ALIFE@WORK

MARIEKE VAN WIER

Body@Work

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The effects of a distance counseling lifestyle program for weight control among an overweight working population

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ALIFE@Work

The effects of a distance counseling lifestyle program for weight control
among an overweight working population

ACADEMISCH PROEFSCHRIFT

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dr. J.C. Dekkers
dr. I.J.M. Hendriksen

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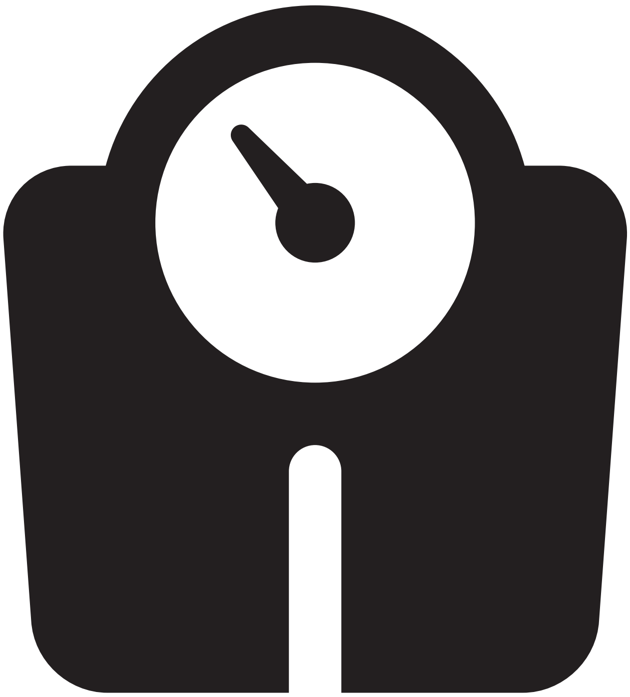
CHAPTER 1:

GENERAL INTRODUCTION



BACKGROUND

About a decade ago, overweight, and obesity in particular, was recognized by the World Health Organisation (WHO) as a major public health problem for both developed and developing countries.[1] Globally a dramatic increase in the number of people that are overweight had occurred. Likewise, the prevalence of overweight and obesity in the Netherlands markedly increased over the previous three decades. According to self-reported data, overweight (obesity) prevalence in adult males increased from 37% (4%) in 1981 to 52% (10%) in 2008, and in adult females from 30% (6%) in 1981 to 41% (12%) in 2008.[2, 3]

OVERWEIGHT, OBESITY AND HEALTH CONSEQUENCES

Having an excess of body weight is a proxy for an unhealthy body composition, with too much body fat.[4] Overweight is usually determined by the ratio of body weight (kg) to squared body height (m); the Body Mass Index (BMI). The WHO defines overweight as a BMI equal to or more than 25 kg/m^2, and obesity as a BMI equal to or more than 30 kg/m^2.[5] BMI between 25 and 30 kg/m^2 is sometimes referred to as pre-obesity. These cut-offs are based on mortality statistics. Nevertheless, risks of chronic conditions like coronary heart disease and especially diabetes type 2 increase progressively in both men and women from a BMI of 20-21 kg/m^2, as can be seen in Figures 1.1 and 1.2 (Adapted from Willett, Dietz, Colditz [1999][4]). Other disorders that are associated with overweight include hypercholesterolemia, cardiovascular diseases, various types of cancer, osteoarthritis and fatty liver disease.[6]

The increase in overweight and obesity, gives rise to a subsequent increase in associated diseases. For instance, the prevalence of (diagnosed) diabetes mellitus in the Netherlands is estimated to rise from 4% in 2005 to 8% in 2025, due to aging and to a further increase in the prevalence of overweight.[7]

SOCIETAL IMPACT OF OVERWEIGHT AND OBESITY

Overweight is associated with a loss in health-related quality of life (HRQL), mainly due to physical problems.[8-10] This relationship is predominantly mediated by overweight-related joint pain and co-morbidities, e.g. diabetes, but there is a direct influence of BMI on HRQL as well.[10] Thus, the current rise in the prevalence of overweight and the impending rise in related diseases will impair the quality and duration of life of the Dutch population.

The Dutch government, health care insurers and employers are concerned about these developments. They and other stakeholders (e.g. the food industry), have agreed to work together in an effort to fight the increase in overweight prevalence within the Convenant Gezond Gewicht (Covenant Healthy Weight).[11] Some of their concerns involve the economic consequences of overweight.[12] Overweight and obesity have a substantial impact on health care expenditures (direct costs) as well as a possible impact on costs due to absenteeism, reduced performance, disability and early retirement (indirect costs).[13] Direct costs of overweight in the Netherlands have been estimated at 2% of the total health care costs in 2003.[14] Regarding indirect costs,

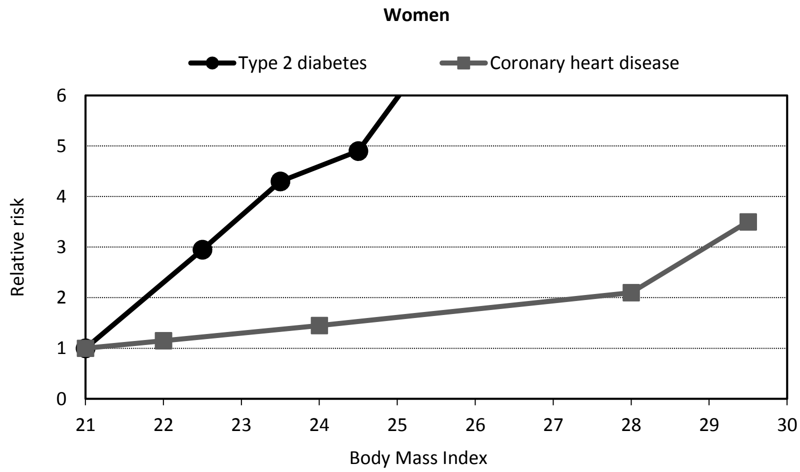


FIGURE 1.1 Relation between BMI up to 30 and the relative risk of type 2 diabetes and coronary heart disease for women in the Nurses' Health Study (Adapted from Willett, Dietz, Colditz [1999][4])

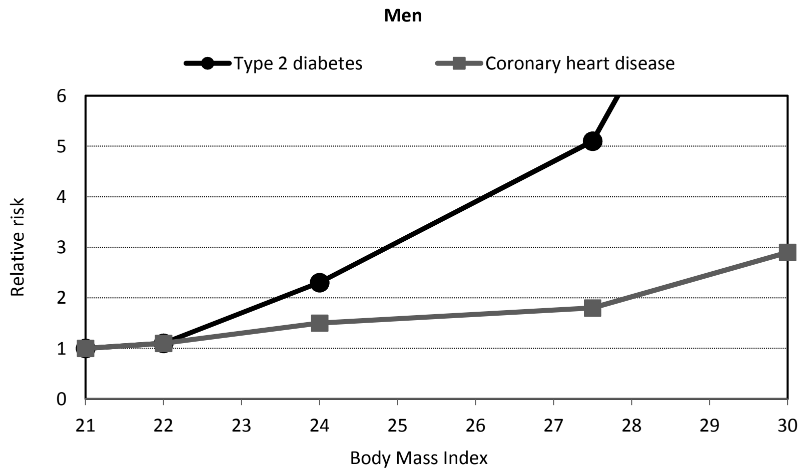


FIGURE 1.2 Relation between BMI up to 30 and the relative risk of type 2 diabetes and coronary heart disease for men in the Health Professionals Follow-up Study (Adapted from Willett, Dietz, Colditz [1999][4])

a recent systematic review of longitudinal studies found a trend for overweight to be predictive of long term spells (> 7 days) of sick leave and strong evidence that obesity is predictive of long term sick leave.[15] Another review showed increased risk for work disability among overweight and obese subjects.[16] A large population based study showed that obesity in early adulthood is associated with almost doubled costs for lifetime productivity losses compared to normal weight.[17] Two other studies found that obesity was associated with presenteeism (i.e. reduced work-performance due to health problems).[18, 19]

These data present justification to invest in the prevention and treatment of overweight in order to contain future health care and labor-related costs, though it is not entirely clear if, in the long run, these investments will result in cost savings for society as a whole and employers in particular. Costs for pharmaceuticals will likely be reduced, but substantial additional costs for long-term care are expected.[20] Although, curative interventions that result in an increase in expected life years can increase costs due to prolonged survival as well.[21] There is also preliminary evidence that additional costs for end-of-life care would be offset by earlier gains in productivity.[17] Nevertheless, the appropriate question that needs to be answered is not whether prevention and treatment of overweight saves money, but whether it offers value for money in improving the duration and quality of life.

ADVANTAGES AND THREATS OF WORKPLACE HEALTH PROMOTION

Community settings like schools and worksites have been recognized as viable places for population-based interventions for weight management.[22] Workplace Health Promotion (WHP) has several strong points from the Public Health perspective. The majority of adults is employed (in the Netherlands about 55% of the population between 20 and 65 years of age); workplaces consist of fairly homogenous groups of people; existing communication channels and social networks can be used; and, depending on the worksite and location, environmental changes are possible.[23] On the other hand, the health profile of the working population is more favorable than that of the general population. Indeed, the prevalence of overweight is lower among workers than in the population at large, but at 37% still considerable.[24] Addressing overweight in the work setting could therefore have a positive impact on public health. There is a possible downside. In the context of a constrained budget for public health, investments in worksite weight management could impede spending for groups that have greater health risks. As weight management-related WHP in the Netherlands presently is financed by employers, and not through public funds, this does not appear to be a real threat.

Weight management at the worksite has advantages but also potential drawbacks for the employee. Research shows that employees who participate in lifestyle programs experience beneficial health outcomes.[25] For the majority of the Dutch employees this is the most important reason for taking part in WHP-activities.[26] The possible adverse effects of workplace weight management for employees involve ethical issues such as restriction of autonomous decision making, discrimination on the basis of health risks and violation of privacy.[27, 28] In light of the health benefits a weight management program could yield for employees, offering (proven to be effective) programs at the worksite is justifiable. However, employees cannot be obliged to take part in WHP and their health status may not be disclosed to the employer. Current Dutch law protects these rights adequately.[29]

The returns that lifestyle-oriented weight management programs could generate for Dutch employers are increased work-productivity and intangible benefits such as employee attraction and retention. Medical care in the Netherlands is funded by a dual system of public and private insurance of which currently about 50% of contributions is paid by employers. The employers' contribution is mostly independent of the health-insurance claims made by the employees. Thus, reductions in health care utilization are of little importance to Dutch employers. The most important advantages of WHP as viewed by them are prevention of sickness absence (25%), improvement of health and well-being of their employees (24%), improvement of work climate (18%) and improvement of working conditions (18%).[26] There is evidence, mostly from US-based research, that WHP results in cost-savings for the employer due to reductions in absenteeism.[30] The financial returns were restricted to studies applying a non-randomized design. Randomized controlled trials showed financial losses.[30] Rigorous research is therefore needed, as well as information about the transferability of these results to the Dutch setting. To date, it is not certain that weight control programs result in cost-savings for Dutch employers, either in the short or long term.

Programs aimed at physical activity and nutrition are seldom used in the Dutch work setting.[26] This has to do with an emphasis on return-to-work interventions and relatively little demand of employers for primary prevention.[31, 32] As of late, this may be changing due to an aging workforce and a rising number of obese employees. Investing in the 'vitality' of employees has become a trend among larger corporations.[33-35] The time seems ripe for a weight management program aimed at employees. Research should give insight into its (cost-)effectiveness for employees, the employer and for society as a whole.

GENERAL PRINCIPLES BEHIND WEIGHT MANAGEMENT PROGRAMS

Weight management guidelines in the US and the Netherlands recommend using a structured program of diet, exercise and behavior therapy.[36, 37] Diet and exercise are aimed at creating a negative balance between energy in from food and beverages and energy out from physical activity. Dutch dietary recommendations for weight loss encourage an energy intake of 600 kcal less than usual intake.[37] Macronutrient (i.e. protein, fat and carbohydrates) composition is not important, as long as calories are restricted.[38] Physical activity should at least amount to the Dutch guideline of a minimum of 30 minutes of moderate to vigorous activity on 5 or more weekdays, but preferably to 60 minutes on all days.[37] Behavior therapy (BT) refers to a set of behavior change techniques that help in modifying behaviors.[39, 40] In the context of weight management, cognitive strategies are usually added to BT. Such programs aim to teach skills that help patients change their dietary and physical activity behaviors.

These skills include self-monitoring of food intake and physical activity, setting behavioral goals, gaining control over external and internal stimuli, substituting unwanted behavior with more favorable alternative behaviors, problem solving techniques, and cognitive restructuring in which dysfunctional thoughts are replaced with more realistic ones.[40] The program can be delivered individually or in groups. Typically a weight management program lasts for about six months and offers weekly sessions.

INDIVIDUAL COUNSELING THROUGH TELEPHONE AND E-MAIL

Current evidence shows that WHP programs aimed at improving nutrition, physical activity, or both, result in modest weight reductions. Two systematic reviews showed an average comparative loss of respectively 1.3 kg (95% CI -2.1, -0.3)[41] and 1.2 kg (95% CI -1.6,-0.7)[42] at 6-12 month follow-up. Structured programs with scheduled sessions appeared more effective than self-directed approaches, and information plus behavioral counseling resulted in more benefit than information alone.[41] However, the sustainability of these results is unknown. Furthermore, participation in weight management programs at the worksite is limited.[43] Lack of time is frequently mentioned by employees as a barrier for participation.[44-46] They favor a worksite health program that is offered at a convenient time and location.[44, 45] Worksite programs making use of telecommunication technology for personal counseling, such as e-mail and phone, have the potential to address these concerns. Distance counseling has been applied to weight loss, dietary behaviors and physical activity in other settings. Results of some trials show that phone counseling is effective for short term weight loss,[47, 48] but other trials did not demonstrate effectiveness.[49-51] The majority of phone counseling studies for physical activity and dietary behavior found behavior changes.[52] Weight loss programs with personal feedback by e-mail have also resulted in short term weight loss[53-57] in some studies and no effect in others.[58] E-mail feedback produced mixed effects on diet[53, 54] and no effect on physical activity.[53, 54, 59] Only one of these distance counseling studies recruited participants from a work setting.[53] It can be concluded that both methods of distance counseling show potential to change lifestyle behaviors and reduce body weight. However, effectiveness among overweight workers, effectiveness from distance counseling without additional face-to-face and group meetings, long-term effectiveness, and differences in effectiveness between the two counseling modes are not known.

ALIFE@WORK

Considering the impact of overweight on public and occupational health, and the possibilities for relieving this impact through WHP, it was decided to study the short-term and long-term effectiveness and cost-effectiveness of a weight management intervention with distance counseling (i.e. the 'Leef je Fit' program). This study was called the Amsterdam Lifestyle Intervention on Food and Exercise at Work study: ALIFE@Work. This thesis describes the design of this study and the results that were found.

