data collection were used representing a 6-year follow-up. Complete data were available for 5,182 employed persons who were 50 years or older and had not yet reached the country specific retirement age at baseline.

PerfectFit study. PerfectFit is a cluster randomised controlled trial evaluating the effectiveness of a lifestyle intervention in 491 employees at increased cardiovascular risk. Software for data retrieval was made available by NIPED Research Foundation (Prevention Compass) and by the department of Public Health. The Prevention Compass is a web based health assessment, which was used to collect self-reported data on general health, medical history, work parameters, lifestyle, individual characteristics, and

personal preferences for behaviour change. Personalised advice with options of choices for interventions was provided to 432 individuals who completed this eHealth-tool. Data collected were used to describe the baseline characteristics and investigate the effectiveness of the PerfectFit study (chapters 3, 4, and 5).

PerfectFit participants participated in a cardioscreening at occupational health centers of the 3 participating organisations, at baseline and after 12 months. These data were used to describe baseline characteristics (chapter 3), and the effectiveness of the intervention (chapter 4).

Follow-up data were collected by online questionnaires sent out 6- and 12-months after the baseline screening. These data were used to investigate the effectiveness of the PerfectFit intervention in employees with increased risk of cardiovascular diseases (chapter 4), and the quality of intervention-implementation (chapter 5). For the extensive intervention group only, data on 1089 motivational interviewing sessions were collected via occupational health physicians. For MI-quality measures, 38 MI-sessions were audio-recorded.

Reis je fit. Reis je Fit ("Travel for Health") is a before-after study on the effectiveness of a blended web-based gaming intervention among 52 overweight or obese employees. BMI and waist circumference were measured at baseline, and 10 and 23 weeks after baseline. In addition, time and intensity of physical activity was measured by an accelerometer during the entire game.

OUTLINE OF THIS THESIS

The first research question is addressed in chapter 2, and describes the role of work-related factors on premature exit from paid employment among workers with cardiovascular diseases.

The second research question is covered by chapters 3 to 7. In Chapter 3, the design and baseline characteristics of the PerfectFit study are presented. Chapter 4 shows the effectiveness of the extensive intervention (Health Risk Assessment supplemented with motivational interviewing) compared to the limited intervention (solely Health Risk Assessment). Chapter 5 describes the implementation process, and shows how quality of the intervention affects the effectiveness. Chapter 6 describes the effectiveness and usage of the eHealth- and gaming-intervention 'Reis je Fit'. The last chapter focuses on methodological aspects of randomised controlled designs, aiming to increase the quality of future studies evaluating lifestyle interventions.

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Chapter 2

Cardiovascular disease, diabetes and early exit from paid employment in Europe; the impact of work-related factors

Tessa. A. Kouwenhoven-Pasmooij, Alex Burdorf, Jolien W. Roos-Hesselink, M.G. Myriam Hunink, Suzan J.W. Robroek

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ABSTRACT

Background/objectives

The aims of the study were to examine (i) the association between cardiovascular disease (CVD) or diabetes and exit from paid employment via disability benefits, unemployment, early retirement or other exit routes; and (ii) the impact of work-related factors on exit from paid employment among individuals with CVD or diabetes.

Methods

Respondents of the longitudinal Survey of Health and Retirement in Europe (SHARE) were included if they were aged >50 years, had paid employment at baseline, and a known employment status after 2 or 6 years (n = 5182). A baseline-interview provided information on the presence of diagnosed CVD and diabetes, and physical and psychosocial work-related factors. During follow-up interviews information on work status was collected. Multinomial regression analyses were used to investigate the association between CVD, diabetes and exit from paid employment, and the impact of work-related factors.

Results

Workers with CVD or diabetes had significantly increased probabilities of disability benefits (OR 2.50, 95% CI 1.69–3.70) and early retirement (OR 1.34, 95% CI 1.05–1.74), but a comparable probability of unemployment (OR 1.10, 95% CI 0.71–1.71). Regarding disability benefits, individuals who had a stroke had the highest probability (OR 3.48, 95% CI 1.31–9.23). Perceived high job demands with low rewards or with low control at work further increased the probability of early exit among individuals with CVD or diabetes.

Conclusions

Our study shows a prominent role of CVD and diabetes in premature losses to the workforce, and it shows that optimising psychosocial work-related factors could be beneficial in people with CVD or diabetes.

INTRODUCTION

In Europe, cardiovascular disease (CVD) has the highest burden of disease [1,2] to which the globally rising burden of diabetes contributes [3,4]. Because of an increase in the average life expectancy of the population, most Western countries are increasing the statutory retirement age from 65 to 67 years and even above. This will lead to a higher proportion of older employees active in the workforce. As employees age, the prevalence of CVD increases, leading to an increasing number of individuals with CVD in the workforce. It therefore becomes increasingly important to gain insight into the impact of CVD on the ability of these people to maintain long-term paid employment. A healthy working environment might be one of the modifiable factors to support workers to maintain their ability to work.

Previous studies have shown that self-perceived poor health is related to early exit from paid work [5,6], but little is known on the ability of workers with specific CVD manifestations, such as stroke and heart disease, or diabetes to remain at work in the long term. Although previous studies have mainly investigated short-term return to work after a cardiac event [7], two recent studies demonstrated that permanent premature exit from the workforce occurred in 19% of the workers with CVD in general [8] and in 50% among workers diagnosed with myocardial infarction [9]. In addition to CVD, diabetes is also related to premature workforce exit. In a systematic review, it was found that among individuals with diabetes type 2, 7.2% of men and 12.8% of women left the workforce prematurely, compared with 2.2% of men and 3.3% of women without diabetes [10].

Among workers with CVD or diabetes, work-related factors may play a role in people's ability to stay at work. Two models that are widely used to describe the impact of work-related factors are the job demand-control model [11] and the effort-reward imbalance model [12]. These models postulate respectively that higher job demands in combination with lower job control or higher efforts in combination with lower rewards contribute to chronic work stress. High physical job demands have shown to increase the risk of staying out of work for at least 12 months after a severe myocardial infarction [9]. Having a combination of high physical demands and a lower job control had a threefold risk of staying out of work for at least 12 months in men with coronary heart diseases [13]. Effort-reward imbalance at work has so far only been associated with elevated risks of onset of CVD [14,15] but as far as we know, has never been studied as a potential determinant of workforce exit among individuals having CVD or diabetes.

In this study, we aim to get insight into how CVD and diabetes influenced early exit from paid work and whether work-related factors can support workers with CVD or diabetes to remain in paid employment. Understanding these associations is necessary to refine strategies for preserving this increasing group of diseased to the workforce in a sustainable way. We hypothesize that CVD and diabetes increase the prevalence of

early exit from the workforce and that a strenuous working environment increases this prevalence even more.

METHODS

Study design, population and flow of participants

The data were derived from the longitudinal Survey of Health, Ageing, and Retirement in Europe (SHARE). SHARE aims to collect health, social, and economic data on the population aged ≥50 years. The first wave of data collection started in 2004 and 2005 in 11 European Union countries, divided in three European regions: northern (Sweden, Denmark), central and western (The Netherlands, Belgium, Germany, Austria, Switzerland, France), and southern Europe (Italy, Spain, Greece).

In the participating SHARE countries, the institutional conditions with respect to sampling were so different that a uniform sampling design for the entire project was not feasible. Different registries at the national or local level were used, enabling stratification by age.

Respondents were included, when at baseline they (a) were aged between 50 years and the country-specific statutory retirement age, (b) had paid employment, and (c) provided information about the presence of CVD and diabetes. In total, 7233 of the 28,517 (47%) respondents met these criteria. Furthermore, information about employment status at two and/or six years follow-up was available for 5182 respondents (72% of those who met the baseline inclusion criteria), which form the study population for the analyses. The SHARE study was reviewed and approved by ethics committee of the University of Mannheim (until 2011) and the Ethics Council of the Max-Planck-Society for the Advancement of Science (since 2011). Informed consents were obtained from all subjects at the time of enrolment.

Work status

The primary outcome measure in this study is self-reported work status. Work status was measured after 2 years and after 6 years. In both follow-up interviews, a single question was asked: "in general, which of the following best describes your current employment status? The possible answers were: retired, employed or self-employed, unemployed and looking for work, permanently sick or disabled, homemaker, other".

We classified individuals as still being in paid employment if they (i) worked until they reached the statutory retirement age, or if they (ii) were still at work at the end of the follow-up period ('employed' or 'self-employed'). We classified individuals into those who made the transition to not working, if they reported at any of the follow-up waves to be permanently sick or disabled, unemployed and looking for work, early retired,

homemaker, or other. The 'disability benefits' category includes individuals receiving a disability benefit. The 'unemployed' category includes those individuals who became unemployed before they reached the statutory retirement age. 'Early retirement' is defined as self-reported retirement before the statutory country-specific retirement age. The category 'other' includes individuals who left paid employment via another pathway than disability benefits, unemployment, and early retirement and mainly consists of homemakers.

Only the first event in time was considered. When multiple transitions out of the workforce took place at the same point in time, the following hierarchy in descending order was used: (i) disability benefits, (ii) unemployment, (iii) other (mainly homemaker), and (iv) early retirement.

CVD and diabetes

At baseline information was collected on self-reported CVD and diabetes. We defined the disease as 'present' when at least one positive answer was given to the question: "Has a doctor ever told you that you had any of the conditions on this card?". For 'CVD', individuals could indicate whether they had had (i) a stroke or cerebral vascular disease, or (ii) a heart disease. The diagnosis 'heart disease' was defined as myocardial infarction, coronary thrombosis, any other heart problems including congestive heart failure, and excluding high blood pressure and high cholesterol. For 'diabetes', individuals were asked whether they had diabetes or high blood glucose levels. When there was more than one diagnosis present multiple diagnoses were taken into account.

In addition to the history of disease, individuals were asked to indicate their age at first occurrence of the disease. We defined a recent case as an individual who was diagnosed within 2 years before enrolment in the study.

Work-related factors

At baseline, physical and psychosocial work-related factors were measured. Physical work demands were asked on a four point scale ranging from 'strongly agree' (1) to 'strongly disagree' (4). High physical work demands were defined as having answered the question 'My job is physically demanding' with 'strongly agree' (1) or 'agree' (2). Psychosocial work-related factors were measured with questions derived from the validated job-demand-control [11] questionnaire and effort-reward imbalance questionnaire [12], since these were previously applied to analyse the intention to retire using the baseline information of SHARE [16]. The items were measured on a four point scale ranging from 'strongly agree' (1) to 'strongly disagree' (2). Time pressure at work was measured by asking 'I am under constant time pressure due to a heavy workload'. High time pressure was defined as answering this question with 'strongly agree' or 'agree'. Job control was measured with two items, asking for (i) freedom to make decisions in how the work is performed, and

(ii) the opportunity to develop new skills. The sum score of these two items were dichotomised based on the sample distribution. A low job control was defined based on the country-specific median values. To assess the job demand control-model, time pressure and physical work demands were combined into one measure for job demands, using the country-specific median values of the sum score of these two items. Four groups were distinguished: high control and low demands, high control and high demands, low control and low demands, and low control and high demands. Rewards were defined in a similar way, based on five items addressing support, recognition, salary/earnings, job promotion prospects and job security. The underlying dimensions of the effort-reward imbalance model were based on a sum score of the two demands items (time pressure and physical demands) for the 'effort'-dimension, and the sum score of the five reward items for the 'rewards'-dimension, both adjusted for the number of items. Subsequently, effort-reward imbalance was defined as the country-specific upper third of the ratio of effort and rewards dimensions [12].

Covariates

Comorbidity

We defined co-morbidity as having one or more of the following diseases at baseline: musculoskeletal disease (arthritis, osteoporosis, hip fracture), COPD, cancer, or depression. The questionnaire included the EURO-D scale for depression diagnosis, which was validated in an earlier cross-European study on depression [17]. The EURO-D scale of depression takes into account the following 12 items: depression, pessimism, suicidal, guilt, sleep, interest, irritability, appetite, fatigue, concentration, enjoyment, and tearfulness. A sum score over dichotomous answers was calculated, varying from 0 (not depressed) to 12 (very depressed). For the purpose of this study we defined a clinically significant depression as a EURO-D score greater than three [18]. In the analysis we used a score from 0 to 3 as reference group, a score of 4–8 as moderately depressed, and a score from 9 to 12 as heavily depressed.

Demographics

In the interview, sex, month and year of birth, educational level, and marital status were asked. The highest level of education was coded according to the 1997 International Standard Classification of Education (ISCED-97) and categorised into low (pre-primary, primary, and lower- secondary), intermediate (upper-secondary) and high (post-secondary) education. Marital status was used to categorise individuals into those who had a registered partner or spouse and those who had no registered partner.

STATISTICAL ANALYSES

Descriptive statistics were used to report on general characteristics of the study population. To decide which diseases needed to be included as potential confounders in the subsequent analyses, the association between co-morbidity and CVD and diabetes was analysed using logistic regression analysis. Only those diseases statistically associated ($p < 0.05$) were included as potential confounders in the subsequent analyses.

Multinomial regression analyses were used to assess a) the relation between CVD, diabetes and exit from paid employment, and b) the relation between unfavorable work-related factors and exit from paid employment among individuals having a CVD or diabetes. Odds ratios (OR) and their corresponding 95% confidence intervals (95% CI) were calculated. First, analyses were conducted for CVD and diabetes, adjusting for age, gender, marital status, education and European region, and comorbidity. Second, a similar analysis was performed for subcategories of CVD, namely (i) stroke (ii) heart disease, and for (iii) diabetes. Then, sensitivity analyses were performed to assess the relation between having had CVD or diabetes recently and early exit from work, and to investigate whether the results differ between European regions and male and female workers. Last, the association between work-related factors and exit from paid work was investigated among those individuals with CVD or diabetes. This included the analysis of additive interaction of the influence of CVD or diabetes and negative work-factors on early exit from paid work, for which we calculated the relative excess risk (RERI) and the corresponding 95% CI. We used the delta method [19,20] and constructed 2×2 tables for each exit route and for each negative work-factor. The RERI was calculated as RERI = OR(CVD + work-factor) − OR(CVD + no work-factor) − OR(no CVD + work-factor) + 1. A RERI greater than zero indicated synergy (more than additivity) and a RERI lower than zero indicated negative interaction (less than additivity).

To study to what extent co-morbidity modified the influence of CVD or diabetes on early exit from paid work, we used the same method to calculate additive interaction. To construct a 2×2 table, 1 or more co-morbidities were combined into one category. The same was done for moderately and heavily depressed. The RERI was calculated as RERI = OR(CVD + co-morbidity) − OR (CVD + no co-morbidity) − OR(no CVD + co-morbidity) + 1. Analyses were done using SPSS, version 22, (SPSS Institute, Chicago, IL, USA). STROBE guidelines were applied for the reporting of case–control studies [21].

RESULTS

The study population baseline characteristics can be found in Table 1. The mean age was 55.4 years (SD 3.6 years). In total, 1459 (28.2%) of these workers exited the work-

force before they reached the official retirement age. Most of these workers left paid employment because of early retirement (14.8%), and to a lesser extent by unemployment (5.2%), other pathways (mainly being a homemaker) (4.5%) and disability benefits (3.6%). Probabilities of exit from work were similar for all three European regions.

Table 1. Individual characteristics, cardiovascular health status and work characteristics among 5182 employed persons aged > 50 years in 11 European countries during the first wave of the Survey on Health and Ageing in Europe (SHARE).

		n	%
Individual characteristics	female	2328	44.9
	Aged 50-54 years	2369	45.7
	Aged 55-59 years	2075	40.0
	Aged 60 years or older	738	14.2
	Education, low	1624	31.3
	Education, intermediate	1686	32.5
	Education, high	1872	36.1
	No partner	976	18.8
Cardiovascular disease (CVD)	CVD or diabetes	488	9.4
	-diabetes or high blood sugar	241	4.7
	-heart disease	231	4.5
	-stroke or cerebral vascular disease	47	0.9
Work related factors	High physical work demands	2404	46.4
	High time pressure at work	2862	55.2
	Below median job control	2827	54.6
	Below median rewards at work	2234	43.1

A total of 488 (9.4%) employees reported having diabetes (n = 241) or CVD (n = 277 of which 47 cases of stroke and 231 cases of heart disease and 31 employees had both). Of those with CVD, 119 (24.4%) individuals had comorbidity, of whom 14.3% had a musculoskeletal disease, 7.2% COPD, 4.7% cancer and 25.5% had a mild or heavy depression. After adjustment for demographics, individuals with CVD or diabetes were more likely to have cancer (OR 1.88, 95% CI 1.19–2.99) or a depression (OR 1.38, 95% CI 1.11–1.72) than individuals without CVD or diabetes. CVD or diabetes were not statistically significantly associated with musculoskeletal disease (OR 0.89, 95% CI 0.67–1.17) and COPD (OR 0.82, 95% CI 0.56–1.19). For early exit from paid work, interaction effects were observed neither between CVD or diabetes and co-morbidity (RERI – 0.36, 95% CI – 1.08;0.35) nor between CVD or diabetes and depression (RERI –0.08, 95% CI 0.73;0.57).

Table 2 shows that individuals with CVD or diabetes were more likely to exit from paid work via disability benefits (OR 2.50; 95% CI 2.69–3.70), and to a lesser extent via early retirement (OR 1.34; 95% CI 1.05–1.74), after adjustment for age, sex, education, marital

status and European region. Additional adjustment for depression and cancer did not change these associations (not shown in table).

Table 2. Associations between cardiovascular health, and transition to disability benefits, unemployment, homemaker, and early retirement among 5182 initially employed individuals aged 50 years or older during 6 years of follow-up.

	Disability benefits	Unemployment	Homemaker / other	Early retirement
	(n = 189)	(n = 271)	(n = 231)	(n = 768)
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Model 1:[a]				
CVD or diabetes	**2.50 (1.69-3.70)**	1.10 (0.71-1.71)	1.27 (0.81-2.00)	**1.34 (1.05-1.74)**
Model 2:[a]				
Diabetes	**2.37 (1.41-3.99)**	1.17 (0.65-2.09)	1.09 (0.57-2.05)	1.06 (0.73-1.53)
Heart disease	**2.68 (1.59-4.52)**	0.91 (0.46-1.82)	1.46 (0.79-2.71)	**1.61 (1.15-2.27)**
Stroke	**3.48 (1.31-9.23)**	1.36 (0.41-4.53)	1.68 (0.49-5.69)	1.18 (0.50-2.76)

Results were marked bold if statistically significant ($p<0.05$).

[a] Adjusted for covariates (i.e., age, gender, education, marital status, European region).

The strongest association with exit via disability benefits was found for stroke (OR 3.48; 95% CI 1.31–9.23), followed by heart disease (OR 2.68; 95% CI 1.59–4.52) and diabetes (OR 2.37; 95% CI 1.41–3.99). Only for heart disease there was a statistically significant increased probability of early retirement. Mutual adjustment for these three health diagnoses decreased the strength of these associations up to 15% for disability benefits and 3% for early retirement, all remaining statistically significant.

Of the 70 employees who had recently (within 2 years prior to baseline) been diagnosed with a CVD, the strength of the relation with exit from work via disability benefits remained similar (OR 2.89, 95% CI 1.26–6.52), but the association with early retirement was smaller (OR 1.04, 95% CI 0.52–2.05) (not presented in table). Within each European region, having CVD or diabetes was related to early exit though disability benefits; northern Europe (OR 3.59, 95% CI 1.66– 7.75), in central and western Europe (OR 2.09, 95% CI 1.25–3.48), and in southern Europe (OR 3.19, 95% CI 1.09–9.59).

Table 3 shows that among individuals with CVD or diabetes, perceived low rewards had the highest increased probability of exiting work via receiving disability benefits (OR 2.54, 95% CI 1.20–5.37) or via becoming unemployed (OR 2.59, 95% CI 1.05–6.40), after adjustment for gender, education, marital status and European region. Having a combination of low job control and high demands showed an increased probability of disability benefits (OR 2.93, 95% CI 0.99–8.64), although this was not statistically significant. A combination of high efforts and low rewards did not show a statistically significantly increased probability of disability benefits (OR 1.84, 95% CI 0.89–3.88), but it did increase the probability of becoming unemployed (OR 4.04, 95% CI 1.63–10.04). Additive

interaction effects were found between CVD or diabetes and negative work-factors (not shown in table). For unemployment, the RERI's varied between 0.06 (95% CI −0.28–0.40) for low job control and 0.82 (95% CI 0.58–1.07) for high time pressure. Although not statistically significant, the highest RERI's were found for disability benefits, up to 1.22 (95% CI −1.17–3.62) for low job control and 1.97 (95% CI −0.33–4.26) for low rewards.

Table 3. Associations between unfavorable physical and psychosocial work-related factors, and exit from paid employment among 488 individuals with CVD or diabetes at baseline.

	Disability benefits	Unemployment	Homemaker / other	Early retirement
	(n = 35)	(n = 24)	(n = 24)	(n = 94)
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Work-related factors, separately:				
High physical work demands [a]	1.49 (0.70-3.16)	2.30 (0.93-5.70)	1.51 (0.62-3.69)	1.43 (0.87-2.34)
High time pressure at work [a]	0.99 (0.48-2.02)	2.14 (0.87-5.29)	1.31 (0.55-3.12)	1.60 (0.98-2.60)
Below median job control [a]	2.14 (0.93-4.94)	1.16 (0.46-2.93)	1.33 (0.51-3.50)	1.22 (0.72-2.06)
Below median rewards at work [a]	**2.54 (1.20-5.37)**	**2.59 (1.05-6.40)**	1.86 (0.79-4.40)	1.58 (0.97-2.57)
Work-related factors, models:				
Job-demands control				
High control, low demands	1.00 (ref)	1.00 (ref)	1.00 (ref)	1.00 (ref)
High control, high demands	1.27 (0.34-4.76)	0.54 (0.16-1.84)	2.52 (0.66-9.55)	1.39 (0.68-2.85)
Low control, low demands	1.96 (0.69-5.62)	0.62 (0.12-3.14)	2.23 (0.58-8.51)	1.08 (0.56-2.10)
Low control, high demands	**2.93** (0.99-8.64)	1.94 (0.65-5.78)	1.52 (0.40-5.74)	1.90 (0.95-3.81)
Effort-reward imbalance	1.84 (0.89-3.88)	**4.04 (1.63-10.04)**	1.63 (0.69-3.85)	1.36 (0.83-2.24)

Results were marked bold if statistically significant ($p<0.05$).
[a] Adjusted for covariates (i.e., age, gender, education, marital status, European region).

DISCUSSION

This longitudinal study shows that CVD or diabetes increased the probability of early exit from paid employment via disability benefits or early retirement, and to a smaller extent via unemployment or other exit routes. Among employees with CVD or diabetes, working in a strenuous environment increased the likelihood of early exit up to 4-fold. The influence of these work-factors was higher than among individuals without CVD or diabetes. We observed similar patterns in all European regions.

The relation between CVD or diabetes and early exit from paid work demonstrates major social and economic consequences of these diseases for individuals, employers and society. Our results regarding disability benefits are in line with other studies focusing on self-perceived general health and other health problems [5,22,23] while other

studies found no association [24]. That permanent premature exit from the workforce is likely in workers with CVD was demonstrated in a large cohort study conducted in male construction workers in Sweden. This study showed that during a 10-year follow-up, 19% of the permanently granted disability benefits, defined as >50% reduced earning capacity, were granted because of CVD [8]. This seems to be supported by a Danish study stating that four years after a myocardial infarction over 50% of the patients had permanently retired from the job market, which meant that they received disability benefits, an old age pension, or a special Danish pension benefit for persons aged 60– 66 years [9]. Although our finding of increased probability of workforce exit is consistent with these previous findings, comparing our results with those from other studies should be done cautiously, because different definitions of disability benefits and early retirement are used. In our current study, 'disability benefits' was restricted to individuals who were permanently sick or disabled and were receiving a disability benefit. 'Early retirement' was defined as retirement before the statutory retirement age. In other studies, disability benefits can be part of early retirement since the latter also includes health-based retirement [25].

Our results also illustrate that CVD or diabetes is related to exit via early retirement, and is not statistically significant related to exit via unemployment. Several studies have reported a significant effect of combined categories of chronic diseases or self-reported poor health on unemployment [6,26]. The different outcome for CVD than for other categories of diseases may partly be explained by a higher mean age at which CVD takes place. Cardiovascular events are most prevalent in the elderly prior to their retirement age, which makes disability benefits or early retirement more likely since the other pathways cause financial uncertainties [27].

For diabetes, our results are in agreement with a study by Herquelot, which found an increased risk of work disability (HR 1.7, 95% CI 1.0– 2.9), defined as receiving a pension for disability or longstanding illness or being on sick leave for more than 365 sick days [28].

Another important finding is that CVD or diabetes and also co-morbidity increased the probability of early exit from paid work, but no additive effect was found. Especially for depression this is remarkable, since O'Neil et al. showed an additive risk on negative work-outcomes in people with CVD and heavy depression [29]. Since we focused on both moderate and heavy depression and the number of people with a heavy depression was low (0.4%), we may have underestimated this interactive effect. Previous studies have reported that depressive symptoms after CVD can be dynamic and negatively affect work performance [30], so we support these being addressed in therapeutic and prevention intervention strategies.

Good working conditions may play a role in keeping diseased employees of value to the workforce. Although heavy physical work has shown to increase the risk of early exit via disability benefits especially in workers with poor cardiorespiratory fitness [25], we

found that among those workers with CVD heavy physical work did not influence exit from paid employment. In our study, low control in combination with high job demands showed an elevated probability of disability benefits, although this association was not statistically significant. This last finding is consistent with two other studies, the first one reporting an association of high job demands and low job control with less return to work within a year after a cardiac event [13,30]. The second had a follow-up period of 4.6 years, after which the same association was seen with receiving disability benefits [23]. We also found that having low rewards at work increased the probability of disability benefits and unemployment among individuals with CVD or diabetes, and that low rewards in combination with high demands further increased the prevalence of early exit by unemployment. CVD or diabetes in combination with unfavorable work-factors increased the likelihood of early exit from paid employment more than the combined independent risks of CVD or diabetes and unfavorable work-factors, suggesting a larger impact of work-factors in these diseased employees, which is interesting in two ways. First, since our workers were originally still working while having CVD or diabetes, it could imply that working with CVD in strenuous psychosocial working conditions affects their level of functioning [31] and therefore makes them more prone to exit early through unemployment. Secondly, it can imply that strenuous psychosocial working conditions aggravate the severity of an existing CVD, which is also suggested in a study on the relationship of autonomic imbalance and CVD [32]. As a result, these people may tend to exit work early. Either way, considering the context of work by optimising psychosocial working conditions seems promising in preventing exit from work in people with CVD or diabetes.

The fact that we used a large sample from 11 European countries makes our study generalisable to the workforce in European countries. However, some limitations must be taken into account in this study. The first limitation is that our study relied on voluntary participation with the potential for bias due to self-selection of the study members. Selection may also have occurred based on the severity of the disease. In our study, although having had a CVD or diabetes in the past, participants were still employed at baseline. This may suggest that despite a severe diagnosis, our study population consists of mildly impaired persons, which can be described as the "healthy-worker-effect" [33]. The selection based on severity of impairment is confirmed by our sensitivity analysis, showing a similar probability of early exit via disability benefits but a reduced probability of exit via early retirement in workers having had a recent (within the last 2 years) cardiovascular event. The fact that a previous long-term study illustrated that less than 50% of individuals returned to work after a stroke [34], strengthens the idea that we are showing an under-estimation of the probability of exiting work after CVD.

A second limitation is that, although we included data from 11 European countries, for this specific health category the numbers were still small with reduced power in our sensitivity analyses and in the calculation of the impact of work-related factors.

Finally, we measured exposure to adverse work-related factors on the basis of one baseline assessment and do not know if and how they changed over time. Cumulative exposure, ascertained by several assessments repeated in time, could be a stronger predictor of the outcome [35].

CONCLUSIONS

The results of this longitudinal study show that having CVD or diabetes is associated with early exit from paid work through disability benefits or early retirement, and having low rewards or high job demands with low control further increased this probability. The focus of preventive and clinical medicine should expand from making the person fit for the job to also making the job fit for the person, and thus integrating the context of work with the clinical approach. In CVD or diabetes, adjustment of the psychosocial work environment to the individual's health condition and abilities may help these workers to stay employed and prevent economic inactivity which benefits both society and the individual.

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Chapter 3

Design and baseline characteristics of the PerfectFit study: a multicenter cluster-randomised trial of a lifestyle intervention in employees with increased cardiovascular risk

Tessa A. Kouwenhoven-Pasmooij, Bosiljka Djikanovic, Suzan J.W. Robroek, Pieter H. Helmhout Alex Burdorf, M.G. Myriam Hunink

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ABSTRACT

Background

The prevalence of unhealthy lifestyles and preventable chronic diseases is high. They lead to disabilities and sickness absence, which might be reduced if health promotion measures were applied. Therefore, we developed the PerfectFit health promotion intervention with a "blended care"-approach, which consists of a web-based health risk assessment (HRA) including tailored and personalised advice, followed by motivational interviewing (MI). We hypothesize that adding MI to a web-based HRA leads to better health outcomes. The objective is to describe the design and baseline characteristics of the PerfectFit study, which is being conducted among employees with high cardiovascular risk in the military workforce, the police organisation and an academic hospital.

Methods

PerfectFit is a cluster randomised controlled trial, consisting of two arms. Based on cardiovascular risk profiling, done between 2012 and 2014, we included employees based on one or more risk factors and motivation to participate. One arm is the 'limited' health program (control) that consists of: (a) an HRA as a decision aid for lifestyle changes, including tailored and personalised advice, and pros and cons of the options, and (b) a newsletter every 3 months. The other arm is the 'extensive' program (intervention), which is additionally offered MI-sessions by trained occupational physicians, 4 face-to-face and 3 by telephone, and is offered more choices of health promotion activities in the HRA. During the follow-up period, participants choose the health promotion activities they personally prefer. After six and twelve months, outcomes will be assessed by online questionnaires. After twelve months the cardiovascular risk profiling will be repeated. The primary outcome is self-reported general health. Secondary outcomes are self-reported work ability, CVD-risk score, sickness absence, productivity loss at work, participation in health promotion activities, changes in lifestyle (smoking, alcohol consumption, physical activity, stress management) and body mass index. Furthermore, a process evaluation and an economic analysis will be performed.

Discussion

Additional coaching using MI is expected to be a key factor for success of the web-based HRA in employees with increased cardiovascular risk. This "blended care"-approach may be an essential strategy for effective health promotion activities.
Dutch Trial Register by registration number NTR4894, 14/11/2014.

INTRODUCTION

Background

Although life expectancy has significantly increased over the past decades in many countries worldwide, the prevalence of unhealthy lifestyles, preventable chronic diseases and disabilities is rising [1-3]. Combined with an ageing workforce, today's sustainable employability and well-being of employees are under increasing pressure. Major risk factors for their well-being are adverse lifestyle habits, such as physical inactivity, unhealthy diet, smoking, alcohol and stress. These lifestyle behaviours are associated with chronic diseases, and among them, the most common are cardiovascular disease (CVD) and diabetes. These diseases not only produce high healthcare costs, but also high indirect costs to society due to productivity losses [4-6]. There is a clear need for health promotion interventions that are effective and feasible among employees.

Web-based health promotion interventions, such as a web-based health risk assessment (HRA), have been increasingly used [7-9]. They have the potential of a broad reach and, if appropriately designed and implemented, may promote health and well-being, reduce absenteeism, and increase work productivity [10-12], thus leading to a positive "return on investment" [13, 14]. A recent meta-analysis showed, however, that these intervention effects were found to decline after intervention completion. This report stated that there is a need for innovative techniques to help participants maintain their lifestyle changes [15]. A counselling technique that has shown promising results in changing and maintaining health behaviour is Motivational Interviewing (MI) [16-23]. MI is a patient-centered coaching technique, and is based on four principles: showing empathy; addressing discrepancy between current behaviour and an alternative lifestyle behaviour; reinforcing the clients' sense of self-efficacy; and respectfully dealing with the clients' resistance to change [24]. Whereas an HRA informs a participant of their risks of CVD and the options for risk reduction, MI is used to help the participant evoke and strengthen intrinsic motivation for lifestyle changes by respecting individual preferences and autonomy. HRA complemented with MI could be considered a form of "blended care". This type of care involves an internet approach and face-to-face care blended into one integrated treatment [25]. As of recently, the blended approach has been increasingly used to effectively influence changes in lifestyle behaviours [26] [27].

Based on a "blended care" approach, we developed and implemented an intervention study called PerfectFit. PerfectFit is aimed at employees who are 40 years or older, have high physical and mental work demands, and possess at least one risk factor for cardiovascular disease [28]. We hypothesized that adding MI to an HRA improves the effectiveness and sustainability in changing unhealthy lifestyles and reducing risk factors for chronic diseases [26]. The objective of this study was to find out whether adding MI to a web-based HRA leads to further improvement in the overall health status and

in secondary outcomes such as participation in health activities, work ability, sickness absence and productivity at work, and lifestyle behaviour. In this paper, a detailed description of the study design is presented, along with the baseline characteristics of participants. Short- and long-term results of the intervention, as well as a process and an economic evaluation will be presented in future papers.

METHODS

Study design

The PerfectFit study is a cluster randomised control trial [29] (cRCT) among employees of three organisations, aimed to compare two groups: a purely internet-based approach (*limited or control* intervention) and a group that is exposed to the internet-based approach supplemented with MI ("the blended approach", *extensive* intervention). The internet approach consists of a web-based HRA (later addressed as " HRA") with tailored and personalised advice for health behaviour change as well as pros and cons of the options for change. In the extensive intervention, the HRA is supplemented with face-to-face care provided by an (in-house) occupational physician (OP) using MI. The elements of the intervention are based on existing modules, previously evaluated RCTs [22, 30-32] and a recent meta-analysis [33]. Measurements were done at baseline and will be repeated after 6 and after 12 months.

Participants were included between 2012 and 2014 after providing written informed consent. There were no risks associated with participating in PerfectFit. Confidentiality was guaranteed during the study for all participants, as no information about the cardiovascular risk profiling, the HRA, or the coaching was provided to others than stated in the Participant Information Form. Ethical approval was obtained from the Medical Ethical Committee of Erasmus MC Rotterdam (METC) by registration number MEC 2012-459. The trial was registered on November 14th of 2014 at the Netherlands Trial Register by registration number NTR4894.

After trial commencement, three OPs withdrew because of other priorities in work or due to personal issues, resulting in the loss of one military cluster and less inclusions than expected. In order to achieve sufficient power, we obtained approval of the METC to include an additional organisation (i.e. an academic hospital).

Study setting

The study is being performed among employees of three Dutch organisations: the military force, the police force, and an academic hospital. All organisations have an in-company occupational health center. Prior to the start of PerfectFit, all involved OPs of these health centers were introduced to the design and the goals of the PerfectFit study.