LEEF JE FIT

In the US, HealthPartners, a Minnesota-based Health Maintenance Organization (HMO), has offered lifestyle counseling by phone since 1994.[60] Counseling for weight management is part of their services and was evaluated in an uncontrolled study among obese HMO members.[61] In this pilot study, an intervention designed according to behavior therapy principles was evaluated. The intervention resulted in a mean 6.1 kg weight loss after six months in participants who completed the trial. Based on the promising results of this pilot study, it was decided to replicate this intervention in the ALIFE@Work study. At the time the study started, an advanced version of the intervention, called 'A Call to Change…Healthy Lifestyles, Healthy Weight', was available. 'A Call to Change' materials consisted of a workbook, food and activity logs, a step counter and phone-counseling protocols. The materials were translated to Dutch and to a Dutch tone of voice. Further adaptations concerned cultural elements such as food and calorie charts, cooking methods, options when eating out and opportunities for everyday physical activity. Also, supplementary content with regard to physical activity was added. Changes in content were made to make the Dutch program appropriate for moderately overweight employees with no, or few, previous weight loss attempts. Furthermore, a website was developed. The website approximated the workbook closely but contained additional interactive elements and web-tools such as a BMI-calculator, a calorie expenditure calculator and graphs. The graphs showed trajectories of calorie intake, calorie expenditure and body weight of the participant. An example of one of the web pages can be seen in figure 1.3.

Phone counseling protocols were modified to reflect the workbook adaptations. E-mail counseling protocols consisted of a mixture of ready-made text tailored to different options, and free-text for personal feedback by the counselor. Instructions for counselor-feedback were similar in the phone- and e-mail protocols. The Dutch

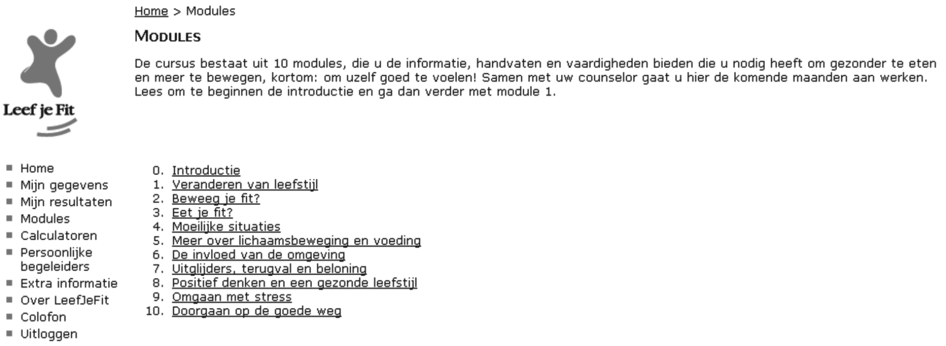


FIGURE 1.3 Webpage www.leefjefit.nl: overview of the modules

intervention was called 'Leef je Fit' (in English: 'Live Yourself Fit') to reflect that a healthy lifestyle is the key to a healthy body. The program emphasized small, stepwise changes in diet and physical activity that are easy to fit into daily life. Participants were stimulated to eat a healthy diet, according to Dutch recommendations for the basic food groups and optimal quantities of basic food items. The use of snacks, sweet and fat food, and alcoholic and sugary drinks was discouraged. Adherence to such a diet will usually lead to a reduction in caloric intake. Participants were also encouraged to acquire 60 minutes of moderate to vigorous exercise on each day of the week. Participants were told to look for everyday opportunities to be physically active, such as taking the stairs, and choosing active transport to work. Furthermore, exercise schedules for walking, running, cycling and swimming, adjusted to different age categories, were provided.

A further description of the intervention can be found in chapter 2 of this thesis.

CONCEPTUAL MODEL AND HYPOTHESES OF THE STUDY

Several reviews have shown that interventions based on behavior therapy are effective in changing diet and physical activity and enhancing weight control, i.e. weight loss and weight maintenance.[62-64] Health outcomes of weight loss are a decrease in fat mass, a reduction of waist circumference, and a possible decrease in blood pressure and total cholesterol.[65-68] Furthermore, a healthy diet and increased physical activity have positive effects independent from weight loss. Physical activity can reduce waist circumference and blood pressure, improve lipid profiles and increase cardiovascular fitness.[69] A diet rich in fruit, vegetables and unsaturated fatty acids helps to lower blood pressure and total cholesterol.[70] Finally, improved health leads to improved health-related quality-of-life. Within economic evaluations this is often measured as Quality Adjusted Life Years (QALYs); an outcome that takes both the duration of life as well as health-related quality-of-life into account.

We hypothesized that a lifestyle intervention program based on behavior therapy would result in favorable changes in diet (fat, fruit and vegetable intake) and physical activity, compared with only providing general information on lifestyle change. Consequently, body weight, waist circumference, fat mass as measured by sum of skinfolds, total cholesterol, blood pressure, cardiovascular fitness and QALYs achieved would improve (more) in the experimental condition.

No direct comparison between phone- and e-mail counseling has taken place so far. Evidence to support a hypothesis about the superiority of either mode of counseling is therefore not available. Confirmation exists that reviewing goals and activities with a counselor and receiving advice and encouragement supports behavior change.[71] As a flowing exchange of information is easier to establish by phone than through e-mail and because verbal contact contains emotional cues, phone contact makes it easier to adapt to the specific situation of the recipient and to establish a bond. This, and because phone counseling is probably perceived as more personal, could make it more effective for supporting behavior change than e-mail counseling. On the other hand, verbal conversations can easily be forgotten, whereas e-mail can be read at a convenient time, can be read again, and, as a consequence of this, may have a more profound effect. We therefore had no assumptions regarding the superiority of the counseling methods.

Several modeling studies have shown that face-to-face lifestyle counseling for weight control can be considered cost-effective from the societal perspective.[72-74] Information about the societal cost-effectiveness of weight control interventions using distance counseling is lacking, as is information about societal cost-effectiveness in employees.[41, 75] Based on the evidence from face-to-face counseling, we hypothesized that a weight control intervention with distance lifestyle counseling would be cost-effective in comparison to the control condition.

In large-scale studies outcomes often have to be collected by self-report of the participants, because it is unfeasible to use direct measurement for all outcomes. However, the self-report of anthropometric outcomes have been found to be biased.[76-80] The accuracy of the self-report of body weight, body height and waist circumference has never been studied in a Dutch population. Based on earlier research, we hypothesized that body weight would be under-reported, body height over-reported,[79] and waist circumference under-reported.[77, 78]

OBJECTIVES

The main aim of this thesis is to evaluate, among an overweight working population, the (cost-) effectiveness of a lifestyle counseling program with two modes of distance counseling, i.e. telephone and internet. The main effectiveness outcome is body weight. Other outcomes of interest are waist circumference, physical activity, eating habits, blood pressure, total cholesterol level, sum of skinfolds and cardiovascular fitness. Cost-effectiveness outcomes are body weight and Quality Adjusted Life Years (QALYs) gained. The secondary objective of this thesis is to compare the effectiveness of the different communication modes. Thirdly, the thesis aims to assess the accuracy of the self-report of body weight, body height and waist circumference.

OUTLINE OF THE THESIS

Chapter 2 of this thesis describes the design of the study, including a description of the lifestyle program and the two versions of counseling. In chapter 3 the agreement between self-reported body weight, body height and waist circumference and measurements by research personnel is presented. Chapter 4 presents the results of the lifestyle intervention on body weight, waist circumference, diet and physical activity after six months, directly after conclusion of the intervention. The results on the same outcomes after two years are described in chapter 5. In chapter 6 the results on blood pressure, total cholesterol level, sum of skinfolds and cardiovascular fitness after six months and after two years are presented. The results of the cost-effectiveness analysis of the lifestyle intervention with regard to effects on body weight and QALYs are presented in chapter 7. In the final chapter the main findings of this thesis are summarized, methodological issues of the study are discussed and implications for public health and directions for future research are given.

CHAPTER 2:

ALIFE@WORK: A RANDOMISED CONTROLLED TRIAL OF A DISTANCE COUNSELING LIFESTYLE PROGRAM FOR WEIGHT CONTROL AMONG AN OVERWEIGHT WORKING POPULATION

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BMC Public Health
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ABSTRACT

Background: The prevalence of overweight is increasing and its consequences will cause a major public health burden in the near future. Cost-effective interventions for weight control among the general population are therefore needed. The ALIFE@Work study is investigating a novel lifestyle intervention, aimed at the working population, with individual counseling through either phone or e-mail. This article describes the design of the study and the participant flow up to and including randomization.

Methods/Design: ALIFE@Work is a controlled trial, with randomization to three arms: a control group, a phone based intervention group and an internet based intervention group. The intervention takes six months and is based on a cognitive behavioral approach, addressing physical activity and diet. It consists of 10 lessons with feedback from a personal counselor, either by phone or e-mail, between each lesson. Lessons contain educational content combined with behavior change strategies. Assignments in each lesson teach the participant to apply these strategies to every day life. The study population consists of employees from seven Dutch companies. The most important inclusion criteria are having a Body Mass Index (BMI) ≥ 25 kg/m^2 and being an employed adult.

Primary outcomes of the study are body weight and BMI, diet and physical activity. Other outcomes are: perceived health; empowerment; stage of change and self-efficacy concerning weight control, physical activity and eating habits; work performance/productivity; waist circumference, sum of skin folds, blood pressure, total blood cholesterol level and aerobic fitness. A cost-utility- and a cost-effectiveness analysis will be performed as well. Physiological outcomes are measured at baseline and after six and 24 months. Other outcomes are measured by questionnaire at baseline and after six, 12, 18 and 24 months.

Statistical analyses for short term (six month) results are performed with multiple linear regression. Analyses for long term (two year) results are performed with multiple longitudinal regression. Analyses for cost-effectiveness and cost-utility are done at one and two years, using bootstrapping techniques.

Discussion: ALIFE@Work will make a substantial contribution to the development of cost-effective weight control and lifestyle interventions that are applicable to and attractive for the large population at risk.

BACKGROUND

As is the global trend, more than 5.6 million adults in the Netherlands (i.e. 46.1% of the population of 20 years and older) are overweight and numbers are still rising.[81] Overweight is defined as having a Body Mass Index (BMI) of 25 or higher. It is a risk factor for a range of health problems, most notably those related to the metabolic syndrome. This syndrome is characterized by abdominal adiposity and several associated metabolic anomalies like insulin resistance, dyslipidaemia and hypertension. These metabolic changes are related to the development of coronary heart disease and type 2 diabetes mellitus. The growing prevalence of overweight and the increase in severity will result in an increase in these diseases. We have to look at ways to turn this tide.

Research shows that intentional weight loss in overweight people with symptoms of the metabolic syndrome produces a significant improvement in these symptoms and reduces the risk for developing diabetes.[66, 82, 83] Reduction in overall mortality as a result of intentional weight loss still needs to be established,[84-86] but research shows that maintaining a normal BMI during adulthood protects against diabetes and cardiovascular disease.[83] Therefore, preventing weight gain is crucial in both people who are already overweight, as well as in those who are at risk for becoming overweight.

Overweight develops when the energy balance between physical activity and foods eaten is generally positive.[87] Prevention of weight gain should concentrate on restoring this balance by increasing physical activity and improving quality of diet. In those seeking weight loss, a negative energy balance should be achieved. Both an increase in physical activity and a well balanced diet have positive effects by themselves. Physical activity reduces blood pressure, improves lipid profiles and protects against cardiovascular disease, type 2 diabetes and certain types of cancer.[88] A diet rich in fruit, vegetables and unsaturated fatty acids helps to lower blood pressure and blood total cholesterol, and prevents against the development of cardiovascular diseases.[70] Improvement of physical activity and diet therefore not only has positive effects on weight control, but also contributes to the amelioration of risk factors for coronary heart disease and type 2 diabetes mellitus. Weight control (i.e. weight loss, maintenance of lost weight and prevention of weight gain) interventions should promote these lifestyle changes.

While there is consensus on the incorporation of both diet and physical activity for weight control, less is known about how these behaviors can be sustainably changed. Most research in the field of weight control has concerned weight loss and to a lesser extent maintenance of lost weight. Little research has been directed towards prevention of weight gain and effective interventions still need to be determined.[89] Behavioral and cognitive behavioral therapies are commonly used for weight loss interventions.[62] They facilitate better maintenance of weight loss than other interventions. These therapies can be used either in a group approach as well as in individual treatment. In both approaches, multiple visits to a treatment centre are required. This is demanding for both the patient as well as the health care system and makes this mode of delivery not well suited for the large section of the population that needs to be reached. New approaches are therefore necessary. Two studies in the United States show that distance counseling programs (i.e. personal coaching by mail, phone or e-mail) based on behavioral principles can be successful in producing weight loss.[53, 90] Distance counseling promises to be cheaper and more accessible than traditional treatments. However, effects on weight maintenance and prevention of weight gain, changes in diet and physical activity, changes in metabolic risk factors and cost effectiveness still have to be established. The ALIFE@Work trial is designed to study these outcomes. This trial is carried out in a working population. Increasing numbers of employees have a sedentary profession and are therefore at risk of developing overweight, or are already overweight. Research shows that productivity losses due to overweight can amount to 10%.[87] Offering distance counseling to the working population might be a feasible and cost-effective way to reach a large group of those in need to change their lifestyle.

The main objective of the ALIFE@Work study is to evaluate, among an overweight working population, the effectiveness of a lifestyle intervention program on body weight, physical activity and eating habits. Secondary objectives of this study are 1) to compare the effectiveness of the use of two different communication technologies, i.e. telephone and internet, and 2) to evaluate the cost-effectiveness of this lifestyle program. In this article we describe the design of the study and the participant flow up to baseline measurements.

METHODS/DESIGN

ALIFE@Work is a randomized controlled trial with a two-year follow-up. Randomization takes place to three groups: to a control group (control) and to an intervention program either counseled by phone (phone), or counseled by email (internet). The recruitment and data collection for this study started in January 2004. Data collection continued until September 2006.

The study design, procedures and informed consent form were approved by the Medical Ethics Committee of the VU University Medical Center (under number 03/193), and all participants provided written informed consent.

Study population

Participants are employees of seven different companies in the Netherlands, including two IT-companies, two hospitals, an insurance company, the head office of a bank and a police force. Of the approximately 21,000 employees working at these companies about 40%, i.e. 8400, were estimated to be overweight. All 21,000 employees were approached per company, through an invitational letter and a screening questionnaire. This was done in six months time, with an interval of three weeks to one month between the companies. The screening questionnaire included demographic questions and questions on body weight and body height.

Inclusion & exclusion criteria

Inclusion criteria of the study were: 1) BMI $\geq$25 kg/m^2, 2) paid employment of at least 8 hours a week, 3) adequate knowledge of the Dutch language, 4) access to internet and skilled in using it, 5) at least 18 years of age. Employees were excluded for the following reasons: pregnancy, diagnosis or treatment of cancer, any other disorder that makes physical activity impossible.

Sample size

A power calculation was carried out for the main outcome variable, i.e. weight change. Calculations were made for a comparison between two equal size groups. Power calculation for weight change was carried out for three levels of power, namely 80%, 85% and 90%. The standard deviation (SD) for two-year weight loss was expected to be 6.8 kg, based on prior weight treatment studies.[91, 92] Calculations showed that differences in mean two-year weight loss of about 1.4 kg between conditions will be detectable with 90% power in two-tailed tests with a significance level of 0.05 for a sample of 500 employees in each group. The sample size for the study was therefore determined at 1500.

Randomization

Randomization took place at an individual level. After baseline measurements, the employee was randomized to one of the three study groups and either to a group receiving basic weight measurements (80% of each study group) or to a group receiving additional measurements (20% of each study group). This two-step randomization meant that there were six groups an employee could be assigned to. Randomization to these six groups was done by block randomization, with each block containing 15 allocations.

A computerized random number generator drew up an allocation schedule. An administrative assistant put the group allocation in opaque sealed envelopes, numbered 1 to 1500. These envelopes were taken to the locations of the baseline measurements and opened in the given order. The researchers were blinded for the allocation schedule, but were not blinded for allocation after randomization. The participants were, in consequence of the nature of the intervention, not blinded for allocation after randomization. Employees were not allowed to change groups after randomization.

Study groups

Control group

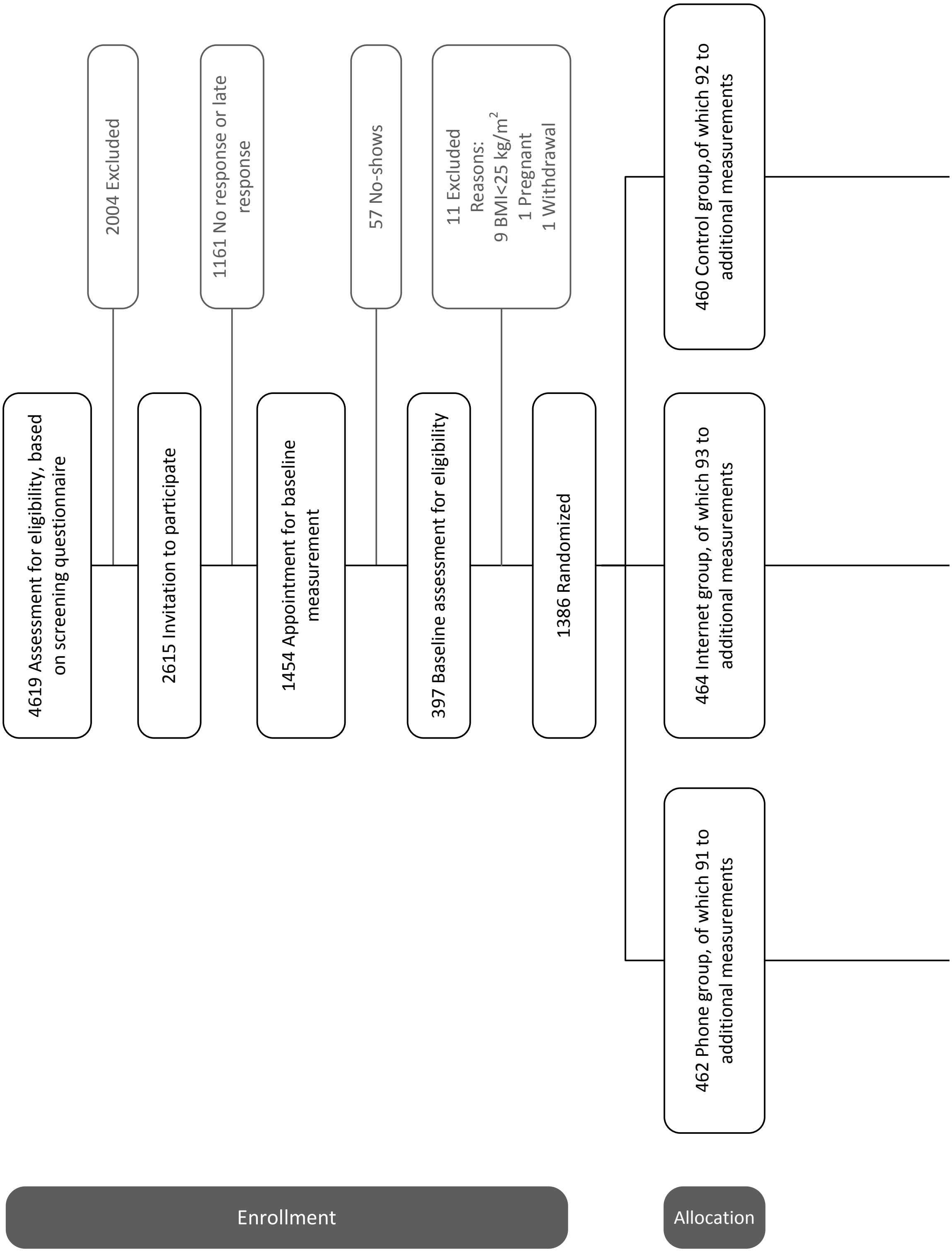
The employees in the control group received three information brochures with general information on overweight, physical activity and nutrition, and a calorie chart. These materials were briefly explained to the employee. All materials were published by the Netherlands Heart Foundation, for general use.

Intervention groups

Both intervention groups received a lifestyle intervention program. This intervention was similar in content, but differed in the way the content was distributed to them and in the way the participant communicated with a personal counselor that was appointed to them. The intervention conditions are described later on.

Participant flow

The study design and participant flow (achieved at recruitment closure and with participant flow during baseline measurements included, August 2004) are shown in Figure 2.1.



4619 Assessment for eligibility, based on screening questionnaire
2004 Excluded
2615 Invitation to participate
1161 No response or late response
1454 Appointment for baseline measurement
57 No-shows
397 Baseline assessment for eligibility
11 Excluded
Reasons:
9 BMI<25 kg/m2
1 Pregnant
1 Withdrawal
1386 Randomized
462 Phone group, of which 91 to additional measurements
464 Internet group, of which 93 to additional measurements
460 Control group,of which 92 to additional measurements
Enrollment
Allocation

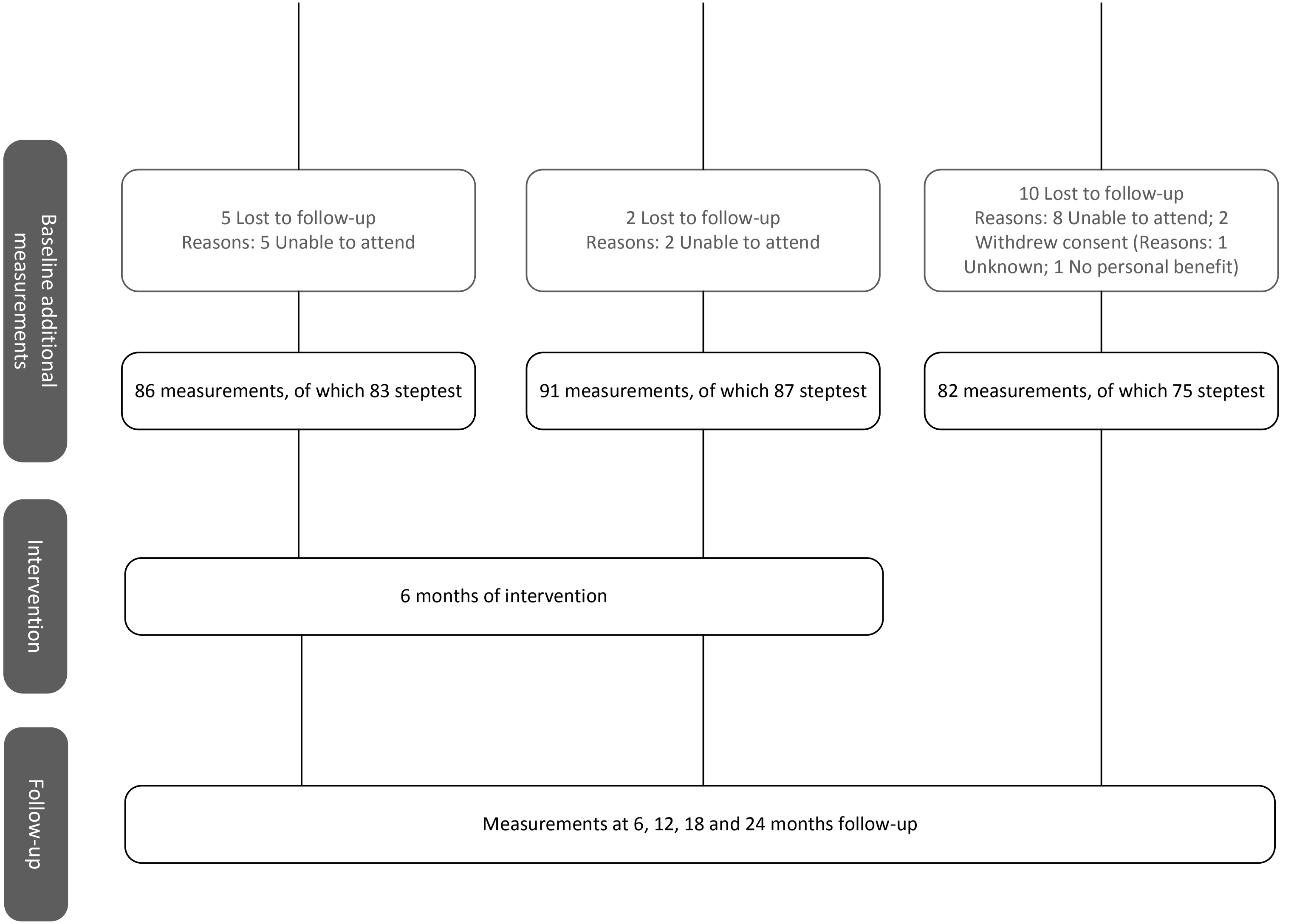


FIGURE 2.1 Participant flow

Out of a total of approximately 21,000 employees, 4619 returned the screening questionnaire. Of these, 2615 were eligible and had no objections to receiving further information. They received an information brochure in which the study protocol was clearly described. Employees were free to further inquire about the study without any engagement. 1454 employees were willing to participate and applied in time. They were all individually invited for a first appointment in which the basic measurements body weight and body height were assessed by the researchers. From these measurements, BMI was calculated. Those with a BMI lower than 25 kg/m^2, which was the case for nine employees, were excluded. One employee became pregnant between screening and baseline measurements and was also excluded. One employee withdrew before randomization. 57 employees did not show up for the baseline measurements. Therefore, 1386 employees were randomized to the two intervention conditions (phone group N=462, internet group N=464), or to the control group (N=460). Within these groups a number of subjects received additional measurements as follows: phone group N=91, internet group N=93 and control group N=92. A second appointment was arranged within one week after randomization, to perform these measurements. In each group a few employees were unable to attend the additional measurements: five out of the phone group, two out of the internet group, and ten out of the control group.

Intervention

Intervention program

The lifestyle intervention program is an adapted version of previous work of HealthPartners in Minnesota, USA.[90] This Dutch version of the lifestyle program is called "Leef je Fit". The program is based on social cognitive theory[93] and emphasizes 1) identifying behaviors in need of change, 2) setting goals for change, 3) monitoring progress, 4) modifying environmental cues to facilitate change, and 5) modifying consequences to motivate change. An essential part of the program is coaching on these activities by a personal counselor.

The program consists of ten lessons or 'modules'. These provide information on nutrition and physical activity, and teach techniques for changing behavior (e.g. self-monitoring). Assignments in the modules assist in applying these techniques. The program can be worked through either at work or at home. Participants are asked to study a module and finish the assignments every two weeks, so they are able to finish the program within six months. After finishing each module, participants are contacted by their counselor. Counseling is done according to two comparable standardized counseling protocols (i.e. for the two communication methods).

Next to the program materials, the participant receives a pedometer at the start of the program.

Phone intervention

Program materials for the phone group are provided after randomization. The employee receives a binder with the ten modules, and the same brochures that are given to the control group. The intervention starts when the personal counselor first calls the participant, about two weeks after randomization. In this first contact the counselor explains the workings of the program and sets a time and date for the next contact in which the first module will be addressed. In between these contacts, the employee studies the module and fills out the assignments. The counselor calls the employee at the scheduled date and time, to go through the module and to talk about the assignments according to the standardized protocol. At the end of the call, a new date and time are set for the next call about two weeks later. This interactive process continues until the employee completes all modules, or until the participant declines contact. Participants also have the possibility to contact their counselor by phone between modules, if they have additional questions.

Internet intervention

A website is developed for the intervention. The internet-based lifestyle intervention starts when the employee receives a welcome e-mail, about two weeks after randomization, with a unique username and password. The first time an employee logs on to the site, he is directed to an introduction which explains the workings of the program. The employee is asked to fill out some personal details for the counselor. The employee then starts with the first module. The assignments are filled out on the site and stored in a personalized area of the website. The personal counselor receives an alert when the employee has finished a module. The counselor then checks the assignments and comments on them through e-mail within 5 working days, according to the standardized protocol. One week after finishing a module, the participant is able to start with the assignments of the next module. Modules have to be worked through in the given order.

When an employee does not log on to the website according to schedule, he receives an e-mail reminder twice a week. These reminders are continued for the full duration (i.e. six months) of the program. Besides being reminded by e-mail, employees can also choose to be reminded by text message on their mobile phone. Participants have the possibility to e-mail their counselor between modules, if they have additional questions.

Counseling

Four counselors with a degree in nutrition or physical activity provide coaching for the participating employees. Prior to the start of the intervention, they receive four weeks of training. The counselors are made familiar with the principles behind the program and go through the intervention materials. A psychologist trains them in counseling techniques. A pilot group is put together to give the counselors the opportunity to practice with the counseling protocols, counseling skills and administrative procedures.

Counseling takes place according to a standardized protocol, which is developed for each communication method. Both protocols are similar to each other in approach. The protocol for the phone-condition consists of a timed outline for each module and

provides the counselors with guidelines on how to counsel the assignments.
The protocol for the internet-condition consists of a semi-prepared e-mail for each module. The e-mail discusses the module by giving generic comments. To this the counselor adds the answers the participant has filled out in the assignments and addresses those individually in the same manner as in the phone calls.

In order to keep track of appointments, purport of phone calls and e-mails, and the progress of the participants, a web-based participant management system is developed. Counselors have access to the assignments and progress from the internet group through this participant management system.