Study population

The study population consisted of military personnel of ten Dutch military bases in different geographical regions in the Netherlands (n=4,207), executive personnel of three units of the police force in the western, central, and northern part of the Netherlands (n=4,086), and all health professionals of six wards (intensive cares and emergency rooms) of an academic hospital (n=207). Based on previous data of 10,624 employees from a range of companies [34], we estimated 57.3% (n=5,444) to be eligible, based on having at least one of three risk factors (obesity, smoking, lack of physical activity).

An entry point for recruitment of the study population was cardiovascular risk profiling (later in text: cardio screening). In the military force, all military employees of 40 years and over are expected to have this cardio screening once every three years. In the other two organisations, this type of screening is voluntary.

Recruitment of participants

Aiming for optimal participation and commitment among participants and OPs, we obtained endorsement for this intervention study from both the boards of directors and the workers' councils to perform this study. Recruitment in the military force started in 2012, in the police force in 2013, and in the hospital in 2014. Follow-up measurements will be completed by October 2015.

Information on the cardio screening and the PerfectFit study was repeatedly given in different formats (e.g., intranet publications, organisational magazine, and PerfectFit flyers, that were given out to applicants to the cardio screening). In the hospital, an additional information session was organised for the managers of the participating wards. Employees who were 40 years or older received the PerfectFit-flyer and a letter of invitation for the cardio screening signed by the highest manager. Participation in the PerfectFit study was voluntary and free of charge. The cardio screening and coaching sessions could be done during working hours, in contrast to completing the HRA and undertaking any individually chosen health activities.

Inclusion criteria for the study

Participants in this study were 40 years and older who presented with at least one CVD risk factor during the baseline cardio screening. The age group 40 years and older was chosen for two reasons. Firstly, cardiovascular risk scores such as the Framingham Risk Score [35] and the European SCORE function start at the age of 40. Secondly, cardio screening is mandatory for military personnel in this age group [36]. The screening was performed by the OPs of the participating health centres.

The cardio screening consisted of three components: (1) a short questionnaire with questions related to personal lifestyle and family history; (2) anthropometric measure-

ments; and (3) blood measurements. In a face-to-face session, the OP provided "usual care"-advice according to the applicable Dutch guidelines [37].

The short questionnaire used in the cardio screening consisted of eight questions on health behaviour such as smoking (yes, no); meeting the Dutch physical activity norm of exercising five times a week at moderate intensity for at least half an hour (yes, no); family and personal history of cardiovascular diseases (yes, no), such as suffering from atrial fibrillation (yes, no); a first degree family member with angina pectoris or a history of heart attack (yes, no); and ever being diagnosed with diabetes (yes, no) or hypertension (yes, no). Participants were also asked whether they were being treated with prescription drugs for hypertension or heart problems (yes, no).

For blood pressure, weight, height and serum measurements, the OPs or their assistants used the instruments that are available for their daily practice. These instruments could vary between OPs, but were the same throughout the study. Systolic and diastolic blood pressures (in mmHg) were measured twice in a seated position at rest, and average blood pressure values were used. Waist circumference was measured halfway between the lower rib and the iliac crest, as is advised by the Dutch obesity recommendations for general practitioners [38]. Serum was analysed for total cholesterol, HDL, LDL, triglycerides (mmol/l), and glucose (mmol/l). If the glucose level exceeded 11.1, then also HbA1c (%) was measured.

These three components of the cardio screening provided entry points for the study, as it was used to identify employees at high risk for CVD. Inclusion criteria were met if a person had at least one of the following risk factors for CVD:

1) Angina or myocardial infarction in first degree relatives;
2) Physical inactivity, i.e. not meeting the guideline of physical activity at moderate intensity less than 30 minutes a day for 5 days per week or comparable effort;
3) Smoking;
4) Self-reported diabetes mellitus or random glucose ≥ 11.1 mmol/l;
5) Obesity, defined as BMI ≥ 30 kg/m^2 and / or waist circumference ≥ 102 cm for men or BMI ≥ 30 kg/m^2 and/or ≥ 88cm for women.
6) Hypertension (diastolic value > 90 mm Hg or a systolic value > 140 mmHg) or the use of antihypertensive drugs;
7) Dyslipidaemia (total cholesterol ≥ 5mmol/l or LDL cholesterol ≥ 2.5 mmol/l or triglycerides: ≥ 1.7,mmol/l or HDL cholesterol: ≤ 1.0 mmol/l).

Employees who met the above mentioned inclusion criteria were excluded from participation if they had (1) manifest CVD (history of myocardial infarction, heart failure, or cerebrovascular accident); (2) a terminal illness; or (3) a history of psychosis. A flowchart of participants is shown in Figure 1.

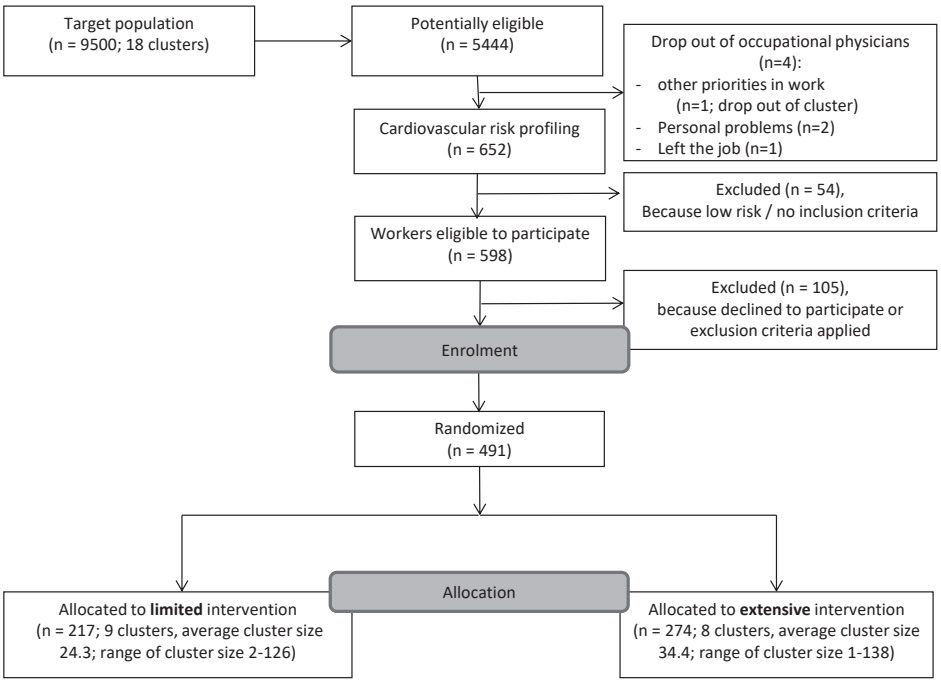

Figure 1. Flow of clusters and participants until allocation within the trial.

Study interventions

After the cardio screening at baseline, employees who were included in both the extensive and the limited study intervention groups, were invited by the OP to log on to the web-based HRA, by giving them a personal voucher-code.

Web-based HRA. The web-based HRA consists of a web-based electronic questionnaire, including questions on lifestyle, work, family history, medical history, and motivation to change, which takes 30 to 45 minutes to fill out. Based on the answers on these questions, as well as on the baseline anthropometric and blood measurements that are integrated in the online system, the web-based HRA generates tailored and personalised advice to the participant, which are presented as low-risk (green), intermediate-risk (orange), or high-risk (red) profiles. Personalised advice includes a suggestion of choice out of health promotion activities, based on the participant's risk profile, preferences and motivational aspects, according to the transtheoretical model of health behaviour change [39]. These optional choices can be selected from a list of activities that are "usual care" for each organisation. Prior to the inclusion period, this list was constructed by the OPs and the research team, and it includes health promotion activities on lifestyle items (i.e. sports facilities, dietician, psychologist). This web-based HRA can be considered as a patient decision aid, since it meets the six qualifying criteria [40]. The flowchart of the intervention is shown in Figure 2.

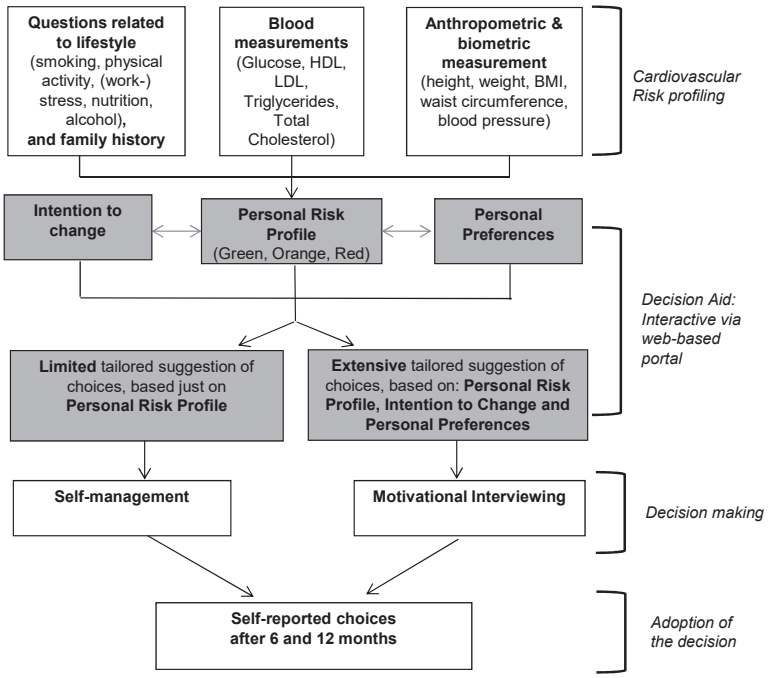

Figure 2. Flowchart of the interventions, including a web-based Health Risk Assessment (HRA) with tailored advice and suggestions of choices, and motivational interviewing.

For the participants in both intervention arms, follow-up questionnaires are conducted after 6 and 12 months, but without any tailored advice as feedback. In case of non-response to a questionnaire after two weeks, an automatic electronic reminder is sent to the employee. After another two weeks without response, the employee is contacted by a member of the research team reminding him/her to fill out the questionnaire and/or to provide assistance if needed.

Limited (control) intervention

The limited health intervention program consists of the following elements:

a) a web-based HRA (described above), including tailored and personalised advice for health behaviour change, with a suggestion of choice out of three "usual care" health promotion activities for every identified risk factor. This is followed by usual care, according to Dutch OP guidelines [41].
b) an electronic newsletter of approximately two pages, sent every three months. The newsletter includes general information on PerfectFit and on a healthy lifestyle.

Extensive intervention

In the extensive intervention group, the limited intervention program is extended with personalised MI sessions with an OP, together with additional tailoring based on motivational elements in the web-based HRA and an additional motivational paragraph in the newsletters.

MI is conducted in the form of individual coaching sessions run by trained OPs. Altogether, they include seven motivational coaching sessions: three face-to-face sessions (30-45 minutes per contact) and four telephone contacts (15-30 minutes per contact) [42]. The MI training for OPs was organised as a continuous medical education (CME) session and after successful completion of the training OPs received credits. The training was free of charge and it consisted of three full days of group training by a certified MI trainer with 3 follow-up coaching sessions of 4 hours each [43]. During the training, OPs became familiar with the basic principles of MI and they practiced techniques needed for conducting MI. The aim was to elicit long-term healthy behaviour in the participants.

To assure and maintain a high level of quality of MI during the intervention period, we conducted two quality assurance activities[44]. First, after every three months, each OP was asked to audio record the first face-to-face consultation with a participant, using a voice recorder. Recorded sessions were transcribed verbatim and analysed using the validated Motivational Interviewing Treatment Integrity code (MITI) for the presence of core elements of the MI technique, such as reflexivity, open-questioning, and empathy [45, 46]. Scorings were done by the first author and a co-investigator in this study, who are both experienced MI-coaches and familiar with the scoring technique. Within a month after the recordings, the OPs received feedback on the quality of their MI-techniques. Second, after every MI session with participants, OPs had to fill out a form related to the MI session with a participant, such as if it was a face-to-face or telephone session, the amount of time it took, and what stage of change the participant was in (5 stages, ranging from pre-contemplation to maintenance).

The online advice within the HRA additionally includes tailoring based on motivational aspects such as intention to change and personal preferences, and it includes three more suggestions of choice for health promotion activities. In contrast to usual care, these additional suggestions of choice include e-health interventions, fitness centers with national coverage, and the use of an activity tracker (accelerometer). The accelerometer is offered for free and is primarily aimed at providing "biofeedback" to those participants who are physically inactive and who are motivated to improve their level of physical activity by using this small monitoring device during twelve consecutive weeks [47].

Outcome measures

The following outcome measures will be taken into account:

Primary outcome measure:

General health

At baseline, 6 months and 12 months, we measure(d) general health using the first question of the Short Form 36 Health Survey (SF-36) [48] ('Overall, how would you rate your health?'), which has five possible answers, ranging from 'poor' to 'excellent'.

Secondary outcome measures:

Quality of life

Quality of life and its utility values will be calculated using the EuroQol 5 dimensions self-report questionnaire (EQ-5D) [49] and two domains from the SF-36 (physical functioning and vitality) [48]. The EQ-5D is a health status classification system consisting of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. We distinguish three levels for each dimension: no problems, moderate problems, and extreme problems. Within the SF-36, 4 questions are asked for physical functioning with 5 answering options, ranging from "totally agree" to "totally disagree". For vitality 4 questions are asked with 6 answering options ranging from "all the time" to "never".

CVD-risk score

CVD-risk will be estimated at baseline and after 12 months, using the European SCORE function (EuroSCORE), the Framingham Risk Score (FRS), and the QRISK2. The EuroSCORE [50] estimates the 10-year risk for total fatal CVD-risk, based on age, sex, smoking, blood pressure, and total cholesterol. The FRS estimates the 10-year risk for CVD mortality and morbidity by adding hypertension treatment status, HDL-cholesterol, and diabetes status [36, 51, 52]. The QRISK2 [28] estimates the risk of CVD by adding ethnicity, diabetes, family history for angina or heart attack, chronic kidney disease, atrial fibrillation, blood pressure treatment, rheumatoid arthritis, cholesterol/HDL ratio, and body mass index.

Obesity

Obesity, measured with waist circumference (in cm) and Body Mass Index (BMI, kg/m2), was determined at baseline and will be repeated at 12 month follow-up.

Lifestyle

At baseline and after 6 and 12 months, current behaviour is assessed for smoking, physical activity, alcohol consumption, and nutrition, measured as adherence to Dutch public health guidelines (yes/no), i.e., not smoking [53], being moderately physically active for 30 minutes on at least 5 days a week [54], not drinking more than 1 (women) or 2 (men) glasses of alcohol a day [55], eating at least 200 g of vegetables per day [55], and eating at least 2 pieces of fruit per day [55] .

At baseline, self-reported intentions to change behaviour targeting smoking, physical activity, alcohol, dietary behaviour or body weight will be assessed. For smoking, intentions to change are measured using dichotomous response scales (yes/no). For the other lifestyle items, the answering options are dichotomised into 'I will start this month; I will start within 6 months; I will start, but I don't know when' and 'I would like to, but I don't have enough time; I would like to, but I can't because of a disease, a disability or a doctor advised me not to; other'.

After 6 months, actual lifestyle behaviour change will be measured by the number and type of health promotion activities they choose to participate in, within the 6 months after baseline (participants' responsiveness to the intervention). Also the chosen mode of delivery (provided by employer or not) will be assessed.

Work ability

Work ability will be measured at baseline, 6 months and 12 months, using the Work Ability Index (WAI) questionnaire [56], which consists of seven dimensions: an individual's (i) physical and (ii) mental demands related to work, (iii) diagnosed diseases, (iv) experienced work limitations due to disease, (v) sick leave in the previous 12 months, (vi) work ability prognosis, and (vii) mental resources. The WAI index is derived as the sum score of the ratings on each dimension. The range of the summative index is 7–49, which is categorised into "poor" (7–27), "moderate" (28–36), "good" (37–43), and "excellent" (44–49) work ability [57].

Productivity at work

Productivity at work and, if applicable, the reason for any self-reported loss in productivity was measured at baseline and will be repeated after 12 months. We use the Quantity and Quality (QQ) method [58], which is derived from the PRODISQ [59, 60]. On 10-point numerical scales, participants are asked how much work they performed during regular hours on their last regular workday and what the quantity of the work was compared to normal.

We also quantify to what degree employees are present at work but limited in their job performance due to any health problems, by using the short version of the Work Limitations Questionnaire (WLQ-8) [61-63]. The WLQ-8 consists of four dimensions: physical demands (2 items), time management (2 items), mental-interpersonal demands (2 items), and output demands (2 item). Individuals are asked to base their responses on their previous two weeks of work and to rate impairment on a 5-point scale ranging from "always" to "never" with an additional response item "does not apply to my job".

Process evaluation

After the intervention period, several process characteristics will be evaluated using the RE-AIM model [64, 65], which consists of the following five elements:

1) Reach (eligibility, number of cardio screenings, percentages of inclusions and exclusions, individuals' characteristics, and compliance and determinants of the participants to the screening, HRA, MI-counselling sessions, and 6 and 12 months follow-up measurements);
2) Effectiveness (outcomes at 6 and 12 months);
3) Adoption (characteristics of OPs and clusters);
4) Implementation (amount, duration, timing and quality of MI-counselling sessions, satisfaction of participants with the sessions); and
5) Maintenance (long-term implementation).

Participants' opinions of the perceived usefulness of the web-based HRA, of the coaching, and of the impact on their lifestyle change will be evaluated at six months, on a 5-points Likert scale (from 1= strongly disagree to 5=strongly disagree). Participants' satisfaction with the OP will also be measured at six months, using standard questions based on the PSOHQ [66] .

Sample size and power calculation

The primary outcome measure in this study is general health. Based on a study of more than 4000 asymptomatic Dutch individuals [67], we assumed that the average value for general health score measured by the SF-36 within our target study population is 71 (SD 19, scale 0-100). Based on an intervention study that assessed general health, albeit with a less intensive intervention [68], we assume a relevant difference in the general health score between the intervention and control groups after 12 months of 10% in favor of the intervention group. With a power of 80%, a significance level of 5%, two-tailed testing, a compensation for cluster randomisation with an estimated intra-cluster correlation coefficient of 0.05, the assumption of similar groups, and with the intention of demonstrating superiority, approximately 220 participants per group are needed to demonstrate a difference in treatment effect of 10% between the two groups. With an expected participation of 50% (based on previous studies of health interventions for military personnel) and a loss to follow-up of 30%, the RCT required inviting 2 x 634 individuals, so 1268 in total.

Randomisation, blinding, and allocation to interventions

Military bases, regional police forces, and hospital wards were randomly assigned as 'clusters' to one of the two intervention groups. A total of 18 clusters were randomised, which were equally divided in 9 clusters that were allocated to the limited intervention and 9 clusters that were allocated to the extensive intervention. In each of these clusters,

one or more OPs were assigned to contribute to PerfectFit, based on shown interest. We chose for a cluster design to ensure that the OPs were only active within a single study arm. The organisational unit was the preferred cluster for two reasons. First, OPs from the same organisational unit were all trained to execute the intervention so that discussions among colleagues would not bias the results. Second, grouping participants from the same organisational unit into the same intervention group will prevent so-called "contamination effects" among participants, i.e., talking and sharing experiences about involvement in two different types of interventions, which might influence their behaviours [69, 70].

In the military force we constructed ten clusters consisting of military ground force army bases located in different regions in The Netherlands. Since the police force was facing a large reorganisation with possible replacements of OPs from one organisational unit to another, only two clusters could be constructed, based on organisational units in different regions. Randomisation in the academic hospital was performed at the ward level, creating a total of 6 clusters.

For all organisations, the OPs only perform work for the health center within that particular organisational unit. Clusters were ordered according to their sizes, i.e. the number of potential eligible participants. For each pair of clusters of similar size within one organisation, one of the clusters was randomly allocated to the extensive intervention and the other to the limited intervention. Randomisation took place after an OP from the unit had confirmed participation, and prior to the inclusion of individual participants. A researcher who was not otherwise involved in the trial used version 3.0.1 of The R Foundation for Statistical Computing for the randomisation. Researchers, participating OPs, and participants were not blinded for the group allocation, since this was impossible given the nature of the intervention and the cluster design.

STATISTICAL ANALYSES

Demographic and socio-economic characteristics of participants such as age, gender, education, profession, and income level, were collected at the beginning of the study. For the baseline characteristics of table 1 and 2, we used descriptive statistics to generate number and percentages for dichotomous and categorical variables, and to generate means and standard deviations of continuous variables. To get insight into the differences between groups, Chi-Square tests and ANOVA-tests were performed.

Future analyses will be performed according to the Intention-to-treat principle [71]. Repeated measurements with mixed models techniques will be used to compare the primary outcome (general health scores) between the extensive and limited intervention groups, adjusted for potential confounders such as socio-economic determinants

Table 1. Baseline characteristics of participants included in the PerfectFit-study according to organisation (n=491)

	Organisation 1 (Police)	Organisation 2 (Military)	Organisation 3 (Hospital)	P value
	n=262 (53%)	n=170 (35%)	n=59 (12%)	
Age, mean (sd)	52 (5.8)	49 (4.6)	53 (6.5)	<0.000*
Gender:				
Male	201 (82.7%)	163 (98.2%)	16 (27.6%)	<0.000*
Educational level				
Low	39 (16.7%)	16 (9.9%)	11 (20%)	<0.000*
Medium	147 (63.1%)	87 (53.7%)	22 (40%)	
High	47 (20.2%)	59 (36.4%)	22 (40%)	
Hypertension[1]	78 (31.2%)	73 (44.5%)	22 (39.3%)	0.021*
Body Mass Index category				
<25 kg/m2	62 (24.9%)	34 (20.1%)	32 (55.2%)	<0.000*
25-30 kg/m2	141 (56.6%)	101 (59.8%)	22 (37.9%)	
>30 kg/m2	46 (18.5%)	34 (20.1%)	4 (6.9%)	
Waist circumference, cm :				
High (female >88 cm; male >102 cm)	100 (41.3%)	71 (43.0%)	30 (52.6%)	0.299
Obesity[2]	104 (43.5%)	75 (45.5%)	30 (52.6%)	0.462
Family history of CVD[3]	97 (37.6)	61 (39.4)	24 (42.9)	0.754
Diabetes mellitus (DM) type II [4]	10 (4.0)	3 (1.9)	1 (1.8)	0.408
Dyslipidemia[5]	238 (92.6%)	154 (91.7%)	56 (94.9%)	0.715
Health risk behaviour:				
Lack of physical activity	107 (42.0)	42 (26.9)	20 (37.0)	0.009*
Smoking	42 (16.5)	27 (16.9)	3 (5.4)	0.088
Framingham 10-year CVD risk score category[6]				
Low (<10%)	153 (66.5%)	120 (78.9%)	32 (58.2%)	0.003*
Intermediate (≥10%, <20%)	68 (29.6%)	22 (14.5%)	20 (36.4%)	
High (≥20%)	9 (3.9%)	10 (6.6%)	3 (5.5%)	
Number of inclusion criteria:				
1	51 (19.8%)	26 (15.4%)	7 (11.9%)	0.235
2	68 (26.5%)	62 (36.7%)	21 (35.6%)	
3	77 (30.0%)	43 (25.4%)	20 (33.9%)	
≥4	61 (23.7%)	38 (22.5%)	11 (18.6%)	

*statistically different, continuous measurements based on ANOVA test and categorical measurements based on Chi-Square test.

[1] Hypertension is defined as diastolic blood pressure higher than 90 mmHG or systolic blood pressure higher than 140mmHG or taking antihypertensive drugs.

[2] Obesity is defined as BMI >30 kg/m^2 or waist circumference >88 cm for females or >102 cm for males.

[3]Family history of CVD is defined as a first degree family member who suffered a CVD at any age

[4] Diabetes is defined as having a sober blood glucose higher than 6.1 or self-reported diagnosis of diagnosis.
[5] Dyslipidemia is defined as having increased levels of at least one type of lipids in the blood (total cholesterol ≥ 5mmol/l, or LDL cholesterol ≥ 2.5 mmol/l; or triglycerides: ≥ 1.7,mmol/l, or HDL cholesterol: ≤ 1.0 mmol/l).
[6] EuroSCORE and QRISK2 will be calculated after completion of the intervention, at 12 months.

(including employment status, profession, income level, education), and taking into account the cluster randomisation (multilevel analysis). A cost analysis will be performed to determine the costs of the extensive health intervention compared to the limited health intervention, including the change in health care consumption.

Economic evaluation

An economic evaluation will be performed, according to the Dutch guidelines for cost-effectiveness analyses, to evaluate the trade-off between costs and benefits. Analyses will be performed both from the perspective of the organisation and from a societal perspective. In this study we will consider direct and induced costs of the intervention. The timeframe of the analyses is 12 months and we will use a model for extrapolation to long-term results. The cost-benefit analysis performed from the organisational perspective will include the differences in employability (in monetary units) and the additional organisational costs for applying the elements from the extensive intervention in addition to the limited intervention. A secondary analysis will be performed in which we will simulate a no-HRA-scenario and calculate the costs and benefits without either one of our interventions as reference. In the cost-effectiveness analyses from a societal perspective, effectiveness will be expressed using QALY's, whereas costs will be expressed as total healthcare costs (direct plus induced costs) and societal costs. Direct healthcare costs consist of costs of the intervention programs and costs for adapting the intervention for the target groups (including construction and use of the web-portal and MI-training of OPs). Induced healthcare costs consist of healthcare consumption (outpatient visits, diagnostic and therapeutic procedures, medication, and hospital admissions). Societal costs consist of costs of employee absence in order to participate in the intervention, absenteeism, productivity at work, individual costs for undertaking health promotion activities (including contribution fees to a sports centre and time costs), and any additional travel costs and parking expenses.

Table 2. Baseline characteristics of the study population (demographics, health and work-related factors) in two intervention arms

	Limited Intervention	Extensive Intervention	P value
	n=217	**n=274**	
Age, mean (sd)	52.1 (6.0)	50.7 (5.4)	<0.006*
Organisation			0.007
Police	124 (57.1)	138 (50.4)	
Military	60 (27.6)	110 (40.1)	
Hospital	33 (15.2)	26 (9.5)	
Gender:			
Male	154 (77.0%)	226 (84.6%)	0.036*
Educational level			0.011*
Low	33 (17.5%)	33 (12.6%)	
Medium	116 (61.4%)	140 (53.6%)	
High	40 (21.2%)	88 (33.7%)	
Hypertension[1]	73 (35.1%)	100 (38.2%)	0.493
Body Mass Index category			0.294
<25 kg/m2	64 (29.9%)	64 (24.4%)	
25-30 kg/m2	117 (54.7%)	147 (56.1%)	
>30 kg/m2	33 (15.4%)	51 (19.5%)	
Waist circumference, cm :			
High (female >88 cm; male >102 cm)	79 (39.7%)	122 (46.0%)	0.173
Obesity[2]	81 (40.7%)	128 (48.9%)	0.082
Family history of CVD[3]	78 (38.0%)	104 (39.4%)	0.767
Diabetes mellitus (DM) type II [4]	8 (3.9%)	6 (2.3%)	0.314
Dyslipidemia[5]	197 (91.6%)	251 (93.3%)	0.484
Health risk behaviour:			
Lack of physical activity	73 (35.6%)	96 (36.9%)	0.770
Smoking	23 (11.1%)	49 (18.6%)	0.026*
Framingham 10-year CVD risk score category[6]			0.430
Low (<10%)	123 (66.5%)	182 (72.2%)	
Intermediate (≥10%, <20%)	52 (28.1%)	58 (23%)	
High (≥20%)	10 (5.4%)	12 (4.8%)	
Number of inclusion criteria:			0.323
1	43 (20.3%)	41 (15.0%)	
2	64 (30.2%)	87 (31.9%)	
3	63 (29.7%)	77 (28.2%)	
≥4	42 (19.8%)	68 (24.9%)	

*statistically different, continuous measurements based on ANOVA test, categorical measurements based on Chi-Square test.

[1] Hypertension is defined as diastolic blood pressure higher than 90 mmHG or systolic blood pressure higher than 140mmHG or taking antihypertensive drugs.
[2] Obesity is defined as BMI >30 kg/m^2 or waist circumference >88 cm for females or >102 cm for males.
[3]Family history of CVD is defined as a first degree family member who suffered a CVD at any age
[4] Diabetes is defined as having a sober blood glucose higher than 6.1 or self-reported diagnosis of diagnosis.
[5] Dyslipidemia is defined as having increased levels of at least one type of lipids in the blood (total cholesterol ≥ 5mmol/l, or LDL cholesterol ≥ 2.5 mmol/l; or triglycerides: ≥ 1.7,mmol/l, or HDL cholesterol: ≤ 1.0 mmol/l).
[6] EuroSCORE and QRISK2 will be calculated after completion of the intervention, at 12 months.

RESULTS

Figure 1 shows the CONSORT diagram [72] of the flow of clusters and participants through the first phases of the trial. In total, 9 clusters (n=217), were assigned to the limited intervention (control), and 9 clusters (n=274) to the extensive intervention (intervention). One cluster dropped out after randomisation and before any cardio screenings were done, because the only OP within this cluster had other priorities in work. Three more OPs dropped out before any cardio screenings were done, two because of personal problems and one because she left her job. A total of 652 employees undertook the cardio screening. Based on these cardio screenings, 91.4% (n=598) were found to have risk factors for CVD, of whom 82.1% were included (n=491). Reasons for no inclusion were the presence of exclusion criteria or retirement or having to go abroad for work in the near future. For 16 participants the baseline questionnaire was missing, but we did receive blood- or anthropometric-measurements. The number of missings ranged from n=1 (for the variable age) to n=40 (for the variable level of education).

Baseline characteristics of participants in the three organisations are presented in Table 1. The military and police forces included a majority of males, whereas the hospital included mostly females. Among participants of the police force more than 76% had a BMI higher than 25 kg/m2, and in the military force this percentage was 80.5%. The percentage in the hospital of 46% is lower and is similar to the average for the Dutch population.

Table 2 presents the baseline characteristics of the extensive intervention versus control study groups. The average age of the participants was 52, and 81.4% were male. The randomisation was successful in creating study groups with similar characteristics. Only for smoking a difference between the groups was found (p=0.026). The CVD risk based on the Framingham score showed that more than 30% of our study population is at intermediate or high risk, without differences in distribution between the two groups (p=0.430).

DISCUSSION

The PerfectFit study aims to establish whether adding MI to a web-based HRA is a key-factor for improving effectiveness in changing unhealthy lifestyles and reducing risk factors for chronic diseases. MI is known to improve BMI, total blood cholesterol, systolic blood pressure, and blood alcohol concentration [73]. By adding MI, this superiority RCT combines the advantages of an online personalised and tailored approach with the advantages of a face-to-face approach, thus aiming to improve participation and sustained effectiveness of workplace health promotion programs [74].

Web-based healthcare (eHealth) is receiving growing attention since it can tailor interventions to target population characteristics (e.g., specific risk factors), thereby facilitating wider access and encouraging self-care, and possibly reducing health-care costs and improving efficacy [75]. However, a proven feature of eHealth is that its effect decreases after the intervention has been completed [15]. Our blended approach of adding MI to a web-based HRA is promising in several ways. First, we expect an increase of lifestyle changes, since previous research showed dose-response relationships between exposure to an intervention (number and duration of exposures) and behaviour change outcomes [73, 76]. Second, it may lead to a higher sustainability of these lifestyle changes, since there is evidence that providing face-to-face counselling with a higher number of overall contacts was associated with greater short and long-term effectiveness [76]. MI has a large potential to fill the gap between the intention to change and the actual behaviour change, commonly referred to as the intention-behaviour gap [77]. This potential was previously demonstrated for lifestyle changes such as physical activity and a healthy diet [78-80]. MI is a unique tool for evoking and strengthening intrinsic motivation for a more sustainable change in lifestyle [13-19].

Our study design is unique for both its blended design of the intervention using a qualified decision aid and the follow-up at 6 and 12 months, which enables us to evaluate not just the initiation of health activities [9] but also the sustainability of lifestyle changes [81]. A second strength is the target population of employees in highly demanding jobs from three types of working organisations, whose workplace productivity and sickness absence might benefit from our intervention. Another strength is that the intervention is implemented within existing health centers and by their own OPs, improving external validity and making the results generalisable to larger companies. For the purpose of this study, a large investment was done for the OPs to master MI, which will remain beneficial to the organisations after completion of the study. Both the OPs from the extensive group and those from the limited group (after completion of the study), are educated to use the MI-technique, and skills they acquire and master during the time of the study and immediately afterwards can be internalised and incorporated in their everyday practice with all employees. From the perspective of the organisation

and society, these investments may pay off in the long run: an economic evaluation will be performed to analyse whether this truly is the case.

The study has three primary limitations. First, the effects on lifestyle changes may be affected by the healthy volunteer bias, since the study sample consists of employees of organisations who were actively recruited and who volunteered to participate [82]. Although we found differences in characteristics between organisations (Table 1), the potential bias will effect both the intervention and limited group alike, and will not have a large effect on our results (Table 2). Second, an attrition bias may occur at the follow-up measurements since those who achieve lifestyle changes might be more willing to do the final assessment than those who do not [83]. We will try to prevent this by sending personal invitations for final measurements by the OPs and having the OPs stimulate the participant to also fill out the questionnaire. A third issue is that blinding of the OPs, the participants and the investigators would have been preferred but could not be done in this real-life pragmatic trial.

The equal distribution of health factors of our participants between both the intervention and control groups, suggests that we will be able to evaluate the intervention-effects with minimal adjustments. Although there is no statistical difference in BMI between the groups, the percentages of participants that are overweight (BMI>25 kg/m2) exceeds 70% in both groups, which is high compared to 47% within the general population [84]. This is in line with previous research reporting increasingly high percentages of overweight and obesity in the military force [85] and in police officers [86]. However, we are cautiously interpreting overweight in population groups that are doing physically demanding work, since it is well known that muscular type of body composition might lead to higher BMI [87]. Therefore, in our study we also rely on the waist circumference, in order to have an accurate estimation of obesity.

Dyslipidemia, another risk-factor for CVD, exceeds 90% within both study groups, which could be caused by our strict cut-off value for LDL-cholesterol (>2.5 mmol/l). Nevertheless, since we found that a majority of our participants has more than 1 inclusion criteria and that over 30% has intermediate or high Framingham risk scores, we can assume that changes in health behaviours can tackle these health and occupational hazards. Actual lifestyle changes will be measured and will also be related to the intention to change at baseline, which will give us a more accurate picture of the participants' intention-behaviour gap.

To keep the workforce vital and productive, there is a growing need for effective and affordable health promotion strategies which can also be easily implemented. A key component of this study is MI, which has several elements that promise to be beneficial for both participants and healthcare providers. MI is a well-described and practical approach that respects individual choices and leads to an increased responsibility for their own health [24, 40]. By adding counselling sessions using MI in the intervention

group, participants will be involved in a shared decision making-process related to their lifestyles. We hypothesize that, once participants discover their inner strengths and motivations, their health-behaviour gains will be more sustainable and will be maintained over time [15]. Upcoming papers will assess to what extent this hypothesis can be confirmed and whether this blended care approach is an essential strategy for future health promotion programs.