Outcome measures, confounding- and mediating variables

Primary outcomes of the study are 1) weight change and change in BMI, 2) change in physical activity level, and 3) change in dietary intake of fat, fruit, vegetables, sugar and alcoholic beverages. Effects in both intervention groups combined against the effects in the control group are studied, as well as effects in the phone group against effects in the internet group. Besides these primary outcomes, other outcomes are studied also. Among those are changes in waist circumference, sum of skin folds, blood pressure, total blood cholesterol and aerobic fitness. Other outcomes that are studied include change in work performance/productivity, perceived health, empowerment, stage of change and self efficacy concerning weight control, physical activity and eating habits. Changes in direct medical costs and changes in indirect costs for sickness absence and loss of work productivity are studied as well.

In conclusion, a process evaluation of the execution of the intervention and of participant satisfaction is carried out after completion or the intervention.

Assessment of the aforementioned outcomes is done either by questionnaire or by physiological measurements. Physiological measurements take place at the work site or near the work site. Questionnaires are sent to the home address of the participant. The scheduling of all measurements is shown in Table 2.1.

Primary outcome measures

Body weight and BMI

Body weight and body height are assessed in all participants. Body weight is measured in kg, to the nearest 0.1 kg, with a digital scale (Seca 770; Seca GmbH & Co, Hamburg, Germany). Participants are wearing light clothing and no shoes. Body height is measured in m, to the nearest 0.001 m, with a portable stadiometer (Seca 214, Leicester Height Measure; Seca GmbH & Co, Hamburg, Germany). Positioning of the body is standardized by asking the subject to stand straight, without shoes and with the heels together. Both weight and height are measured twice, and for each mean value of the two measurements is computed. BMI is calculated by dividing the measured body weight (kg) by the squared measured body height (m).

In addition, in a questionnaire self-reported body weight is assessed. Participants are asked to weigh themselves wearing light clothing and no shoes.

TABLE 2.1 Schedule of measurements, outcome measures are directly measured (D), measured by questionnaire (Q) or measured otherwise (O)

Outcome measure	D, Q, O	Base-line	6 months	12 months	18 months	24 months
Body weight	D Q	✓ ✓	✓ ✓	 ✓	 ✓	✓ ✓
Body height	D Q	✓ ✓	 ✓	 ✓	 ✓	 ✓
Dietary intake	Q	✓	✓	✓	✓	✓
Physical activity	Q	✓	✓	✓	✓	✓
Waist circumference	D Q	✓ ✓	✓ ✓	 ✓	 ✓	✓ ✓
Sum of skin folds	D	✓	✓			✓
Blood pressure	D	✓	✓			✓
Total blood cholesterol	D	✓	✓			✓
Aerobic fitness	D	✓	✓			✓
Perceived health	Q	✓	✓	✓	✓	✓
Empowerment	Q	✓	✓	✓	✓	✓
Stage of change	Q	✓	✓	✓	✓	✓
Self efficacy	Q	✓	✓	✓	✓	✓
Work performance	Q	✓	✓	✓	✓	✓
Confounding and mediating variables	Q	✓	✓	✓	✓	✓
Sickness absence and health care utilization	O[1]	➤	➤	➤	➤	
Program costs	O[2]	➤				
Data for process evaluation	Q O[3]	 ➤	✓ 			

1 Sickness absence data and data on health care utilization are collected by a six-monthly diary. Sickness absence data are also derived from employer payroll records, from six months before baseline till two years after baseline;

2 Program costs are assessed continuously during development and implementation of the program;

3 Participants appraisal of the program is measured by questionnaire at six months after baseline. Objective measures are collected from the database underlying the participant tracking system and the website;

➤ continuous measurement from this period till next period.

Dietary intake and physical activity

Dietary intake and physical activity are assessed by means of a questionnaire. The focus of dietary intake is on fat, fruit and vegetables. Fat intake is assessed by the validated Dutch Fat List.[94] Fruit and vegetable intake are asked with a short fruit and vegetable questionnaire, that has been validated as well.[95, 96] Intake of sugar and alcoholic beverages is assessed with a set of questions which were developed for this study. Physical activity level is assessed with the validated Short Questionnaire to Asses Health enhancing physical activity (SQUASH).[97]

Physiological outcome measures

For a random sample of each group, several additional physiological measurements are assessed in the following order: waist circumference, sum of skin folds, blood pressure, total blood cholesterol, and aerobic fitness. They are all done according to standardized protocols and take approximately 45 minutes per session.

Waist circumference

Waist circumference (in cm) is measured twice with a measuring tape (Gulick; Creative Health Products, Ann Arbor, MI, USA) with a range of 0-150 cm. Waist circumference is measured to the nearest 0.1 cm, at the midpoint between the lower border of the ribs and the upper border of the pelvis. A mean value of the two measurements is computed.

In addition to the objectively assessed waist circumference in the sub-sample, all 1386 employees are asked to report their self measured waist circumference in each questionnaire. For that aim, a measuring tape is sent to all participants along with the baseline questionnaire. This measuring tape is developed for the study and has a range of 0-135 cm. Participants get instructions on how to use the measuring tape and are asked to report their waist circumference to the nearest cm.

Sum of skin folds

According to the method of Weiner and Lourie[98] the following four skin folds are measured twice with a Harpenden caliper (HSK-BI; Baty International, Burgess Hill, UK) up to the nearest 0.1 mm and on the right side of the body: sub scapular, suprail-iac, triceps and biceps. In case the two measurements of a fold differ more than 1.0 mm, the skin fold is measured a third time. Next, for each skin fold, a mean value of the measurements is computed and the four skin folds are added up.

Blood pressure

Blood pressure is measured with a fully automated blood pressure monitor (Omron HEM 757E [M5-I]; Omron Healthcare Europe BV, Hoofddorp, The Netherlands). This blood pressure monitor is validated and recommended for clinical use.[99] A regular size cuff is used on the right upper arm. When the subject has an upper arm circumference of 33 cm or more, a large size cuff is used. The right arm is placed on a table so as the cuff is on a level with the heart. After the employee has rested for 5 minutes in a sitting position, blood pressure is measured twice. A mean value of the two measurements is computed.

Employees that have a blood pressure of 140/90 mmHg or higher are advised to visit their general practitioner.

Total blood cholesterol

Total blood cholesterol level is determined with the Reflotron® Plus (Roche Diagnostics GmbH, Mannheim, Germany) portable blood analysis system. The Reflotron® Plus provides a good risk classification.[100] Total cholesterol is determined in non-fasting capillary blood, collected from a finger prick. If total cholesterol is lower than 3.0 mmol/l or exceeds 6.5 mmol/l, the measurement is repeated. If both measurements are over 6.5 mmol/l, the employee is advised to visit his general practitioner.

Aerobic fitness

Aerobic fitness is assessed by means of the Chester Step Test (CST).[101] The CST is a sub-maximal test that gives a reliable prediction of VO_2 max.[102] The employee is asked not to drink coffee or smoke two hours prior to the test. During the CST, the employee steps on and off a 10, 15, 20 or 25 cm gym bench. The height of the bench depends on the participant's age and current fitness level, as described in the manual of the test.[103] The test starts at the pace of 15 steps per minute. The pace increases every two minutes to 20, 25, 30 and 35 steps per minute, respectively. A metronome sets this stepping rate. The heart rate of the participant is monitored continuously by means of a heart rate monitor (Polar S610; Polar Electro Oy, Kempele, Finland). Also, the subject must report his subjective rate of exertion at the end of each stage, using a Borg scale ranging from 6 tot 20.[104] The test is terminated at the end of a stage at which the subject's heart rate reaches 80% of his age predicted maximal heart rate (220 minus age), or when the reported rate of perceived exertion exceeds 14 (hard).[103] The estimated VO_2 max is calculated with calculator software that comes with the Chester step test (ASSIST creative resources Limited, Redwither Business Park, UK).

Other outcome measures

Perceived health and empowerment are respectively assessed with the RAND-36 [105] and the Mastery Scale of Pearlin.[106] Stage of change in relation to weight control, physical activity and eating habits is assessed using questions about intentions to start changing these behaviors.[107-109] The behavioral determinant self efficacy, concerning weight control, physical activity and eating habits is assessed with a set of questions developed for this study.

The cost-effectiveness and the cost-utility of the lifestyle program will be ascertained. The cost-effectiveness analysis will be performed from both a company perspective as well as from a societal perspective. The primary outcome measures weight change, change in physical activity level, and change in dietary intake will be included in this cost-effectiveness analysis.

For the company perspective, intervention costs will be compared with obtained benefits from reduced sickness absence and increased work productivity. Intervention costs include costs for the development of the intervention, such as the development of the website and the binders, and costs for the implementation of the intervention, such as salary costs of the counselors and costs for hosting the website. Self-reported sickness absence is prospectively measured by keeping a six-monthly diary. On a monthly basis the employee records full days absence from work due to sick leave. Diaries are provided at the start of each six month measuring period. In addition, data on sickness absenteeism will be derived from employer records, from six months before baseline till two years after baseline. Work productivity is measured with the work related questions from the WHO Health and Work Performance Questionnaire (HPQ).[110] Work productivity assessed by the HPQ is based on self-report. The HPQ is validated and available in several languages, including Dutch.

The cost-effectiveness from a societal perspective will be addressed by assessing health care utilization and medical costs. Health care utilization is based on actual resource use, using prospective data collected by a diary in which the employee records use of medical services and medication on a monthly basis. This diary is combined with the diary recordings on sickness absence. Direct medical costs of health care utilization are calculated using cost prices if available and otherwise tariffs will be used. Utilities for the cost-utility analysis are based on the EuroQol.[111]

Confounding and mediating variables

Possible confounders that are assessed include certain demographics, smoking behavior, health conditions, weight outcome evaluation and weight control behaviors. Demographic variables that are measured are age, educational level, personal income, country of birth, gender, marital status and number of adults and children living in the employee's household. Smoking is defined as use (yes/no) of cigarettes, or other tobacco products (cigars, pipes). Having quit smoking (yes/no) in the past six months is also assessed. Health conditions related to overweight, physical inactivity and unhealthy eating habits are assessed using a series of questions about the use of medication for hypercholesterolemia, hypertension, angina, heart disease, myocardial infarct, depression and diabetes. Weight outcome evaluation is assessed by three questions concerning acceptable weight, desirable weight in six months and the wish for weight loss or weight management. Weight control behaviors are measured by reports of frequency of self weighing, frequency of weight loss attempts in the last two years, and employed methods for weight control.

Process evaluation

The process evaluation among participants assesses the participants opinion of the allocated study group, use and appraisal of the components of the lifestyle intervention program or (in the case of the control group) of the provided general brochures, evaluation of coaching by the personal counselor (if applicable) and a generic grade for the program. Additional questions are asked about contentment with achieved results, reasons for not finishing the program, and how much the participant would be willing to pay for the offered program.

Objective measures for use of both intervention methods will be obtained from the database that underlies the participant management system and the intervention website.

STATISTICAL ANALYSES

Baseline values will be analyzed for differences in the three groups, by one-way-analysis of variance for numerical data and chi-square for categorical data.

Analyses for the primary outcomes, for the physiological outcomes and for the other outcomes (e.g. perceived health) will be at six months (short term) and after two years (long term). They will be performed according to the intention-to-treat principle. Analyses for short term results will be performed with multiple linear regression. Analyses for long term results will be performed with multiple longitudinal regression.

Bootstrapping will be used for comparison of mean direct, indirect and total costs between groups.[112] Confidence intervals for the mean difference in costs will be obtained by bias corrected and accelerated bootstrapping. Cost-effectiveness ratios and cost-utility ratios will also be calculated with bootstrapping according to the bias corrected percentile method. Separate cost-effectiveness ratios will be calculated for the primary outcomes.[113] Bootstrapped cost-effect pairs will be graphically represented on a cost-effectiveness plane.[114] Acceptability curves will be calculated, which show the probability that a treatment is cost-effective at a specific ratio.

DISCUSSION

The ALIFE@Work study is motivated by the increasing prevalence of overweight and obesity.[81] Overweight is a risk factor for, among others, cardiovascular diseases and type 2 diabetes.[115] The study aims to result in sustainable changes in physical activity and diet, to enhance weight control. Thus, by inducing weight control, ALIFE@Work aims to limit the future burden of overweight and obesity related diseases.

The rising prevalence of overweight and obesity has created a need for cost-effective lifestyle interventions that can reach a broad population on an individual level. One approach is behavior counseling based on social cognitive theory. This is shown to be effective for weight loss, but has not yet been applied to the prevention of weight gain.[62, 89] Counseling programs usually require participants to visit a treatment centre during office hours and to do so on a regular basis. This is both demanding for the health care system as well as for the participant. Distance counseling channels like phone and internet could be feasible ways to offer the same counseling in a more cost-effective way. Two other studies have looked at the effect of counseling by either phone or e-mail on weight loss.[53, 90] ALIFE@Work is the first study to allow for a direct comparison of the effects of these different types of distance counseling. Also, it is the first study to apply personal counseling to the prevention of weight gain. The target group of the intervention are employees that are approached through their employer. Working people represent a large part of the population at risk, especially since most jobs have become sedentary. Also, approaching people through their employer is a new way to reach individuals that might otherwise not partake in weight control programs. The approach is similar to the way the program could be implemented, if proven cost-effective.

Because the future effects of the intervention on the prevalence of overweight related diseases and mortality are hard to study, intermediate endpoints are chosen. Short-term effects (6 months) and long term effects (24 months) on weight and BMI, physical activity and eating behavior are studied. A strong point of the ALIFE@Work study is the follow-up of two years, which makes it possible to evaluate weight loss and weight management up till one-and-a half years after the intervention is finished.

Overweight is associated with (abdominal) adiposity and other cardiovascular risk factors, such as hypercholesterolemia and hypertension. As the main outcomes weight and BMI are associated with, but not directly reflect (abdominal) adiposity, waist circumference and sum of skin folds are assessed in a sub-sample of the study population. Aerobic fitness is assessed in the same sub-sample to serve as a proxy for physical activity, which is otherwise measured by self-report. Blood pressure and total blood cholesterol are also studied in the sub-sample. These physiological measures add outcomes that are one step further in the chain of the development of cardiovascular disease. Also, ALIFE@Work is one of the few lifestyle intervention studies that evaluates the effect on biological cardiovascular risk factors in overweight adults who are apparently healthy.[116]

Cost-effectiveness and cost-utility for both counseling strategies will be assessed at one- and at two-year follow-up. As far as we know, economic evaluations from the societal perspective of weight control interventions based on change in physical activity, diet or behavior counseling have not been performed as yet.[117, 118] Our study would be the first to give information based on real costs and outcomes.

In conclusion, principal findings of the ALIFE@Work study concern the (cost-) effectiveness of a 6-month lifestyle intervention based on social cognitive theory and personal counseling by phone or e-mail, in an overweight but otherwise healthy working population. Due to report in 2007, the ALIFE@Work study has the potential to make a substantial contribution to the development of cost-effective weight control- and lifestyle interventions that are applicable to and attractive for the large population at risk.