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Chapter 4

Effectiveness of the blended-care lifestyle intervention 'PerfectFit': a cluster randomised trial in employees at risk for cardiovascular diseases.

Tessa A. Kouwenhoven-Pasmooij [a, b, c], Suzan J.W. Robroek [b], Roderik A. Kraaijenhagen [d], Pieter H. Helmhout [e], Daan Nieboer [b], Alex Burdorf [b], M.G. Myriam Hunink [a,f,g]

Submitted

ABSTRACT

Objectives

To evaluate the effects of a selective workplace health promotion intervention on health and work outcomes among employees with increased cardiovascular risk.
Study design: Multicentre cluster-randomised controlled trial (PerfectFit).

Methods

491 workers in 18 work units from military, police, and a hospital with increased cardiovascular risk were randomised into a limited intervention (n=213; 9 clusters) consisting of a web-based Health Risk Assessment with advice, and an extensive intervention (n=271; 8 clusters) with additional coaching sessions by occupational health physicians using motivational interviewing. One cluster dropped out after randomisation but before any inclusion of subjects. Primary outcome was self-rated health. Secondary outcomes were body weight, body mass index (BMI), work productivity, and health behaviours. Follow-up measurements were collected at 6 and 12 months. Effect sizes were determined in mixed effects models.

Results

There was no difference in self-rated health between the groups. At 12 months in the extensive intervention group body weight (-3.1 kg; 95% CI -2.0 to -4.3) was statistically significantly reduced, whereas in the limited intervention group body weight (+0.2 kg; 95% CI -1.4 to 1.8) slightly increased. However, after adjusting for diversity in age, gender, and education, the difference between the extensive and limited intervention became statistically insignificant. In both groups physical activity increased and excessive alcohol use decreased significantly at 12 months.

Conclusions

Health behaviours improved after a web-based tailored Health Risk Assessment including personalised advice. Adding motivational coaching increased its effectiveness by reducing body weight.

Registered at the Netherlands Trial Registry with number NTR4894 (http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4894).

INTRODUCTION

Non-communicable diseases are a major burden all over the world. Health risk behaviours, such as smoking, unhealthy diet, and physical inactivity, are associated with obesity and cardiovascular diseases (CVD) (1), and are also responsible for substantial health care costs and indirect costs in the workplace (2, 3). In ageing societies, health promotion programs that contribute to healthy ageing of the workforce are increasingly important (4, 5).

Two approaches that have shown promise in improving unhealthy behaviours are a web-based Health Risk Assessment (HRA) and individual counselling by using Motivational Interviewing (MI). Some studies have demonstrated that a web-based HRA stimulated individuals to undertake health-promoting activities and achieved a healthier lifestyle, a decreased CVD risk, and reduced absenteeism in both work (6-8) and primary care settings (9). Motivational interviewing as coaching technique has shown beneficial effects on behavioural and biomedical outcomes in individuals with increased CVD risk (10-12), with maintenance of the effect at 12 months follow-up (13). Web-based HRAs are appealing for their reach in large populations without extensive human interaction (9). The major shortcoming of a purely web-based approach is low sustained participation (14). A systematic review reported that maintenance of behavioural changes was higher in interventions with face-to-face contact than those without (15). Addley et al recently suggested adding face-to-face contact in a health mentoring program to an HRA to achieve enhanced benefits on health and work outcomes (16). Motivational interviewing is recommended as face-to-face communication strategy by The American Heart Association (17). By nonjudgementally addressing a person's innate needs and values during different phases of change, MI-approaches contribute to sustainable change (18). Although MI has potential benefits above tailored advice, it requires intensive human and financial resources (19, 20). Although optimising personalised prevention by blending a web-based HRA and face-to-face motivational counselling seems promising, little is known whether adding these components to workplace health promotion programs will increase their effectiveness.

The main aim of the current study was to evaluate the effects of adding MI-coaching to a web-based HRA including tailored advice on health and work outcomes among employees with increased cardiovascular risk in the military workforce, the police organisation and an academic hospital.

METHODS

Study design

The PerfectFit study was designed as a cluster-randomised controlled trial with randomisation carried out at organisational units within three large organisations: the military (9 clusters), the police force (3 clusters), and an academic hospital (5 clusters) (21). The cluster design ensured that occupational health physicians (OP) delivering the intervention were only active within a single study arm. Reporting of the study was performed according to the CONSORT extension for cluster trials (22)(Supplementary file 1, not printed in thesis).

Baseline measures were obtained from all participants between 2012 and 2014 after written informed consent was given. Web-based follow-up questionnaires were collected at 6 and 12 months. Anthropometric and blood measurements were repeated at 12 months. An extensive description of the study design and baseline characteristics is provided elsewhere (21). The Medical Ethics Committee of Erasmus MC Rotterdam (METC) approved the study with number MEC-2012-459. The study was registered in the Netherlands Trial Registry with number NTR4894.

The academic hospital was included in the trial after trial commencement, for which approval of the METC was obtained. Reasons were the loss of one military cluster, leading to less inclusions than expected.

Randomisation, blinding, and sample size calculation

To guarantee allocation concealment, randomisation was performed by a researcher who was not otherwise involved in the trial, using R version 3.0.1.

A total of 18 clusters were randomised, and since 1 cluster dropped out prior to any inclusion of employees, analyses were performed on 17 clusters. Participants were included by 21 OPs. For the hospital, the first MI-session was performed by the OP and follow-up sessions by a lifestyle coach. Due to our design, OPs, lifestyle coaches and participants were not blinded.

The sample size calculation took into account the cluster design with an estimated intracluster correlation coefficient of 0.05. We estimated that approximately 220 participants per study arm were needed to demonstrate an effect size of 10% in self-rated health between the two groups (21).

Participants

A total of 652 employees of 40 years and over attended the 'cardioscreening' at occupational health centers, which consisted of a short web-based questionnaire, anthropometric measurements, and blood measurements, and is described in detail elsewhere (21). Inclusion criteria were: 1) angina or myocardial infarction in first degree

relatives; 2)physical inactivity; 3)smoking; 4)self-reported diabetes mellitus or random glucose ≥ 11.1 mmol/l; 5)obesity; 6)hypertension; and 7)dyslipidaemia. Those with an elevated risk for CVD (n=598; 91.7% of all screened individuals), defined as having at least one of the inclusion criteria, were invited by the OP to participate in the study of which 491 (82.1%) subjects provided informed consent.

Interventions

The limited (control) intervention program consisted of the following elements:

a) A web-based HRA, including tailored and personalised feedback based on the participant's risk profile, with suggestions for particular health promotion activities, available within each organisation.
b) An electronic newsletter, providing information on the intervention (PerfectFit) and general information on a healthy lifestyle, which was sent to email-addresses using newsletter-software (23), every 2 to 3 months during the study period.

In the extensive intervention group, the intervention was extended with:

c) Seven individual coaching sessions (3 face-to-face and 4 by telephone) with an OP, together with more personalised suggestions for health promotion activities based on motivational elements in the HRA, and an additional motivational paragraph in the newsletters.

During the coaching sessions, the OP applied a client-centered counselling style with MI techniques such as asking open questions, reflecting, supporting, and raising ambivalence. Starting point of the counselling was problem feedback(24) by discussing the person's CVD risk profile and motivation to change health behaviour, which was integrated with important life goals and values. All OPs in the extensive intervention group received a basic training in MI of 3 full days and 3 follow-up coaching sessions of 4 hours.

Outcome measures

The primary outcome measure was self-rated health, assessed by the first question of the Short Form 36 Health Survey (SF-36) (25) ('Overall, how would you rate your health?') with 5 answers, ranging from 'very poor' to 'very good'. Answers were dichotomised in 'less than good' and 'good or very good' health.

The secondary outcome measures were body weight, BMI, work performance, and health behaviours. Body weight was expressed in kilograms and Body Mass Index (BMI) in kg/m^2. 'Obesity' was defined as BMI ≥30 kg/m^2. Body height and weight were measured at each OP's clinic at baseline and at 12 months with scales available for daily practice.

Work performance was estimated by work ability, sickness absence, and productivity loss at work. Work ability was measured with the first question of the Work Ability Index (WAI) questionnaire (26), rating a worker's current work ability relative to the best work

ability during life on an 11-point scale ranging from 0 (unable to work) to 10 (current work ability equals best work ability ever). Sickness absence in days off work due to illness was determined by the 5th question of the WAI, and answers were categorised into no sickness absence (0 days), short-term (1 – 9 days), and long-term (≥10 days). Productivity loss at work was assessed with the short version of the Work Limitations Questionnaire (WLQ-8) (27-29), consisting of four dimensions: physical (2 items), time management (2 items), mental-interpersonal (2 items), and output demands (2 item). Individuals rated impairments on a 5-point scale from 'always' to 'never', or 'does not apply to my job'. The WLQ-8 coding algorithm produced a summary score representing the percentage of productivity lost at work over the last two weeks due to health reasons.

Health behaviours addressed were physical activity (PA), fruit and vegetables, smoking, alcohol, and perceived stress. Compliance with the Dutch guideline on physical activity (PA) (30) was measured by asking 'are you at least 5 days a week, for at least 30 minutes per day, physically active at a moderate intensity (i.e. with a slightly increased heart rate and breathing rate, such as in vigorous walking or cycling)?' (yes/no). Compliance with the guidelines on a healthy diet (31) was assessed by self-reported daily intake of vegetables on a 6-point scale ('no vegetables' to '4 or more spoons of 50 grams each per day'), and fruits on a 7-point scale ('never' to 'twice a day'). The recommendation was not met if less than 200 grams of vegetables and less than 2 pieces of fruit were consumed every day. Smoking was measured with the question 'do you smoke?' (yes/no). Alcohol intake was measured by asking the number of alcohol-units consumed per week with a 7-point scale (1='less than 1 glass per week', 7= '43 to 50 glasses per week'). The guideline was not met if more than 7 (women) or 14 (men) glasses per week were consumed (31). The level of stress was measured by the INTERHEART-questionnaire (32). We defined 'high stress level' as several periods or permanent stress at work or at home, severe financial stress, or 2 or more life events in the past year (32). With the exception of healthy diet and high stress level, health behaviours were measured at 6 and 12 months.

Delivery of the intervention

The quantity of the intervention delivered was expressed by number of face-to-face and telephone MI sessions, and the mean duration in minutes of MI counselling received. The fidelity of the intervention, i.e. the quality of MI, was determined by audio-records of a session every three months per OP (33). Recorded sessions were transcribed verbatim and analysed using the validated Motivational Interviewing Treatment Integrity code (MITI) version 3.1.1(34). Coding was done by two experienced MI-coaches (TK, MW) who were also familiar with the scoring technique. Quality of MI was expressed by the MITI global score 'empathy' and the behaviour-count 'MI-adherence', since these may be predictive of successful client outcome (33). 'Empathy' referred to the OP's efforts in understanding the client's perspective, ranging from 1 (low) to 5 (high). 'MI-adherence'

referred to provision of information (teaching or feedback on personal information) in a MI-consistent way, and was calculated as percentage of MI-adherent remarks. MI quality was based on 35 recordings, ranging from 1 to 4 recordings per OP.

Data analyses

Differences between the limited and extensive intervention groups at baseline were evaluated with Chi-Square tests for dichotomous variables and ANOVA-tests for continuous variables.

All analyses were performed according to the intention-to-treat principle, including all participants regardless of whether or not they received the intervention according to protocol. Non-response analyses were conducted to determine whether drop-out was associated with any baseline characteristics or with the type of intervention. Non-response was defined as no response to the questionnaire at 6 or 12 months. The changes in health, work outcomes and health behaviours within each group were evaluated at 6 and 12 months using paired T-tests for continuous variables and McNemar's test for categorical variables.

The effectiveness of the intervention after 6 and 12 months on health, work outcomes, and health behaviours was evaluated in mixed effects models, where adjustment for organisation cluster was done by adding a random intercept for the cluster. Furthermore, the intervention effect was adjusted for baseline health, work outcomes, and health behaviours, sex, age, and education, which were added as fixed effects. Missing values in the adjustment variables were imputed using chained equations. The intra-cluster correlation was assessed to evaluate the within cluster variation, and was 0.08 at the highest, implying that the clustering had little effect on the results. Data were analysed using SPSS Statistics version 21. For the mixed effects model, we used the R package lme4.

RESULTS

In Figure 1 the flow of participants is shown with 9 clusters (n=217) in the limited and 8 clusters (n=274) in the extensive intervention group.

Our study population was 50.8 years on average, predominantly male with intermediate or high education (Table 1). Overall, 18.3% considered themselves to be in less than good health, and health behaviours showed that 65.4% did not meet the Dutch physical activity guidelines and 86.6% did not meet the healthy diet guidelines. In total, 16.9% of the participants smoked, 11.8% used excessive alcohol, and 37.4% reported a high stress level. Since both groups differed in age, sex, and educational level, all statistical

analyses were fully adjusted for these factors. No adverse events of the intervention were reported.

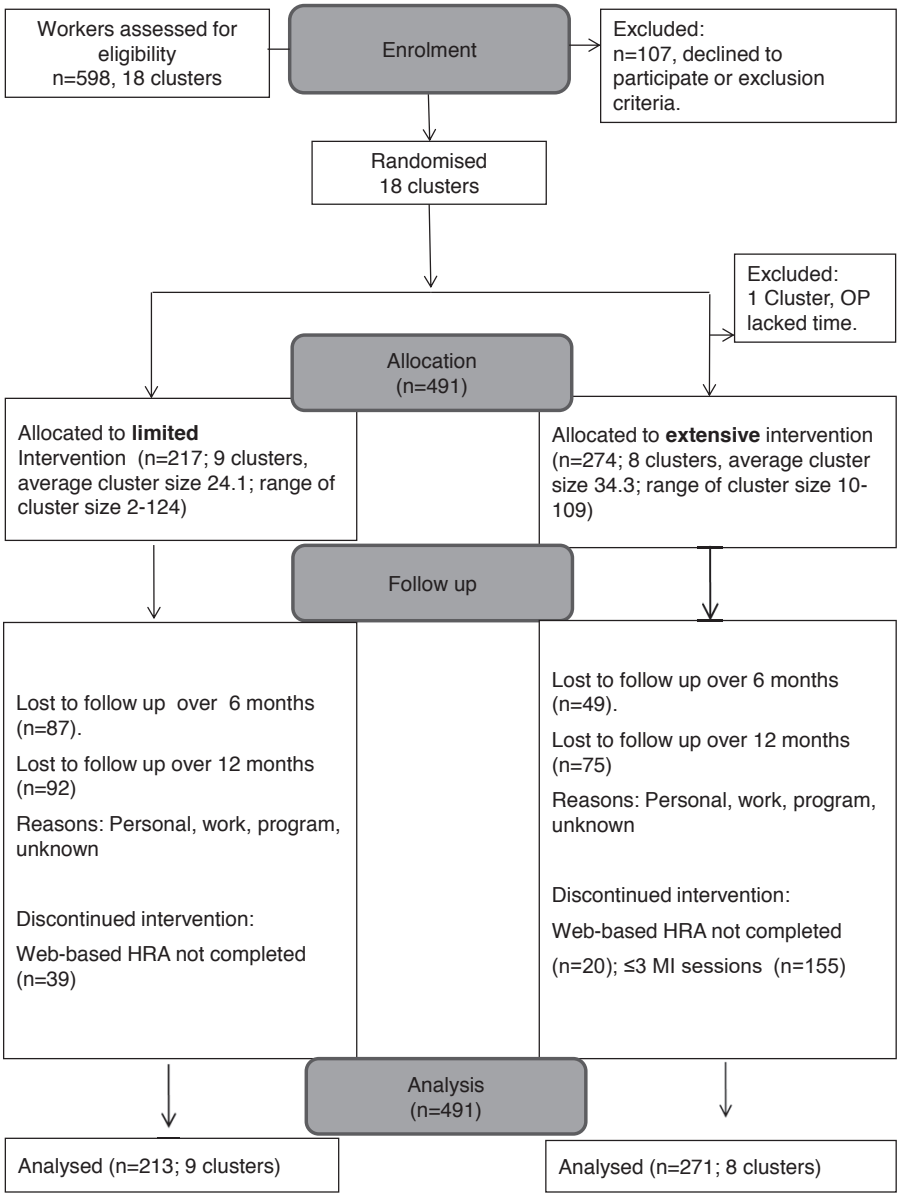

Figure 1. Flow of clusters and participants within the trial.

The response was 72% at 6 months and 66% at 12 months. The extensive intervention approach contributed to retaining individuals in the study, and more MI sessions improved adherence (Supplementary file 2). Response was higher among those with a higher workability (8 versus 7.5) and less productivity loss at work. There were no differ-

Table 1. Baseline characteristics of the study population (n=491).

Characteristics	Limited intervention n=217 (44.2%)	Extensive intervention n=274 (55.8%)	P value	Missings n (%)
Individual characteristics:				
Age, years (mean, SD)	51.62 (6.0)	50.19 (5.6)	0.003	1 (0.2)
Male (n,%):	166 (76.5)	233 (85.0)	0.016	0
Level of education (n,%):			0.009	20 (4.1)
Low	34 (17.9)	33 (12.6)		
Medium	116 (61.1)	140 (53.6)		
High	40 (21.1)	88 (33.7)		
Health characteristics:				
Self-rated general health:				
Less than good	32 (17.2)	58 (22.3)	0.185	45 (9.2)
BMI (kg/m2)(mean, SD)	26.9 (3.4)	27.5 (3.6)	0.066	15 (3.1)
Work characteristics:				
Work ability (mean, SD)	7.91 (1.61)	7.92 (1.47)	0.946	50 (10.2)
Sickness absence (n,%)			0.894	53 (10.8)
0 days	92 (50.3)	123 (48.2)		
1-9 days	72 (39.3)	106 (41.6)		
≥10 days	19 (10.4)	26 (10.2)		
Productivity loss at work (mean%, SD)	2.93 (3.46)	2.97 (3.62)	0.916	103 (21.0)
Health risk behaviour[1], n (%):				
Lack of physical activity	133 (72.7)	188 (72.3)	0.932	48 (9.8)
Unhealthy diet[2]	173 (94.5)	252 (97.7)	0.082	50 (10.2)
Smoking	28 (12.9)	55 (20.1)	0.071	0
Excessive alcohol use[3]	26 (15.9)	32 (14.0)	0.617	99 (20.2)
High stress level[4]	59 (32.2)	106 (41.1)	0.059	50 (10.2)

[1]Defined as non-adherence to Dutch guidelines at baseline.
[2]Unhealthy diet is defined as eating less than 200 g vegetables per day , and eating less than 2 pieces of fruit per day
[3]Meeting the alcohol guideline, which is not drinking more than 1 (women) or 2 (men) glasses of alcohol a day
[4]High stress level is defined as several periods or permanent stress at work or at home or severe financial stress or 2 or more life events (Ref. Lancet 2004 Rosengren).
BMI, body mass index
SD, standard deviation

Table 2. Changes in health, work and health risk behaviour after 6 and 12-months follow-up in the limited and extensive intervention groups. The estimated effect is the difference between the extensive intervention vs. the limited intervention, adjusted for baseline characteristics. For example, the negative difference for BMI implies that the extensive intervention had a greater effect in reducing BMI.

	Effect follow-up minus baseline[1]				Estimated effect[2] (difference) between intervention groups % (95% CI)	
	Limited intervention		Extensive intervention			
Outcome:	**6 months**	**12 months**	**6 months**	**12 months**	**6 months**	**12 months**
Health characteristics:						
General health (%)						
less than good	3.1	4.1	-1.8	0	2.6 (-8.4;9.2)	4.3 (-5.3;12.8)
BMI (kg/m^2), (mean, 95%CI)	na	0.24 (-0.20;0.67)	na	-0.69* (-1.00;-0.39)	na	-0.81 (-1.87; 0.26)
Bodyweight (kg)	na	0.17 (-1.44;1.77)	na	-3.12* (-4.26;-1.99)	na	-2.16 (-5.49;1.17)
Work characteristics:						
Work ability (0-10) (mean, 95%CI)	-1.89 (-0.43;0.05)	-0.18 (-0.45;0.09)	-0.02 (-0.20;0.16)	-0.11 (-0.35;0.13)	0.08 (-0.19;0.36)	-0.01 (-0.47;0.46)
Sickness absence (%)						
≥10 days	2.4	10.9*	-1.4	-1.5	-1.6 (-7.0;5.2)	-7.2 (-15.5;1.2)
Productivity loss (mean%, 95%CI)	1.84* (1.15;2.53)	2.31* (1.56;3.07)	1.46* (1.00;1.93)	1.47* (0.94;2.00)	-0.17 (-1.07;0.73)	-0.44 (-1.80;0.92)
Health risk behaviour:						
Lack of physical activity (%)	-58.6*	-53.6*	-49.2*	-50.3*	-6.5 (-14.6;5.2)	-5.6 (-14.2;5.0)
Smoking (%)	-4.6	-3.2	-2.3	0	10.5 (2.4;15.5)	8.6 (-0.1;15.7)
Excessive alcohol use (%)	-5.2	-11.1*	-5.1*	-9.4*	2.0 (-2.1;6.9)	0.0 (-2.1;6.9)

[1] Unadjusted

[2] Difference calculated with a mixed effects model and adjusted for age, gender, education, cluster and, in case of continuous outcome measures, also for baseline values.

na, 'not applicable'.

ref, reference

SD, standard deviation

*P<0.05

ences between OPs in both intervention groups in years affiliated with the organisation (mean 11.9, range 0.5 to 45.0) and working hours per week (mean 36.7, range 32.0 to 40.0). None of the OPs in the limited group had ever been MI-trained.

Table 2 shows the changes in health, work performance, and health behaviours during the study, and the effectiveness of the intervention. The proportion of subjects in 'less than good health' remained stable over time in the extensive group, but increased slightly in the limited group. Compared to baseline, BMI decreased significantly by 0.69 kg/m^2 (3.1 kg body weight) in the extensive group and remained stable in the limited group, resulting in a beneficial effect of 0.81 kg/m^2 (2.16 kg) reduction in the extensive group compared to the limited group. However, after adjustment for age, gender and education this difference became insignificant. A reduction of 7.2% points in long-term sickness absence after 12 months and 1.6% points after 6 months was found in the extensive group, although not statistically significant. The proportion of individuals meeting the physical activity guidelines increased by more than 50% in both groups. Alcohol consumption was equally reduced by 10% after 12 months in both groups. In both groups the prevalence of smoking reduced somewhat. There with no significant effect-differences in health behaviours between the groups.

The extensive group attended 4 MI-sessions on average (SD 2.41) with a total mean duration of 104 minutes (SD 64.8). The analysis on delivery of the intervention showed that, on average, the level of received MI was 3.5 for empathy (SD 0.54) and 83.7% was delivered at sufficient MI-adherence (SD 10.25).

DISCUSSION

The results of this study show additional beneficial effects and sustainability of weight loss by adding MI-coaching to a web-based HRA among employees at increased CVD-risk in the military workforce, the police organisation and an academic hospital. In the extensive intervention group BMI and body weight reduced considerably. Both in the extensive and limited intervention group the proportion of subjects who engaged sufficiently in physical activity increased sharply and excessive alcohol use declined.

The additional reduction of 0.81 kg/m^2 in BMI (3.1 kg or 3.2% body weight loss) by the extensive intervention group compared to the limited group is high compared to other CVD-risk reducing interventions. Beishuizen et al (35) showed in a meta-analysis of 47 studies a mean reduction in body weight of 1.3 kg in web-based interventions in individuals older than 50 years and at increased risk for CVD. While MI was associated with a significant reduction in body weight of 1.5 kg in overweight and obese individuals(36), no effect of MI on BMI was found in a pooled analysis of 3 studies that included individuals at increased CVD risk (12). Nevertheless, the effects on body weight found in our trial

are even more pronounced than the 1.8 kg difference between intervention groups in Groeneveld's study (37), which was most similar to ours in terms of target population and intervention. Our study differed in that a web-based HRA with personalised and tailored feedback was provided and used as starting point for counselling instead of just a cardioscreening. The substantial reduction in BMI could be due to targeting multiple health behaviours, which was found to be more effective than focussing on just one component(38). Although it has been shown that effects are more pronounced in studies with shorter follow-up time (35), both Groeneveld et al (37) and our study also showed reductions in BMI after 12 months.

In contrast to the effects on BMI and body weight, the effects on productivity loss, smoking and physical activity in our study are harder to interpret. In contrast to previous studies reporting that risky behaviour was associated with increased productivity loss at work (39), our study showed an increased productivity loss at follow-up, while health behaviour improved. This increase of productivity loss may be related to major national reorganisations in both the police and the military during the study period, with consequent work-related stress leading to productivity loss (40). Our results on smoking cessation following a workplace intervention are in line with other studies (41). We observed a smaller effect in the extensive compared to the limited group, which is in contrast to abundant evidence by others (42, 43). Since previous research has shown that smoking is better targeted as the primary or only outcome instead of being integrated in a program targeting multiple risk factors (41), this most likely explains our results. The sharp increase in the proportion of subjects meeting the Dutch guideline for physical activity cannot be attributed to the motivational interviewing, given that physical activity improved in both groups. Nevertheless, the HRA result may have acted as a warning signal that subjects needed to improve rapidly in particular in the military and police where a good physical condition is a prerequisite for the job. This may also explain the strong decrease in excessive alcohol use in both intervention groups.

There are several possible reasons why the intervention showed a statistically significant effect on BMI compared to baseline in the extensive group but no statistically significant differences on other outcomes. Several issues may have reduced the beneficial effects of the extensive intervention, such as methodological issues, insufficient delivery of the intervention, or ineffectiveness for certain outcomes. The methodological limitation is linked to our cluster design with large cluster-size differences (ranging 1-124), which may have caused under-powering of the study. A linked issue is that a cluster RCT is sensitive to allocation bias, as was indeed present as illustrated by the disbalance in age, gender, and education at baseline between the extensive and limited intervention groups. Adjustment for these factors led to the lack of precision in the estimated effect of the extensive intervention group compared to the limited intervention group. Concerning the delivery of MI, both quantity and quality as provided by OPs need to

be considered. Since the prescribed dose of 7 MI-sessions was not met by 75% of the individuals, whereas BMI decreased statistically significantly, this may suggest that the optimum MI-dose is lower than 7 or, alternatively, that this is determined by personal needs rather than one-size-fits-all. This is in line with the inconclusiveness in previous publications on the optimal dose restricted to individuals at risk or diagnosed with CVD (11), creating the need for future research focusing on what is the optimal dosage for whom. The quality of MI in this study appeared fairly low according to the MITI thresholds (34), with an insufficient level of MI-adherence and empathy at beginner's level. Since the awareness of the quality of MI as a factor in effectiveness of MI has grown (44), a more detailed exploration of MI-fidelity is needed (33, 44).

A potential limitation is that the intervention has failed to target individuals who needed it most, based on low work ability and high productivity loss at work. However, the average response rate of 77.8% in this study was high compared to 33% in other studies (45). A second limitation is that this study lacked a third arm including a non-intervention-group. Although this means that changes in the intervention groups are not necessarily a result of the HRA, there is sufficient evidence that a purely web-based HRA impacts health and work at least in the short-term (6-9). A third limitation is that our intervention was confined to targeting the individual and did not include the individuals' environment and job-specific risks. Individual health behaviour change is mediated by a multitude of factors (46), including a more job-specific approach (47) and involving multiple levels of the workplace such as management and colleagues (48), could improve the individual's work and health outcomes.

Strengths of our study are the performance in a real-life setting, the assessment of the additional effect of supplementing a web-based HRA with tailored advice and face-to-face coaching on both clinical and societal outcomes, and the assessment of sustainability by prolonged follow-up. Many interventions are effective in controlled research settings, but to achieve scaling-up such interventions they must be embedded within multiple sectors (49). Since our study was performed in a real-life setting, in a multi-center approach in different sectors, and by the OPs who are working in these organisations, our findings may be generalisable to other organisations and applied in future implementation.

Supplementary file 2. Characteristics of non-responders at 6 or 12 months follow-up (n=109).

Baseline characteristics:	**Responded at follow-up** n= 382 (77.8%)	**Did not respond at follow-up** n=109 (22.2%)
Intervention-group		
Limited	**155 (71.4)**	**62 (28.6)**
Extensive	**227 (82.8)**	**47 (17.2)**
Organisation		
Military	202 (77.1)	60 (22.9)
Police	137 (80.6)	33 (19.4)
Hospital	43 (72.9)	16 (27.1)
Individual characteristics:		
Age, years (mean, SD)	50.84 (5.50)	50.74 (6.33)
Gender (n,%):		
Male	311 (77.9)	88 (22.1)
Female	71 (77.2)	21 (22.8)
Level of education (n,%):		
Low	51 (76.1)	16 (23.9)
Medium	208 (81.3)	48 (18.8)
High	108 (84.4)	20 (15.6)
Health characteristics:		
Self-rated general health:		
Less than good	70 (77.8)	20 (22.2)
Body mass index (kg/m2)(mean, SD)	27.2 (3.6)	27.2 (3.0)
Work characteristics:		
Working hours per week (mean, SD)	37.4 (5.8)	36.3 (5.5)
Work ability (mean, SD)	**8.0 (1.4)**	**7.5 (1.9)**
Sickness absence		
0 days	187 (87.0)	28 (13.0)
1-9 days	141 (79.2)	37 (20.8)
≥10 days	36 (80.0)	9 (20.0)
Productivity loss at work (%, SD)	**2.7 (3.3)**	**4.2 (4.3)**
Health risk behaviour[1,] n (%)**:**		
Lack of physical activity	261 (81.3)	60 (18.7)
Unhealthy diet[2]	352 (82.8)	73 (17.2)
Smoking	62 (74.7)	21 (25.3)
Excessive alcohol use[3]	51 (87.9)	7 (12.1)
High stress level[4]	141 (85.5)	24 (14.5)
Intervention-group only: Characteristics of the intervention		
MI-sessions (mean, SD)	**4.5 (2.2)**	**1.4 (1.6)**
≥4 MI-sessions (n,%)	**150 (96.8)**	**5 (3.2)**
Duration (mins) (mean, SD)	**117.7 (60.2)**	**41.1 (45.4)**

Supplementary file 2. Characteristics of non-responders at 6 or 12 months follow-up (n=109). (continued)

Baseline characteristics:	**Responded at follow-up** n= 382 (77.8%)	**Did not respond at follow-up** n=109 (22.2%)
Empathy (1-5)(mean, SD)	3.5 (0.52)	3.6 (0.62)
MI-adherence (%)	83.7 (9.7)	83.9 (12.7)

[1]Defined as no adherence to Dutch guidelines at baseline.
[2]Unhealthy diet is defined as eating less than 200 g vegetables per day , and eating less than 2 pieces of fruit per day
[3]Meeting the alcohol guideline, which is not drinking more than 1 (women) or 2(men) glasses of alcohol a day
[4]High stress level is defined as several periods or permanent stress at work or at home or severe financial stress or 2 or more life events (Ref. Lancet 2004 Rosengren).
BMI: body mass index
SD: standard deviation
Numbers in bold are statistically significant with a $p<0.05$

CONCLUSIONS

Adding personalised coaching to a web-based HRA in a 'blended care'-approach increases its effectiveness by reducing BMI and body weight in employees at increased CVD risk. These findings have implications for preventive strategies in clinical occupational practice to promote sustainable employability. Future research may be aimed towards personalised prediction modelling to determine in advance who optimally benefits from just a web-based HRA and who needs additional coaching, and towards including the working environment, aiming for both effective and efficient implementation.

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Chapter 5

Quality of motivational interviewing matters: the effect on participation in health promotion activities in a cluster randomised trial.

Tessa A. Kouwenhoven-Pasmooij[a,b,c], Suzan Robroek[b], Daan Nieboer[b], Pieter H. Helmhout[d], Machteld F. Wery[a], M.G. Myriam Hunink[a,e,f], Alex Burdorf[b]

Submitted

ABSTRACT

Background

Health promotion interventions at the workplace have the potential to promote health and work productivity. However, the overall effects are often small, which could be due to suboptimal delivery of the intervention. Therefore, defining key-components of health promotion interventions is beneficial for future implementation strategies.

Methods

Within a cluster randomised trial, 491 employees at increased risk of cardiovascular disease were allocated to the limited (n=217; 9 clusters) or extensive (n=274; 8 clusters) intervention. The extensive intervention consisted of Motivational Interviewing (MI) within the framework of a web-based Health Risk Assessment (HRA), a blended care approach. The limited intervention received solely the web-based HRA. The intervention was delivered by 21 occupational health physicians within 3 organisations. The following components of implementation were investigated: reach of web-based HRA, participation in HRA, reading newsletters, number of MI-sessions, and quality of MI-sessions. MI-quality was determined by scoring audiotaped MI-sessions, using the Motivational Interviewing Treatment Integrity (MITI) code. At 6- and 12-months follow-up, effects on participation in health promotion activities and its associations with components of implementation were determined by mixed effects models.

Results

Reach was 12% at the employee level. In total, 88% of participants completed the HRA, and 57% participated in at least 4 MI-sessions. MI-quality was at least beginner's level. Over 80% of employees participated in health promotion activities, with an additional participation of 8% in the extensive compared to the limited group. In the extensive intervention, those with more MI sessions and with MI sessions of better quality were more likely to participate in health promotion activities. Increased MI-quality was associated with sustained participation.

Conclusions

Quality of intervention implementation of workplace health promotion affects participation in health promotion activities. Interventions with MI should include optimising delivery and quality of MI-sessions.

Registered at the Netherlands Trial Registry with number NTR4894. Retrospectively registered Nov 14, 2014.

BACKGROUND

Workplace health promotion (WHP) has the potential to decrease cardiovascular (CVD) risk [1-3], and has shown positive, but small, effects on productivity at work, sickness absence, and work ability [4]. A systematic review demonstrated that the effectiveness of a workplace health promotion program depends on the study population, the intervention content, and the methodologic quality of a study [4]. However, little is known regarding the influence of the quality of implementation on the effectiveness.

Several studies have reported serious problems with the actual implementation of WHP. Recurring problems are low participation [5], high attrition [6], and large diversity in the quantity and quality of the delivered intervention [7]. A thorough evaluation of the quality of implementation alongside an effect evaluation is recommended [8-10], enabling optimisation of the intervention for increasing effectiveness and for broader implementation across settings.

The PerfectFit intervention study investigated motivational interviewing (MI) supplementing a web-based Health Risk Assessment (HRA) among older workers (40+) with an increased CVD risk, a so-called blended care approach [11]. The HRA included tailored and personalised feedback based on the participant's risk profile. MI allows a more patient-centred approach, focusing both on specific behaviour changes and on the most preferred action by the individual [12]. A limited intervention group received solely the web-based HRA. Within the framework of this cluster randomised trial (cluster RCT), a detailed evaluation of both participation in health promotion activities and the implementation was possible.

So far literature on the required number of MI-sessions and the duration of MI has been indecisive [13]. A previous study showed that a higher frequency of MI sessions was associated with a more advanced stage of change in individuals at increased CVD risk [14]. Several reviews suggest that MI-quality, i.e. compliance to MI principles, is an important factor in the management of health behaviour such as weight loss [15], physical activity [16], or alcohol usage [17]. Nonetheless, MI-quality appears to be either rarely measured [18] or is not investigated in relation to primary health behaviour outcomes. High empathy and MI adherent behaviour were suggested to be predictive for behaviour change in addiction treatment [19-21], but none of the MI-elements were previously related to any health outcome in a randomised setting. This lack of insight in the working mechanism of MI hampers optimisation of intervention delivery and effectiveness.

Therefore, the current study addressed the quality of implementation and its influence on health behaviour. The PerfectFit study objectively measured components of quality of implementation, i.e. reach, quantity of implementation, and quality of MI, as well as the effects on participation in health promotion activities. The aims of the current study were to determine the quality of implementation of a workplace health promo-

tion intervention, and to evaluate its influence on employees' participation in health promotion activities.

METHODS

Design

An extensive description of the PerfectFit study design was previously published [11]. In this multicenter cluster RCT, 18 military bases, regional police forces, and hospital wards were equally randomised as 'clusters' to the intervention and control arm of the study. Individuals from these units were allocated by the occupational physician (OP) based on having at least one risk factor for CVD at the cardiovascular risk profiling, the so-called "cardioscreening". The trial consisted of two intervention groups: 1) limited intervention group, who received a tailored and web-based health risk assessment (HRA) with personalised feedback, and 2) extensive intervention group, who additionally received counselling sessions using MI by the OP. Follow-up measures were taken by online questionnaires at 6 and 12 months after baseline, and a cardioscreening at the health center at 12 months. Participation in health promotion activities was measured, since this is positively related to health behaviours [22]. A standardised form with results of each MI-session and cardioscreening was sent to the principal investigator (PI). The CONSORT extension for cluster trials was used to report on performance of the study [23] (Additional file 1, not printed in thesis).

A PerfectFit flyer was custom-made for each organisation. The flyer was handed to employees during the cardioscreening. Only for military employees, it was mandatory to attend this screening every three years. Information on PerfectFit was also published on the intranet, and sent in a memo to managers of each cluster. Participation in the study was voluntary and free of charge. The initiation of recruitment differed between clusters and started between 2012 and 2014. Follow-up was completed by September 2015.

The Medical Ethics Committee of Erasmus MC Rotterdam (METC) approved the study with number MEC-2012-459. The study was registered in the Netherlands Trial Registry with number NTR4894. Additional approval was obtained for participation of hospital wards.

Sample

Since one cluster dropped out prior to any inclusion of employees, analyses were conducted for 17 clusters of employees. The reason for drop out was other priorities in work for the OP. The target population consisted of employees aged 40 years and older at increased CVD risk, either working the military, for the police force, or at an academic hospital. Prior calculations estimated eligibility of 5,444 employees. A total of 652 indi-

viduals (12%) were screened, of whom 598 (91.7%) had at least one CVD risk factor, and 491 (82.1%) could be included in the study, based on having at least one CVD risk factor, i.e. smoking, obesity, hypertension, dyslipidaemia, diabetes, physical inactivity, or CVD in first degree relative, and having no exclusion criteria, i.e. manifest CVD, a terminal illness, or a history of psychosis. Screening took place at the in-company occupational health centres.

Intervention

The extensive intervention consisted of three face-to-face and four telephone sessions with an OP, in addition to a web-based HRA that was administered in both intervention groups. Counseling was performed using the principles for MI, and focused on the personal medical profile and preferences for change of each individual, in order to achieve long-term healthy behaviour. An online newsletter with general information on PerfectFit and healthy ageing, including a section on motivational aspects (only for the extensive group), was sent every three months to all participants and OPs.

Both interventions were performed by 21 OPs including one general practitioner (military), of whom 12 (57.1%) men, and who had been employed for 11.9 years on average, ranging from six months to 45 years. Prior to any inclusions, the ten OPs assigned to the extensive intervention received three full days of training by a certified trainer. During the intervention period, they additionally received three follow-up coaching sessions of four hours each. This was taught by the PI, who was trained by the same trainer with an extra three days module on scoring MI according to the Motivational Interviewing Treatment Integrity method (MITI), version 3.1.1. [26]. For the hospital, the first MI-sessions were performed by the OP, and follow-up MI-sessions by a lifestyle coach with extensive experience in using MI.

Measures

Quality measures were components of intervention implementation, i.e. reach of web-based HRA, participation in HRA, reading newsletters, number of MI-sessions, and quality of MI-sessions. Effect measures were participation in health promotion activities and stages of change in health behaviour.

***Quality of intervention implementation* (table 1)**

1. Reach of web-based HRA

Reach was determined at individual level. Based on other studies, it was expected that 57% of the individuals would meet the eligibility criteria [24]. Enrolment, and allocation of individuals were based on the baseline cardioscreening profiles.

2. Quantity of the intervention

Quantity aspects of the intervention were assessed on three intervention components:

- *Web-based HRA:* All included participants were personally handed an invitational letter by the OP to log-on and complete a web-based HRA. The HRA was considered 'completed' if a personalised report including suggestions of choice of health promotion activities was generated, which meant that the participant logged on to the system, registered to the system, and filled out all items of the HRA.
- *Newsletters read:* The proportion of participants who read the online newsletters was measured electronically by at least opening the newsletters [25].
- *MI-sessions:* Information on the type of contact (face-to-face or by phone) and the duration of the session was retrieved from the MI-forms sent by OPs to the PI after each session.

3. Quality of MI

To evaluate the overall quality of MI, aggregated scores of 35 double-coded audio-recorded MI-sessions were used, ranging from 1 to 4 recordings per OP. The OPs and the lifestyle coach in the extensive group were asked to record the first session of every third month and send this to the PI. The entire sessions were transcribed verbatim and coded independently by two coders using the validated MITI version 3.1.1. [26]. Coders were the PI (TK) and a co-investigator (MW), both experienced in MI-coaching and -coding. To avoid inter-coder interpretation differences, the coders discussed their respective ratings of three recordings [19].

Of the 38 recordings received, three recordings were excluded for technical problems. Coding focused on behaviour counts and global scores, both considered core-elements of MI. Behaviour counts were based on the assignment of every OP's utterance to one of three primary behaviour codes: 1) MI statements; 2) questions; 3) reflections. Within these categories, a sub-classification was made into: adherence to MI (yes/no), open or closed question, and simple or complex reflection. Summary scores on behaviour counts were calculated presenting the percentage open questions, complex reflections, MI adherence, and a reflection to question ratio. Global scores were given on a five-point Likert scale (1 to 5), with a higher score indicating better MI skills. Five global dimensions were rated: evocation, collaboration, autonomy/support, direction, and empathy. Calculated summary scores present 'MI-spirit' (evocation + collaboration + autonomy/support), and a mean global score (global dimensions / 5). The interrater-reliability (IRR) between coders of summary scores was fair to excellent (IRR ranging from 0.51 to 0.75) [19], except for the global scores 'empathy', 'spirit', and 'mean global' (IRR<0.40, classified as poor) (Additional file 2). Therefore, consistent with Jelsma et al, aggregated scores of both coders were calculated and used in further analyses [19].

According to the MITI code, a clinician's competence level can be classified as beginner's or advanced level based on: percentage open questions (≥50% or ≥70%), percentage complex reflections (≥40% or ≥50%), percentage MI adherent (≥90% or ≥100%), reflection to question ratio (≥1 or ≥2), and a mean global score (≥3.5 or ≥4).

Table 1. Quality of intervention implementation: Components, measurements, levels, and description of data sources.

Components:	Measurements	Levels	Data sources	n(%)
Reach of web-based HRA	Potentially eligible	Individual	Organisations	5444
	Uptake of cardiovascular risk profiling "cardioscreening"	Individual	Cardioscreening at baseline	650 (11.9)
	Eligible to participate based on at least one risk factor for CVD	Individual	Cardioscreening at baseline	596 (91.7)
	Number allocated after cardioscreening & to whom HRA was offered:	Individual	Consent forms	491 (82.4)
	· Limited intervention group			217 (44.2)
	· Extensive intervention group			274 (55.8)
Quantity of the intervention	HRA:			
	· Number who fully completed the HRA	Individual	HRA-registration	432 (88.0)
	Newsletters:			
	· Number of newsletters sent	Individual	Newsletter-software	7.3 (range 4 – 10)
	· Number of newsletters read	Individual	Newsletter-software	60% (range 55-67%)
	MI-sessions[1]:			
	· Number of individuals who were offered MI-sessions	Individual	Study-protocol	274
	· Number of sessions offered per individual:			
	Face-to-face			4
	Telephone			3
	· Mean number of MI-sessions received	Individual	MI-forms	3.97 (56.7)
	· Duration of consultation received per individual (minutes)	Individual	MI-forms	103.9
	· Total number of MI-sessions delivered	OP	MI-forms	1089
Quality of MI[1]: MI-Fidelity	Number of audiorecorded MI-sessions per OP	OP	MITI-scoring of audiofragments	3.5 (range 2-6)
	Total consultation-time scored per OP (minutes)	OP	MI-forms	78 (range 45-161)
	MI-quality based on MITI	OP	MITI-scoring of audiofragments	Table 2

[1]Extensive intervention only

OP Occupational health physician; MI motivational interviewing; MITI motivational interviewing treatment integrity score; HRA health risk assessment CVD cardiovascular diseases

Table 2. Quality of intervention implementation among individuals of participating organisations.

Components:	Measurements:	Total	Police	Military	Hospital
Reach	Allocated to intervention groups after cardioscreening (n, %)	491	262 (89.7)	170 (71.1)	59 (90.8)
Quantity (dose received)	HRA fully completed (n, %)	432 (88.0)	152 (89.4)	229 (87.4)	51 (86.4)
	Newsletters read (%, SD)	60.44 (5.06)	66.44* (0.54)	58.76* (2.39)	56.13* (1.15)
	Applicable to extensive intervention group only (n, %)	274	110 (40.1)	138 (50.4)	26 (9.5)
	MI-sessions:[1] (mean, SD)				
	· Total consultation length (mins)	103.9 (64.8)	125.8* (63.0)	95.9* (62.2)	59.2* (53.3)
	· Face-to-face sessions	2.49 (1.58)	2.65* (1.28)	2.57* (1.80)	1.38* (1.02)
	· Telephone sessions	1.46 (1.53)	2.35* (1.58)	0.95* (1.22)	0.42* (0.64)
	· At least 4 MI sessions (n, %)	155 (56.6)	80* (72.7)	71* (51.4)	4* (15.4)
Quality of MI[1] (mean, SD):	Behaviour counts:				
	· Open questions (%)	40.72 (13.09)	50.25* (9.53)	31.07* (9.04)	30.99* (2.54)
	· Reflections versus questions	1.18 (0.60)	1.17* (0.60)	0.94* (0.41)	2.18* (0.35)
	· Complex reflections (%)	69.02 (13.18)	73.35* (13.63)	69.34* (4.40)	44.61* (8.36)
	· MI adherent statements (%)	83.69 (10.25)	82.52* (11.93)	83.99* (8.32)	88.70* (5.60)
	Global scores:				
	· Empathy-score (1-5)	3.50 (0.54)	3.50* (0.36)	3.58* (0.69)	3.09* (0.41)
	· Direction (1-5)	4.40 (0.54)	4.61* (0.52)	4.16* (0.52)	4.32* (0.15)
	· MI-spirit (1-5)	3.60 (0.50)	3.77* (0.45)	3.43* (0.53)	3.42* (0.27)
	· Mean global score (1-5)	3.75 (0.42)	3.88* (0.42)	3.64* (0.42)	3.53* (0.21)

*Significant differences between groups ($p<0.05$)

[1]Extensive intervention only, based on aggregated scores of both coders.

Effect measures:

1. Participation in health promotion activities

Self-reported participation in health promotion activities was asked after 6 and 12 months: 'In the past 6 months, did you start a health promotion activity, such as….' Answering options were: take up physical activity, improve diet, quit smoking, reduce alcohol consumption, reduce stress, improve working situation, participate in other health promotion activities, or no participation. For our analyses, 'reducing stress' and 'improving work situation' were combined into one category, because of low frequencies. Participation in 'at least one health promotion activity', was considered positive if at least one answering option was ticked, with the exception of 'no participation'.

2. Stage of change in health behaviour

The actual stage of change in the targeted health behaviour of the individual was reported by the OP by ticking one out of five boxes on the MI-form after each session: pre-contemplation, contemplation, preparation, action, maintenance (according to the transtheoretical model by Prochaska & Di Clemente) [27].

ANALYSES

Descriptive statistics were used to generate frequencies and percentages for dichotomous and categorical variables, and to generate means and standard deviations for continuous variables. To test the differences between groups, Chi-Square tests and ANOVA-tests were performed.

The effects of the intervention after 6 and 12 months on the uptake of health promotion activities (Table 3) was evaluated using mixed effects models with the intervention as fixed effect. All mixed effects models were adjusted for cluster, gender, age and education, and included the baseline value of the measure of interest. The intra-cluster correlation values to evaluate the within cluster variation were 0.08 at the highest, implying that the clustering had little effect on the results. An additional analysis was conducted to assess whether quantity and quality of MI were associated with at least one health promotion activity during the trial period (Table 4).

Inter-rater reliability scores were calculated by intra-class correlation coefficients (ICC), using a two-way mixed model with absolute agreement (Additional file 2). Since these were neither good nor excellent according to the benchmark values [19] (ICC empathy 0.28; 95%CI -0.05;0.56 and MI-adherence 0.51; 95%CI 0.22;0.72), aggregated scores of both coders were used in the analyses.

Missing values were imputed 5 times using multiple imputation and results from the imputed datasets were pooled using Rubin rules. Data were analysed using SPSS Statistics version 21. For the mixed effects model, we used the R package lme4.

Table 3. Participation in health promotion activities at follow-up, with sub-analysis on the activity of choice.

	Limited intervention n (%)		**Extensive intervention n (%)**		**Estimated effect (difference)[2,3] % (95% CI)**	
Participation in health promotion activities[1]	**6 months**	**12 months**	**6 months**	**12 months**	**6 months**	**12 months**
At least one health promotion activity	112 (86.2)	104 (83.2)	213 (94.7)	181 (91.0)	8.3% (-1.4%; 14.4%)	8.2% (-4.1%; 17.6%)
More physical activity	95 (73.1)	89 (71.2)	176 (78.2)	165 (82.9)	0.8% (-10.2%;9.3%)	9.5% (-6.7%;15.6%)
Improve diet	61 (46.9)	67 (53.6)	142 (63.1)	137 (68.8)	13.5%* (0.1%;28.4%)	13.8%* (0.5%;25.7%)
Smoking cessation	6 (4.6)	3 (2.4)	14 (6.2)	14 (7.0)	-0.4% (-6.5%;3.9%)	4.2% (-0.1%;8.6%)
Reduce alcohol intake	17 (13.1)	18 (14.4)	37 (16.4)	31 (15.6)	2.2% (-10.0%;7.9%)	2.0% (-10.7%;8.8%)
Reduce (work) stress	31 (23.8)	23 (18.4)	55 (24.4)	40 (20.1)	-1.9% (-13.7%;5.6%)	0.0% (-5.6%;14.3%)
Other health promotion activity	7 (5.4)	0	10 (4.4)	4 (2.0)	-1.0% (-2.0%;1.0%)	3.0% (0.0%;3.4%)

[1]Dependent variables [2]Adjusted for age, gender, level of education, clustering, and also adjusted for baseline health risk behaviour

[3]The estimated effect is the difference between the extensive intervention vs. the limited intervention. For example, the positive difference for improving diet implies that the extensive intervention had a greater effect in improving diet.

*Significant differences between groups ($p<0.05$)

Table 4. The association between MI and participation in at least one health activity at follow-up.

		OR[1,2]; 95%CI	
		6 months n=225 (82.1%)	12 months n=199(72.6%)
Organisation			
	Hospital	Ref	Ref
	Military	7.63 (0.96, 8.65)	2.56 (0.45, 2.05)
	Police	1.61* (1.42, 13.54)	0.43 (0.54, 3.15)
MI-intervention characteristics[3]:			
Quantity of MI-sessions:			
	Total consultation length (mins) (mean, SD)	1.01* (1.00, 1.03)	1.00 (0.99, 1.01)
	Face-to-face sessions (mean, SD)	1.58 (0.92, 2.71)	0.91 (0.60, 1.38)
	Telephone sessions (mean, SD)	1.38 (0.80, 2.39)	0.91 (0.62, 1.32)
	At least 4 MI sessions	1.58 (0.92, 2.71)	0.90 (0.60, 1.37)
Quality of MI:			
	Behaviour counts:		
	Open questions (per 10%)	1.60* (1.00, 2.20)	1.50* (1.00, 2.00)
	Reflections versus questions	0.45 (0.15, 1.30)	0.66 (0.26, 1.65)
	Complex reflections (%)	1.02 (0.97, 1.08)	1.02 (0.98, 1.06)
	MI adherent statements (%)	0.99 (0.92, 1.08)	1.00 (0.94, 1.06)
	Global scores (mean, SD):		
	Empathy-score (1-5)	1.48 (0.35, 6.16)	1.59 (0.49, 5.22)
	Direction (1-5)	2.34 (0.56, 9.80)	3.25* (1.07, 9.88)
	MI-spirit (1-5)	1.84 (0.42, 8.00)	2.24 (0.76, 6.56)
	Mean global score (1-5)	2.04 (0.38, 10.87)	2.54 (0.75, 8.57)

Ref = reference group

[1]Adjusted for age, sex, education, clustering. [2]Odds ratios (OR) higher than one indicate greater uptake of health activity in the group with the baseline determinant.

[3]extensive intervention group only

*Significant differences between groups ($p<0.05$)

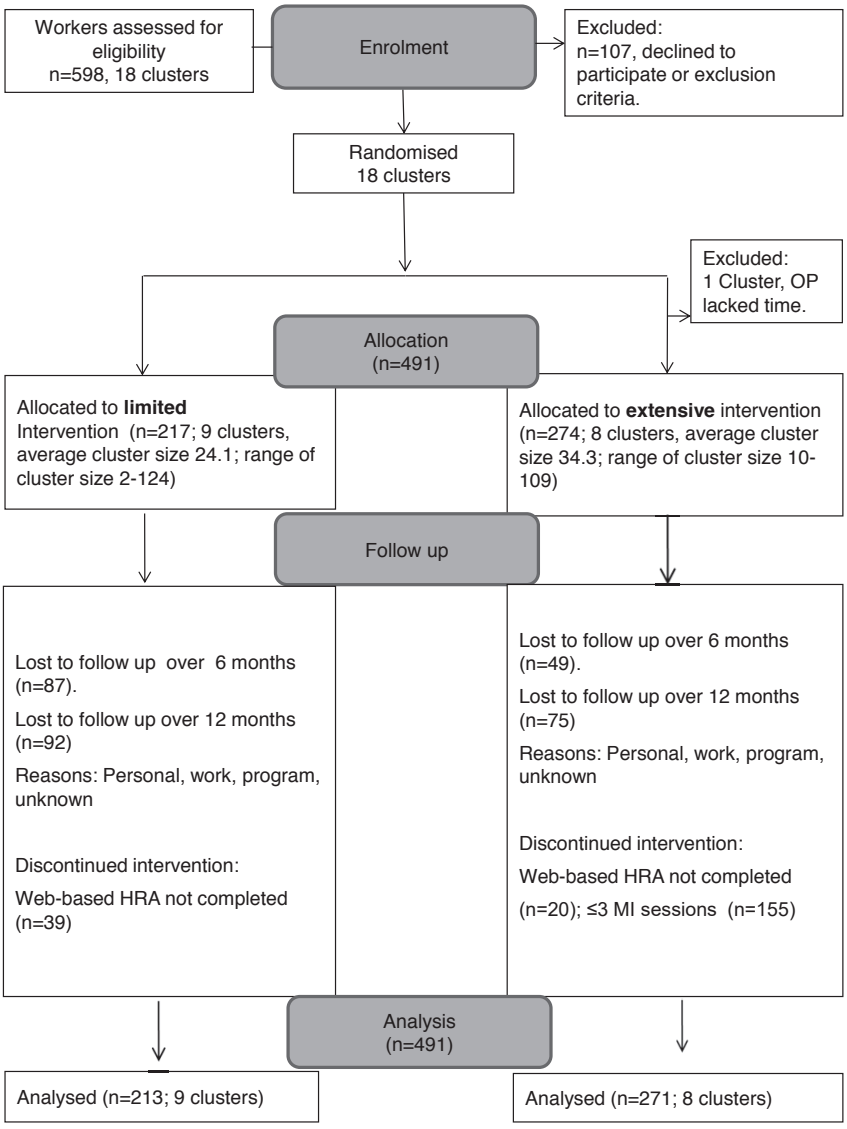
RESULTS

Figure 1 shows a total of 491 individuals (18 clusters) who were included, of whom 217 (within 9 clusters) were allocated to the limited intervention and 274 (within 8 clusters) to the extensive intervention group. Response to follow-up questionnaires was 355 (72.3%) at 6 months and 324 (66.0%) at 12 months.

Table 1 provides an overview of the components of implementation. The overall uptake of the cardioscreening was 12%. Of those who were eligible, 82% could be allocated to either intervention-group. Once included in the study, 88% fully completed the HRA, on average 60% of the newsletters was read, and on average four MI-sessions were attended (extensive group only).

Table 2 shows differences between organisations in all components of the implementation. The uptake of cardioscreening differed between organisations: military 12%, police 13%, and hospital 34% (not shown), as well as the numbers of employees allocated to the study, from 71% for the military to 90% for police and hospital. Overall, newsletters were read most frequently in the police force. At least 4 MI-sessions were received by 15%

Figure 1. CONSORT flow chart of clusters and participants within the trial.



in the hospital, 51% in the military, and by 73% of the police force. MI was performed at least at beginner's level of competence for all scored items, except for open questions and MI statements. MI-quality differed between OPs and between organisations. Analyses of variances on the behaviour counts in the evaluation of the quality of MI delivered showed up to 66% of the variance originated within OPs, which could not be explained by changes over time (table not shown). Analyses of variances in global scores showed the variance originated up to 44% within OPs, and up to 56% between OPs.

Table 3 presents 8% higher participation in health promotion activities (at least one activity) in the extensive intervention group compared to the limited group, at both 6 months and 12 months follow-up. In total, more than 80% participated in at least one health activity. The extensive group showed 13.8% more participation in improving diet activities (statistically significant), and 9.5% more in physical activities than the limited group at 12 months, albeit non-significant. In addition, they showed a near significant higher participation in activities for smoking cessation (4.2%) and other activities (3%), and no differences in stress-reduction activities, in the extensive compared to the limited group.

Table 4 displays the association between quantity and quality of MI and participation in health promotion activities. A longer duration of MI (OR 1.01, 95%CI 1.00;1.03) was associated with increased participation in health activities after 6 months, explaining more participation in activities by the police than by other organisations. However, the strength of this association was absent after 12 months (OR 1.00, 95%CI 0.99, 1.01). More open questions in the MI-sessions was associated with increase participation in activities (OR 1.60, 95%CI 1.00;2.20), which remained after 12 months, albeit non-significant. For all global scores a positive association with participation in activities was found, with "direction" having the strongest association, especially after 12 months (OR 3.25, 95%CI 1.07;9.88).

Figure 2 shows that after two MI-sessions 63% of the participants in the extensive group was at least in the action phase, i.e. stage 4 or 5 of the stage of change model.

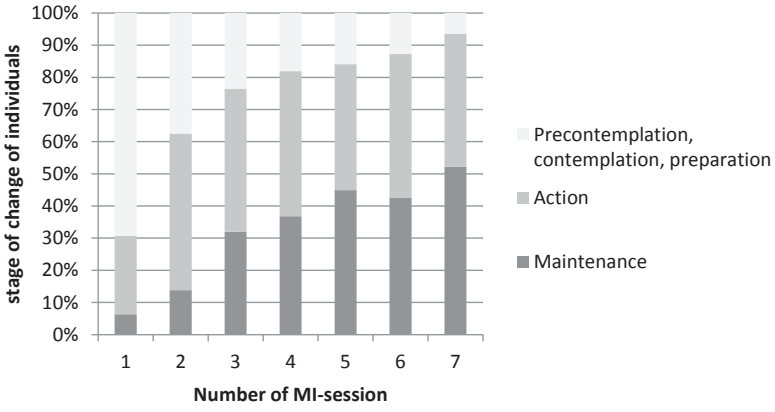


Figure 2. Stage of change during MI sessions

DISCUSSION

The reach of the intervention was limited, but the majority of initial participants completed the HRA, and opened the newsletters regularly. There were large differences in the quality of the implementation between the participating organisations. A higher quantity and quality of MI was related to more participation in activities, and this effect sustained with a higher MI-quality. Over 80% of the participants participated in health promotion activities, with an additional 8% in the extensive intervention group at short and long-term follow-up, compared to the limited group.

Low overall uptake of the cardioscreening may be due to personal internal factors (perceived relevance and readiness to face screening outcomes) [28, 29]. Differences in reach between organisations are likely to be due to organisational factors, such as (a) concurrent reorganisations from regional into national forces (police), and cut downs (military), with insecurities about job positions; (b) lack of commitment for the cardioscreening by the management (military); and (c) more active role by human resources in health communication (hospital). A low grade of participation to the study in the military compared to the other organisations may be due to soldiers leaving for missions abroad. In future implementation, optimising communication and the organisational context would make more people benefit.

Although the HRA completion and newsletter reading were high, just 25% of the individuals received all seven protocoled MI-sessions. The participation in the HRA (88%) was much higher than the reported average of 32% in other studies [30]. Potential explanations are that participants with one or more CVD-risk factors were asked to participate [30], and the baseline cardioscreening acted as informed decision making, and thus created a feeling of personal relevance [31]. Receiving the number of MI-sessions according to the protocol appeared more difficult in the hospital than in the other organisations. It could be speculated that either physical fitness is more important to individuals who work in the military and police force due to a selection bias in job requirements, or that hospital employees are hesitant to visit a lifestyle coach instead of an OP. Overall, 43% attended less than four MI-sessions, which may have been due to busy calendars of OPs and of workers, or to perceived less added value of multiple sessions by OPs or workers. In line with Burkirk's review [32], who found as few as one MI-session to be effective in enhancing readiness to change and action directed towards reaching health behaviour-change goals, our study showed that the majority of individuals were in action or maintenance phase after just a few MI-sessions.

Over 80% of all participants participated in health activities, which was high compared to the 33% reported in a review [33]. Determinants for participation as shown by Rongen et al [34] are expected participation by colleagues and supervisors, and a positive attitude regarding the importance of WHP programs. Both are likely to have influenced

the high participation in health activities in this study. The additional 8% participation in the extensive group could have been due to the blended approach, which is in line with other studies reporting more pronounced effects if the web-based intervention was offered in combination with face-to-face support [35, 36].

More sessions of MI with better quality led to more participation in health promotion activities. This is in line with Lundahl et al [37]. In order to facilitate appropriate planning of MI-sessions, clients and OPs could introduce supportive eHealth technologies [38, 39]. However, for long-term participation in health activities, increased MI-quality appeared essential, which is in line with Fjeldsoe's suggestion that face-to-face contact may be a crucial factor in the period after initiation of behaviour change [40]. Particularly the MI-techniques "asking open questions" and "giving direction" enhanced participation in health activities. Barriers to asking more open-ended questions versus closed-ended questions could have been a gradual decrease of performance level after MI-training, a lack of skills or a lack of consultation-time. Changes in MI-performance over time were not found, most probably due to the introduced feedback on audio-recordings during the study period [41, 42]. Nevertheless, MI-quality could be increased by advanced training. This could also solve the perceived lack of time, since for advanced MI-coaches regular consultation time is sufficient for achieving behaviour change [43]. 'Giving direction' by influencing the direction of the session towards the target behaviour in an MI-adherent way was the strongest component in increasing the likelihood of changing health behaviour. Previous literature suggested that 'empathy' [21, 44], 'MI-adherence' [19], or 'MI spirit' [45] are the most promising mechanisms of MI, but these studies did not include 'giving direction' as therapist behaviour component [10]. Overcoming the differences between OPs in global scoring such as 'direction', would further increase the effectiveness. The variance for global scores showed differences between OPs in mastering global scoring, and the global level by OPs varied between clients. Detailed information on OP-characteristics in relation to level of mastery of the MI technique would be useful to optimise MI-training for OPs. Information on client evaluations of MI-performance by the OP would provide insight into the differences within OPs. Furthermore, the MITI-coding could have attributed to these differences, since reliability of coding for global scores was less than for behavioural counts, as was previously reported in another study [46]. Thus, coders should consider discussing global scores for agreement and include client's perception in rating MI, for example by using the Client Evaluation of Motivational Interviewing scale (CEMI) [47]. In future interventions, all aspects of MI-quality should be integrated and mastered, and applied in a feasible number of MI-sessions for achieving sustainable health behaviour changes. This would require introducing a personalised approach for the number of sessions prescribed, in combination with efforts to increase MI-quality.

Strengths of this study include the controlled design, objective measuring of both quality of the intervention implementation and effect measurements, and the adequate training for OPs. Analyses of intervention-details and of the behavioural components provided insight in which characteristics of the implementation process contribute to higher effectiveness of the WHP, and what could be addressed in future implementation. Another strength is that the implementation took place in a real-life setting, and was administered by OPs who were familiar with organisational aspects, such as culture, workplace health risks, and on-site options for health activities. This makes it easier to incorporate suggested intervention improvements, and other large organisations could benefit from these lessons learned by this study. A limitation of the study is the use of self-reported measures of participation in health promotion activities. The use of accelerometers and more objective dietary measures could have improved our understanding of behavioural changes associated with the intervention. However, this will require more time and effort of the individuals, which may lead to non-adherence with follow-up measurements. Another limitation is the risk of selection bias, since participants who received higher quantity of MI showed a higher response rate at follow-up, which was also found for "giving direction" (table not shown). However, since 78% responded to follow-up at 6 and/or 12 months, a fair picture of the intervention is expected. Last, the impact of organisational factors on individual health behaviour was not considered in this study.

CONCLUSIONS

This study showed that quality of intervention implementation matters with regard to participation in health promotion activities among individuals at increased cardiovascular risk. Aiming for optimal effectiveness, future implementation should focus on increased quality of MI by OPs.

Additional File 2. Quality of MI including intercoder-differences.

Scoring:	Item:	Aggregated ratings of both coders mean (SD)	Average rating by Coder 1 (mean, SD)	Average rating by Coder 2 (mean, SD)	Interrater-reliability (Intra-class correlation coefficient, 95% CI)
Behaviour counts:	Percentage open questions	34.90 (11.93)	33.42 (16.22)	36.37 (20.48)	0.71 (0.49, 0.84)
	Percentage complex reflections	63.92 (14.33)	65.77 (19.89)	62.06 (22.55)	0.75 (0.56, 0.87)
	Percentage MI adherent	84.16 (9.30)	85.21 (13.16)	83.12 (17.23)	0.51 (0.22, 0.72)
	Reflection to question ratio	1.43 (0.62)	1.35 (1.15)	1.50 (1.45)	0.69 (0.48, 0.83)
Global scores:	Empathy (1-5)	3.31 (0.60)	3.66 (0.87)	2.97 (1.15)	0.28 (-0.05, 0.56)
	Spirit (1-5)	3.44 (0.51)	3.76 (0.88)	3.12 (1.20)	0.34 (0.01, 0.60)
	Direction (1-5)	4.31 (0.47)	4.17 (0.98)	4.46 (0.92)	0.60 (0.34, 0.77)
	Mean global score	3.76 (2.83)	3.9 (0.7)	3.4 (0.9)	0.35 (0.03, 0.61)

[1]Global scores were given on a five-point Likert scale (1 – 5), with a higher score indicating better MI skills

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Chapter 6

A Blended Web-Based Gaming Intervention on Changes in Physical Activity for Overweight and Obese Employees: Influence and Usage in an Experimental Pilot Study

Tessa A Kouwenhoven-Pasmooij, Suzan JW Robroek, Sui Wai Ling, Joost van Rosmalen, Elisabeth FC van Rossum, Alex Burdorf, and MG Myriam Hunink.

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ABSTRACT

Background

Addressing the obesity epidemic requires the development of effective interventions aimed at increasing physical activity (PA). eHealth interventions with the use of accelerometers and gaming elements, such as rewarding or social bonding, seem promising. These eHealth elements, blended with face-to-face contacts, have the potential to help people adopt and maintain a physically active lifestyle.

Objective

The aim of this study was to assess the influence and usage of a blended Web-based gaming intervention on PA, body mass index (BMI), and waist circumference among overweight and obese employees.

Methods

In an uncontrolled before-after study, we observed 52 health care employees with BMI more than 25 kg/m^2, who were recruited via the company's intranet and who voluntarily participated in a 23-week Web-based gaming intervention, supplemented (blended) with non-eHealth components. These non-eHealth components were an individual session with an occupational health physician involving motivational interviewing and 5 multidisciplinary group sessions. The game was played by teams in 5 time periods, aiming to gain points by being physically active, as measured by an accelerometer. Data were collected in 2014 and 2015. Primary outcome was PA, defined as length of time at MET (metabolic equivalent task) ≥3, as measured by the accelerometer during the game. Secondary outcomes were reductions in BMI and waist circumference, measured at baseline and 10 and 23 weeks after the start of the program. Gaming elements such as "compliance" with the game (ie, days of accelerometer wear), "engagement" with the game (ie, frequency of reaching a personal monthly target), and "eHealth teams" (ie, social influence of eHealth teams) were measured as potential determinants of the outcomes. Linear mixed models were used to evaluate the effects on all outcome measures.

Results

The mean age of participants was 48.1 years; most participants were female (42/51, 82%). The mean PA was 86 minutes per day, ranging from 6.5 to 223 minutes, which was on average 26.2 minutes per day more than self-reported PA at baseline and remained fairly constant during the game. Mean BMI was reduced by 1.87 kg/m^2 (5.6%) and waist circumference by 5.6 cm (4.8%). The univariable model showed that compliance, engagement, and eHealth team were significantly associated with more PA, which remained significant for eHealth team in the multivariable model.

Conclusion

This blended Web-based gaming intervention was beneficial for overweight workers in becoming physically active above the recommended activity levels during the entire intervention period, and a favorable influence on BMI and waist circumference was observed. Promising components in the intervention, and thus targets for upscaling, are eHealth teams and engagement with the game. Broader implementation and long-term follow-up can provide insights into the sustainable effects on PA and weight loss and into who benefits the most from this approach.