CHAPTER 3:

ACCURACY OF SELF-REPORTED BODY WEIGHT, HEIGHT AND WAIST CIRCUMFERENCE IN A DUTCH OVERWEIGHT WORKING POPULATION

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ABSTRACT

Background: In population studies, Body Mass Index (BMI) is generally calculated from self-reported body weight and height. The self-report of these anthropometrics is known to be biased, resulting in a misclassification of BMI status. The aim of our study is to evaluate the accuracy of self-reported weight, height and waist circumference among a Dutch overweight (Body Mass Index [BMI] ≥ 25 kg/m^2) working population, and to determine to what extent the accuracy was moderated by sex, age, BMI, socio-economic status (SES) and health-related factors.

Methods: Both measured and self-reported body weight and body height were collected in 1298 healthy overweight employees (66.6% male; mean age 43.9 ± 8.6 years; mean BMI 29.5 ± 3.4 kg/m^2), taking part in the ALIFE@Work project. Measured and self-reported waist circumferences (WC) were available for a sub-group of 250 overweight subjects (70.4% male; mean age 44.1 ± 9.2 years; mean BMI 29.6 ± 3.0 kg/m^2). Intra Class Correlation (ICC), Cohen's kappa and Bland Altman plots were used for reliability analyses, while linear regression analyses were performed to assess the factors that were (independently) associated with the reliability.

Results: Body weight was significantly ($p < 0.001$) under-reported on average by 1.4 kg and height significantly ($p < 0.001$) over-reported by 0.7 cm. Consequently, BMI was significantly ($p < 0.001$) under-reported by 0.7 kg/m^2. WC was significantly ($p < 0.001$) over-reported by 1.1 cm. Although the self-reporting of anthropometrics was biased, ICC's showed high concordance between measured and self-reported values. Also, substantial agreement existed between the prevalences of BMI status and increased WC based on measured and self-reported data. The under-reporting of BMI and body weight was significantly ($p < 0.05$) affected by measured weight, height, SES and smoking status, and the over-reporting of WC by age, sex and measured WC.

Conclusion: Results suggest that self-reported BMI and WC are satisfactorily accurate for the assessment of the prevalence of overweight/obesity and increased WC in a middle-aged overweight working population. As the accuracy of self-reported anthropometrics is affected by measured weight, height, WC, smoking status and/or SES, results for these subgroups should be interpreted with caution. Due to the large power of our study, the clinical significance of our statistical significant findings may be limited.

BACKGROUND

The high and still increasing prevalence of overweight (Body Mass Index [BMI] ≥ 25 kg/m^2) and obesity (BMI ≥ 30 kg/m^2) seriously threaten public health worldwide. Overweight and obesity are associated with multiple health problems[6] and with excess mortality.[6, 119, 120] The Body Mass Index (BMI) is the most commonly used measure of overweight or general adiposity, and is calculated as body weight (in kg) divided by squared body height (in meters). Consequently, knowledge on body weight and height in a population is relevant to be able to assess the prevalence of overweight and obesity, and to identify subgroups that are at increased risk to develop overweight and obesity-related health problems and to die prematurely.

As self-measurement of body weight and height is simple and inexpensive, it is a suitable method to collect data from a large number of individuals.[121] Previous studies have shown that adult people tend to under-report their body weight and to over-report their body height,[79, 122-128] especially those with increased weight.[79, 123, 127, 128] In addition, self-reported anthropometrics are more biased in older than in younger subjects.[122] Inaccurate measurements of body weight and height will lead to biased calculations of BMI, and consequently to an inaccurate assessment of the disease and mortality risk of a population.

Waist circumference (WC) is a measure of abdominal or central adiposity. As abdominal fat is a better predictor of risk for obesity-related disorders than general adiposity,[129] it may be a more useful clinical tool to identify the prevalence of overweight and obesity and their related risk factors than BMI. Therefore, it is important to know whether WC can be accurately self-reported. In the limited number of studies that have been performed on the accuracy of self-reported WC in adults,[77, 78, 130-136] underreporting of WC in both men and women has been the most consistent finding. Only two studies assessed the accuracy of self-reported WC as well as that of body weight and height in the same population,[134, 136] of which one included only women.[134]

The prevalence of overweight is known to vary with socio-economic status (SES).[137] Obesity has been reported to be inversely associated with SES, especially in women. The extent of misreporting anthropometrics seems to be greater in persons with a higher body weight or BMI.[77, 134] Therefore, it is conceivable that the prevalence of misreporting in those from a low SES will be higher than in those from a higher SES. As yet, the limited number of studies investigating the effect of SES on the accuracy of self-reporting body weight and height has been inconclusive. Both an effect[123, 124, 138, 139] and no effect[140] of SES on the accuracy of self-reported body weight and height has been found. Regarding self-reported WC, the few studies addressing this issue found no effect of SES on the misreporting of WC.[130, 133, 136]

Several studies on the accuracy of self-reported anthropometrics have included health-related factors that may be associated with the accuracy, such as smoking status,[124, 140] physical activity level,[128, 140] adhering to a special diet,[140] weight history,[124] and medication for cardiovascular risk factors.[123] It is conceivable that the number of attempts to lose weight and frequency of weighing oneself may also be associated with the accuracy of self-reported anthropometrics, but to our knowledge these associations have not been investigated previously.

The accuracy of self-reported weight, height and WC has never been studied in a Dutch population, neither in relation to SES or health-related factors. The main objective of this study was to evaluate the accuracy of self-reported body weight, height and waist circumference among a Dutch overweight working population. A secondary objective was to assess to what extent the accuracy was affected by sex, age, overweight status, SES and the health-related factors smoking status, medication use, frequency of weighing oneself and number of attempts to lose weight.

METHODS

Subjects

Subjects were 1298 overweight employees, taking part in the ALIFE@Work project. The ALIFE@Work project is an ongoing randomized controlled trial, in which a lifestyle intervention program aimed at changing physical activity and nutrition in an overweight working population is being evaluated.[141]

For these 1298 subjects (66.6% male; mean BMI 29.5±3.4 kg/m^2; mean age 43.9±8.6 years), both measured and self-reported body weight and body height measures were available at the start of the study. Self-reported WC was available for 1276 of the 1298 participants, and measured WC only for a random sub-sample of 250 participants. Consequently, both measured and self-reported WC were available for 250 subjects (70.4% male; mean BMI 29.6±3.0 kg/m^2; mean age 44.1±9.2 years).

The Medical Ethical Committee of the VU University medical center reviewed and approved the study. Written informed consent was obtained from all participants. All subjects participated voluntarily and were free to cancel their participation, without reason, at any time throughout the course of the study.

Study design and procedures

Eligible subjects (i.e. BMI ≥ 25 kg/m^2) who agreed to participate in ALIFE@Work were invited to have their body weight and body height measured. All eligible subjects had been sent an information brochure on the project, upon which they could decide to participate in the study. Right after these measurements, a randomization allocated a sub-sample of 20% to a group receiving additional biological and anthropometric measurements, including WC. These additional measurements took place within two weeks after the assessment of body weight and height. Because of limited resources, it was not feasible to do these additional assessments for all study subjects. All measurements were done by the same two trained researchers according to standardized protocols, at or near the employee's work site.

Together with the invitation to have their body weight and height measured, participants received a questionnaire at home, approximately two weeks before the measurement took place, in which they were asked, among other questions, to report their body weight, height and waist circumference. The questionnaire also asked, among other issues, about their education level and health-related characteristics. Subjects were asked to bring the questionnaire with them to the baseline measurement appointment or sent it back in a pre-stamped envelope. A detailed description of the study design has been published elsewhere.[141]

Anthropometrics

Measured body weight and height

Body weight (in kg to the nearest 0.1 kg) was measured with a reliable weighing scale (Seca 770; Seca GmbH & Co, Hamburg, Germany) while participants were wearing light clothing and no shoes. Body height (in cm to the nearest 0.1 cm) was measured with a portable wall-mounting height scale with a measuring slide and a heel plate

(Seca 214, Leicester Height Measure; Seca GmbH & Co, Hamburg, Germany). Position of the head was standardized by asking the subject to stand straight, without shoes and with the heels together. Height and weight were measured twice without delay between the measurements, and for both the mean value of the two measurements was taken. Next, the BMI was calculated from these averaged values. Based on BMI, subjects were classified as being overweight ($25\ kg/m^2 \leq BMI < 30\ kg/m^2$; N=861 [66.3%]) or as being obese ($BMI \geq 30\ kg/m^2$; N=437 [33.7%]).

Self-reported body weight and height

Besides the objectively measured weight and height, participants were asked to report their body weight and height in a questionnaire that was sent to their home about two weeks before the measurement took place. Consequently, at time of the self-reporting, they were not (yet) aware of their measured body weight and height. Self-reported body weight was collected with the question: "What is your current body weight?" in kg with the accompanying text "Do weigh your self by preference in the morning before breakfast in underwear or light clothing (round to 0.5 kg)". Self-reported height was obtained with the question: "What is your height?" in cm.

Measured waist circumference

WC (in cm), as a measure of central adiposity, was measured twice to the nearest 0.1 cm with a measuring tape (Gulick; Creative Health Products, Ann Arbor, MI, USA) at the midpoint between the lower border of the ribs and the upper border of the pelvis. Next, the two measurements were averaged. The two measurements were taken right after each other, without delay.

Self-reported waist circumference

In addition, employees were asked to report their WC by answering the question: "What is your waist circumference?" in cm. The accompanying sentence read: "Use the tape measure and instructions that were sent to you along with the questionnaire". A non-stretchable paper measuring tape (range 0-135), which was especially produced for the study, and measuring instructions for use were sent to all participants along with the questionnaire. Subjects were instructed to measure their WC twice without delay between measurements (to the nearest 0.5 cm) at the midpoint between the lower border of the ribs and the upper border of the pelvis, on bare skin with clothing removed, during exhalation, while standing straight-up with the legs 25 to 30 cm apart. They were explicitly instructed to perform the measurement themselves and not having it done by someone else. To ensure proper assessment of the midpoint between the lower border of the ribs and the upper border of the pelvis, subjects were asked to first localize these body points and to mark them on skin with a pen. They were instructed to hold the measuring tape in horizontal position while measuring. Next, they were instructed to average the two readings, and to report the averaged value. Researchers followed the same instructions when measuring the WC. Participants and researchers were not aware of each others measurement outcomes.

According to National Institutes of Health cutoff points, males with a WC of 102 cm or higher and females with one of 88 cm or higher are considered to have an increased WC, placing them at increased risk to develop several health problems.[129] Therefore, for both males and females two groups were created based on their measured WC resulting in groups with normal (males, N=76 [30.4%]; females, N=20 [8%]) and with increased WC (males, N=100 [40%]; females, N=54 [21.6%]). When these groups were created based on their self-reported WC, 28% of the males (N=70) and 6.8% of the females (N=17) had a normal waist and 42.2% males (N=106) and 22.8% of the females (N=57) an increased WC.

Socio-economic status

SES was represented by education level. Subjects were asked to indicate their highest education level on an ordering 6-point scale, ranging from no education to post-graduate education (1 'no education' [0.2%]; 2 'primary' [0.4%]; 3 'lower vocational' [4.3%]; 4 'medium vocational' [34.6%]; 5 'upper vocational' [47.2%]; 6 'university/postgraduate' [13.3%]). Next, education level was divided into two categories: low education level (N=513; no education to medium vocational level) and high education level (N=784; upper vocational level to postgraduate education level). The low and high education level groups were perceived as low and high SES groups, respectively. Education level was missing for one subject.

Health-related characteristics

Apart from measured body weight, height and BMI, age and SES, health-related variables considered to affect the bias were also studied. These variables included: medication use for overweight-related health complaints, smoking status, and number of attempts to lose weight and the frequency of weighing oneself.

Information on the use of medication for overweight-related health conditions was obtained by the question: 'Do you use medication for one of the following health conditions: hypercholesterolaemia, hypertension, diabetes, depression, myocardial infarct, angina pectoris, stroke?' (0 'no', N=1031 [79.4%]; 1 'yes', N=218 [16.8%]). Information on medication use was missing for 49 subjects.

Smoking status was assessed by the question: 'Do you smoke cigarettes, shag, cigars or pipe?' (0 'no', N=1103 [85.1%]; 1 'yes', N=193 [14.9%]). There were two missings for smoking status.

Frequency of weighing oneself was obtained by the question: 'How often do you weigh yourself?' (0 'never', N=61 [4.7%]; 1 'once a year or less', N=81 [6.2%]; 2 'every other month', N=219 [16.9%]; 3 'monthly', N=178 [13.7%]; 4 'every two weeks', N=132 [10.2%]; 5 'weekly', N=428 [33%]; 6 'daily', N=194 [14.9%]; 7 'more than once a day', N=5 [0.4%]). Frequency of weighing oneself was divided into a group with a low frequency of weighing oneself (0 'every two weeks or less', N=671 [51.7%]) and a group with a high frequency of weighing oneself (1 'weekly or more often', N=627 [48.3%]).

Information on the number of attempts to lose weight was obtained by the following question: 'How often did you try loosing weight in the past two years?' (0 'never', N=417 [32.1%]; 1 'once', N=304 [23.4%]; 2 'two to three times', N=301 [23.2%]; 3 'four to five times', N=37 [2.9%]; 4 'more than five times', N=40 [3.1%]; 5 'continuously', N=196 [15.1%]). The variable was divided into three categories: 'no attempt' (N=420 [32.4%]) 'one to three attempts' (N=605 [46.6%]) and '4 and more attempts' (N=273 [21%]). Number of attempts to lose weight was missing for three subjects.

Statistics

Reliability between measured and self-reported values of continuous variables was evaluated with the use of Intra Class Correlation Coefficient (ICC) and 95% Confidence Interval (95% CI). To assess the agreement between measured and self-reported prevalence of overweight and increased WC Cohen's kappa was used. The strength of the agreement was classified as suggested by Landis and Koch.[142] The percentage of agreement was calculated as well.

In addition, Bland and Altman[143] plots were used in order to examine the individual agreement between self-reported and measured anthropometrics. In these plots, the differences between measured and self-measured values (measured minus self-reported) were plotted against the mean of measured and self-reported values. Limits of agreement were calculated as the mean difference ± 1.96 standard deviations (SD). Paired t-tests were used to assess statistically significant differences between measured and self-reported values.

Regression analysis was used to evaluate what variables were (independently) associated with the difference between measured and self-reported anthropometrics. Separate models were built for bias in the self-report of body weight, height, BMI and WC. The following variables were included in the regression models as independent variables: sex, age, SES, measured weight, measured height, measured BMI, measured WC, smoking status, medication use, frequency of weighing oneself and number of attempts to lose weight. For the latter variable, two dummy variables were created and coded such that the 'one to three attempts' and 'more than four attempts' groups were compared with the 'no attempt' group.