INTRODUCTION

Worldwide, 2.1 billion individuals are overweight or obese and the prevalence keeps increasing [1]. This is a major burden for not only individual health but also for health care and societal costs [2]. Physical activity is important to enhance weight loss and for the prevention of weight gain, reducing the risks of serious health problems such as cardiovascular disease, cancer, diabetes, osteoarthritis, and depression [3,4]. Adherence to physical activity recommendations among obese individuals is poor [5,6], creating an urgent need for a scalable, effective, and sustainable approach to enhance physical activity in the prevention and treatment of obesity. Although eHealth has this potential, attrition rates in eHealth programs are high [7,8], which means that sustainable behaviour change may require a more intense approach [9]. The most promising approach for promoting healthy behaviour in an efficient manner seems to be the combined use of successful eHealth components and non-eHealth components [10].

The eHealth components that have been shown to be promising elements of a successful Web-based health intervention are use of accelerometer or activity tracker [11] and gamification [12]. Accelerometers monitor the level of physical activity, which plays a critical role in reducing health risks and improving body composition [13-16] and is essential for long-term weight management in overweight and obese individuals [17]. There is a growing availability of such "quantified self" devices, which objectively measure an individual's level of physical activity by means of the total amount, intensity, duration, and frequency of physical activities. In addition to objective registration of the level of physical activity, using an accelerometer can raise the individual's awareness of his or her activity level [18] and consequently increase the level of physical activity [19,20]. Gamification is an emerging field and has shown to be promising, achieving its effectiveness by rewarding, social bonding, and making the health intervention fun to engage in [12], which is in common with proven health behaviour change approaches [21,22]. Despite the advantages of a broad reach and easy accessibility [23], eHealth-only approaches tend to suffer from high attrition and dropout rates [8], which should be prevented if aiming for a sustainable lifestyle change.

Apart from eHealth, direct human contact by way of counseling can be an important component in lifestyle behaviour programs. Motivational interviewing is a suitable counseling technique to improve exercise adherence [24] and weight loss [25,26], taking into account a patient's readiness to make lifestyle changes as well as for planning and goal setting. A recent review suggested that direct human contact may help intensify the effect of eHealth technologies [10]. There is a lack of evidence on the effectiveness and usage of programs in which eHealth and non-eHealth components are blended for optimal effectiveness, reach, adherence, and costs.

Aiming for a both effective and efficient intervention with blended usage of eHealth components and non-eHealth components, we developed our program and implemented it in a pilot setting. The results of this pilot study will inform us whether broader implementation with longer follow-up is useful for this target population. Therefore, the aims of this study were to analyse the sustainability of physical activity during the game and to assess changes in body mass index (BMI) and waist circumference. In addition, we aimed to assess the influence of compliance, engagement, and eHealth teams on these outcomes.

METHODS

Study Design and Population

This uncontrolled, before-after pilot study evaluates a blended Web-based gaming intervention for overweight and obese employees to become more physically active and adopt a healthy diet in a way that suits their personal preferences and abilities and, ultimately, to lose weight. The program was developed and implemented by the occupational health center of the Erasmus MC, University Medical Center in Rotterdam to improve the vitality and well-being of its overweight and obese employees. The main idea was developed and tested in 2010 and upgraded to the current version in 2013, which was tested by a test group before implementation in our study population. Key objectives of this program are to encourage overweight employees to become more physically active and adopt a healthy diet in a way that suits their personal preferences and abilities and, ultimately, to lose weight. The program consists of a face-to-face individual session with an occupational health physician, 5 group sessions, and a 20-week movement game that is played in real life, using accelerometers to measure physical activity.

Participants were recruited by memos on the company's intranet in December 2013 and in September 2014 and were selected based on being overweight or obese (BMI ≥25 kg/m^2) or having a large waist circumference (≥102 cm for men and ≥88 cm for women) and being motivated to change their lifestyle. Because of the Web-based approach, affinity with computers was desirable, but only computer accessibility was required. Excluded from participation were employees who (1) were using medication with weight gain being a side effect, (2) were unable to be physically active, (3) were currently pregnant or breastfeeding, or had the wish to be pregnant within 23 weeks, (4) did not speak Dutch, or (5) needed an intervention for an additional problem (alcohol intervention, thyroid regulation). Selection for the program took place during a 30-minute individual session with the occupational health physician.

Participation in the program was voluntary and no individual information was shared with anyone, especially not with the employer or direct supervisor. The program was free of charge for the first 24 applicants because this was covered by a grant. When

the program was offered half a year later to an additional 28 applicants, the program content remained identical, but a participation fee of €450 was introduced to cover the workshop and the accelerometer. The study protocol was approved by the Medical Ethics Committee of the Erasmus University Medical Center (registration numbers MEC-2015-134 for overweight participants and MEC-2012-257 for obese participants), and signed informed consent forms were obtained from all participants. Although this is not a randomised controlled trial, reporting of the study was performed according to the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) standards where applicable [27]. See Multimedia Appendix 1 for the CONSORT-EHEALTH checklist (not printed in thesis).

Intervention

Gaming components of social bonding, rewarding, and competition are included throughout the program, which is offered in a combination of eHealth and face-to-face care (non-eHealth), that is, a blended intervention.

Non-eHealth

Session With Occupational Health Physician

During this session, motivational interviewing was used to determine motivation to make lifestyle changes and to start individual planning and goal setting [28]. After being selected, participants received a confirmation letter stating the start date of the program and instruction on how to purchase the obligatory accelerometer.

Group Sessions

Group sessions took place in the 1st, 2nd, 3rd, 4th, and 12th week of the program and lasted 2.5 to 3 hours each. Each group consisted of a maximum of 20 participants. Because obesity requires a multidisciplinary approach [29], the sessions were alternately given by a physician, a dietician, a physical therapist, and a psychologist. During the group sessions, participants (1) were educated on the health risks of obesity and the benefits of a healthy lifestyle, including physical activity, diet, alcohol consumption, and relaxation; (2) were guided in individual goal setting and planning and challenged to makes choices that would be sustainable in regard to personal preferences and social context, with the aim to increase physical activity and lower caloric intake; and (3) received explanation on the movement game and on the use of the accelerometer. Social networking with fellow group members was stimulated during all sessions.

eHealth: Movement Game

The movement game is a Web-based tour around the world, which is played by being physically active in the "real world." Touring the world takes 20 weeks, and every 4 weeks

the tour crosses another continent (Europe, North America, Asia, Australia, Africa). The game was played by 2 competing teams aiming to win the continent by scoring the most "movement points." An independent "game coach" randomly divided the participants of one program into 2 eHealth teams, which he announced during the third group session along with the rules of the game. Every team member strove to reach his or her personal target, which was set before the first continent by the physical therapist. Movement points were granted according to the duration and intensity of physical activity, which was registered by an accelerometer. Players were asked to upload the accelerometer data into the Web-based movement game via a USB connection at least once a week and were educated on the Dutch norm of physical activity, which is being physically active at least 5 times a week for 30 minutes (21.4 minutes/day) at MET (metabolic equivalent task) 3 or higher, and on the "fit norm," which is physical activity at least 3 times a week for 20 minutes (8.6 minutes/day) at MET 6 or higher [30]. If a personal target was reached within a continent, a written advice for raising the target for the next continent appeared on the personal webpage. Participants could visually monitor their progression toward their individual targets and against the other team at any time, both on a desktop computer and on a mobile phone. Figure 1 shows a screenshot of the gaming intervention. Multimedia Appendix 2 provides additional screenshots of the movement game, illustrating the competition.

Registration of physical activity was performed by the Activ8 system (Remedy Distribution Limited, Valkenswaard, The Netherlands), which is a small triaxial accelerometer that is worn in the pocket of any pants or with a leg strap on the upper leg [31]. The Activ8 output was tested against video analysis, and sensitivity scores of postures and movements ranged from 81% to 98%. The game coach handed out instructions for installing the Activ8 software on the computer and assisted if necessary. A critical requirement for sufficient valid functioning is wearing the device in the correct position and without (excessive) tilting; this was specifically instructed by the game coach in our study. During the game, the Activ8 device needed to be worn at all times, except during swimming and sleeping. Because swimming was not registered by the Activ8 device, the number of swim minutes could be filled out manually on the game's webpage.

Every 2 weeks an automatic email was sent to the participants, providing general information on multiple lifestyle aspects related to the upcoming continent. If participants failed to log on to the game's website for more than 2 weeks, an email reminder was sent by the game coach. An online social network was provided by the game by means of a digital forum page. Written messages, as well as responses to these messages, could be posted by the participants or the game coach. The game coach could be consulted every working day at the occupational health center and was the same person throughout the program.

Figure 1. Screenshot of the movement-game.

Awards could be won both individually and as teams. Virtual bronze, silver, and gold medals would appear for every individual achieving 80%, 90%, or 100% of their individual target within a continent. In addition, after completion of a 4-week continent, 1 individual player and all members of the winning team received tangible gifts related to a healthy lifestyle, such as a sports towel or a water bottle. The individual winner was selected by the game coach based on having collected the most movement points, having made the most progress, or showing the best team spirit on the forum. The game coach announced the continent winners by a message on the Web-based forum and granted the awards personally.

Although uploading of movement points by the accelerometer could only be done using a desktop computer, all other aspects of the game were accessible by mobile phone as well. Confidentiality of users was ensured by using only first names in the game. To ensure security of content and users, the game used password-protected accounts, encrypted password storage, encrypted log-in details, and secure external servers. During the program, no interfering bug fixing was needed.

Measurements

Collection of baseline characteristics (age, sex, level of education, shift work, working hours per week) was done during the individual selection session with the company's occupational health physician (TK), between February 2014 and July 2015. Educational level was categorised into 2 categories (low or medium and high) according to the Dutch educational system.

Participants with BMI ≥30 kg/m^2 were additionally seen by the specialist for internal diseases and endocrinology (EvR) of the Obesity Center CGG ("Centrum Gezond Gewicht") of the Erasmus Medical Center of Rotterdam to ensure appropriate treatment of underlying or complicating diseases. Costs were covered by the health insurance company, with the exception of an individual's deductible. Because participants with BMI ≥30 kg/m^2 were remeasured at 10 weeks by this specialist, we added this 10-week measurement to participants with BMI 25-30 kg/m^2 in groups 3 and 4 in order for the measurements to be identical for all BMI categories.

Primary Outcome: Average Physical Activity per Day (Average MVPA)

The Activ8 accelerometer provided information on the number of seconds spent at a certain MET level, which was collected by the supportive information and technology company (ICT) at the end of the 20-week movement game. We categorised physical activity into time spent in moderate physical activity (MPA) and time spent in vigorous physical activity (VPA), expressed in MET-hours. The cutoff energy levels used for this study were ≥3 to 6 METs for MPA and ≥6 METs for VPA. The cutoffs are based on the Dutch recommendations for healthy behaviour [30]. Moderate to vigorous physical activity (MVPA) was the sum of MPA and VPA, also expressed in MET-hours. The accelerometer had to register ≥10 hours per day of activity at >1 MET to count as a "valid day." We registered a "nonvalid day" when no more than 10 hours of activity was registered or when there was no registration at all because the battery ran out, because we interpreted this as nonusage of the device. We calculated the average MVPA in MET-hours by dividing MVPA during the game by the number of valid days.

Secondary Outcomes: Body Mass Index and Waist Circumference

For weight measurements, the occupational health physician used the scale that was available for daily practice (Inventum PW705BG (Arnhem, The Netherlands)), which is calibrated once a year and remained the same throughout the study period. For calculating BMI in kg/m^2, body height was self-reported at baseline, which differed less than 1% from objective measures at 10 and 23 weeks, and the value was kept the same in all BMI calculations. Waist circumference was always measured by the same occupational health physician and was measured halfway between the lower rib and the iliac crest, as is advised by the Dutch obesity recommendations for general practitioners [32]. Both

measurements were done at baseline and 10 and 23 weeks after baseline. Delta BMI and delta waist circumference were used as outcome parameters, which were the measurements at baseline minus those at 10 and 23 weeks.

Determinants: Compliance, Engagement, eHealth Team, and Other

Compliance

A program-specific demand was used as behavioural measure of compliance, which was the percentage of days with more than 10 hours of accelerometer wear during the 20-week game (ie, accelerometer wear).

Engagement

Engagement was measured as the number of times at least 100% of the personal target level was reached (ranging from 0 to 5) and categorised into ≤3 times and 4 or 5 times.

eHealth Teams

All participants were randomly assigned to an eHealth team (8 teams in total) for social influencing. For the purpose of analyses, we categorised teams into dummy numbers 1 to 8.

Other Measures of Usage

To further assess usage of the game, we measured the number of log-ins on the game website and the number of messages posted on the forum.

Data Analysis

Descriptive statistics were used to present the baseline characteristics of the study population. We excluded data of 1 participant because of pregnancy. The primary outcome measure was average MVPA (time-weighted area under the curve of the MET level) during the 20-week period of the game. Secondary outcomes were reductions in BMI and waist circumference versus baseline. Determinants were compliance to and engagement with the game and team effects.

In univariable linear regression analyses we investigated the association between age, sex, educational level, BMI at baseline, working hours per week, shift work, eHealth team, compliance (accelerometer wear), engagement (number of times the target level was reached), and other measures of usage (number of log-ins and messages on the forum) as independent variables and the average amount of MVPA per day as the dependent variable. To compare eHealth teams, we chose the team with the lowest average MVPA as the reference category. We log-transformed MVPA to create an approximately normal distribution of our outcome variable.

Univariable and multivariable analyses were performed using linear mixed models to account for the within-subject correlations due to intrateam effects and, in the case of BMI and waist circumference, for repeated measurements. The average amount of MVPA per day was used as outcome measure of the multivariable analyses, and the reductions in BMI and waist circumference at 10 and 23 weeks versus baseline were outcome measures of both univariable and multivariable analyses. We evaluated multiple models by combining different determinants in each model, aiming to get insight into the (combination of) independent variables with the most effect on the outcomes. The independent variables in separate and combined models were accelerometer wear as a measure of compliance and the number of times the individual target was reached as a measure of engagement; in the linear mixed models for the change in BMI and waist circumference during the intervention, we added the average amount of MVPA during the game and changes in time (10 and 23 weeks). All models were further adjusted for sex, age, and BMI at baseline. The variances between eHealth teams were included as random effects. A random intercept was included to account for the within-subject correlations. Collinearity between independent variables was assessed by calculation of the variance inflation factors. We considered including interaction effects between each independent variable and time, but this was not necessary because tests showed no significant interaction effects.

All statistical tests were two-sided and used a significance level of .05. All statistical analyses were performed using IBM SPSS version 22 (IBM Corporation).

RESULTS

In total, 52 employees participated in this program, of whom 1 participant was excluded from analyses because of pregnancy. Figure 2 shows the flow of participants in the program, including the number of participants, the grouping, and the program flow over time. Of the participants with BMI ≥30 kg/m^2, 3 were not additionally screened at study inclusion by the specialist for internal diseases and endocrinology because of personal choices.

Baseline characteristics for all study participants are provided in Table 1. The mean age of the participants was 48.1 years, ranging from 29 to 65 years, and 69% received higher education. The majority of participants were female (42/51, 82%).

Figure 3 shows that the average MVPA remained fairly constant during the entire game and that the Dutch norm of physical activity was met by every individual in each continent, which is high as opposed to 26% at baseline based on self-reported data. The "fit norm" was not met by 90% of the participants (data not shown). The average MVPA during the game was 7.08 MET-hours, ranging from 0.5 to 18.89 MET-hours.

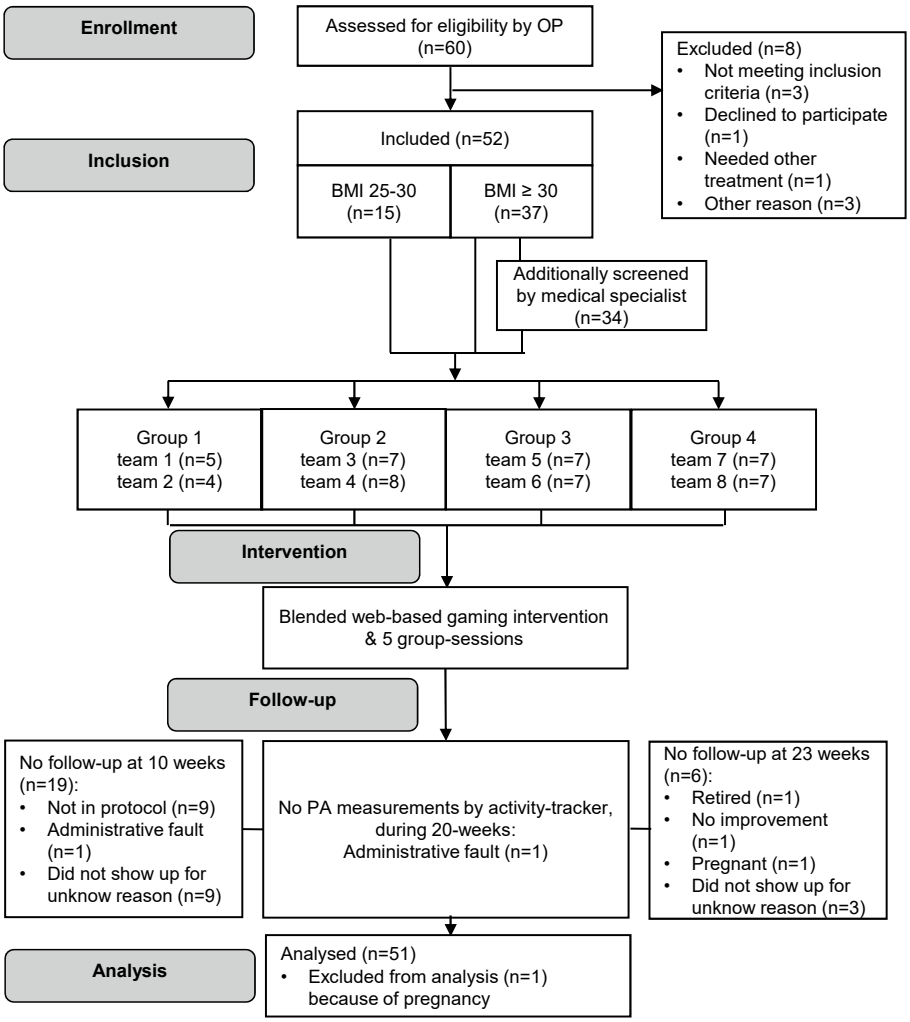


Figure 2. Flow of participants.
BMI: body mass index; OP: occupational health physician; PA: physical activity.

Table 2 shows that sex, age, level of education, BMI, and waist circumference at baseline as well as work parameters were not significantly associated with the average MVPA. Several elements of the game seem to be associated with a higher level of MVPA. After inversion of the log-transformed MVPA, the eHealth teams showed a 7.9-fold difference in increase in average MVPA (95% CI 4.2-14.8), illustrating the large variability in improvement in MVPA across teams. The average MVPA of teams ranged from 1.9 to 13.3 MET-hours per day. More compliance was also significantly associated with an increase in average MVPA. For example, 20 more days of wear would mean an increase of 35% of MVPA (95% CI 2%-79%) on the days the accelerometer was worn. On average, the accel-

Table 1. Baseline characteristics of participants (n=51).

Characteristics	n (%)	Mean (SD)
Sex		
Men	9 (18)	
Women	42 (82)	
Age, years		48.1 (9.2)
Educational level (n=45)		
Low or medium	14 (31)	
High	31 (69)	
Insufficient physical activity[a] (n=42)	31 (74)	
Weight, kg		96.3 (16.9)
Waist circumference, cm		
Men		124.3 (14.59)
Women		109.7 (10.8)
Body mass index, kg/m^2		32.7 (5.1)
25-30	15 (29)	27.2 (0.9)
≥30	36 (71)	35 (4.4)
Work		
Hours/week		30.8 (7.1)
Shift work[b]	10 (20)	

[a]Defined as no adherence to the Dutch guideline at baseline.
[b]Evening or night shifts.

erometer was worn for more than 10 hours per day on 89% of the available days, ranging from 44% to 100%. This percentage was above 80% in all 5 continents of the game. Compared with low engagement during the game (ie, infrequently reaching individual targets), there is an absolute gain in MVPA of 2.8-fold relative increase (95% CI 1.7-4.6) when being highly engaged. The individual target of physical activity was reached at the most 3 times by 32 (63%) participants and more than 3 times by 19 participants (37%).

The attrition curve in Figure 4 shows a decrease in compliance and engagement and other measures of usage toward the end of the game, although the average MVPA remained fairly constant. A total of 4 participants showed no accelerometer wear in the last continent. Reasons for no uploads were vacation abroad for 2 participants, a lost device for 1 participant, and a lack of motivation for another participant. We note that some teams switched to alternative social media in the last continent, which may explain the decrease in messages on our forum.

Table 3 suggests that team membership has a fairly robust effect on average MVPA, because the standard deviation of the random effect of eHealth team remains similar in models 3 through 6 and because 0.45 (0.99 in model 2 minus 0.54 in model 3) of the variance between participants was explained by eHealth team. The heterogeneity be-

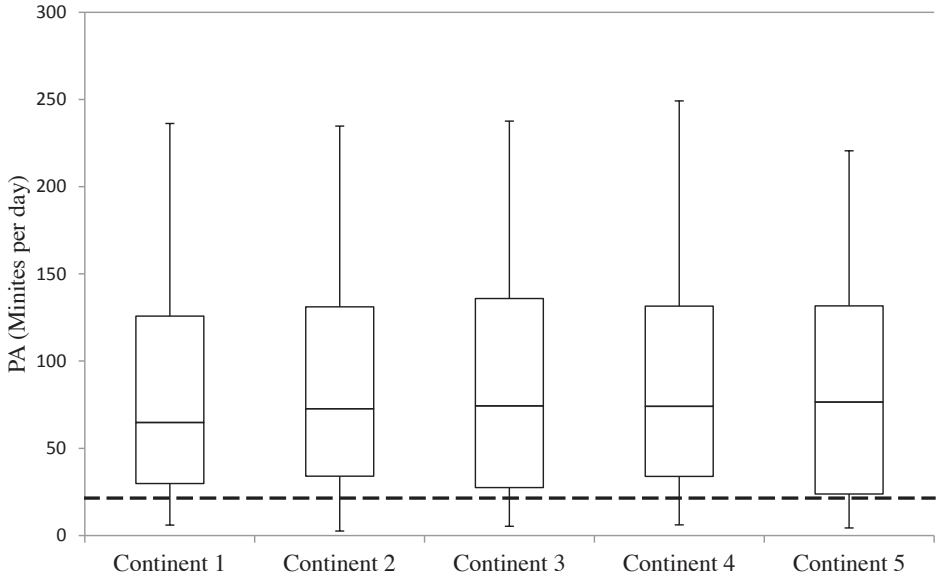


Figure 3. Box plot showing moderate to vigorous physical activity in minutes per day in all 5 continents of the game.
The dashed line marks physical activity (PA; metabolic equivalent task or MET≥3) for 30 minutes at least 5 times a week (=150 minutes per week, which is on average 21.4 minutes per day). The top and bottom borders of the box mark the 75th and 25th percentiles; the horizontal line in the middle indicates the median. The whiskers mark the lowest and highest scores.

tween eHealth teams is presented as the standard deviation of the normally distributed random effects of eHealth teams for the log-transformed MVPA value. The value of 0.88 for this standard deviation in model 3 implies a 3.7-fold relative difference in average MVPA between two teams randomly chosen from the population, thus suggesting large differences between teams that could not be explained by age, sex, or BMI at baseline, nor were they additionally affected by compliance or engagement. The variance inflation factor did not exceed 1.5 for any independent variable, which indicates that there was no multicollinearity problem.

Figure 5 shows the categories of reductions in BMI and waist circumference after 23 weeks. The mean BMI was reduced by 1.87 kg/m^2 (range -8.7 to 2.4 kg/m^2) during the program, corresponding to 5.6% (range -20.2% to 7.6%), and the mean waist circumference was reduced by 5.6 cm (range −4.5 to 23 cm). Univariable analysis showed significantly more reductions in BMI and waist circumference (BMI: B 0.12, 95% CI 0.04-0.20; waist circumference: B 0.22, 95% CI 0.09-0.36) when BMI and waist circumference values were higher at the start of the program (Multimedia Appendix 3).

Model 5 in Table 4 shows that more engagement was the only component associated with reductions in BMI (B 1.23, 95% CI 0.17-2.29) and waist circumference (Multimedia

Table 2. Association between baseline characteristics and program usage and physical activity (n=51): univariable linear regression analyses.

Characteristics	Moderate to vigorous physical activity[a]	
	B (95% CI)	*P* value[b]
Sex		
Women	Reference	
Men	0.38 (−0.35 to 1.10)	.30
Age, years	0.01 (−0.03 to 0.04)	.76
Educational level		
Low or medium	Reference	
High	0.44 (−0.20 to 1.08)	.18
Body mass index, kg/m^2	−0.02 (−0.07 to 0.04)	.53
Waist circumference, cm	0.10 (−0.01 to 0.03)	.36
Work, hours/week	−0.02 (−0.07 to 0.02)	.26
Shift work		
Yes	Reference	
No	0.23 (−0.50 to 0.96)	.53
Characteristics of program usage		
eHealth team (1-8)		
Team 1	2.06 (1.43 to 2.70)	<.001
Team 2	2.04 (1.37 to 2.72)	<.001
Team 3	2.06 (1.46 to 2.66)	<.001
Team 4	1.72 (1.14 to 2.29)	<.001
Team 5	1.01 (0.43 to 1.59)	.001
Team 6	0.09 (−0.48 to 0.67)	.75
Team 7	0.45 (−0.13 to 1.02)	.13
Team 8	Reference	
Compliance: accelerometer wear[c]	0.02 (0.00 to 0.04)	.04
Engagement		
≤3 times target reached	Reference	
4 or 5 times target reached	1.03 (0.52 to 1.53)	<.001
Number of log-ins	−0.00 (−0.01 to 0.01)	.74
Number of messages	0.01 (0.00 to 0.02)	.04

[a]Log-transformed average moderate to vigorous physical activity (metabolic equivalent task or MET>3), in MET hours.

[b]Statistical significance was defined as $P<.05$.

[c]Percentage of days with >10 hours of physical activity registration.

Appendix 4; B 4.44, 95% CI 0.84-8.03) even with adjustment for the effect of the eHealth team. Thus, reaching a relatively high personal level of physical activity seems more important than aiming for the absolute highest level of physical activity of a group. Addition of more elements to the models (models 6 and 7) attenuated the effects of

Table 3. Multivariable association between baseline characteristics and program usage and physical activity (n=51): separate models using linear mixed models.

Characteristics of program usage: models			Moderate to vigorous physical activity[a]		
			Sources of variance, SD[b] (95% CI)		B (95% CI)
Model: description	Independent variables (additional)	Categories	Between eHealth teams	Between participants	
Model 1: raw			N/A[c]	0.98 (0.80 to 1.19)	N/A
Model 2: baseline characteristics			N/A	0.99 (0.81 to 1.22)	
	Age				0.01 (−0.03 to 0.04)
	Sex	Women			Reference
		Men			0.43 (−0.33 to 1.19)
	BMI[d] at baseline				−0.02 (−0.08 to 0.04)
Model 3: model 2 + eHealth team			0.88 (0.51 to 1.55)	0.54 (0.43 to 0.67)	
Model 4: model 3 + compliance			0.86 (0.49 to 1.52)	0.55 (0.44 to 0.69)	
	Compliance[e]	<85%			Reference
		85%-95%			0.15 (−0.34 to 0.65)
		≥95%			0.17 (−0.31 to 0.64)
Model 5: model 3 + engagement			0.83 (0.46 to 1.50)	0.54 (0.43 to 0.68)	
	Engagement[f]	≤3			Reference
		4 or 5			0.19 (−0.25 to 0.64)
Model 6: model 3 + compliance + engagement			0.82 (0.45 to 1.48)	0.56 (0.44 to 0.70)	
	Compliance	<85%			Reference
		85%-95%			0.17 (−0.34 to 0.67)
		≥95%			0.06 (−0.50 to 0.62)
	Engagement	≤3			Reference
		4 or 5			0.17 (−0.32 to 0.66)

[a]Log-transformed average moderate to vigorous physical activity (metabolic equivalent task or MET>3), in MET hours.
[b]SD is the standard deviation of the random effect between teams or between participants.
[c]N/A: not applicable.
[d]BMI: body mass index.
[e]Compliance is expressed as percentage of days with >10 hours of physical activity registration (accelerometer wear).
[f]Engagement is expressed as the number of times at least 100% of the target was reached (1-5).

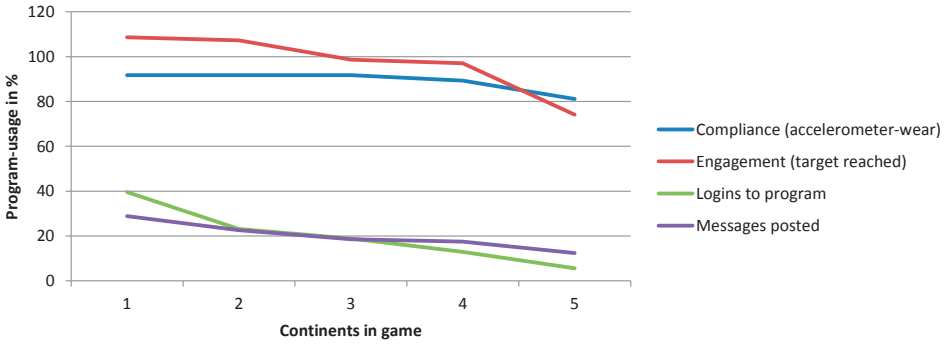


Figure 4. Attrition curve: program usage in the continents of the movement game.
Compliance (accelerometer wear) is expressed as the average number of days with at least 10 hours of physical activity registration at >1 MET (metabolic equivalent task). Engagement (target reached) is expressed as physical activity registered by the accelerometer divided by the individual target level of physical activity within a certain continent. Log-ins to the program are expressed as the number of online log-ins within a certain continent divided by the number of online log-ins during the entire game. Messages posted are expressed as the number of messages posted on the Web-based forum within a certain continent divided by the number of messages posted during the entire game.

engagement. The frequency of accelerometer wear (compliance) affected neither BMI nor waist circumference significantly (model 4). The value 0.53 for the standard deviation of the random effect of eHealth team in model 3 shows a maximum difference of 2 kg/m^2 between teams in reduction of BMI (1.96x2x0.53 kg/m^2) and the value 1.79 shows a maximum difference of 7 cm in reduction of waist circumference (1.96x2x1.79 cm). Although this exceeds the average reduction in BMI (1.87 kg/m^2) and in waist circumference (5.6 cm), the variance between participants of eHealth teams hardly changes by adding eHealth team to the model, implying no effect of eHealth team on the reduction in BMI and waist circumference.

DISCUSSION

Principal Findings

In this clinical pilot study in an overweight or obese working population, we evaluated the levels of physical activity during a Web-based gaming intervention using a triaxial accelerometer and we assessed changes in BMI and waist circumference versus baseline. In addition, we evaluated individual characteristics and characteristics of program usage as determinants of our outcomes. We found that levels of physical activity remained high during our intervention and, in addition, reductions in BMI and waist circumference were achieved. Key components for success were social interaction by eHealth teams and the level of engagement. These results indicate that broader implementation

Table 4. Determinants of reductions in body mass index, at 10 and 23 weeks versus baseline, combined in models using linear mixed models.

Characteristics of program usage: models			Δ BMI[a,b], kg/m^2		
			Sources of variance, SD (95% CI)		B (95% CI)
Model: description	Independent variables (additional)	Categories	Between teams	Between participants	
Model 1: raw			N/A[c]	1.38 (0.97 to 1.96)	N/A
Model 2: baseline characteristics			N/A	N/A	
	Age				−0.001 (−0.06 to 0.06)
	Sex	Women			Reference
		Men			−0.28 (−1.61 to 1.04)
	BMI at baseline				0.11 (0.01 to 0.21)[h]
Model 3: model 2 + eHealth team			0.53 (0.10 to 2.73)t	1.36 (0.95 to 1.94)	
Model 4: model 3 + compliance			0.39 (0.001 to 0.59)	1.08 (0.65 to 1.78)	
	Compliance[d]	<85%			Reference
		85%-95%			-0.14 (-1.41 to 1.13)
		≥95%			0.60 (-0.57 to 1.77)
Model 5: model 3 + engagement			0.43 (0.001 to 0.60)	1.26 (0.86 to 1.84)	
	Engagement[e]	≤3			Reference
		4 or 5			1.23 (0.17 to 2.29)
Model 6: model 3 + MVPA[f]			0.44 (0.001 to 0.60)	1.06 (0.65 to 1.74)	
	MVPA				0.16 (−0.39 to 0.70)
Model 7: model 3 + compliance + engagement + MVPA			0.50 (−0.00 to 0.64)	1.04 (0.62 to 1.75)	
	Compliance	<85%			Reference
		85%-95%			−0.09 (−1.37 to 1.19)
		≥95%			0.13 (−1.22 to 1.47)

Table 4. Determinants of reductions in body mass index, at 10 and 23 weeks versus baseline, combined in models using linear mixed models. (continued)

Characteristics of program usage: models			Δ BMI[a,b], kg/m^2		
			Sources of variance, SD (95% CI)		B (95% CI)
Model: description	Independent variables (additional)	Categories	Between teams	Between participants	
	Engagement	≤3			Reference
		4 or 5			1.01 (−0.13 to 2.15)
	MVPA				−0.05 (−0.64 to 0.55)
	Time	0-10 weeks			Reference
		0-23 weeks			0.99 (0.35 to 1.62)[g]

[a]BMI: body mass index.

[b]Δ of outcome = reduction in outcome calculated by measurement at baseline minus measurement at follow-up.

[c]N/A: not applicable.

[d]Compliance is expressed as percentage of days with >10 hours of physical activity registration (accelerometer wear).

[e]Engagement is expressed as the number of times at least 100% of the target was reached (1-5).

[f]MVPA: moderate to vigorous physical activity.

[g]Statistically significant at $P<.05$.

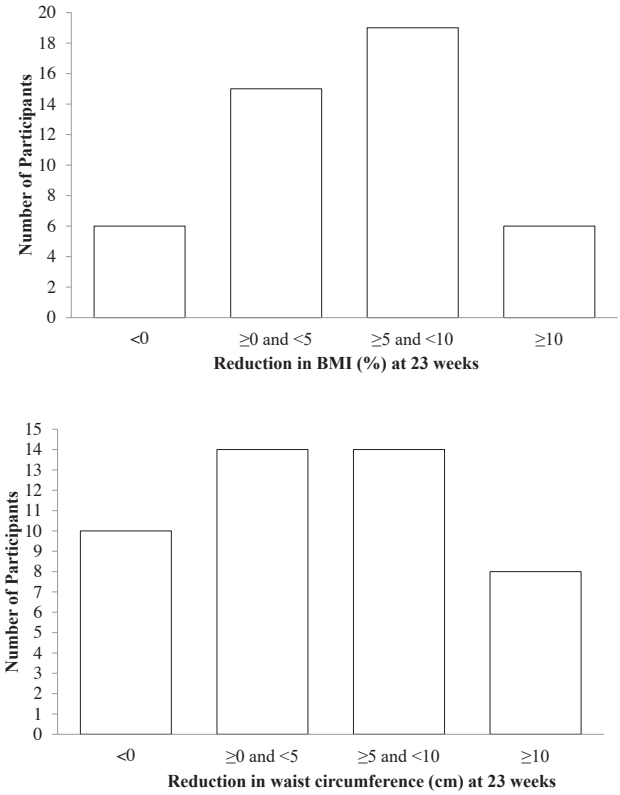


Figure 5. Reduction in weight and waist circumference of eHealth program participants, at 23 weeks versus baseline, in categories.
BMI: body mass index.

of a Web-based gaming intervention with focus on eHealth teams and engagement will be beneficial for overweight and obese individuals, and long-term effects should be studied.

Accelerometer measurements showed a mean MVPA of 86 minutes per day at moderate or vigorous level in our participants, which was high in comparison with an average of 35.5 minutes of MVPA per day in men and 32 minutes in women reported by Hallal et al [33]. The authors reviewed studies with the same wear time criteria of at least 10 hours/day, but subjects were healthy instead of overweight or obese and were observed for a short period of time instead of involved in an active intervention. Our mean MVPA is also high considering that adherence to physical activity guidelines among obese individuals is reported to be even poorer than among healthy weight individuals [5]. When we compare our results with the general Dutch population, we note that a relatively large proportion of our participants met the recommendation of MPA (100% vs 65%) but relatively few met the recommendation of VPA (10% vs 20%). This lack of sufficient

vigorous activity was also reported in a systematic review on active video gaming, showing physical activity hardly exceeding 3 METs [34]. The international recommendation to promote and maintain health recommends any person to be moderately active for at least 30 minutes at least 5 days per week, or vigorously active for at least 20 minutes at least 3 days per week, but advises more physical activity for more health benefits [35,36]. The required time and energy expenditure for weight loss is still unclear [37]. MPA, such as walking, is a common, accessible, and inexpensive form of physical activity, which has shown multiple health effects including reduction in BMI [38]. Nevertheless, physical activity at vigorous level is advised for additional health benefits in the WHO (World Health Organisation) Global Recommendations on Physical Activity for Health [36], which also requires less time. Therefore, we could debate whether innovative approaches toward Web-based games should also be aimed at increasing the percentage of VPA for further improvement of weight parameters.

Our finding that more accelerometer wear was not associated with more MVPA in multivariable models supports the finding of previous research that just wearing an accelerometer is not sufficient to promote more MVPA [39,40]. There are more benefits of accelerometer wear than just behavioural, though, which extend to objective measurement and providing personalised feedback based on measurements. Objective measurements by body-worn monitors are preferred over self-reported physical activity [41,42], because self-reported information on physical activity is known to be overestimated compared with the actual amount [43], with an even greater inconsistency between self-reported physical activity and that measured using accelerometers among obese individuals [44]. On the other hand, data by accelerometer wear only provide information on the time the device was worn, in contrast to self-reported information, which gives a more general idea of physical activity. Average of 89% days with valid wear time was high in comparison with 73% in another study among workers [18], which could be due to our selection criteria of overweight or obese and highly motivated participants. Other challenges to the use of accelerometers include the loss of the device and incorrect placement of the device [45]. Nevertheless, we will keep considering usage of an accelerometer as a key element of a Web-based gaming intervention for the purpose of accurate registration needed in individual target setting and in competition with others.

Our finding of a mean reduction of 1.87 kg/m^2 in BMI during the program is high, considering the reported effectiveness of exercise programs among adults who are overweight or obese with a pooled reduction between 0.3 and 0.7 kg/m^2 [46]. Our results are within the range 0.6 to 4 kg/m^2 that they reported when a diet was added. BMI was reduced by more than 5%, which means a reduction of obesity-related health risks [47] and a potential gain of psychosocial benefits, such as a decrease in stress and depression [48] and less sick leave at work [49]. Because primarily Web-based interven-

tions are likely to be more cost-effective and have a wider reach, our intervention may be interesting for policy makers and health professionals.

Two important gaming components in our Web-based program were eHealth teams, as a measure of social bonding, and individual engagement, by way of target setting including virtual rewards. Although eHealth team was not associated with the reduction in BMI or waist circumference, both elements showed beneficial effects on the level of physical activity. This is in line with other studies that reported social support to be associated with obesity-specific health-related quality of life [50], with positive health behaviour, such us more physical activity and fruit and vegetable intake [51], and with adherence to treatment [52,53]. Kreps and Neuhauser [54] describe how using eHealth for social bonding can really make a difference in enhancing the quality of health care and health promotion effects. A recent study by Zuckerman and Gal-Oz [40] reported no differences in physical activity by adding gaming elements to daily physical activity registration with feedback on progress. The contradiction between these findings and our study could be explained by their short follow-up of several days and thus the novelty effect. A systematic review by Maher et al [55] on the effectiveness of online social networks on changes in diet and weight or physical activity found evidence that online social networks may be effective in changing health behaviour. They noted that integrating social networks in gamification is promising and that the user interface of online social networks should be selected carefully so that it is accessible, interactive, contextually tailored, and can be delivered to larger audiences. Online social interaction during our intervention took place on the Web-based forum of the game within and between teams. We suspect an underestimation of the number of Web-based contacts because several teams also communicated through other social media forums. Unclear is why certain teams ended up choosing other social media than that provided by the game, but they may have foreseen that our website would not be accessible anymore after the 23rd week of the game. Although social influence by eHealth teams seems a strong component, the differences between teams were large, and more research is needed to find out how and by whom social support should be delivered and to predict for whom this could work.

Personal targets were set by the individual and reaching targets appeared to be an important gaming component, which can be explained by comparing it to the theory of *flow*, which is popular among video game designers and was described by Eysenbach as one of the popular gamification tactics [12,56]. By setting targets, people become absorbed and engaged in an activity when they are doing something where their skill level is perfectly matched to the challenge level [12]. Nevertheless, maintaining high levels of activity seems challenging because high attrition rates are commonly seen and considered a disadvantage of eHealth [8]. In our game, the average MVPA did not drop despite the common decrease in usage. We suspect that the embedding of target

setting in eHealth teams enhanced sustainability of the level of MVPA. Thus, the two gaming components in our Web-based program, that is, eHealth teams and individual engagement, seem to have positively influenced each other.

Blending components of gamification with face-to-face elements may have attributed to our results, although the study design did not allow quantification. A commonly identified benefit of Web-based interventions is their ability to reach a broad population, but Xu et al [57] showed that interventions successful for groups may not always translate to successful behaviour change at the individual level. Offering additional face-to-face coaching to individuals with readiness to change behaviour may increase intrinsic behaviour for personal lifestyle changes by addressing intrinsic motivation [28], thus aiming for behaviour changes to be sustained beyond the gaming period.

Limitations

First, this clinical pilot study was performed among a small number of individuals without preintervention measurements of physical activity and without a control group, leading to a lack of power in some analyses and to the inability to accurately assess the strength of the effects of multiple blended elements [58]. Nevertheless, this compact setting and the increase in physical activity in comparison with self-reported baseline physical activity provided enough information to suggest broader implementation along with a follow-up study including more individuals in a randomised controlled setting.

Second, gaming elements in our intervention were mainly focused on physical activity. Dietary behaviour was only addressed during the non-eHealth sessions. Because the focus was on physical activity, the effects on body composition might have been greater than on only BMI and waist circumference, which is beneficial in reducing cardiovascular risk [59]. Although there is sufficient evidence that physical activity in the absence of a dietary intervention can produce weight loss [37,60], these effects could be increased by including healthy diet in the game [29,46]. The mode of delivery should be carefully chosen because the effects differ among technologies and features [10], and the effect on diet should be measured by a food frequency questionnaire.

Finally, the follow-up time of half a year is insufficient to determine the effectiveness of weight loss maintenance and to ignore potential seasonal variations [61].

Strengths

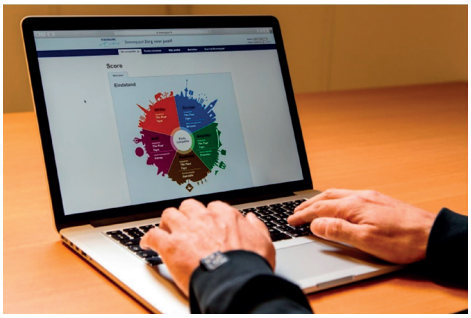
This study is unique in combining strong and proven effective elements of eHealth with a personalised non-eHealth approach while keeping it fun to engage in. This blended approach is in line with the US guidelines for primary care physicians, advising an initial evaluation by a physician before entering a lifestyle program to increase the chances of long-term success [62,63], and was also advised by Hutchesson et al [10].

The second strength is that we are targeting a high-risk population (selective prevention). Slootmaker et al [18] showed that eHealth interventions are not suitable for all individuals and should be aimed at individuals with risk factors.

Finally, our Web-based program aims at developing, adopting, and maintaining a healthy lifestyle. When proven effective, the prototype can be easily adapted to other target groups such as obese adolescents [64] and children [15], the elderly [20,65], and those in oncology rehabilitation [66].

CONCLUSIONS

This blended Web-based gaming intervention was beneficial in helping participants become physically active above the general recommendation of 30 minutes 5 days per week during the entire intervention period, and a favorable effect on BMI and waist circumference was seen. Promising components in the intervention are teams effects and engagement with the game. Game development should focus on strengthening these elements while keeping the fun factor. Broader implementation and long-term follow-up can provide insights into the sustainable effects on physical activity and weight loss and into who benefits the most from this approach.



Multimedia Appendix 2. Screenshots of the movement-game.

Multimedia Appendix 3. Univariable association between baseline characteristics and program-usage, and reductions in body mass index and waist circumference (n=51), at 10 and 23 weeks versus baseline, using a linear mixed model.

Baseline characteristics:		Δ BMI[a] (kg/m^2)		Δ Waist[a] (cm)	
		B (95% CI)	***P***-value	B (95% CI)	***P***-value
Gender	women	reference		reference	
	men	-0.29 (-1.43;0.85)	.612	-0.44 (-5.09;4.22)	.852
Age (years)		-0.03 (-0.08;0.02)	.270	-0.12 (-0.35;0.10)	.290
Educational level	low or medium	reference		reference	
	high	0.28 (-0.74;1.31)	.582	3.00 (-1.00;7.00)	.138
BMI (kg/m^2)		0.12 (0.04;0.20)	**.005**	0.42 (0.07;0.76)	**.020**
Waist circumference (cm)		0.04 (0.00;0.07)	**.03**	0.22 (0.09;0.36)	**.001**
Work (hrs / week)		0.008 (-0.06;0.08)	.822	0.18 (-0.08;0.45)	.172
Shift work	yes	reference		reference	
	no	0.14 (-0.95;1.25)	.801	-3.44 (-8.11;1.23)	.145
Characteristics of program-usage:					
Ehealth-team	1	-0.29 (-2.30;1.73)	.778	0.16 (-0.74;7.38)	.965
	2	1.23 (-0.95;3.42)	.263	4.16 (-3.61;11.93)	.287
	3	1.39 (-0.12;2.90)	.076	7.16 (-0.06;14.38)	.052
	4	-0.31 (-1.47;2.93)	.703	-0.09 (-7.86;7.68)	.981
	5	0.62 (-0.82;1.29)	.404	-1.90 (-7.37;3.60)	.488
	6	-0.51 (-2.01;1.00)	.504	-2.49 (-9.02;4.05)	.448
	7	1.24 (-0.26;2.74)	.104	1.80 (-4.74;8.34)	.582
	8	reference		reference	
Compliance[b]	<85%	reference		0.04 (-0.04;0.132)	.323
	85-95%	-0.04 (-1.13;1.05)	.944	-1.45 (-6.21;3.32)	.545
	≥95%	0.76 (-0.17;1.69)	.108	2.37 (-1.67;6.41)	.244
Engagement[c]	≤3 times	reference		reference	
	4 or 5 times	1.05 (0.17;1.93)	**.020**	4.80 (1.27;8.33)	**.009**
MVPA[d]		0.02 (-0.05;0.10)	.566	0.24 (-0.09;0.56)	.152
Number of logins		0.02 (0.01;0.02)	**<.001**	0.03 (0.00;0.06)	**.045**
Number of messages		0.02 (0.00;0.03)	**.012**	0.09 (0.01;0.18)	**.026**
Individual awards	1	reference		reference	
	>1	0.23 (-0.81;1.27)	.664	0.65 (-3.70;5.01)	.764
Team awards	≤1	reference		reference	
	>1	1.00 (0.16;1.84)	**.021**	1.04 (-2.56;4.63)	.566

[a]Δ of outcome = reduction in outcome calculated by measurement at intake minus measurement at follow-up.

[b]percentage of days with > 10 hours of PA registration (accelerometer-wear).

[c]number of times at least 100% of the target was reached (1-5)

[d]MVPA is expressed as the average moderate-to-vigorous PA in METhours per day.

95%CI = 95% confidence interval

Multimedia Appendix 4. Determinants of reductions in waist circumference, at 10 and 23 weeks versus baseline, combined in models using linear mixed models.

Characteristics of program-usage, models:		Δ Waist[a] (cm)		
		Sources of variance (SD;95%CI)		B (95% CI)
		Between Teams	Between participants	
Model 1: raw		NA	4.40(2.30;8.40)	NA
Model 2: Baseline characteristics		NA	3.37(1.33;8.56)	
Age (yrs)				-0.09 (-0.31;0.14)
Gender	women			reference
	men			-4.95 (-9.96;0.06)
Waist at baseline				**0.27** (0.12;0.42)
Model 3: Model 2 + eHealth-team		1.79(0.33;9.61)	3.17(1.23;8.20)	
Model 4: Model 3 + compliance		1.54(-0.17;12.91)	3.19(1.32;7.70)	
Compliance[b]	<85%			reference
	85-95%			-1.98 (-6.61;2.66)
	≥95%			0.80 (-3.41;5.01)
Model 5: Model 3 + engagement		1.50(-0.24;9.52)	2.43(0.44;13.30)	
Engagement[c]	≤3			reference
	4 or 5			4.44 (0.84;8.03)
Model 6: Model 3 + MVPA		1.24(-0.00;21.87)	3.02(1.07;8.47)	
MVPA[d]				0.20 (-0.16;0.55)
Model 7: Model 3 + compliance + engagement+ MVPA		1.68(-0.26;10.45)	2.70(0.74;9.78)	
Compliance[b]	<85%			reference
	85-95%			-1.25 (-5.93;3.44)
	≥95%			-0.91 (-5.58;3.76)
Engagement[c]	≤3			reference
	4 or 5			4.03 (-0.93;8.98)
MVPA[d]				0.01 (-0.44;0.45)
Time	0-10 wks			reference
	0-23 wks			-1.69(-6.14;2.75)

[a]Δ of outcome = reduction in outcome calculated by measurement at intake minus measurement at follow-up.

[b] percentage of days with > 10 hours of PA registration (accelerometer-wear).

[c]number of times at least 100% of the target was reached (1-5)

[d]MVPA is expressed as the average moderate-to-vigorous PA in METhours per day, not log-transformed.

95%CI = 95% confidence interval; NA = not applicable

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Chapter 7

Randomised study designs for lifestyle interventions: a tutorial

John O Younge, Tessa A Kouwenhoven-Pasmooij, Rosanne Freak-Poli, Jolien W Roos-Hesselink, and MG Myriam Hunink

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ABSTRACT

Unhealthy lifestyle behaviours are considered modifiable risk factors for many diseases.

Lifestyle interventions that target these behaviours need rigorous evaluation to assess their effectiveness. The randomised controlled trial is the study design of choice when it comes to the evaluation of interventions. However, lifestyle interventions are often complex and subject to several important issues, such as patient preference and non-adherence, that may threaten the internal and external validity of studies. There is a strong demand for high-quality randomised controlled trials of interventions that promote healthy lifestyle behaviours.

With this tutorial we aim to provide guidance in the choice of an optimal randomised controlled trial design in future trials of lifestyle interventions.

INTRODUCTION

Unhealthy lifestyle behaviours such as an unhealthy diet, excessive energy intake, smoking, excessive alcohol use, physical inactivity and poor stress-coping behaviour can act as causal factors in the pathway of many diseases and have been identified as key modifiable risk factors [1]. There are various types of interventions available to address these risk factors and to help people adopt a healthier lifestyle, in the settings of both primary and secondary prevention [2-4]. As with all medical interventions, lifestyle interventions should undergo rigorous evaluation to assess their effectiveness before widespread implementation.

There are several methods for evaluating lifestyle interventions, and each has strengths and weaknesses [5]. Cohort studies and case series may provide findings suggesting effectiveness, but drawing conclusions from such studies is limited due to confounding and other forms of bias [5]. The state-of-the-art study design for the evaluation of interventions is the double-blind randomised controlled trial (RCT) [6], considered as the foundation of evidence-based medicine (EBM) [7], where eligible individuals are randomly assigned to the intervention of interest or a control group. The RCT is widely used to evaluate new drugs, devices, surgery or other treatment modalities. Due to randomisation, known and unknown confounders are equally distributed between groups and bias is avoided. However, randomisation may not correctly account for patient preferences and non-adherence, which are important issues in lifestyle interventions and may threaten the internal and external validity of studies [8-10].

The aim of this paper is to provide guidance in the choice of an optimal RCT design in future trials of lifestyle interventions. For the purpose of this paper, a lifestyle intervention is defined as an intervention that focuses upon improving health through one or more modifiable risk factors, which includes interventions that promote healthy nutrition, smoking cessation, moderation in alcohol use, physical activity and stress reduction.

GENERAL CONSIDERATIONS

Lifestyle interventions are often complex, that is, they are interventions with several interacting components, which has implications for the design and execution of studies evaluating such interventions. Issues to consider are the interacting components within the experimental and the control interventions, the number and difficulty of behaviour changes required by those delivering or receiving the intervention, variability of measured outcomes depending on which behaviours change, individualised tailoring of the intervention, and the different groups or organisational levels targeted by the intervention [11]. Evaluating complex interventions requires identification of interactions, me-

diators and contextual factors in order to choose the optimal design and data-analytical techniques and to interpret the results correctly [12]. In particular this is a result of the variation that arises due to the multiple components of complex lifestyle interventions and their interaction, which occurs less often in pharmacological (drug) trials [13].

Objective research question

The underlying research question of a clinical trial is inextricably linked to its design and should be relevant and feasible to answer. As for all interventions, future evaluations of lifestyle interventions should commence with a thoughtful consideration of aspects which have not yet been assessed, which do not have definitive answers and which will provide evidence that can change practice. There are several factors one must consider when developing the research question in the context of lifestyle interventions. First and foremost, one needs to choose whether to assess the intervention in a controlled setting which addresses 'efficacy', vs assessing it in a real-world setting which addresses 'effectiveness'. RCTs tend to focus on efficacy rather than effectiveness, which often leads to questionable external validity [14]. Second, one needs to distinguish between evaluating the offer of a lifestyle intervention (with possible non-adherence) vs actual uptake of and adherence to the intervention. Third, one needs to decide whether to evaluate specific parameters of the lifestyle intervention that may influence its effectiveness, cost and cost-effectiveness, including duration, frequency and intensity of the program. An explicit statement of the study objective will lead the investigators to the identification of a clear study design.

Defining the active and control interventions

Evaluations of lifestyle interventions can be complicated by low recruitment, high rates of non-adherence and high loss to follow-up affecting their validity [15]. To improve all three, it is prudent to consider the following aspects of the active and control interventions [15,16].

i. Target group: a primary prevention program should target the general population, whereas a selective prevention program would target high-risk individuals.
ii. Control intervention: individuals should (at least) receive usual care [17]. (The choice of the control intervention is discussed in more detail below.)
iii. Clinical equipoise: because of ethical considerations, randomisation can only be performed if it is uncertain whether the intervention is effective and which strategy is the best choice.
iv. Viability: is the lifestyle intervention implementable and affordable if shown to be effective?

v. Administration of the intervention: consider individual face-to-face coaching vs group sessions vs e-health.
vi. Duration of the intervention: a long duration may lead to non-adherence and drop-out, but too short a duration could lead to an ineffective intervention.
vii. Intensity (workload) of the intervention: a too demanding intervention may lead to low adherence, but low intensity may lead to an ineffective intervention.
viii. Run-in period: randomising only subjects who are compliant with an initial (placebo) intervention and outcome measurements may improve adherence of subjects in the trial [18].
ix. Duration of enrolment: external circumstances may change over time and influence recruitment.
x. Recruitment tactics [19]: maximise recruitment in order to complete the study in a timely fashion.
xi. Time-frame for follow-up measurements: both short and long-term outcomes are important since lifestyle interventions may take time to achieve their desired effect and long-term adherence may be suboptimal.
xii. Pilot study: consider performing a pilot study to test feasibility of the active and placebo interventions, especially for complex interventions, and to work out logistics.

Blinding and placebo interventions

Successful and complete blinding (that is, blinding of participants, caregivers and outcome assessors) is often difficult to achieve and generally not feasible in evaluating lifestyle interventions. Participants in lifestyle interventions are actively involved in the intervention, precluding adequate blinding. For example, someone running, cycling or practising yoga will know that they are doing that activity. Nevertheless, sometimes it is possible to blind participants to knowledge about which trial arm is the active intervention, for example by using e-health or special dietary products, but even this can be challenging. E-health provides opportunities by offering a passive information-only module. Double-blinding could be achieved in dietary interventions if foods are provided with certain elements eliminated or substituted (e.g. sugar substitute), but true blinding is only achievable with a limited number of foods.

It is difficult to distinguish the placebo effect from the actual effect of a lifestyle intervention, and offering a placebo lifestyle intervention is hardly possible. Any placebo lifestyle intervention is likely to have some effect, due to non-specific therapeutic mechanisms like attention (the Hawthorne effect) [20], structure, hope and working alliance [21-23]. Thus, providing any placebo lifestyle intervention in the control group would underestimate effectiveness of the active intervention compared with what can be expected in real-world practice. Rather than trying to determine the actual effect of the intervention, it is more meaningful to consider this additional placebo effect of a lifestyle intervention as part and

parcel of the intervention as it would be implemented in real-world practice. This is no different from considering the placebo effect of surgery as part and parcel of the procedure. The control group should receive either a competing lifestyle intervention or usual care as implemented in real-world practice, which will commonly include some form of lifestyle advice provided orally during a face-to-face meeting or through a pamphlet or website. This implies that the study will measure effectiveness rather than efficacy and that it is pragmatic rather than explanatory. Such a pragmatic trial design sacrifices some internal validity in order to achieve external validity and generalisability [24].

Allocation concealment will prevent foreknowledge of treatment assignment both among participants and among investigators performing enrolment. Allocation concealment can easily be undertaken and prevents selection bias [25]. Blinding of the outcome assessors is more difficult but important in order to avoid performance and ascertainment bias [26].

Informed consent procedure

If the active intervention is a no-risk lifestyle intervention designed to be attractive so that participants will comply and be adherent, then many participants will probably want to try it. A conventional randomised controlled trial design with full disclosure of the active intervention to all participants prior to obtaining informed consent would, according to the existing literature on lifestyle interventions, lead to several problems [27-30]: (i) slow recruitment because many participants would probably want to try the intervention rather than being randomised; (ii) bias and limited generalisability due to selection of only those participants who do not care whether they receive the intervention or not and are presumably less motivated; (iii) because the active intervention is attractive, participants allocated to the control group are likely to be disappointed, dissatisfied and demoralised which can lead to selective withdrawal of controls, poor response to follow-up measurements on questionnaires, non-adherence with the control intervention and cross-over (contamination) of controls who seek the active intervention on their own elsewhere, also known as 'drop-ins' [31]. An alternative would be an informed consent procedure which does not disclose the details of the intervention. However, this may raise ethical concerns, because withholding information about the intervention could result in an uninformed choice by the participant when entering the study.

OPTIONS FOR RANDOMISED DESIGNS

Table 1 presents a summary of randomised designs and includes several key points, advantages and disadvantages of each design. The key points are explained in detail below, with illustrative examples from the literature.

Table 1. Main features of randomised controlled trial designs for the evaluation of lifestyle interventions

	Main design features	Advantages	Disadvantages
Parallel group (Hill 1952)	· Allocation remains unchanged throughout the duration of the study · Randomisation to two or more arms (active intervention, control) · Participant is unit of randomisation	· Simplicity · Universal acceptance · Clear temporal sequence · Internally valid comparison	· Double-blinding not always possible · Time consuming and expensive · Large sample size needed (in case of low incidence outcomes) · Inefficient for diseases with rare outcomes · Lifestyle interventions that have a long lag time require a long follow-up period · Often low recruitment rate · Questionable external validity and generalisability
Cross-over (Louis 1984)	· All study interventions are given to each subject in successive periods · Random allocation of intervention/control · Washout period in between study periods · Number of treatment periods may be larger than two	· Participants act as their own control · Reduces variation in response · Smaller sample size needed · More efficient · Participants receive both treatments which increases attractiveness of participating which increases recruitment rate	· Condition needs to reverse to baseline during washout period · Effects of intervention need to be reversible · Possible period effect and carry-over effect · Not appropriate for acute conditions and progressive disorders · Only intermediate endpoints · Participants serve as their own control, and no comparisons can be made if the treatment has not been received
Cluster (Donner 1981)	· 'Clusters' (groups) of individuals are randomised · Cross-sectional or cohort-type clusters can be used · Matching of clusters can increase study power · Stepped-wedge design can facilitate organisation · Unit of analysis are the participants within the cluster	· Accounts for "contamination" and intra-cluster correlation between participants within a cluster · Easier to randomise groups of patients rather than individual patients · Design of choice when the intervention is at the group level or. when outcomes of participants are not independent · Social effects are included · Easier to organise	· Recruitment bias/selection bias · Selection bias of individuals after the clusters have been randomised because treatment allocation is known · Sufficient clusters needed for adequate power · Ecological fallacy: predictor variables can be present in either the individual or at the cluster level which can lead to causal inference errors · Entire clusters, rather than individuals, may be lost to follow-up

Table 1. Main features of randomised controlled trial designs for the evaluation of lifestyle interventions (continued)

	Main design features	Advantages	Disadvantages
Longitudinal cohort with nested RCT	· Participants are first asked to participate in longitudinal observational cohort study, then the RCT · Other design features same as parallel group RCT	· Better reflection of real world practice · Partial (rather than full) disclosure of details of lifestyle intervention during informed consent reduces drop-ins in control arm · Participants who refuse the intervention and drop-outs are followed as part of the cohort study	· Twice informed consent · Partial (rather than full) disclosure of details of lifestyle intervention during informed consent may increase drop-outs in active intervention arm · Other disadvantages same as parallel group RCT
Fully randomised preference design (Torgerson 1996)	· Preference recorded before randomisation · Randomisation and consent conducted in the usual way · Preferences taken into account during the analyses by including interaction between preference and treatment	· Advantages of 'full' randomisation · Convenient way of taking preference into account	· Requires bigger sample size to analyse the interaction effect · Unethical to ignore patients' preferences when proceeding with randomisation · Interaction of preference and treatment difficult to analyse
Zelen partially randomised patient preference design (Zelen 1979, 1982)	· Subjects are randomised before giving consent to participate · Single consent: Subjects in control group receive usual care; subjects in intervention group are offered the active intervention; if they refuse they receive usual care · Double consent: all subjects are asked to consent after randomisation; subjects declining the active intervention are offered usual care. Subjects declining usual care are offered another treatment	· The Zelen design makes it easier for physicians to recruit patients – consent procedure is as it would be in clinical practice and physician-patient relation is not compromised · Simplification of information given to the patient (which can be seen as a disadvantage as well) · Almost all eligible participants are included · Evaluation of 'true effectiveness' as would be observed in practice · Useful for population based interventions	· Does not meet (most) ethical requirements (primarily single consent design) · Cannot be single/double blind and is therefore an open trial · Should not be used in placebo controlled trials · Only suitable if data collection is limited to routine data · Dilution of treatment effect (can even be larger in the double consent design) if participants refuse intervention · Loss of statistical power if participants refuse intervention · Success depends on high proportion accepting the intervention · More subjects need to be randomised; loss of statistical efficiency · Treatment differences will be underestimated

Table 1. Main features of randomised controlled trial designs for the evaluation of lifestyle interventions (continued)

	Main design features	Advantages	Disadvantages
Wennberg partially randomised patient preference design (Wennberg 1993)	· Eligible participants are asked for consent to be randomised to a random allocation vs preference group · Participants in the preference group are offered their treatment of choice · Participants allocated to the random allocation group are randomised between active and control intervention without taking preference into account · All participants are included	· Better adherence · Reduces attrition · No bias due to refusing initial randomisation · Compared to Zelen, no ethical problems concerning consent, which is asked prior to randomisation · Evaluates treatment and preference effects	· Participants still need to consent for randomisation · No knowledge of preference in the 2nd randomised group and how this will affect the outcomes · Unknown confounders when comparing a randomised group and preference group · No knowledge of level of preference · Patient preference known only after randomisation · Large sample size needed · High costs
Rucker partially randomised patient preference design (Rucker 1989)	· Similar to Wennberg design, except participants who are randomised to the preference group after the first stage and who do not have a strong preference for a treatment, are randomised again in the second stage to active vs control intervention	· All subjects are randomised from the start · Evaluates treatment, selection and preference effects	· Only subjects that consent to be randomised enter the study · Subjects' characteristics may influence choice of treatment · Estimation of preference effect is complex
Brewin partially randomised patient preference design (Brewin 1989)	· Each eligible participant is asked for his or her preference · Randomisation takes place if no strong preference exists between the intervention or the control group · Participants with a preference are given their treatment of choice	· Almost all those eligible enter the study · Preferences are taken into account in treatment allocation	· Unknown confounders in the preference group · Bigger sample size · Sample size calculation difficult · Expensive

Parallel group RCT

The most commonly used randomised design is the parallel group design. Participants are allocated to one intervention arm (the lifestyle intervention or the control group) for the duration of the study. This design is frequently used because of the clear temporal sequence and its simplicity (Figure 1). Eligible participants are selected based on the pre-defined inclusion and exclusion criteria. The informed consent procedure fully informs patients about the randomisation process, the details of the active and control interventions and the measurements to be performed. Measurement of baseline characteristics is performed either before or immediately following the randomisation process. As randomisation can be dependent upon key variables of interest, for example age, sex, education or a specific health outcome, it may be purposefully undertaken after baseline measurement. The study is terminated after a specific period of follow-up. The outcome variables are measured in, preferably, a blinded fashion.

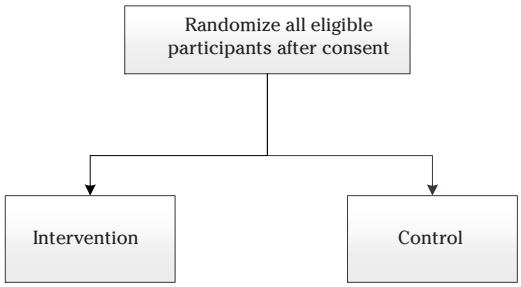

Figure 1. Parallel group RCT

Although the parallel group design provides an internally valid comparison, the main disadvantage is that the recruitment rate can be low because subjects may have preferences for specific lifestyle behaviours. Low recruitment rates lead to questionable generalisability (Table 1). Furthermore, if subjects participate in group sessions to learn about the lifestyle behaviour, "contamination" may occur, which may lead to correlated outcomes between subjects. Large sample sizes are needed if the primary outcome of interest has a low incidence. Additionally, the RCT may not be feasible if the outcome has a long lag time.

An example of a parallel group RCT for lifestyle is demonstrated by Estruch et al [32]. In this large multi-centre study, participants at high cardiovascular risk were randomly assigned to one of three Mediterranean diets. Once randomised to one of the three diets, participants remained in that arm for the duration of the study and were analysed as such using an intention-to-treat analysis. An as-treated analysis was also performed, in which only participants who were adherent to the assigned diet were included. New public health policies for lifestyle changes can be evaluated with pragmatic parallel group RCTs, as was done in Wales to assess the effectiveness of the National Exercise Referral Scheme [33].

Cross-over RCT

In a cross-over RCT, eligible subjects are initially randomly allocated to either the intervention or the control condition, as in a parallel group RCT (Figure 2). After a period of time, the initial treatment is stopped, a washout period without any treatment usually follows, and then subjects 'cross-over' to the other treatment modality. The difference from a parallel group RCT is that all participants receive both active and control interventions but in random order. The washout period reduces the risk of period effects and carry-over effects: these are effects that may occur from one period to the next due to the course of the disease and due to the switch from one intervention to the other, respectively. Because subjects undergo both active and control interventions, they can serve as their own control which reduces the random variation between active and control arms. Cross-over trials can consist of half of the subjects when compared with the parallel group design with the same precision, which is an advantage for the feasibility and execution of the study. Furthermore, because patients receive both treatments, participation in the trial may be more attractive to them, increasing recruitment.

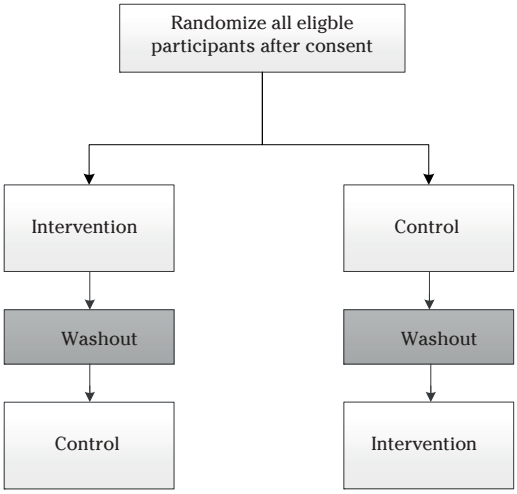

Figure 2. Cross-over RCT

Cross-over RCTs can, however, only be performed under certain conditions (Table 1). First, the outcome of interest should be an intermediate outcome since after a hard outcome such as death, cross-over to the other arm of the study is impossible. Second, the effect of the behaviour change needs to be reversible since a prolonged effect of the intervention can have significant carry-over effects in the subsequent control period. Because of the carry-over effect, not all lifestyle interventions can be studied with this design (e.g. behavioural programs with an anticipated lasting effect, such as cardiac rehabilitation, would probably have significant carry-over effects). Third, there should

be no difference between results from subjects who are randomised to the lifestyle intervention group and subsequently a control period, and those who are randomised to first a control period and subsequently to the lifestyle intervention. All-in-all, not all conditions are amenable to be studied in a cross-over RCT. Whereas chronic conditions with measurable symptoms are well-suited for crossover RCTs, acute or quickly progressive conditions are not, because of the changes from one period to the next (period effect).

An example of a cross-over RCT is the study by Katz and colleagues [34] on subjects with overweight who were randomised to two 8-week sequences of a diet enriched with walnuts vs a diet without walnuts, to evaluate the effect on flow-mediated vasodilatation. In between the sequences, subjects had a 'washout' period of 4 weeks. The effect of eating walnuts on flow-mediated vasodilatation was assumed to be reversible within the period of 4 weeks.