All reliability analyses were performed for all subjects, as well as for sex (864 males, 434 females), BMI groups (overweight [N=861], obese [N=437]), SES groups (low [N=514], high [N=782]), age groups (low [N=649], high [N=649]), smoking status (smoking [N=193], non-smoking [N=1103]), medication use (use [N=218], no use [N=1031]) and frequency of weighing oneself (low frequency [N=671], high frequency [N=627]). A median split for age had yielded a younger age group (age ≤ 44.5 yrs, mean age 36.7±5.2 yrs, N=649) and an older age group (age > 44.5 yrs, mean age 51.1±4.3 yrs, N=649).

All analyses were performed using SPSS software (version 12.0.1) and p-values < 0.05 were considered to be significant.

RESULTS

Reliability of self-reported body weight, height, BMI and WC

The average intra-class correlation coefficients for body weight, height, BMI and WC demonstrated high concordance between measured and self-reported measures (Table 3.1). Comparably high average intra-class correlation coefficients were found for the anthropometric measures in the different subgroups (ICC range males: 0.96-0.99; females: 0.91-0.99; low age group: 0.96-0.99; high age group: 0.95-1.00; overweight: 0.92-0.99; obese: 0.95-0.99; low SES: 0.95-1.00; high SES: 0.96-1.00; smoking: 0.93-0.99; non-smoking: 0.96-1.00; medication use: 0.98-1.00; no medication use: 0.95-1.00; low frequency of weighing oneself: 0.96-0.99; high frequency of weighing oneself: 0.95-1.00) (see Additional file 1: Average intra-class correlation coefficients [95% CI] by sex, and by age, BMI groups, SES groups, smoking status, medication use and frequency of weighing oneself groups; accessible at http://www.biomedcentral.com/1471-2288/8/69/additional/).

Body weight ($p<0.001$) and height ($p<0.001$) were respectively, significantly under-reported by 1.4 kg and over-reported by 0.7 cm (Table 3.2). This resulted in BMI being under-reported by 0.7 kg/m^2 ($p<0.001$). WC was significantly ($p<0.001$) over-reported by 1.1 cm (Table 3.2).

As a consequence of the misreporting, the prevalences of overweight, obesity and WC were, respectively, over-reported by 3.4%, under-reported by 6.9% and over-reported by 3.6% (Table 3.3). The overall prevalence of overweight (overweight and obesity combined) was under-reported by 3.5% (not shown). The percentages agreement between self-reported and measured prevalence of overweight and obesity and of increased WC were substantial (overweight/obese: 91.4%, kappa 0.80; WC: 86.8%, kappa 0.72).

TABLE 3.1 Average intra-class correlation coefficients (95% CI) for body weight, height, BMI and waist circumference in all 1298 subjects

Anthropometrics	ICC	95% CI
Body weight (kg)	1.00	0.99 to 1.00
Body height (cm)	0.99	0.99 to 0.99
BMI (kg/m^2)	0.99	0.98 to 0.99
WC (cm)*	0.96	0.94 to 0.97

BMI, Body Mass Index; WC, waist circumference;
* Results on WC are based on a sub-sample of 250 subjects (176 males and 74 females).

TABLE 3.2 Mean (SD) measured and self-reported anthropometrics, the mean differences (SD) and the p-value of the paired t-test for all 1298 subjects

Anthropometrics	Measured	Self-reported	Difference	p-value
Body weight (kg)	92.7 (14.0)	91.3 (13.8)	1.4 (1.9)	<0.001
Body height (cm)	177.0 (9.1)	177.7 (9.2)	-0.7 (1.5)	<0.001
BMI (kg/m^2)	29.5 (3.4)	28.9 (3.3)	0.7 (0.8)	<0.001
WC (cm)*	101.8 (9.7)	102.9 (9.8)	-1.1 (4.0)	<0.001

* Results on WC are based on a sub-sample of 250 subjects (176 males and 74 females).

TABLE 3.3 Prevalences (%) of overweight, obesity and increased WC based on measured and self-reported values for all 1298 subjects

	All subjects (N=1298)
Overweight measured	66.3
Overweight self-reported	69.7
Obesity measured	33.7
Obesity self-reported	26.8
Increased WC measured*	61.6
Increased WC self-reported*	65.2

* Results on WC are based on a sub-sample of 250 subjects (176 males and 74 females).

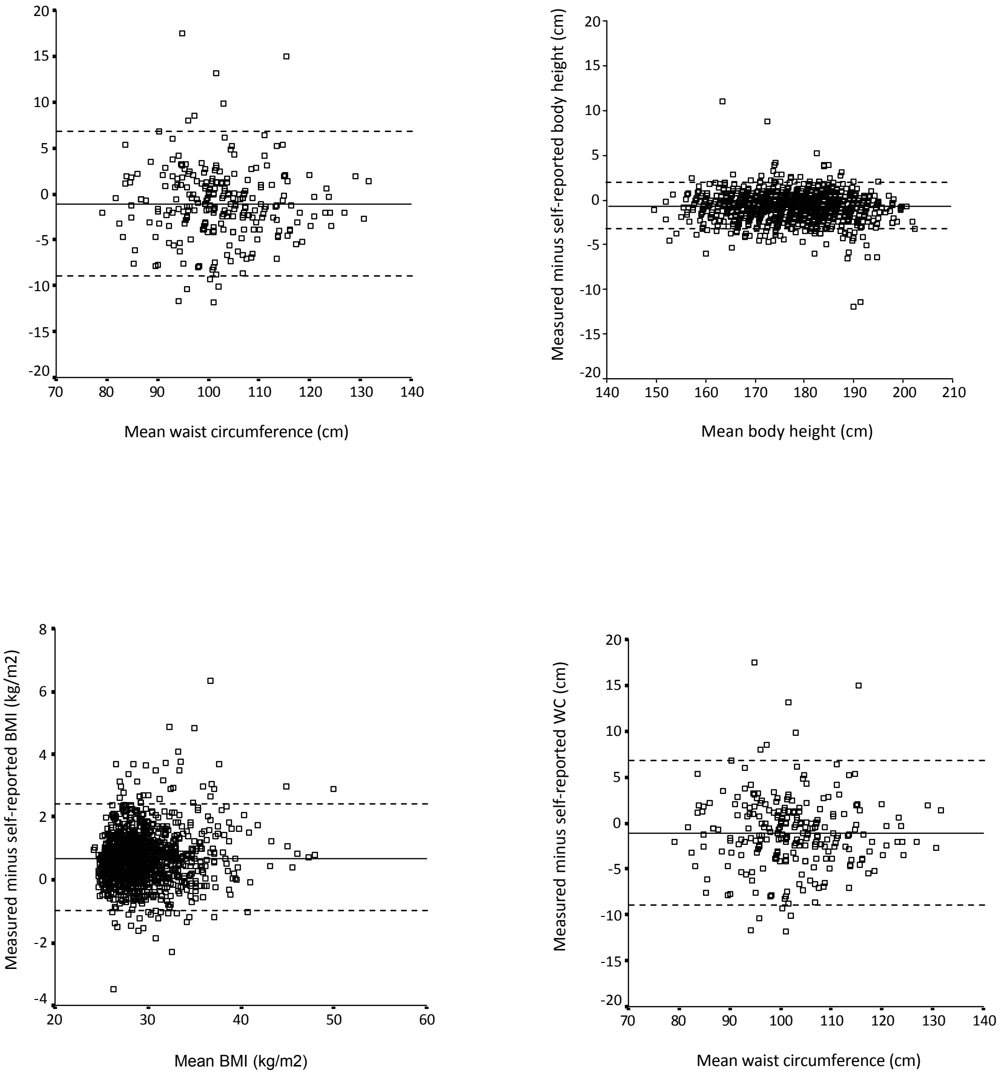


FIGURE 3.1 a-d Bland-Altman plots of the difference between measured and self-reported body weight (a), height (b), BMI (c) and WC (d) plotted against the mean

In each figure, the solid line represents the mean difference between the measured and self-reported value (body weight: 1.4kg; height: -0.7cm; BMI: 0.7kg/m^2; WC: -1.1cm) and the dashed lines represent the 95% limits of agreement (body weight -2.4, 5.2; body height -3.7, 2.3; BMI -0.9, 2.3; WC -8.9, 6.8).

Figure 3.1a-d shows the extent of misreporting of body weight, height, BMI and WC. It can be observed that there were individual differences in the accuracy of self-reported anthropometrics. For example, the difference between measured and self-reported values of WC ranged from -8.9 cm (over-reporting) to 6.8 cm (under-reporting).

Accuracy of self-reported anthropometrics in relation to sex, BMI status, age, SES and health-related characteristics

Additional analyses were performed to assess the accuracy of self-reported anthropometrics in relation to sex (male/female), BMI status (overweight/obese), age (low/high), SES (low/high), medication use for overweight-related health conditions (use/no use), smoking status (smoking/non-smoking) and frequency of weighing oneself (low/high). In all subgroups, body weight was significantly under-reported and body height significantly over-reported, resulting in BMI being significantly (all p's < 0.001) under-reported (Table 3.4).

As a consequence of the misreporting of BMI, the prevalence of overweight was over-reported and that of obesity under-reported (Table 3.5). The overall prevalence of overweight (overweight and obesity combined) was under-reported in all subgroups, except for the BMI groups (not shown). For example, in males the prevalence of overweight was over-reported by 4.1%, the prevalence of obesity under-reported by 6.8% and the overall prevalence of overweight under-reported by 2.7% (6.8 minus 4.1). The over-reporting of the prevalence of overweight in the subgroups is due to the fact that obese subjects who under-report their BMI status automatically fall into the overweight category.

Regarding the BMI groups (i.e. overweight and obese groups), in the overweight group the prevalence of overweight was under-reported by 6.5% and in the obese group the prevalence of obesity was under-reported by 22.9% (Table 3.5).

The percentage of agreement between self-reported and measured BMI status was substantial to almost perfect in all groups (males: 91.6%, kappa 0.79; females: 91.2%, kappa 0.81; low age group: 92.3%, kappa 0.83; high age group: 90.6%, kappa 0.77; low SES group: 90.3%, kappa 0.79; high SES group: 92.2%, kappa 0.80; smoking: 91.2%, kappa 0.81; non-smoking: 91.5%, kappa 0.79; medication use: 89.4%, kappa 0.78; no medication use: 91.8%, kappa 0.80; low frequency of weighing: 78%, kappa 0.78; high frequency of weighing: 92.8%, kappa 0.82).

TABLE 3.4 Mean (SD) measured and self-reported anthropometrics, the mean differences (SD) and p-values by sex, age, BMI status, SES, smoking status, medication use and frequency of weighing oneself

Anthropometrics	Measured	Self-reported	Difference	p-value	Measured	Self-reported	Difference	p-value
	Males (N=864)				**Females (N=434)**			
Body weight (kg)	96.8 (12.7)	95.4 (12.6)	1.5 (2.0)	<0.001	84.5 (12.7)	83.3 (12.4)	1.2 (1.8)	<0.001
Body height (cm)	181.5 (6.7)	182.2 (6.7)	-0.7 (1.6)	<0.001	168.2 (6.3)	168.9 (6.3)	-0.7 (1.5)	<0.001
BMI (kg/m^2)	29.4 (3.1)	28.7 (3.0)	0.7 (0.8)	<0.001	29.9 (4.0)	29.2 (3.9)	0.7 (0.8)	<0.001
Waist (cm)*	104.5 (8.5)	105.9 (8.5)	-1.4 (3.3)	<0.001	95.3 (9.5)	95.5 (8.9)	-0.3 (5.2)	0.66
	Low age (N=649)				**High age (N=649)**			
Body weight (kg)	92.9 (14.5)	91.5 (14.2)	1.3 (2.0)	<0.001	92.6 (13.4)	91.1 (13.3)	1.5 (1.8)	<0.001
Body height (cm)	176.7 (9.5)	177.4 (9.6)	-0.7 (1.4)	<0.001	177.3 (8.6)	178.0 (8.8)	-0.7 (1.6)	<0.001
BMI (kg/m^2)	29.7 (3.6)	29.0 (3.5)	0.7 (0.9)	<0.001	29.4 (3.2)	28.7 (3.1)	0.7 (0.8)	<0.001
Waist (cm)*	100.7 (10.3)	102.4 (10.2)	-1.7 (3.9)	<0.001	102.9 (9.1)	103.3 (9.4)	-0.4 (4.0)	0.21
	Overweight (N=861)				**Obese (N=437)**			
Body weight (kg)	87.1 (9.6)	85.9 (9.6)	1.3 (1.7)	<0.001	103.8(14.6)	102.1 (14.4)	1.7 (2.3)	<0.001
Body height (cm)	177.3 (8.8)	177.9 (9.0)	-0.6 (1.5)	<0.001	176.5 (9.6)	177.4 (9.7)	-0.9 (1.6)	<0.001
BMI (kg/m^2)	27.6 (1.3)	27.1 (1.4)	0.6 (0.7)	<0.001	33.2 (3.3)	32.4 (3.3)	0.9 (1.0)	<0.001
Waist (cm)*	97.8 (7.2)	98.9 (7.2)	-1.1 (3.9)	<0.001	109.3 (9.5)	110.2 (9.9)	-0.9 (4.2)	<0.05
	Low SES (N=513)				**High SES (N=784)**			
Body weight (kg)	94.0 (14.7)	92.3 (14.4)	1.7 (2.0)	<0.001	91.9 (13.4)	90.7 (13.3)	1.2 (1.8)	<0.001
Body height (cm)	176.6 (9.2)	177.4 (9.4)	-0.8 (1.6)	<0.001	177.3 (9.0)	178.0 (9.1)	-0.7 (1.5)	<0.001
BMI (kg/m^2)	30.1 (3.7)	29.3 (3.6)	0.8 (0.9)	<0.001	29.2 (3.2)	28.6 (3.2)	0.6 (0.8)	<0.001
Waist (cm)*	102.1 (9.6)	102.6 (9.8)	-0.5 (4.3)	0.28	101.6 (9.9)	103.0 (9.9)	-1.5 (3.8)	<0.001
	Smoking (N=193)				**Non-smoking (N=1103)**			
Body weight (kg)	93.8 (14.4)	92.5 (14.2)	1.2 (2.2)	<0.001	92.6 (13.9)	91.1 (1.9)	1.4 (1.9)	<0.001
Body height (cm)	176.4 (9.3)	177.2 (9.4)	-0.8 (1.4)	<0.001	177.1 (9.0)	177.8 (9.2)	-0.7 (1.6)	<0.001
BMI (kg/m^2)	30.1 (3.5)	29.4 (3.5)	0.7 (0.9)	<0.001	29.4 (3.4)	28.8 (3.3)	0.7 (0.8)	<0.001
Waist (cm)*	101.1 (9.9)	102.4 (9.9)	-1.3 (5.0)	0.13	101.9 (9.8)	102.9 (9.9)	-1.0 (3.8)	<0.001
	Medication use (N=218)				**No medication use (N=1031)**			
Body weight (kg)	95.6 (15.6)	94.0 (15.4)	1.6 (2.1)	<0.001	91.9 (13.4)	90.6 (13.2)	1.4 (1.9)	<0.001
Body height (cm)	176.8 (8.6)	177.6 (8.7)	-0.9 (1.4)	<0.001	177.0 (9.2)	177.7 (9.3)	-0.7 (1.6)	<0.001
BMI (kg/m^2)	30.5 (3.8)	29.7 (3.7)	0.8 (0.9)	<0.001	29.3 (3.3)	28.6 (3.2)	0.6 (0.8)	<0.001
Waist (cm)*	105.2 (11.3)	106.6 (10.5)	-1.4 (3.4)	0.02	101.3 (9.5)	102.3 (9.7)	-1.0 (4.1)	<0.001
	Low frequency of self-weighing (N=671)				**High frequency of self-weighing (N=627)**			
Body weight (kg)	94.4 (14.1)	92.9 (13.9)	1.4 (2.2)	<0.001	91.0 (13.6)	89.6 (13.5)	1.4 (1.6)	<0.001
Body height (cm)	178.1 (9.0)	178.8 (9.2)	-0.7 (1.6)	<0.001	175.9 (9.0)	176.6 (9.1)	-0.7 (1.5)	<0.001
BMI (kg/m^2)	29.7 (3.4)	29.0 (3.2)	0.7 (0.9)	<0.001	29.4 (3.5)	28.7 (3.4)	0.7 (0.7)	<0.001
Waist (cm)*	104.1 (9.4)	105.1 (9.2)	-1.1 (3.6)	<0.001	99.4 (9.6)	100.5 (10.0)	-1.1 (4.4)	<0.01

* Results on WC are based on a sub-sample of 250 subjects (176 males and 74 females; low age group [N=125], high age group [N=125]; low BMI group [N=163], high BMI group [N=87]; low SES group [N=99], high SES group [N=151]; smoking [N=36], non-smoking [N=212]; medication use [N=33], no medication use [N=209]; low frequency of weighing [N=125], high frequency of weighing [N=123]).