Cluster RCT

Rather than randomising individuals as observed in Figure 1, groups of individuals or "clusters" are randomised to the active intervention or control treatment (Figure 3). Clusters may be families, physician practices, departments, schools, companies or even entire towns. Eligible clusters are evaluated and informed consent is obtained from a representative for the cluster (known as the 'guardian' of the cluster). Data collection can be on a group basis, for example use of public parks, or on an individual level, for example self-reported physical activity. If individual data collection is undertaken, informed consent from individual participants is obtained. The effectiveness of the intervention is generally assessed and analysed at the patient level, taking into account the intra-cluster correlation between participants within the clusters [35]. A key limitation of cluster RCTs is that intra-cluster correlation requires a larger sample size, which can be achieved by increasing the cluster size or the number of clusters.

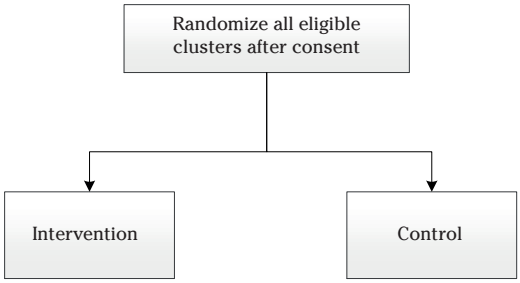

Figure 3. Cluster RCT

A cluster RCT is the appropriate study design to evaluate a lifestyle intervention that involves a group process. For example, an exercise program provided to a group (the

cluster) uses the social interaction between participants to enhance adherence and benefit. Cluster RCTs are also useful to evaluate interventions that involve educating health care professionals, which would subsequently affect an entire group of patients. For example, interventions that target physicians to adhere to new guidelines would affect all patients seen by the targeted physicians. Cluster RCTs can also be useful to avoid spill-over effects between individuals from different arms of the study, which may lead to 'contamination'. For example, employees in the same department in a company are likely to talk and influence each other's behaviour. Thus, if the company were to evaluate an employee lifestyle program, a cluster RCT with clustering at the departmental level or at different locations of the company would be an appropriate study design. Furthermore, due to necessity, practical or ethical considerations, a cluster RCT can be preferred (Table 1).

An example of a cluster RCT is provided by the Hutchinson smoking prevention project which evaluated 40 Washington school districts [36]. Based on a group-randomised matched-pair design, 40 districts with 3rd-grade classes were randomly assigned to control or intervention and followed until the 12th grade. Although this cluster size was sufficient to accommodate intraclass correlation, the design unfortunately failed to exploit the social influences of the intervention in the clusters.

A stepped-wedge cluster design may be useful when implementation of the intervention is time consuming, resource intensive and expensive. Such circumstances justify random allocation of clusters in a step-wise approach, which facilitates organisation of the study and can even benefit trial recruitment [37]. After a control 'step', clusters are randomly allocated to the intervention [38]. At the end of the study, all clusters will have a study period before and one after introducing the intervention—thus each cluster will have performed a before-after study. An example of a stepped-wedge cluster design study is provided by Mhurchu and colleagues [39], which clustered at the level of schools and evaluated the effect of free school breakfasts. Although stepped-wedge cluster RCTs have been shown to be suitable for community-level public health interventions, especially in situations where policy makers feel that nobody should be denied the intervention [40,41], there is a continuing debate as to the relative advantages and disadvantages [42,43].

Longitudinal cohort study with nested RCT

The longitudinal observational cohort study with a nested RCT design has many similarities with the parallel group RCT but embeds the RCT within a cohort study (Figure 4). Eligible participants first need to give informed consent to participate in the observational cohort study, and then are subsequently asked to participate in a randomised trial.

The main advantage of a nested RCT design is the available follow-up information of those who refuse the lifestyle intervention(s) or are non-adherent (Table 1). By having

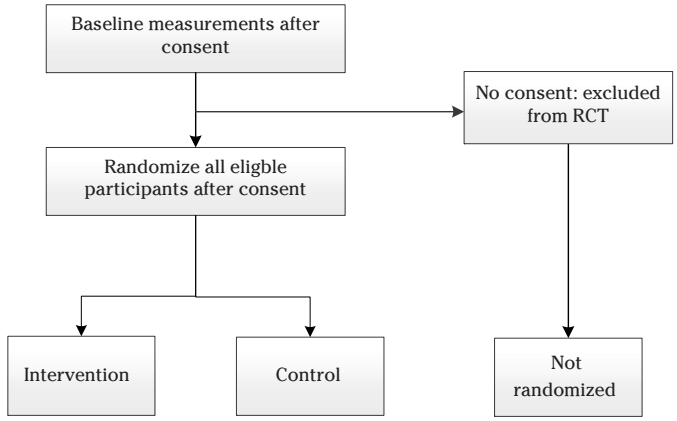

Figure 4. Longitudinal cohort with nested RCT

asked informed consent for the observational study before offering the RCT intervention, baseline and follow-up data can be collected from all individuals, including those who refuse the intervention. Furthermore, participants are only eligible for the nested RCT if they have complied with the observational cohort data collection, which ensures that participants randomised are motivated to participate.

When the information provided through treatment allocation can be considered part of the lifestyle program, a case can be made to use partial, rather than full, disclosure of the active intervention during informed consent to the nested RCT. Details about the active intervention are then only given after treatment allocation, since giving this information can be considered the educational part of the lifestyle program. Partial disclosure reduces the chance of drop-ins (cross-over) in the control arm but may increase the number of drop-outs in the active intervention arm (Table 1). However, partial disclosure is not commonly utilised, due to ethical concerns as it may be viewed as deception.

Preference trials and pre-randomisation

Although randomisation distributes characteristics of study subjects equally and thus controls for confounding, it does not take pre- and post-randomisation subjects' preferences into account, which may affect outcome. Preferences of participants can be an important source of bias [9]. A high drop-out rate prior to randomisation, due to patient preference, may affect generalisability of the study [8]. Especially in lifestyle interventions, preference may play an important role. If the active intervention is attractive, participants may prefer it. Therefore, if a participant preferring the intervention is randomised to the control group, it can lead to a high rate of drop-out from the study and/or a high drop-in rate to the active intervention, affecting the internal validity of the study. Also in terms of professional relationships, if the active intervention is preferred,

physicians tend to be less motivated to recruit patients for a trial that may affect their physician-patient relationship.

Several types of modified trial designs, incorporating participant preference, have been described in the literature [9,44-48] but, until now, use of preference trials is still scarce (Table 1, Figures 5–10) [49,50]. In fully randomised preference trials (Figure 5), participant preferences are documented as part of the baseline data [47]. Subsequently, participants are randomised in a regular manner. In the data analysis the interaction between preference and treatment is taken into account to evaluate preference as a potential effect modifier. This 'solution' requires an increase in sample size in order to perform valid analyses of the interaction [51]. In partially randomised preference trials, not all groups are randomised (Table 1). In the single-consent Zelen (pre-randomisation) design, participants are randomised to intervention or control groups before informed consent. Informed consent is asked only from patients allocated to the intervention group (Figure 6) [45] since the control group receives usual care for which informed consent is (usually) unnecessary. This design can be useful for large studies evaluating lifestyle advice for primary prevention. For example, a study evaluating a telephone consultation for smoking cessation was performed using this design [52]. Nevertheless, the single-consent Zelen design raises ethical concerns. In the double-consent Zelen design [44], consent is asked in both groups after randomisation (Figure 7). Limitations of the Zelen design include ethical concerns about absence of consent for randomisation, loss of statistical power when there is a high drop-out rate in the intervention group, and problems with data collection from patients who refuse participation (Table 1).

Several other preference designs have been proposed in the literature, such as the Wennberg (Figure 8), Rücker (Figure 9) and Brewin (Figure 10) designs (Table 1). The Wennberg design randomises participants to a preference or randomisation group. Those in the preference group are offered their treatment of choice, and participants in the randomisation group are randomly allocated to one of two treatments [46].

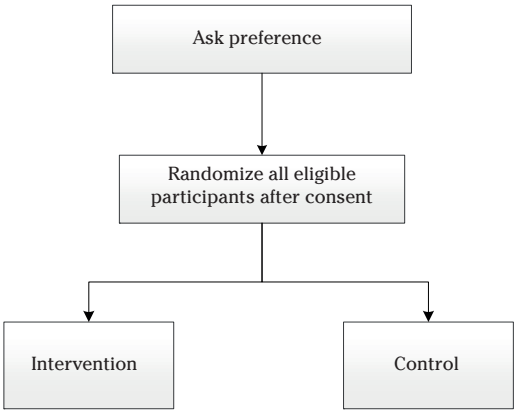

Figure 5. Fully randomised preference design

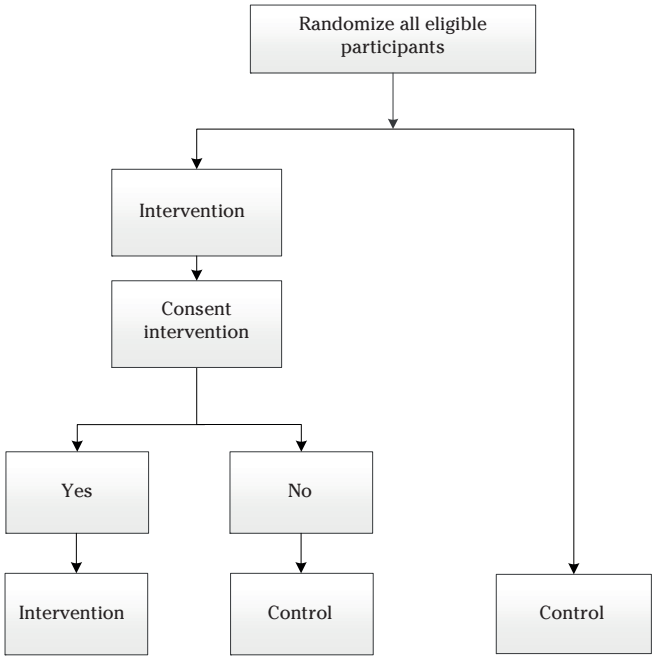

Figure 6. Single-consent Zelen preference RCT

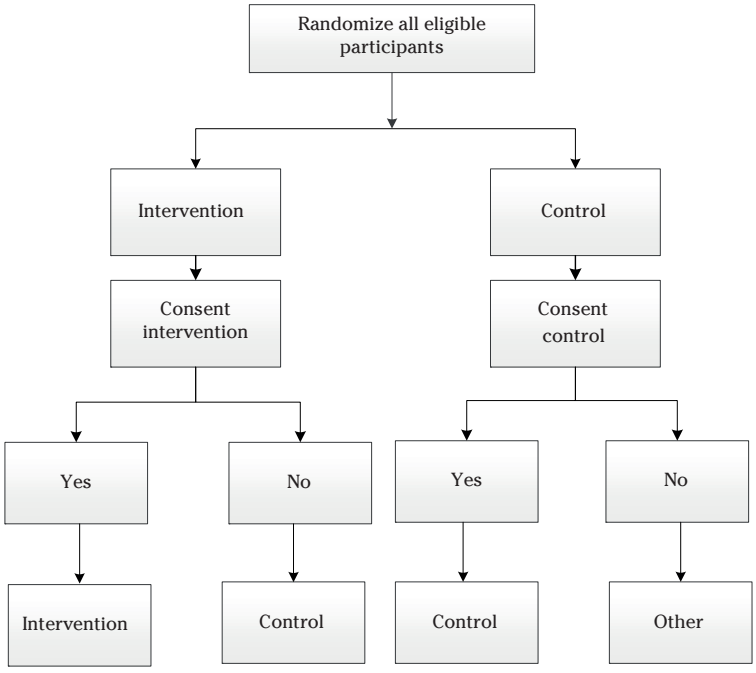

Figure 7. Double-consent Zelen preference RCT

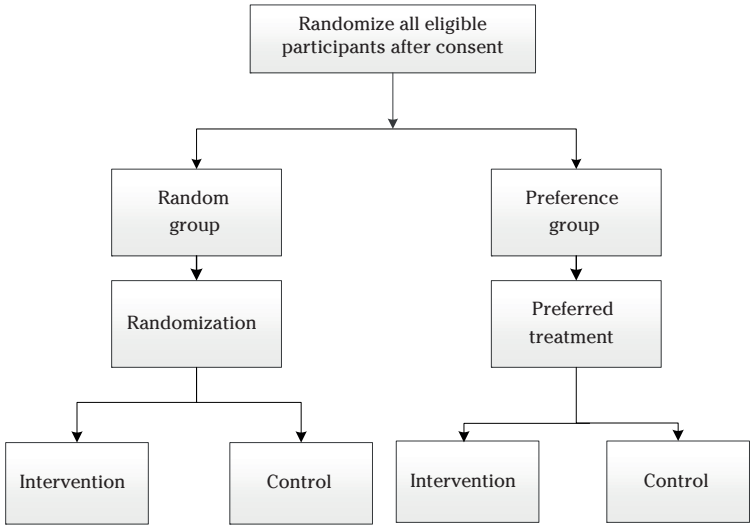

Figure 8. Wennberg preference RCT

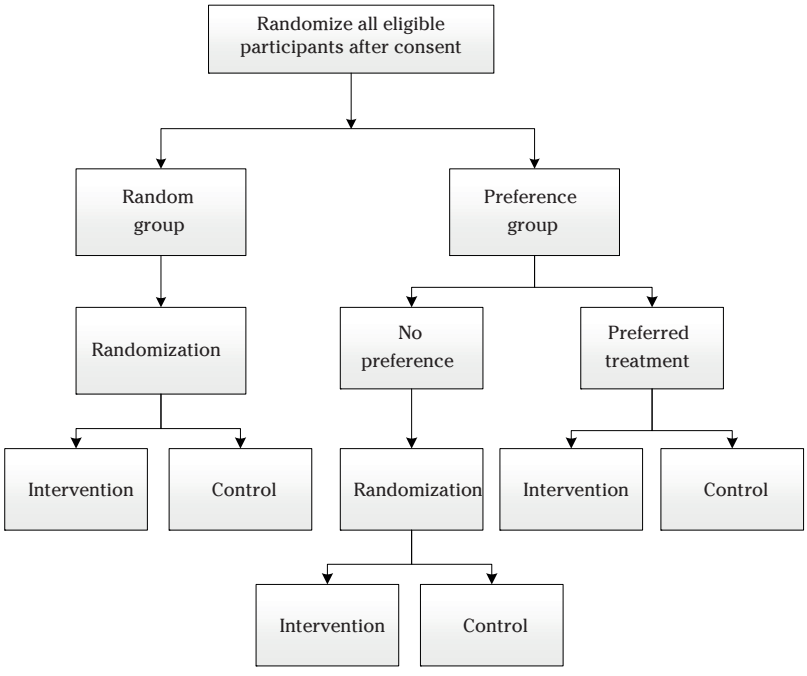

Figure 9. Rücker preference RCT

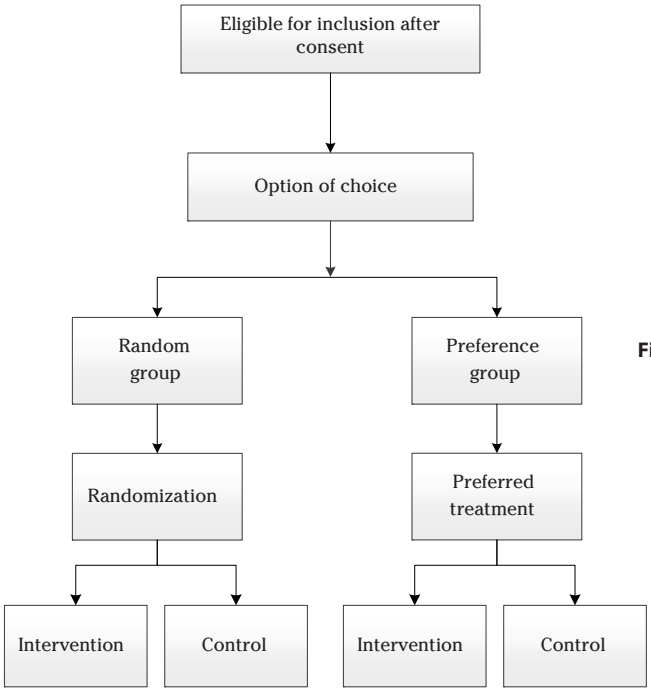

Figure 10. Brewin preference RCT

Similarly, the Rücker's design starts with a randomised allocation to a random and preference group [48]. Patients in the preference group can choose their treatment. Patients without a preference and those in the random group are randomised between treatments. In contrast to Rücker's and Wennberg's designs, the study design by Brewin enables all patients to choose in the first stage: they can either enter the random group (where randomisation will allocate them to a treatment) or enter the preference group in which they make a treatment choice themselves [9]. These designs have been used in a variety of clinical settings [49,50] and allow for the evaluation of the effect of preference on the benefit of the intervention. A disadvantage is that the results in the non-randomised groups are prone to confounding bias [51] and these designs are generally more expensive due to the greater sample needed.

DISCUSSION

This tutorial shows that difficult methodological choices have to be made to optimise the quality of an RCT evaluating the effectiveness of a lifestyle intervention. RCTs evaluating lifestyle interventions have generally a more complex design than RCTs evaluating medical therapy. Although RCTs are considered the cornerstone of evidence-based

medicine, a straightforward parallel group randomised design will not necessarily lead to a high-quality study, and other randomised study designs may be a better choice.

The parallel group RCT, where one or more interventions can easily be compared with a control, is frequently used because of its simple design and universal acceptance. Parallel group RCTs are, however, less useful in evaluating lifestyle interventions. Cross-over studies can be more efficient, because participants act as their own control, reducing confounding and leading to smaller required sample sizes. The biggest disadvantage of cross-over studies is that the effect of the intervention needs to be reversible. Crossover RCTs are particularly helpful in evaluating the effect of single reversible dietary interventions on intermediate outcomes (e.g. reduced salt intake and blood pressure). A cluster design can be preferred when social influences are an important aspect (such as group exercise programs) or when the intervention is naturally performed at the group level (e.g. targeting physician practices, companies or cities). Many clusters are, however, needed to provide sufficient power, and losing an entire cluster due to organisational problems can have a disastrous effect. If the dropout rate is high and the characteristics of drop-outs are of interest (e.g in a smoking cessation program), an RCT nested within a longitudinal cohort study is useful because information can be collected from participants not consenting to the RCT. Giving partial information rather than full information about the intervention may reduce drop-ins in the control group, but this comes at the price of an increased drop-out rate in the active intervention group after being fully informed about the intervention. For the majority of RCTs on lifestyle interventions, a pragmatic approach is recommended to evaluate the effectiveness of the intervention as it would be implemented in clinical practice compared with usual care as control. All in all, cluster RCTs and pragmatic designs are promising when it comes to evaluating complex lifestyle interventions.

Special consideration should be given to the use of patient preferences in randomised trials of lifestyle interventions. There is a growing interest in the understanding of treatment choices and there are both practical and ethical reasons to incorporate patient preferences in RCTs of lifestyle interventions [53]. Whether preference can lead to a better estimation of treatment effects when incorporated in the study design is still under debate, and the required statistical analysis is far from straightforward [54-56]. Additionally, sample size calculations are difficult and often the larger sample size required for preference trials leads to a greater expense.

In the current tutorial we did not focus on several other aspects that are important in the design of an RCT, such as randomisation procedures, statistical power, data analysis, economic evaluation, and reporting. Most of these aspects have been clarified extensively in the literature. In fact, the CONSORT statement has resulted in uniform and structured reporting of clinical trials [57], providing a very helpful guide for researchers both in developing a structured protocol and in reporting the results. We welcome the

fact that the CONSORT study group is expanding their reporting guidelines to other study designs such as cluster [58] and pragmatic designs [59], and also the reporting of non-pharmacological interventions [60].

The complexity of lifestyle interventions could potentially lead to challenges in evaluating effectiveness and cost-effectiveness. It is prudent to perform a pilot trial to test the feasibility of complex interventions and the feasibility of performing the trial [11,61]. Lifestyle interventions are often complex in two ways. On the one hand they consist of multiple components which may interact, making it difficult to define which is the active ingredient. On the other hand they are introduced at different organisational levels in complex systems such as families, schools, communities or public places. Complex systems are sensitive to initial conditions, make non-linear phase-transitions, tend to be self-organising through feedback loops and demonstrate emergent properties [13]. Both forms of complexity influence the choice of effectiveness measure and the costs that are considered, making the economic evaluation a challenge [13,62]. Furthermore, a process evaluation of introducing the lifestyle intervention is needed before widespread implementation, which should consider anticipated delivery mechanisms, intervention components, impact mechanisms, implementation process in practice, participant responses, mediators, unintended consequences and contextual factors [63].

In conclusion, the increased focus on healthy lifestyle behaviours has resulted in a strong demand for wellperformed high-quality RCTs. Evaluating lifestyle interventions calls for special considerations in designing the study, which are inextricably linked to the research question. We recommend considering alternatives to the conventionally used parallel group RCT. Our discussion of several types of RCTs suitable for evaluating lifestyle interventions, including their advantages and disadvantages, provides guidance in the choice of an optimal RCT design.

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Chapter 8

General Discussion

"The function of protecting and developing health must rank even above that of restoring it when it is impaired"
(Hippocrates)

GENERAL DISCUSSION

The burden of cardiovascular disease (CVD) is increasing (1), while at the same time the proportion of older employees active in the workforce is increasing. As a result, within the workforce the percentage of employees with CVD or at risk for CVD is increasing (SER rapport). Having CVD is associated with decreased employability, such as absenteeism, productivity loss at work, or premature exit from the workforce (2). In addition, being employed benefits health and well-being (3, 4). This has led to increased awareness by organisations that CVD should be addressed.

This thesis aimed to investigate how blended web-based health promotion interventions at the workplace influence health behaviour among workers at increased risk for cardiovascular disease. This section includes a summary of the main findings, methodological considerations, interpretation and new insights, and recommendations for researchers and occupational health professionals.

MAIN FINDINGS

What is the impact of work-related factors on exit from paid employment via disability, unemployment, and early retirement, in employees with cardiovascular disease?

Data of the longitudinal Survey of Health and Retirement in Europe (SHARE) were analysed to give insight in work-related factors as determinants for exit from paid employment in employees with cardiovascular disease (CVD) or diabetes (chapter 2). It was shown that the probability to exit work before the retirement age was increased by workers with CVD or diabetes compared to employees without CVD or diabetes. This was seen for receiving disability benefits (Odds ratio (OR) 2.50) or early retirement (OR 1.34), and not for unemployment (OR 1.10). Individuals who had a stroke had the highest probability of receiving disability benefits. Regarding the impact of work-related factors, perceived high job demands with low rewards or with low control at work further increased the probability of early exit among individuals with CVD or diabetes.

What is the effectiveness of blended workplace health promotion programs?

We investigated the effectiveness of two blended web-based health intervention programs in employees at increased cardiovascular risk. The first intervention was the PerfectFit study (chapters 3, 4 and 5), which showed no difference in self-rated health between groups, but health behaviours improved significantly. Adding motivational coaching increased the effectiveness in reducing bodyweight. Evaluation of implementation showed that increasing the quality of implementation offers great potential to

further increase health behaviour in a sustainable way and with enlarged reach. The second intervention implemented and evaluated, was a blended web-based gaming intervention (chapter 6), aimed at overweight or obese employees. Participants with overweight or obesity were instructed to wear a triaxial accelerometer for 23 weeks, and to engage in any kind of physical activity to reach personal and team targets. This study resulted in all participants being physically active above the recommended activity levels during the entire intervention period, and a favorable influence on BMI and waist circumference. Promising gaming-components were the use of eHealth teams and higher engagement with the game.

Chapter 7 is a methodological paper, in which we aimed to increase the quality of the study design of randomised trials in future studies evaluating lifestyle interventions. The advantages and disadvantages of each study design were discussed. This paper provides tools for researchers to choose the optimal randomised study design when assessing the efficacy or effectiveness of a lifestyle intervention (e.g. parallel, cross-over, cluster, or preference design).

METHODOLOGICAL CONSIDERATIONS

Generalisability

Both implementations of blended workplace health promotion programs resembled current practice in the organisations and occupational health services that participated in our studies.

In the PerfectFit study, all participants were employees of three large organisations, with a wide variety of occupational functions in the study population. There was no interference with clinical treatments, which is reflective of the occupational health setting. Within the Netherlands, the study findings can be generalised to large organisations, but may not be feasible for small and medium-size organisations. The large organisations in our study had their own occupational health centers with measurement facilities and an occupational health physician (OP) focusing on just this organisation, while smaller-sized organisations usually have contracts with occupational health centers with multiple customers and facilities at a distance from the workplace. However, this limitation would only apply to the face-to-face component, and not to the usage of online intervention components, since these are independent of the actual location of the user. Within the participating organisations, this study targeted employees in predominantly active jobs, such as police officers, nurses, and soldiers. This was illustrated by 42%, 37% and 27% not meeting the health recommendations for physical activity in the police force, the hospital, and the military force respectively, versus 65% in the general population (5). Thus, the study results may not be valid for predominantly administrative jobs.

On the other hand, a more sedentary population would have more to gain in the level of physical activity, so it would be interesting to evaluate the effects of this intervention in such a population as well.

In the web-based gaming intervention, participants were employees in different jobs of one large organisation, who worked at one or two different sites but still in the same city. The latter might have been an advantage to the attendance of workshops and thus face-to-face bonding by eHealth-teams, which would be harder for employees of smaller or of a variety of organisations. However, the number of face-to-face contacts was limited, and the online gaming environment provided, could be accessed at any time during the total intervention-period, independent of the actual location of participants. In the Netherlands, almost 100% of the adults before retirement age have access to internet (6). In regards to generalisability of this blended approach we conclude, that the gaming intervention can be introduced by both large and smaller organisations, as long as the face-to-face sessions are within a certain region.

Outside the Netherlands, study results may not be valid, since occupational health care, and social security systems in countries differ. However, some countries, e.g. the United States of America, are expected to be more keen on interventions aimed at preventing disabling diseases, since health care costs are paid by organisations, and disability benefits are less generous for employees. In addition, the global obesity prevalence is rising (7), leading to an increased need of effective programs for workers. Therefore, a cross-nation implementation would be interesting for both workplace health promotion programs.

Effective components

Both web-based health promotion programs consisted of multiple intervention components. Although this complicates the isolation of the most important component to the effectiveness, the evaluations provided some insights. For the PerfectFit study, the 'reach' was low (12%), and there were differences between organisations, most probably due to either ongoing reorganisations, a change in management-strategy concerning health-screening, and different communication strategies. To improve 'reach' in future implementations, all these aspects should be addressed. Of those employees taking the cardioscreening, over 92% were found to be at increased CVD-risk. This could be due to just mostly high-risk employees responding to the screening due to a sense-of-urgency, although many studies previously reported higher participation in workplace health promotion programs in healthier and more motivated individuals (8, 9). Another reason could be that within these organisations the majority of employees over 40 years of age was at increased CVD-risk. This is most likely since our inclusion criteria were broad and in the Western population the majority of the adults have a modifiable cardiovascular risk factor, e.g. just 5% eats sufficient fruits and vegetables (10), 48% meets the recom-

mendations of healthy physical activity (5), and 24% smokes (11). It can be concluded that the PerfectFit intervention is applicable for the majority of adults in the working population, but the cardioscreening may be unnecessary as a pre-screening and should be integrated in the HRA.

The web-based intervention components of PerfectFit, newsletters and HRA, were well received by participants. Although evidence on the long-term effects on behaviour change by newsletters, i.e. period message interventions, is contradictory (12, 13), this component is often integrated in web-based interventions. This may be due to periodic reminders improving adherence to the core health behaviour intervention (14), since poor adherence has been extensively documented in studies on web-based interventions (15). Periodic newsletters may have contributed to the high proportion of completion of the HRA among participants in our study, and to the response at follow-up. Overall, an increase in physical activity and a reduction in alcohol usage, as well as more than 80% participation in health promotion activities were observed in our study. However, increased participation in health activities and long-term changes in health by reducing BMI were observed in the extensive group, i.e. those participants who received additional MI-coaching by an OP, suggest that MI is a crucial intervention component.

In the PerfectFit study, increased quantity of the MI-sessions and better quality of MI by the OP led to more participation in health promotion activities. At long-term follow-up, the strongest association was found for MI-quality, thus being a promising intervention component. Key to MI as communication strategy is to approach clients in a nonjudgmental way, explore ambivalence towards behaviour change, and provide guidance towards actual behaviour change (16). MI is used as stand-alone treatment, and in the last few years, MI has increasingly been used as an adjunct to other approaches. For example, adding MI to traditional weight-loss treatment was beneficial to health behaviour changes and weight loss (17). However, results were not always positive, and intentions to change or even changes in a positive direction may not always translate into actions or behaviour that is maintained (18). The quality of MI, i.e. MI-fidelity, during sessions is mentioned as a potential factor determining its effectiveness, but studies often fail to measure and report on fidelity of delivery (18, 19). Reasons may be that objective measurements of MI-fidelity is time-consuming, and requires audiotaping consultations by OPs, listening and typing all taped material, and MI-coding by a trained professional. However, since our study showed MI-quality as a crucial component in sustainable behaviour change, optimising MI-fidelity in future health promotion programs is strongly recommended. Furthermore, coded audiofragments can be used as an educational tool in post-training coaching (20), aiming to improve MI-quality and increase its impact.

The contribution of face-to-face contacts to the effects of the web-based gaming intervention could not be assessed, since an appropriate control-group for this purpose

lacked in the study. However, eHealth team-members connected both real-life and online, and eHealth teams (i.e. social influence of eHealth teams) was found to be a crucial component in relation to our outcomes. This fits the idea that social factors are determinants to healthy behaviour (21). Other components studied were "compliance" with the game (ie, days of accelerometer wear), and "engagement" with the game (ie, frequency of reaching a personal monthly target). Although use of an accelerometer was not related to our study outcomes, usage remains essential to playing the game and online self-tracking in groups is suggested to be more effective than self-tracking alone (22). Engagement by target setting towards personalised goals was found to another key component in our study, in line with another study (23). These elements combined provided a persuasive gaming context (24). To conclude whether this intervention guides participants towards habit formation in order to optimise health in a sustainable way (25), long-term follow-up is needed.

Study design

PerfectFit was designed as a cluster randomised controlled trial. This was chosen, since the randomised controlled trial is the state-of-the-art in evaluative health intervention research for drawing causal inferences between intervention groups. Clustering was needed for two reasons. First, OPs in the extensive group received extensive motivational interviewing (MI) training prior to the inclusion period, and we needed physicians in both arms to adhere to their 'treatment' and prevent 'contamination-effects' between arms. To make sure no aspect of MI was applied in the other study-arm, clustering ensured OPs were only active within a single study arm. Second, we implemented the intervention within organisations, where social interaction takes place. Thus, the cluster design was needed to prevent participants from different organisational departments sharing their experience, i.e. about their study-involvement or about organisational interventions, which might influence their behaviours.

The cluster-design may have led to under-powering of the study, since the power of this design benefits from an increased number of clusters, and from similar cluster sizes. After the inclusion-period, the study showed large cluster-size differences (ranging 1-124). Cluster-size differences originated from insecurities in working locations due to upcoming reorganisations. At the time of implementation within the police, neither OPs nor employees knew whether they would be transferred to another department. Therefore, departments that would potentially transfer OPs or employees were joined in the same cluster. This resulted in a less than expected number of clusters, and in much bigger cluster-sizes for Police than within the other organisations. Last, clustering was vulnerable to drop-out, since most clusters only had a single OP performing the intervention. Nevertheless, just one cluster was lost to the study, which happened before any inclusions took place.

In chapter 7, guidance is provided for choices in randomised study designs. Although the cluster RCT design was carefully chosen, we could not prevent allocation bias, as was illustrated by the heterogeneity in age, gender, and education at baseline between the extensive and limited intervention group creating a disbalance between the groups. Adjustment for these factors led to the lack of precision in the estimated effect of the extensive intervention group compared to the limited intervention group. In addition, blinding of individuals and OPs was impossible, and the robustness and time-consuming aspects of the RCT did not always match with high pace health innovations organisations would have liked to achieve. Although high quality research is essential for evaluation of intervention effectiveness, the value of science to organisations can be increased by searching methods that match daily business. Burdorf and Van der Beek recently described, that for some public health situations, nonRCT designs could be preferred (26). Thus, RCT and nonRCT designs should be included in the careful selection of a study design for workplace health intervention programs.

Measurement methods

Dilemmas on using self-reported or objective measurements are widely described in the literature. Data on physical activity in the PerfectFit study (chapters 3,4, and 5) were based on self-report, while the gaming-intervention (chapter 6) used objective measurement using a triaxial accelerometer. Both ways of measuring provide information on duration and intensity of physical activity, allowing an interpretation of meeting the recommendations. However, objective measurements by using accelerometers are promoted for more objective and continuous measures (i.e. measuring over a longer period of time), and it has been suggested that just wearing the meter would increase physical activity levels (27). The latter was however not found in the PerfectFit study. A systematic review of 173 studies comparing self-report with objective measured PA among adults, showed that differences were mainly found for vigorous PA levels (compared to lower PA) (28). Since for health gain, both moderate and vigorous PA levels are of importance, the use of objective measurements would be preferred in future interventions (29).

BMI was objectively measured in both intervention-studies. This was chosen in order to be able to rely on the quality of our repeated BMI-measures as one of our quantitative outcomes. Previous studies on the accuracy of self-reported BMI report heterogeneous results, ranging from being a valid method (30) to a lack of accuracy since individuals tend to overestimate height and underestimate bodyweight (31), especially in overweight and obese individuals (30, 32, 33). During our studies, participants would visit the occupational health center in order to be weighed and measured by calibrated scales under equal circumstances (empty pockets, no shoes). Although this resulted in reliable quality measurements, one could consider introducing Quantified Self technologies for measuring BMI. Quantified Self is the term that embodies self-knowledge through self-tracking (34),

using information technology. Self-tracking of bodyweight for example can be done by so-called "smart scales", which objectively measure bodyweight which is then uploaded to a web-based application. A recent study showed good concordance between measurements by a smart scale and by a health professional, although clear protocols for users are advised as well as future studies on individuals weighing more than 110 kg (35). Measuring by smart scale would overcome difficulties in scheduling appointments at a health center, and would thus lead to more accuracy in timing of the measurements, and to less loss-to-follow up since measurements can be done at the person's preferred time. In addition, measurements could be done more frequently to assess the time course, additional behaviours could be monitored, such as sleep patterns, it would reduce costs, and it creates opportunities for linking web-based feedback and support for behaviour change to every electronic upload. Regular self-weighing has been reported as a useful tool for weight loss because it might provide feedback on energy balance status and consequent improvement in self-regulation (36). Despite the potential benefits, widespread adoption in occupational care is facing several barriers, such as practical issues of electronic safety, mindset by both physicians and users (37, 38), and a lack of validation of many new technologies. It was recently suggested that participation in online health social networks could encourage quantified self-related behaviour (37), which was confirmed by our study (chapter 7).