WC was significantly over-reported in all subgroups, except in females, high age subjects, low SES subjects and smoking subjects (Table 3.4). This led to the prevalence of increased WC to be over-reported in all subgroups, except in the high age, obese, low SES and medication use subgroups (Table 3.5).

The percentage of agreement between self-reported and measured increased WC was substantial in all groups (males: 86.4%, kappa 0.72; females: 87.7%, kappa 0.68; low age: 84.8%, kappa 0.68; high age: 88.8%, kappa 0.72; overweight: 81.0%, kappa 0.62; obese: 97.7%, kappa 0.79; low SES: 89.9%, kappa 0.77; high SES: 84.8%, kappa 0.68; medication use: 93.9%, kappa 0.80; no medication use: 92.8%, kappa 0.78; smoking: 94.4%, kappa 0.89; non-smoking: 98.6%, kappa 0.78; low frequency of weighing: 88.0%, kappa 0.76; high frequency of weighing: 92.7%, kappa 0.83).

Univariate regression analyses showed that sex ($p<0.05$), measured weight ($p<0.001$), BMI status ($p<0.001$), SES ($p<0.001$) and medication use ($p<0.01$) significantly affected the difference between measured and self-reported body weight, height and/or BMI (Table 3.6). Males, obese and low SES subjects under-reported their body weight significantly more than females, overweight and high SES subjects, respectively (on average 0.25 kg, 0.49 kg and 0.46 kg more, respectively). Obese subjects also significantly ($p<0.001$) over-reported their body height on average 0.3 cm more than overweight subjects. The underreporting of BMI status was significantly ($p<0.001$) greater in obese subjects, low SES subjects ($p<0.001$) and subjects using medication ($p<0.01$) compared to, respectively, overweight, high SES subjects and subjects using no medication. Also, heavier subjects under-reported their body-weight and BMI status and over-reported their height to a significantly ($p<0.001$) greater extent than less heavy subjects.

The multivariate regression analyses showed that measured weight, height and SES were significantly ($p<0.01$) independently associated with differences between measured and self-reported body weight and BMI status (Table 3.7). Smoking turned out to be a significant predictor ($p<0.05$) of the difference between measured weight and self-reported weight as well, with non-smoking subjects under-reporting their body weight to a greater extent than smoking subjects. BMI status was a significant ($p<0.01$) independent predictor of the bias in the self-reporting of height with obese subjects over-reporting their height to a greater extent than overweight subjects.

Measured WC, sex and age were significantly ($p<0.05$) associated with the difference between measured and self-reported WC, indicating that males, younger subjects and subjects with a lower measured WC over-reported their WC to a significantly greater extent than females, older subjects and subjects with a larger measured WC (Table 3.6).

TABLE 3.5 Prevalences (%) of overweight, obesity and increased WC based on measured and self-reported values for sex, age, BMI status, SES, smoking status, medication use and frequency of weighing oneself

	Males (N= 864)	Females (N=434)
Overweight measured	68.1	62.9
Overweight self-reported	72.2	64.7
Obesity measured	31.9	37.1
Obesity self-reported	25.1	30.2
Increased WC measured[1]	56.8	73.0
Increased WC self-reported[1]	60.2	77.0
	Low age (N=649)	**High age (N=649)**
Overweight measured	64.4	68.3
Overweight self-reported	66.3	73.2
Obesity measured	35.6	31.7
Obesity self-reported	29.1	24.5
Increased WC measured[1]	59.2	64.0
Increased WC self-reported[1]	66.4	64.0
	Overweight (N=861)	**Obese (N=437)**
Overweight measured	100.0	0.0
Overweight self-reported[2]	93.5	22.9
Obesity measured	0.0	100.0
Obesity self-reported	1.3	77.1
Increased WC measured[1]	44.2	94.3
Increased WC self-reported[1]	49.7	94.3
	Low SES (N=513)	**High SES (N=784)**
Overweight measured	61.0	69.8
Overweight self-reported	66.7	71.7
Obesity measured	39.0	30.2
Obesity self-reported	31.2	24.0
Increased WC measured[1]	68.7	57.0
Increased WC self-reported[1]	68.7	62.9

TABLE 3.5 Continued

	Smoking (N= 193)	Non-smoking (N=1103)
Overweight measured	59.6	67.5
Overweight self-reported	63.7	70.9
Obesity measured	40.4	32.5
Obesity self-reported	34.7	25.4
Increased WC measured[1]	41.7	39.2
Increased WC self-reported[1]	47.2	41.0
	Medication use (N=218)	**No medication use (N=1031)**
Overweight measured	54.6	69.0
Overweight self-reported	61.5	71.5
Obesity measured	45.4	31.0
Obesity self-reported	36.7	24.5
Increased WC measured[1]	60.6	36.8
Increased WC self-reported[1]	54.5	40.7
	Low frequency of weighing oneself (N=671)	**High frequency of weighing oneself (N=627)**
Overweight measured	63.9	68.9
Overweight self-reported	69.4	70.0
Obesity measured	36.1	31.1
Obesity self-reported	28.0	25.5
Increased WC measured[1]	51.2	27.6
Increased WC self-reported[1]	52.0	31.7

1 Results on WC are based on a sub-sample of 250 subjects (176 males and 74 females; low age group [N=125], high age group [N=125]; low BMI group [N=163], high BMI group [N=87]; low SES group [N=99], high SES group [N=151]; smoking [N=36], non-smoking [N=212]; medication use [N=33], no medication use [N=209]; low frequency of weighing [N=125], high frequency of weighing [N=123]);

2 45 subjects (5.2%) had a healthy weight based on their self-reported BMI.

TABLE 3.6 Results (regression coefficients [b] and 95% confidence intervals [95% CI]) of univariate regression analyses for sex, age, BMI status, SES, measured weight, measured height, measured WC and health-related factors in relation to differences (bias) between measured and self-reported BMI, body weight, body height and WC

	Bias BMI		Bias body weight		Bias body height		Bias WC	
	b	95% CI	b	95% CI	b	95% CI	b	95% CI
Sex	-0.01	-0.11, 0.08	0.25*	0.03, 0.47	0.02	-0.16, 0.20	-1.13*	-2.21, -0.04
Age	0.03	-0.06, 0.12	0.14	-0.07, 0.35	0.03	-0.14, 0.20	1.23*	0.24, 2.21
BMI status	0.30‡	0.21, 0.39	0.49‡	0.26, 0.71	-0.30‡	-0.47, -0.12	0.25	-0.79, 1.30
SES	-0.20‡	-0.28, -0.10	-0.46‡	-0.67, -0.25	0.09	-0.08, 0.27	-0.93	-1.94, 0.09
Measured weight (kg)	0.01‡	0.01, 0.01	0.02‡	0.02, 0.03	-0.01‡	-0.01, -0.00	0.01	-0.04, 0.03
Measured height (m)	-0.00	-0.01, 0.00	0.01	-0.00, 0.02	0.00	-0.01, 0.01	-4.35	-9.78, 1.07
Measured WC (cm)							0.08†	0.02, 0.13
Smoking status	-0.04	-0.16, 0.09	-0.21	-0.50, 0.09	-0.07	-0.30, 0.17	-0.27	-1.69, 1.15
Medication use	0.16†	0.04, 0.28	0.26	-0.02, 0.54	-0.20	-0.43, 0.02	-0.45	-1.94, 1.03
Frequency of weighing	-0.03	-0.12, 0.06	-0.05	-0.26, 0.16	0.08	-0.09, 0.25	0.03	-0.97, 1.02
Weight loss attempts								
1 to 3	0.05	-0.06, 0.15	0.13	-0.12, 0.37	0.05	-0.14, 0.24	-0.30	-1.49, 0.89
≥ 4	0.09	-0.04, 0.21	-0.10	-0.40, 0.19	-0.18	-0.41, 0.06	0.93	-0.45, 2.31

* †‡ significant different from the estimate of the reference group (i.e. females, low age, overweight, low SES, non-smoking, no medication use, low frequency of weighing oneself, no attempts to lose weight) or from 0 for measured body weight, height, and WC (* $p<0.05$; † $p<0.01$; ‡ $p<0.001$).

TABLE 3.7 Results (regression coefficients [b] and 95% confidence intervals [95% CI]) of multivariate regression analyses for sex, age, BMI status, SES, measured weight, measured height, measured WC and health-related factors in relation to differences (bias) between measured and self-reported BMI, body weight, body height and WC[1]

	Bias BMI		Bias body weight		Bias body height		Bias WC	
	b	**95% CI**	**b**	**95% CI**	**b**	**95% CI**	**b**	**95% CI**
Intercept	2.80	1.89,3.71	2.73	0.57,4.89	-0.61	-0.71,-0.50	-39.13	-56.13,-22.12
Sex							-3.35‡	-4.84,-1.86
BMI status					-0.30†	-0.47,-0.12		
SES	-0.14†	-0.23,-0.05	-0.39‡	-0.60,-0.18				
Measured weight (kg)	0.02‡	0.01,0.02	0.03‡	0.02, 0.04			-0.25‡	-0.34,-0.16
Measured height (m)	-0.02‡	-0.03,-0.01	-0.02†	-0.04,-0.01			15.08†	5.15,25.01
Measured WC (cm)							0.36‡	0.26,0.46
Smoking			-0.30*	-0.60,-0.01				

....

1 Only the significant variables are being displayed;

* p<0.05; † p<0.01; ‡ p<0.001.

Measured WC and sex remained significantly ($p<0.001$) associated with the difference between measured and self-reported WC in the multivariate analysis (Table 3.7). In addition, measured weight ($p<0.001$) and measured height ($p<0.01$) turned out to be independently associated with the difference between measured and self-reported WC, suggesting heavier subjects and less tall subjects to over-report their WC more than less heavy and taller subjects.

DISCUSSION

This study aimed to evaluate the accuracy of self-reported body weight, height and WC in an overweight working population and to assess whether accuracy was affected by sex, age, BMI, SES and health-related characteristics.

In line with previous findings,[122, 123] our results showed that body weight was significantly under-reported and body height significantly over-reported. As a result, BMI was significantly under-reported. The under-reporting of body weight and over-reporting of height is understandable, considering the fact that being tall and slim is seen as ideal in Western society.[140, 144] Also, if subjects weighed themselves at home with less clothing then the clothing they were wearing during the measurement, this could have contributed to the under-reporting of body weight. It is also possible that overweight subjects are less likely to weigh themselves and consequently do report their body weight with less accuracy.[145]

The under-reporting of BMI in this study led to the under-reporting of obesity prevalence and the over-reporting of the overweight prevalence, the latter being due to the fact that our population consisted of only overweight and obese subjects. However, the overall prevalence of overweight (overweight and obesity combined) was under-reported in our population. As found in other studies[125, 127] and in line with the aforementioned, the under-reporting of BMI was significantly greatest among the heavier subjects. In contrast with previous results,[122, 146, 147] the reporting of body weight and height was not more biased in older subjects than in younger subjects. We observed that WC was over-reported, especially in males, heavier subjects and less tall subjects. This was an unexpected finding, as under-reporting of WC has been consistently found in most other studies.[77, 136, 148] However, a slight over-reporting of WC has been observed in postmenopausal women aged 55 to 69 years.[130] Explanation for the over-reporting of WC is unclear. It has been suggested that subjects find it hard to measure their WC accurately,[136] but there is no evidence to suggest that this would lead to an over-reporting of WC. Subjects may not have held the tape in horizontal position while measuring,[130] may not have placed the measuring tape tight enough around their waist or may have measured their WC inadvertently at another, larger site than at the midpoint because of difficulty identifying this point. Also, subjects may have measured their WC at the end of an inhalation when their waist is being pulled out, instead of at the end of an exhalation.

Our finding that low SES subjects under-reported their body weight and BMI to a greater extent than those from a high SES concords with previous findings.[138, 147]

In addition, it has been suggested that women who had a higher family income were more aware of their current weight and therefore more correctly self-reported their body weight,[149] probably as they may have more access to weight loss programs and diet foods.[124] In line with the latter, low SES subjects will be less likely, due to their lower incomes, to buy an accurate weighing scale that is relatively expensive.

We also observed that subjects from a high SES over-reported their WC, whereas low SES subjects did not. If this finding may be interpreted as low SES subjects being more likely to under-report their WC than high SES subjects, it is in line with the under-reporting in these subjects of body weight and BMI to a greater extent than high SES subjects. It would have been interesting to also study the effect of income on the bias in the self-report of anthropometrics, as this is another socioeconomic variable with which SES can be conceptualized. However, we had many missing values for income, whereas education level was only missing for two subjects.

Except from the significant association between smoking status and the bias in self-reported body weight which is in line with a previous finding in men,[140] none of the other health-related variables showed significant independent associations with the difference between measured and self-reported anthropometrics. Future studies including health-related variables are needed in order to get more insight into the association of these variables with bias in self-reported anthropometrics.