Although Quantified Self by using information technology is promising, just measuring should be seen as facilitators, not drivers, of health behaviour change (39). For overcoming the gap between awareness and actual behaviour change, face-to-face sessions using MI by an OP were added to the web-based approach. The quality of MI was measured by coding audiotaped fragments according to the Motivational Interviewing Treatment Integrity Code (MITI) (40) By this way of measuring, the utterances of the physician are scored. These are categorised into specific MI-components: technical behaviour counts and an overall global score. It thus assumes that an increased level of MI by the physician leads to increased behaviour change by individuals. This was confirmed for MI-components 'open questions' and 'direction giving', leading to increase participation in health promotion activities in our study (chapter 5). However, aiming for a more patient-centered approach, it would be of additional interest to monitor the interaction between physician and individual. The importance of perceived physician's empathy by the patient was highlighted in a recent thesis by Derksen (41), who showed that a human connection is irreplaceable by any technology. To optimise a sustainable behaviour change, a perfect fit between the patient and the physician's communication style would be beneficial. Although the last update of the MITI (MITI 4.2) (42) adjusted both behaviour and global scoring items, this way of measuring is still limited to the physician's behaviour. For future interventions, including measurement of patient's perception in rating MI, for example by using the Client Evaluation of Motivational Interviewing scale (CEMI)(43) is promising for further personalising the human factor.

INTERPRETATION AND NEW INSIGHTS

Cardiovascular disease and work interact

A negative influence of work-related factors on participation at work was found for a diversity of chronic health conditions (44). Psychosocial work-related factors increased the chance of receiving disability benefits for all health conditions included in the study. Chapter 2 confirms these findings, by showing that having CVD is associated with increased dropout to the workforce before the legal retirement age. It also suggests that adjusting the working environment could be beneficial in keeping these diseased employees employed. This means that beside optimal medical and lifestyle treatment, work-related factors can contribute to health, well-being, and participation at work. This adds to the evidence for the burden of chronic diseases in the workplace (45), and supports the vision that interventions aimed at working environment, health status, social environment, and resilience are valuable to both individual and organisation (46). Furthermore, clinicians should incorporate attention for work into their CVD-treatment protocols.

Blended Workplace Health Promotion Programs can be effective

Until now, workplace health promotion programs have shown little effect on health outcomes (47). Most interventions were delivered by solely eHealth or solely face-to-face contacts. Combined use of both eHealth and face-to-face contacts is promising, since advantages of both approaches yield a broader reach, a tailored risk profiling, and a personalised approach. Little is known about the effectiveness of so-called "blended" workplace health promotion programs. Two such blended workplace health promotion programs are evaluated in this thesis. The blended web-based intervention PerfectFit showed a reduction in BMI compared to baseline in the extensive group, although not statistically significant (chapter 4), and positive changes in health behaviour and participation in health promotion activities (chapters 4 and 5). The blended web-based gaming intervention was beneficial in reducing BMI, and maintaining a healthy level of physical activity during the intervention-period (chapter 6).

Effective components of the gaming intervention appeared to be social bonding and individual engagement, by way of target setting including virtual rewards (chapter 6). The importance of the social component was previously illustrated by Bot et al, showing a healthier lifestyle in adults at risk of CVD or diabetes if their social network was more extensive and included more close-knit relationships (48). Also social networks, such as Facebook, showed positive effects on health-related behaviours (49). Our study combined real-life social contact during workshops with online social contacts among team-members, which had beneficial effects. Although eHealth-teaming was illustrated to be a key-component, differences between teams should be addressed by

stimulating team-members to actively contribute to their teams. The importance of the gaming component 'engagement', i.e. personal target setting, can be explained in two ways. First, participants were challenged at a perfectly matched physical activity level to get them engaged and absorbed in the activity (Theory of Flow) (50, 51). Second, participants were challenged at group performance level by relating group performance and group incentives to each participant's contribution (52). In conclusion, this intervention combined multiple persuasive contextual factors (24) with a fun factor (53), which should be considered in future health promotion programs.

The face-to-face component in the PerfectFit study, by means of MI-sessions, objectively showed that MI applied at increased quality-levels is beneficial to health behaviour (chapter 5). The addition of MI to eHealth-applications offers OPs a tool to be more patient-centered. However, differences in MI-performance level between OPs suggest that the amount of MI-training required to achieve a sufficient level differs between OPs. Although training protocols were followed, additional training could be provided for those OPs not meeting advanced MI-level. It could even be considered to only include OPs for this intervention once they have shown to have reached advanced MI-level. However, this would only solve part of the problem. Another observation was that OPs lacked consistency in MI-level, which may probably partly be attributed to client behaviour. Thus, future interventions should aim for optimisation of quality of MI by OPs, and include receptiveness of MI by clients.

The PerfectFit study showed beneficial changes in health behaviour and high participation in health behaviour activities, but no statistically significant differences were found on health and work outcomes, e.g. general health, absenteeism (Chapters 4 and 5). The reductions in long-term sickness absence were in the expected direction, but did not reach statistical significance. While the most frequent mentioned reasons by top managers for considering integrating health promotion activities at the workplace are keeping employees healthy and reducing absenteeism (54), the PerfectFit intervention has not shown to meet these requirements. Potential explanations are the above mentioned limitations in our study design, and sub-optimal delivery of our intervention (chapter 5). Despite this lack of effect, beneficial effects were evident for changes in health behaviour. It is expected that these changes will lead to health- and work-related benefits in a later stage, since this is widely known for intermediate health behaviours, such as physical activity (55, 56), diet (57), and alcohol (58). However, actual prevention of chronic diseases among workers and the prevention of losses to the workforce, in a high quality controlled trial setting, may need longer follow-up time. In conclusion, organisations should still be encouraged to implement workplace health promotion programs, but choices for intervention-components and implementation strategies should be made carefully, and researchers should aim for good quality research with long-term follow-up.

RECOMMENDATIONS

Recommendations for practice

Occupational health should strive towards an integrative approach of workplace and health.

Traditionally, occupational health was purely aimed at detecting health risks at work. There are growing insights, that workplace conditions contribute to, but do not solely determine, workers' health. Rather, the health of the workforce results from an interaction of work and health risk factors, as was emphasized by chapter 2. This requires workplace health promotion programs integrating occupational health and safety with disease management, and requires alteration of the landscape of occupational health practice (46, 59). This integrated approach offers the field a tremendous opportunity to increase its positive contribution in promoting health and well-being of the workforce.

Occupational medicine needs to move from a reactive to a proactive discipline, a discipline that is predictive, personalised, preventive and participatory. This by clinical physicians so called "P4 medicine" will benefit from emerging technologies and analytical tools (60). Technological improvements enable self-management by employees, and allow choices that fit people's lives. Thus, it facilitates a patient-centered instead of disease-centered approach, and it supports occupational physicians to optimally connect to their patients (also called 'clients' in occupational health). Expansion of the focus of occupational physicians to detection of high-risk individuals and personalised interventions in the contexts of work, health, social environment, and resilience, contributes to decrease the burden of disease by non-communicable diseases and losses to the workforce. Participating in work is not just for financial purposes, but also for better health and for connection to society. It may also contribute to self-respect and the feeling to matter.

Intensify collaborations

This integrative approach combined with P4Medicine requires an intensification of the collaborations between clinical and occupational physicians. Workers' health should be felt as a joint responsibility of all medical professions. In addition, the clinical guidelines for chronic diseases should addressing work during clinician's care, and the occupational physician should be integrated in the regular health care system.

To achieve genuine innovations in occupational health care, an intensive, long-term, and strategic collaboration between physicians and information technology business is needed (61). Economic evaluations show that health care is becoming unaffordable, and changes in health care management are needed. eHealth seems promising for supporting traditional healthcare, and many eHealth applications for health care use are developed. However, many eHealth initiatives face the 'valley of death', i.e. costly

failures. Involvement of physicians during eHealth development is expected to increase acceptance and usage (62, 63). Issues, ranging from technical possibilities, needs and expectations, financial coverage, to ethical and safety issues, need to be addressed. Addressing these issues appropriately will contribute to widespread adoption by physicians and employees.

Expand occupational health in medical education.
Awareness of the potential value and workers' health being a joint responsibility of all medical professions, could start during medical school (64). In the Dutch educational system, occupational health is only covered by a short internship at an occupational health center. Full awareness of the responsibility of workers' health by all doctors requires coverage of occupational health items during all clinical internships.

Adjust web-based health promotion programs to target groups.
Aiming for a perfect fit between health promotion programs and individuals, web-based tools should be further targeted to optimise personalisation and increase participation. Differences between certain groups could be taken into consideration to tailor programs to the needs of these different groups. Adjustments could be made depending on occupational branch, phase in career and life, or socio- economic position. For the latter, lower socio-economic groups will need extra attention towards the promotion of healthy behaviour, as these groups are known to have unhealthier behaviours, tend to have barriers to participate, and have a higher probability to become diseased and disabled. Lower socio-economic groups may be more involved in physically demanding jobs and less exposed to healthy lifestyle initiatives, which could contribute to the increased percentage of diseased individuals. In addition, health literacy is lower among individuals in lower socio-economic groups (65), which was associated with less perceived involvement in shared decision making. It should be taken into account that lower socio-economic groups may have other needs and preferences compared to higher socio-economic groups concerning communication, costs, implementation, and focus of health promotion activities. Implementing strategies for targeting specific groups within both the web-based and the face-to-face components could further optimise the health promotion approach.

Recommendations for future research

Evaluate the combined effect of workplace health promotion strategies aimed at the individual and aimed at the organisation.
Actively targeting individuals at high risk should be combined with health promotion at the organisational-level. By linking these strategies, it will be easier for individuals to bring the intended change into practice. For example, it may be easier for an overweight

employee to adhere to an individual weight loss intervention, when healthy food is promoted at the company's cafeteria. Or, an individual may act upon signs of personal stress in an earlier phase, when the organisation actively fights burdening stress at the workplace. Such comprehensive strategies have the potential to contribute to major improvements in health and productivity (54).

Continue research on effective components of workplace health promotion intervention.
Detection of effective and non-effective components provides direction for upscaling of workplace health interventions. Since behaviour change interventions often consist of multiple components, isolation of effects of a specific component is demanding. This creates the need for so-called iterative application development (66), i.e. adding potential effective components one by one, alongside evaluating the intervention.

Evaluate the effects of web-based health promotion programs within lower socio-economic groups of workers.
Unhealthy lifestyle is more common among individuals in lower socio-economic position. This results in inequalities in health. Information technology offers numerous possibilities that can create the perfect fit between this target group and web-based health promotion programs. Adapting technological interventions to workers in lower socio-economic position, while pro-actively including the target group in this development, will meet the needs of this priority group. Implementation characteristics and effects of a web-based approach that fits people at lower socio-economic status should be evaluated, aiming to reduce inequalities in health and work prospects.

In conclusion, blended workplace health promotion programs are promising in improving health and employability in employees at increased cardiovascular risk. Recommendations for future practice and research are made.

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Chapter 9

Summary

Samenvatting

SUMMARY

Cardiovascular disease (CVD) is the leading cause of death throughout the world, and is associated with morbidity and decreased employability. The prevalence of CVD and of people at risk for CVD (e.g. obesity, diabetes or hypertension) has been increasing. A healthy lifestyle is important in the prevention of CVD. Thus, preventive health initiatives aimed at healthy lifestyle behaviour to decrease cardiovascular risks are beneficial to health and would improve sustainable employability of workers.

Web-based interventions and motivational interviewing (MI) are both promising methods to change modifiable health behaviour, but studies evaluating a combination of these methods, a so-called 'blended approach', are rare. Therefore, this thesis addressed the following questions:

1. What is the impact of work-related factors on exit from paid employment via disability, unemployment, and early retirement, in employees with cardiovascular disease?
2. What is the effectiveness of blended workplace health promotion programs?

To answer the first question data from 5182 workers of 50 years and older in the Survey of Health, Ageing, and Retirement in Europe (SHARE) were used (**chapter 2**). To answer the second question, two blended workplace health promotion programs were designed, implemented and evaluated. **Chapters 3, 4 and 5** describe the cluster randomised controlled trial 'PerfectFit', which took place in the military force, the police force, and a large academic hospital in The Netherlands. A total of 491 employees aged 40 and over were included based on having at least one cardiovascular risk factor. Follow-up measures were taken 6- and 12-months after baseline. **Chapter 6** describes the uncontrolled before-after study of a web-based gaming intervention. 52 overweight and obese healthcare workers competed in teams by gaining points for being physically active, as was measured by an accelerometer. Measurements were taken 10 and 23 weeks after baseline.

The impact of work-related factors on exit from paid employment via disability, unemployment, and early retirement, in employees with cardiovascular disease.

Chapter 2 shows a prominent role of CVD and diabetes in premature losses to the workforce, and it shows that optimising psychosocial work-related factors could be beneficial in people with CVD or diabetes. Workers with CVD or diabetes had significantly increased probabilities of disability benefits (OR 2.50) and early retirement (OR 1.34), but a comparable probability of unemployment (OR 1.10). Individuals who had a stroke had the highest probability of receiving disability benefits (OR 3.48). Perceived high job demands with low rewards or with low control at work further increased the probability of early exit among individuals with CVD or diabetes.

The effectiveness of blended workplace health promotion programs.

Chapter 3 presents the design and baseline characteristics of the PerfectFit study. Participants of the study received either the limited intervention, i.e. a web-based Health Risk Assessment (HRA) with tailored and personalised advice, and an online newsletter every three months, or they received the extensive intervention, i.e. the limited intervention supplemented by MI-coaching. Trained occupational health physicians (OP) delivered the MI-coaching, 4 face-to-face and 3 by telephone. During the follow-up period, participants chose the health promotion activities they personally preferred.

Chapter 4 evaluates the effects of the cluster randomised trial PerfectFit. In total, 17 clusters (491 participants) were analysed. There was no difference in self-rated health between the limited and the extensive intervention groups. At 12 months in the extensive intervention group body weight (-3.1 kg) was statistically significantly reduced, whereas in the limited intervention group body weight (+0.2 kg) slightly increased. However, after adjusting for heterogeneity in age, gender, and education the difference between the extensive and limited intervention became statistically insignificant. In both groups physical inactivity and excessive alcohol use decreased significantly at 12 months. It could be concluded, that health behaviours improved after a web-based tailored Health Risk Assessment including personalised advice, and that adding motivational coaching increased its effectiveness by reducing body weight.

Chapter 5 shows the effects of the PerfectFit intervention on participation in health promotion activities and aims to isolate key-components of the intervention. The following components of implementation were investigated: reach of web-based HRA, participation in HRA, reading newsletters, number of MI-sessions, and quality of MI-sessions. MI-quality was determined by scoring audiotaped MI-sessions, using the Motivational Interviewing Treatment Integrity (MITI) code. Reach was 12% at the employee level. In total, 88% of participants completed the HRA, and 57% participated in at least 4 MI-sessions. The OPs delivered MI at least at beginner's performance level. Over 80% of individuals in the trial participated in health promotion activities, with an additional participation of 8% in the extensive compared to the limited group. In the extensive intervention, those with more MI sessions and with MI sessions of better quality were more likely to participate in health promotion activities. Increased MI-quality was related to sustained participation.

Chapter 6 assesses the influence and usage of a blended web-based gaming intervention on physical activity, body mass index (BMI), and waist circumference, among overweight and obese employees of a hospital. This blended Web-based gaming intervention was beneficial for overweight workers in becoming physically active above the recommended activity levels during the entire intervention period, and a favorable influence on BMI and waist circumference was observed. Promising components in the intervention, and thus targets for upscaling, are eHealth teams (i.e. social influence of

eHealth teams) and engagement with the game (i.e. frequency of reaching a personal monthly target). Broader implementation and long-term follow-up can provide insights into the sustainable effects on physical activity and weight loss and into who benefits the most from this approach.

Chapter 7 provides guidance in the choice of an optimal randomised controlled trial design in future trials of lifestyle interventions. The randomised controlled trial is the study design of choice when it comes to the evaluation of interventions aiming to change lifestyle behaviour. There is a strong demand for high-quality randomised controlled trials of interventions that promote healthy lifestyle behaviours. However, lifestyle interventions are often complex and subject to several important issues, such as patient preference and non-adherence, that may threaten the internal and external validity of studies.

SAMENVATTING

Hart- en vaatziekten (HVZ) zijn de meest voorkomende oorzaak van mortaliteit in de wereld. Bovendien worden HVZ geassocieerd met ziektelast en verlaagde inzetbaarheid in werk. De prevalentie van HVZ en van mensen met een verhoogd risico op HVZ (bijvoorbeeld obesitas, diabetes of hoge bloeddruk) neemt toe. Een gezonde leefstijl is belangrijk bij de preventie van HVZ. Derhalve zijn preventieve gezondheidsinitiatieven gericht op gezond leefstijlgedrag ter vermindering van het risico op HVZ gunstig voor de gezondheid en zouden ten goede komen aan de duurzame inzetbaarheid van werkenden.

Web-based interventies en motivational interviewing (MI) zijn veelbelovende methodes om veranderbaar gezondheidsgedrag te beïnvloeden, maar studies die de combinatie van beide methoden evalueren, de zogenaamde 'blended' aanpak, zijn zeldzaam. Derhalve gaat dit proefschrift in op de volgende vragen:

1. Wat is de invloed van werk gerelateerde factoren op de uitstroom van betaald werk door arbeidsongeschiktheid, werkloosheid en vroegpensioen, op werknemers met HVZ?
2. Wat is de effectiviteit van blended gezondheid bevorderende programma's op de werkvloer?

Ter beantwoording van de eerste vraag zijn data van 5182 werknemers van 50 jaar en ouder van de Survey of Health, Ageing, and Retirement in Europe (SHARE) gebruikt (**Hoofdstuk 2**). Ter beantwoording van de tweede vraag zijn twee blended gezondheid bevorderende programma's voor de werkvloer ingericht, geïmplementeerd en geëvalueerd. **Hoofdstukken 3, 4 and 5** beschrijven de cluster gerandomiseerde studie 'PerfectFit', welke plaats vond bij Defensie, Politie en in een groot academisch ziekenhuis in Nederland. In totaal werden 491 medewerkers van 40 jaar en ouder geïncludeerd, gebaseerd op het hebben van minimaal één risicofactor voor HVZ. Vervolgmetingen werden 6 en 12 maanden na de startmeting gedaan. **Hoofdstuk 6** beschrijft de ongecontroleerde voor-na studie van een web-based gaming interventie. 52 Werknemers in de gezondheidszorg met overgewicht en obesitas streden in teams voor het behalen van punten door fysiek actief te zijn, wat werd gemeten door een geavanceerde bewegingsmeter. Metingen werden gedaan bij 10 en 23 weken na de startmeting.

De invloed van werk gerelateerde factoren op de uitstroom van betaald werk door arbeidsongeschiktheid, werkloosheid en vroegpensioen, in werknemers met HVZ.

Hoofdstuk 2 laat zien dat HVZ en diabetes een prominente rol spelen bij vervroegde uittreding uit het werk en het laat zien dat het optimaliseren van psychosociale werkfactoren gunstig zou kunnen zijn bij mensen met HVZ of diabetes. Werkenden met

HVZ of diabetes hadden significant meer kans op arbeidsongeschiktheid (OR 2.50) en vroegpensioen (OR 1.34), maar een vergelijkbare kans op werkloosheid (OR 1.10). Mensen met een beroerte hadden de grootste kans op arbeidsongeschiktheid (OR 3.48). De verhoogde kans op vervroegde uittreding uit het werk bij werknemers met HVZ of diabetes nam toe bij het ervaren van hoge werkeisen en lage waardering of van hoge werkeisen en weinig controle op het werk.

De effectiviteit van blended gezondheidsbevorderende programma's op de werkvloer.

Hoofdstuk 3 toont de inrichting en de karakteristieken bij de start van de PerfectFit studie. Deelnemers van de studie kregen de basis interventie of de uitgebreide interventie. De basis interventie bestaat uit een web-based gezondheidsrisicoscreening met op maat en persoonsgericht advies en om de drie maanden een online nieuwsbrief. De uitgebreide interventie is de basis interventie uitgebreid met MI-coaching.

Getrainde bedrijfsartsen gaven de MI-coaching, 4 in de spreekkamer en 3 telefonisch. In de periode hierna kozen de deelnemers een gezondheid bevorderende activiteit van hun voorkeur.

Hoofdstuk 4 evalueert de effecten van de cluster gerandomiseerde studie PerfectFit. In totaal zijn 17 clusters (491 deelnemers) geanalyseerd. Er was geen verschil tussen zelf gerapporteerde gezondheid in de basis interventie en de uitgebreide interventie groep. Na 12 maanden was het lichaamsgewicht in de uitgebreide interventie statistisch significant afgenomen (-3,1 kg), terwijl het lichaamsgewicht in de basis interventie groep enigszins was toegenomen (+0,2 kg). Echter, na correctie voor diversiteit in leeftijd, geslacht en opleidingsniveau was het verschil tussen de beide groepen statistisch insignificant. In beide groepen was de mate van fysieke inactiviteit en overmatig alcoholgebruik significant afgenomen na 12 maanden. We concludeerden dat gezondheidsgedrag verbeterde na een web-based gezondheidsrisicoscreening met op maat en persoonsgericht advies, en dat het effect gericht op reductie van lichaamsgewicht toenam bij het toevoegen van MI.

Hoofdstuk 5 toont het effect van de PerfectFit interventie op deelname in gezondheid bevorderende activiteiten en streeft naar het isoleren van sleutel-componenten van de interventie. De volgende componenten van de implementatie werden onderzocht: het bereik van de screening, deelname aan de screening, het lezen van de nieuwsbrieven, het aantal MI-sessies en de kwaliteit van de MI-sessies. De kwaliteit van MI werd bepaald aan de hand van het scoren van audio-opnames van MI-sessies, waarbij de Motivational Interviewing Treatment Integrity (MITI) code werd gebruikt. Het bereik was 12% op werknemers niveau. In totaal hebben 88% van de deelnemers de screening volledig doorlopen en 57% heeft deelgenomen aan minimaal 4 MI-sessies. De bedrijfsartsen hebben MI uitgevoerd op minimaal beginners niveau. Meer dan 80% van de deelnemers

in de studie namen deel aan gezondheid bevorderende activiteiten, met extra deelname van 8% in de uitgebreide groep ten opzichte van de basis groep. In de uitgebreide groep bleek dat de kans op deelname aan gezondheid activiteiten groter was bij deelnemers met meer MI-sessies en betere kwaliteit MI. Een hogere kwaliteit MI was gerelateerd aan deelname op lange termijn.

Hoofdstuk 6 meet de invloed en het gebruik van een blended web-based gaming interventie op fysieke activiteit, body mass index (BMI), en buikomvang bij gezondheidszorg medewerkers met overgewicht of obesitas. Deze blended web-based gaming interventie was gunstig voor het behouden van fysieke activiteit boven de beweegnorm gedurende de gehele interventie periode, en er werd een gunstig effect op BMI en buikomvang geobserveerd. Veelbelovende componenten van de interventie, en derhalve van belang bij doorontwikkeling, zijn eHealth teams (sociale invloed van eHealth teams) en betrokkenheid bij het spel (de frequentie waarin het maandelijkse persoonlijke doel werd gehaald). Bredere implementatie en deelnemers langer vervolgen kan inzicht verschaffen in de duurzame effecten op fysieke activiteit en gewichtsverlies en in voor wie deze aanpak het meest gunstig is.

Hoofdstuk 7 geeft richting bij de keuze ter optimalisering van het ontwerp van een gerandomiseerde gecontroleerde studie bij toekomstige studies ter evaluatie van leefstijl interventies. De gerandomiseerde gecontroleerde studie is qua ontwerp de eerste keus als het gaat om het evalueren van interventies ter bevordering van gezondheidsgedrag. De vraag is groot naar gerandomiseerde gecontroleerde studies van hoge kwaliteit. Echter, leefstijl interventies zijn vaak complex en onderworpen aan verschillende belangrijke aspecten, zoals voorkeur van de patiënt en uitval tijdens de studie, die nadelig zijn voor de interne en externe validiteit van studies.

Appendices

Dankwoord

About the author

List of publications

PhD portfolio

DANKWOORD

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Eén ding is duidelijker dan ooit: jij en ik zijn een Perfect Fit!

ABOUT THE AUTHOR

Tessa Alexandra Pasmooij was born on March 4th, 1973 in Amstelveen, and has both Dutch and Australian nationalities. After graduating from secondary school (Geert Groote College, Deventer) in 1991, she attended community college in Wyoming, USA. In 1992 she started Medical School at the Rijksuniversiteit Groningen, which included 6-months research at the University of Utah, USA. After her residency in the Isala Klinieken in Zwolle and in Sydney, Australia, she graduated from medical school in 1999. For a year, she worked as a resident at the department of Dermatology of UMC Utrecht. She started her career in occupational health in 2000 at ArboNed in Rotterdam. Since 2003, she has been working at the ErasmusMC University Medical Center. During this time she specialised in occupational health at the Netherlands School of Public and Occupational Health (NSPOH) in Amsterdam, which included a research-thesis "Zwanger? Hoe werk je langer". Her special interests in the field of occupational heath are vital ageing, and eHealth. Intensive collaboration with the Department of Epidemiology and the Department of Public Health took off in 2012. From 2012 to 2014, she implemented the PerfectFit study-intervention at multiple sites of the Military and Police forces, and at the hospital. The results were presented at the World Conferences of Healthy Ageing and of Public Health in Melbourne, Australia, and are presented in this thesis "PerfectFit @ Work".

LIST OF PUBLICATIONS

T.A. Kouwenhoven-Pasmooij, A. Burdorf, J.W. Roos-Hesselink, M.G.M. Hunink, S.J.W. Robroek. Cardiovascular disease and early exit from paid employment in Europe; the impact of work-related factors.Int J of Cardiology 2016; 215:332-7

T.A. Kouwenhoven-Pasmooij, B. Djikanovic, S.J.W. Robroek, P. Helmhout, A. Burdorf, M.G.M. Hunink. Design and baseline characteristics of the PerfectFit study: a multicenter cluster-randomised trial of a personalised lifestyle-intervention on health and sustainable employability among workers of 40 years and older. BMC Public Health 2015; 15:715

T.A. Kouwenhoven-Pasmooij, S.J.W. Robroek, R.A. Kraaijenhagen, P.H. Helmhout, D. Nieboer, A. Burdorf, M.G.M. Hunink.The effect of a web-based health risk assessment with motivational interviewing on health, work and uptake of health promotion activities: the PerfectFit study. Submitted

T. A. Kouwenhoven-Pasmooij, S.J.W. Robroek, M.G.M. Hunink A. Burdorf. Quality of implementation matters: the effect on the uptake of health promotion activities in the PerfectFit study. Submitted

T.A Kouwenhoven-Pasmooij, S.J.W. Robroek, S.W. Ling, J. van Rosmalen, E.F.C. van Rossum, A. Burdorf, M.G.M. Hunink. Influence and usage of a blended web-based gaming intervention on changes in physical activity for overweight employees: an experimental pilot study. JMIR Serious Games 2017; 5(2):e6

J.O. Younge, T.A Kouwenhoven-Pasmooij, R. Freak-Poli, J.W. Roos-Hesselink, M.G.M. Hunink. Randomised study designs for lifestyle interventions: a tutorial. Int J of Epidemiol 2015; 44: 2006-19.

PHD PORTFOLIO

Name: Tessa Alexandra Kouwenhoven-Pasmooij
Erasmus MC Department: Epidemiology
PhD-period: 2012 - 2017
Promotor: Prof dr MGM Hunink & Prof. dr ir A Burdorf
Co-promotor: Dr SJW Robroek

	Year	Workload (ECTS)
1.PhD Training		
General academic skills:		
English biomedical writing, Erasmus MC, Rotterdam	2014	4.0
In-depth courses:		
Master of Science courses at Netherlands Institute for Health Sciences (NIHES), Rotterdam: Erasmus Summer Program - Principles of Research in Medicine - Introduction to Data-Analysis - Methods of Clinical Research Core Curriculum - Biostatistical Methods I: Basic Principles - Public Health Research: Intervention Development and Evaluation Advanced Short Courses - Preventing Failed Interventions in Behavioural Research	2012-2013	7.6
Workshop Systematic Literature Retrieval in PubMed, ErasmusMC, medical library	2013	0.36
Cursus patiëntgebonden onderzoek	2013	0.36
Methodologie van patiëntgebonden onderzoek en voorbereiding van subsidieaanvragen, door consultatiecentrum voor patiëntgebonden onderzoek, ErasmusMC medical library	2013	0.36
Basiscursus Regelgeving en Organisatie Klinisch Onderzoekers (BROK) cursus en -examen	2013	1.5
iMTA Masterclass Introduction on cost-effectiveness modelling	2015	0.4
Workshop health risk assessment, PreventPartner	2015	0.4
Courses at Netherlands School of Public and Occupational Health (NSPOH): guidelines for diagnosis and treatment of obesity in adults and children, part 1 and 2; Burnout and anxiety; Shared decision making; Risicovolle genotmiddelen (drugs) en werk: hoe gaan we hiermee om; SOLK; Sportgeneeskunde, enkel en voet; socratisch motiveren	2012-2017	7.2
Training 'communication using motivational interviewing' and 'motivational interviewing, coding of audiofragments', Academie voor Motivatie en Gedragsverandering, Eindhoven	2012	2.2
Pregnancy and work participation. ErasmusMC.	2016	0.4
Seminars and Workshops:		
Prezi presentations	2012	0.6
Monthly seminar regional occupational physicians in healthcare	2012-2017	2.6
Occupational physicians in health care, national meetings	2012-2014	1.3

ZonMW projectleidersbijeenkomst	2012	0.4
Seminars of the Department of Public Health and Epidemiology	2012-2017	2.0
Implementation sustainable employability and vitality, ErasmusMC	2013	0.2
Seminars of academic female network (VENA), ErasmusMC VENA	2012-2017	2.5
Convenant Gezond Gewicht, Stichting van de Arbeid, Den Haag	2013	0.3
Congres Nederlands Kenniscentrum Duurzame Inzetbaarheid, Arnhem	2013	0.3
Invitational conference "PMO module cardiometabool risico voor werkenden. Welke rol speelt de bedrijfsarts?", Amsterdam	2014	0.2
Nederlands Congres Volksgezondheid, Rotterdam	2015	0.6
Scientific Integrity, the game, ErasmusMC	2015	0.1
KNMG district VI: PMO zelfbeschikking of zelfbescherming, Rotterdam	2015	0.1
Workshop "'Age Management and Healthy Ageing in public/private organisations", European Institue of Innovation & Technology (EIT Health)	2016	0.2
Seminars on sustainable employability, Human resource department, ErasmusMC	2016	1.5
Scientific Presentations:		
Military force, Utrecht -Tailored advice and eHealth, Utrecht	2013	0.6
Police Forces, Zoetermeer -Implementation of a lifestyle intervention	2013	0.6
Board of directors, ErasmusMC -Sustainable employability	2014	0.6
Obesity Center CGG, symposium, Rotterdam -design and implementation of a web-based gaming intervention	2014	1.0
-Overweight and employability, the implementation of an eHealth intervention	2015	0.6
Seminar workinggroup physical activity, ErasmusMC - design and implementation of a web-based gaming intervention Lifestyle group, Ede	2014	0.6
- Obesity and eHealth and sustainable employability	2014	0.6
Occupational health meetings, ErasmusMC -implementation of a web-based lifestyle intervention among employees, the PerfectFit study -sustainable employability and health -implementation process and results of the PerfectFit study	2014-2017	2.4
eHealth symposium ErasmusMC -gamification in overweight and obese employees	2014	0.6
Blonde Tafel women's network, Rotterdam -Reis je Fit and chronic diseases in the workforce	2014	0.6
Women's Health Week, VENA -Gezond functioneren	2015	1.0
Rearch meeting clinical epidemiology, ErasmusMC -PerfectFit design and baseline characteristics	2015	0.6
MedicalDelta eHealth-week, Leiden -'Reis je Fit, blended care in de aanpak van overgewicht' bij	2016	0.6

ArboUnie, Rotterdam -eHealth and a lifestyle intervention	2016	0.6
World Conference on Active Ageing (WCAA), Melbourne, Australia - A blended web-based gaming intervention on changes in physical activity for overweight and obese employees; Influence and usage in an experimental pilot study	2016	0.6
World Conference on Public Health (WCPH), Melbourne, Australia - Effectiveness of the blended-care lifestyle intervention 'PerfectFit': a cluster randomised trial in employees at risk for cardiovascular diseases.	2017	0.6
Military Force, Utrecht -Duurzame inzetbaarheid en gezondheidsvaardigheden	2016	0.6
Seminar regional occupational physicians in healthcare -Diabetes and work RET, Rotterdam	2017	0.4
-Implementation of a health risk assessment	2017	0.4
Conferences:		
Epidemiology Conference of Occupational Health (EPICOH), Utrecht	2013	1.5
World Conference on Active Ageing (WCAA), Melbourne, Australia	2016	1.5
World Conference on Public Health (WCPH), Melbourne, Australia	2017	1.6
Annual Occupational health conference Nederlandse Vereniging voor Arbeids- en Bedrijfsgeneeskunde (NVAB)	2013-2017	2.3
Subtotal:		58.2
2.Teaching activities		
"eHealth at work" for occupational physicians of the Dutch military force, Police force, and academic hospital	2012	1.2
Occupational physicians at the Netherlands School of Public and Occupational Health (NSPOH), "the ageing employee"	2016	1.0
Supervision of 2nd year medical students	2015-2016	1.0
Supervision of 4th year medical students	2015-2017	1.5
Supervision of 4th year business student	2017	1.0
Subtotal:		5.7
3.Professional and personal development		
Formal visitation at the Nederlandse Vereniging voor Arbeids- en Bedrijfsgeneeskunde (NVAB)	2015-2016	9.0
Netherlandse Verenging voor Arbeids- en Bedrijfsgeneeskunde (NVAB): Debatteren en Argumenteren	2016	0.6
Pitch Yourself, ErasmusMC	2017	0.15
Masterclass personal persuasiveness, Debatrix, Rotterdam	2017	0.9
Subtotal:		10.7
Total:		74.6

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Zicht Online

Cardiovascular disease (CVD) is the leading cause of death throughout the world, and is associated with morbidity and decreased employability. The prevalence of CVD and of people at risk for CVD (e.g. obesity, diabetes or hypertension) has been increasing. A healthy lifestyle is important in the prevention of CVD. Thus, effective preventive health initiatives aimed at a healthy lifestyle to decrease cardiovascular risks are beneficial to health and would improve sustainable employability of workers. In this thesis, the association between CVD and exit from paid employment was investigated, followed by intervention-studies on two 'blended' workplace health promotion programs, a combination of eHealth and motivational interviewing. We found positive changes in health behaviour and health outcomes in both health programs. These findings show that blended workplace health promotion programs are promising in improving health and employability in employees at increased cardiovascular risk.

PERFECT FIT