Although the self-reporting of body weight, height, BMI and WC was biased, the mean differences between measured and self-reported anthropometrics were low and the ICC's high, suggesting on average a high degree of accuracy of self-reported anthropometrics. Moreover, the percentages of agreement (and kappa's) pointed to a rather accurate classification of overweight, obesity and of increased WC. Therefore, the assessment of the prevalence of overweight/obesity in this overweight population could be done with reasonable accuracy. Recent evidence suggests that misclassification of self-reported BMI results in overestimated associations between overweight/obesity and concomitant morbidity.[150, 151] Consequently, caution is necessary when assessing the prevalence of overweight-related health conditions based on self-reported anthropometrics.

The limits of agreement suggest that the individual self-reporting was less accurate. Consequently, self-reported anthropometrics are less suitable for the identification of overweight and especially obese individuals in our population. More insight into the characteristics of over-reporters and under-reporters will contribute to the accuracy of the assessment of the prevalence of overweight and obesity on an individual level.

Several limiting points need consideration. First, as our population consisted of overweight employees, the generalization of our results is limited. It would be interesting to know to what extent (non-employed) overweight/obese subjects misreport their anthropometrics compared to (non-employed) subjects with a normal weight (i.e. $18.5 \leq BMI < 25 kg/m^2$).

Second, our subjects had just started to participate voluntarily in a weight control program and therefore may have been well aware of their current weight (and height),[152] resulting in only a slight misreporting of body weight and height.

Third, we tried to minimize measurement errors in body weight, height and waist circumference by strict adherence to standard protocols and by using reliable measuring devices. However, during the six months in which body weight and height were assessed in all subjects, the two weighing scales and stadiometers that we used for these measurements were not calibrated, since it concerned standard commercially available devices. Calibration of both weighing scales, approximately one year after the measurement period, however, yielded no deviations.

Fourth, one may argue whether body weight and WC were self-assessed instead of self-reported, as at the appropriate questions in the questionnaire subjects were asked to weigh themselves and to measure their WC using the tape measure and instructions for use. However, we did not ask whether subjects indeed did weigh themselves or measured their WC prior to filling out the questionnaire. This may have produced some bias in the results, as self-assessed measures will be more accurate than self-reported ones.

Finally, our sample size is relatively large, yielding large statistical power. Therefore, we need to be cautious when interpreting our results; a statistical significant difference does not imply that this difference is of any clinical importance. Although measured weight and measured height showed significant independent associations with the accuracy of self-reported body weight and BMI, the regression coefficients were very small. Thus, the clinical significance of these findings may be limited.

CONCLUSION

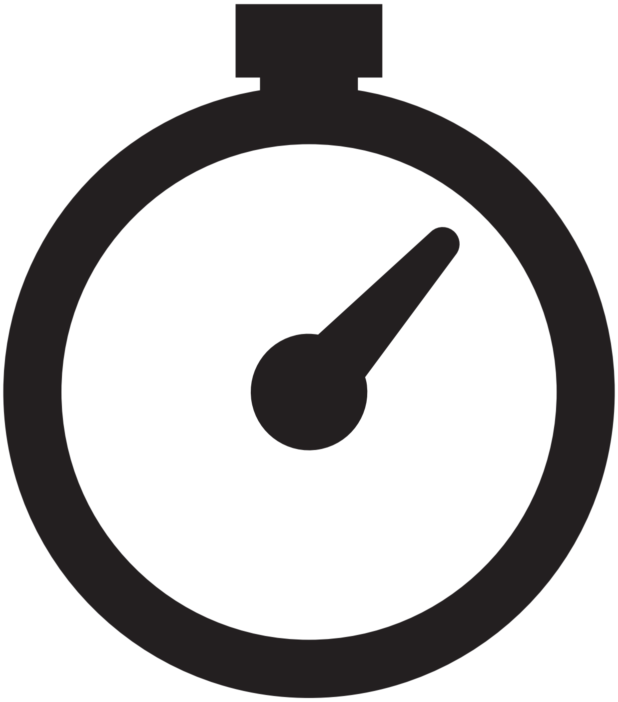
In conclusion, the results of this study suggest that although the self-reported anthropometrics are biased, self-reported BMI and WC are satisfactorily accurate for the assessment of the prevalence of overweight or obesity and of increased WC in an overweight working population. As self-reporting of anthropometrics can be done relatively easy and at low costs, it could be a useful tool to assess the overweight status in populations.

The individual self-reporting of body weight, height and BMI is less accurate, especially in heavier, less tall, low SES and non-smoking subjects. The self-reporting of WC is especially less accurate in males, younger subjects and subjects with a lower measured WC. Results for these subgroups should therefore be interpreted with caution. Also, due to the large power of our study, the clinical significance of our statistical significant findings may be limited.

Further research on the accuracy of self-reported anthropometrics and factors possibly affecting this accuracy in the general population are needed to get more insight into this issue.

CHAPTER 4:

PHONE AND E-MAIL COUNSELING ARE EFFECTIVE FOR WEIGHT MANAGEMENT IN AN OVERWEIGHT WORKING POPULATION



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BMC Public Health.
2009, 9:6.

ABSTRACT

Background: The work setting provides an opportunity to introduce overweight (i.e. Body Mass Index ≥ 25 kg/m^2) adults to a weight management program, but new approaches are needed in this setting. The main purpose of this study was to investigate the effectiveness of lifestyle counseling by phone or e-mail on body weight, in an overweight working population. Secondary purposes were to establish effects on waist circumference and lifestyle behaviors, and to assess which communication method is the most effective.

Methods: A randomized controlled trial with three treatments: intervention materials with phone counseling (phone group); a web-based intervention with e-mail counseling (internet group); and usual care, i.e. lifestyle brochures (control group). The interventions used lifestyle modification and lasted a maximum of six months. Subjects were 1386 employees, recruited from seven companies (67% male; mean age 43 (SD 8.6) y; mean BMI 29.6 (SD 3.5) kg/m^2). Body weight was measured by research personnel and by questionnaire. Secondary outcomes (fat, fruit and vegetable intake, physical activity and waist circumference) were assessed by questionnaire. Measurements were done at baseline and after six months. Missing body weight was multiply imputed.

Results: Body weight reduced 1.5 kg (95% CI -2.2;-0.8, $p<0.001$) in the phone group and 0.6 kg (95% CI -1.3; -0.01, $p=0.045$) in the internet group, compared with controls. In completers analyses, weight and waist circumference in the phone group were reduced with 1.6 kg (95% CI -2.2;-1.0, $p<0.001$) and 1.9 cm (95% CI -2.7;-1.0, $p<0.001$) respectively, fat intake decreased with 1 fatpoint (1 to 4 grams)/day (95% CI -1.7;-0.2, $p=0.01$) and physical activity increased with 866 MET-minutes/week (95% CI 203;1530, $p=0.01$), compared with controls. The internet intervention resulted in a weight loss of 1.1 kg (95% CI -1.7;-0.5, $p<0.001$) and a reduction in waist circumference of 1.2 cm (95% CI -2.1;-0.4, $p=0.01$), in comparison with usual care. The phone group appeared to have more and larger changes than the internet group, but comparisons revealed no significant differences.

Conclusion: Lifestyle counseling by phone and e-mail is effective for weight management in overweight employees and shows potential for use in the work setting.

BACKGROUND

Globally more than one billion adults are overweight (i.e. having a Body Mass Index (BMI) ≥ 25 kg/m^2) and the numbers are still rising.[6] In the Netherlands nearly half of the adult population is overweight.[153] For those who are overweight, weight management (i.e. weight loss and/or prevention of weight gain) is important to alleviate overweight related health problems and to reduce chances of developing cardiovascular diseases and diabetes.[129]

Few people appear to make use of professional help for weight management.[154]

The reasons for this sparse use are not known, but clinicians not referring to professional help,[155, 156] financial costs, lack of time and personal preferences could play a role.[157] The work setting provides an opportunity to introduce a large group of adults to a weight management program. Worksite interventions so far used various combinations of activities and the optimal design is not clear.[22]

Weight loss programs in the health care setting usually rely on lifestyle modification to change dietary intake and physical activity.[40] These strategies are known to produce weight loss.[62, 158] Typically lifestyle modification is supported by (individual or group) face-to-face counseling, requiring multiple visits to a treatment facility. This may be less appealing to working adults, who are often constrained by lack of time for such programs. Behavior counseling by phone and e-mail (i.e. distance counseling) could be more feasible in the work setting. In other settings distance counseling has been applied to weight loss, dietary behaviors and physical activity. Phone counseling trials for weight loss, including trials primarily aimed at changes in diet and/or physical activity, showed mixed results.[47-50, 90, 159] The majority of phone counseling studies for physical activity and dietary behavior found behavior changes.[52] Few trials have investigated e-mail counseling for weight control or lifestyle behaviors. Those that did, found positive effects on body weight, mixed effects on diet,[53, 54] and no effect on physical activity.[53, 54, 59] Only one study recruited participants from a work setting.[53] We found no studies that directly compared the impact of phone counseling with e-mail counseling.

The main purpose of this study was to ascertain effects on body weight of a lifestyle program with 10 biweekly counseling sessions by phone as well as by e-mail compared to self help materials, in overweight workers, at six months. Secondary purposes were to determine effects on waist circumference, diet and physical activity and to compare the effects of counseling by phone with the effects of counseling by e-mail.

METHODS

Study design

The study was a three arm randomized controlled trial in which two arms received a six month lifestyle intervention with behavior counseling by either phone (phone group) or e-mail (internet group). The third arm received usual care in the form of lifestyle brochures (control group). Details of the study design have been published elsewhere.[141]

The study design, procedures and informed consent procedure were approved by the Medical Ethics Committee of the VU University Medical Center and all participants provided written informed consent.

Participants

The logistics of the study dictated certain requirements of companies, like having a minimum of 1000 employees at one location or at close-by locations and the possibility to accommodate measurements at the worksite. The Human Resource Department and/or Occupational Health Department of potentially eligible companies were approached through four large occupational health services and through professional networks (e.g. the Netherlands Society of Occupational Medicine). Seven companies, i.e. two IT-companies, two hospitals, an insurance company, the head office of a bank and a police force, agreed to take part in the study. Over a period of six months approximately 21,000 employees were approached. In the insurance company employees were approached through a health fair and the company intranet. In the other companies all employees received a personal letter informing them about a lifestyle trial that was going to be carried out at their workplace and a screening questionnaire containing questions about the eligibility criteria. Around 25% of the employees was expected to meet the following criteria: BMI ≥ 25 kg/m^2, paid employment for at least eight hours a week, able to read and write Dutch, having access to internet (either at work or at home) and skilled in using it, age at least 18 years, not pregnant and no diagnosis or treatment for disorders that would make physical activity difficult. Eligible employees received further study information and were invited to take part. If they affirmed the invitation, a personal appointment for the baseline body height and body weight measurements was made. BMI was calculated from these measurements; employees with a BMI<25 kg/m^2 were subsequently excluded. Employees were then randomly assigned to one of the three study groups using a concealed allocation schedule based on permuted blocks to ensure equal distribution over the study groups in each company.[141] The participants were, in consequence of the nature of the intervention, not blinded for allocation after randomization. They were not allowed to change groups.

An a priori power calculation to detect a weight loss of 1.4 kg (SD 6.8 kg) with 90 % power in two-tailed tests at a significance level of 0.05, determined the sample size for the study at 1500.[141] Loss to follow-up was not taken into account.

Interventions

All groups received self-help materials published by the Netherlands Heart Foundation, intended for the general public. These materials dealt with overweight, healthy diet and physical activity. Additionally, the phone and internet group received a lifestyle intervention program, which was adapted from previous work by HealthPartners in Minnesota, USA.[90] Based on principles of behavior therapy,[40] it consisted of ten modules. These modules provided information on nutrition and physical activity, and taught lifestyle modification strategies (e.g. self-monitoring, goal setting). Homework in the modules guided the participant in applying these techniques. Physical activity that employees could fit in their daily life (e.g. active commuting, walk at lunch) was encouraged. Participants received a pedometer (WA101, Oregon Scientific, Portland USA) to monitor their physical activity. Nutritional information stressed the reduction of calories by eating a healthy diet with less fat, sugar and alcohol. On the whole, the program emphasized sustainable lifestyle changes rather than weight loss. After finishing each module, participants were contacted by their personal counselor, depending on group allocation either by phone or by e-mail. Counseling was done by four trained counselors (2 dieticians, two movement scientists) and according to two comparable standardized counseling protocols, one for each communication method.[40, 141] Two weeks after randomization, the counselor initiated the intervention by contacting the employees. Participants could also contact the counselor centre themselves.

Phone group

The phone group received the program in a binder. Counseling sessions took place every two weeks, by appointment. In between contacts, the employee studied the module and completed the homework. This interactive process continued until the employee completed all modules, or until the participant declined contact.

Internet group

The internet group had access to an interactive website through a personal access code. Individualized web pages were generated from an underlying database containing general information and from the data that the participant entered in the modules. The counselor was alerted when the employee finished a module, then checked the homework and commented on it through e-mail within five working days. When an employee did not log on to the website according to schedule, he/she received an e-mail reminder twice a week. Participants could also choose to be reminded by text messages on their mobile phone.

Control group

The control group received only the self-help materials and no counseling. At baseline the materials were briefly explained to the employee by the research personnel.

Outcome measures

Outcomes of the study were change in body weight, waist circumference, dietary intake and physical activity between baseline and follow-up. Baseline and six month follow-up weight and height measurements were done at or near the workplace. No-shows were directly reminded by telephone and every effort was made to ensure that the weight measurement could be carried out. Self-reported outcomes were assessed at baseline and six month follow-up by a questionnaire which was sent to the home address of the participant. A maximum of five efforts over the course of two months was made to remind non-responders by mail, e-mail and phone.

Trained research personnel measured body weight and height according to measurement protocol.[141] Body weight (kg) was measured using a digital scale (Seca 770; Seca GmbH & Co, Hamburg, Germany), with participants wearing light clothing and no shoes. Besides the measured body weight, self-reported body weight was collected by questionnaire. If measured weight at follow-up was not present, but self-reported weight at baseline and follow-up was available, this was used in the analyses. In a separate study we found self-reported weight at baseline to be underreported by 1.4 kg,[160] but we assume underreporting to be independent of time of measurement (i.e. baseline, follow-up) and group allocation. Relevant weight loss was defined as a decrease of at least 5% of initial weight as this is considered to be clinically relevant in obese individuals.[66] Weight maintenance was defined as avoiding a 3% increase in initial weight, as recently proposed.[161] Body height (cm) was measured at baseline with a portable stadiometer (Seca 214; Seca GmbH & Co, Hamburg, Germany). BMI was calculated by dividing the body weight (kg) by the square of body height (m^2). Self-reported waist circumference was measured with a non-tearing paper tape developed for the study.[141, 160]

The focus of dietary intake was on fat, fruit and vegetable intake in the previous month. Fat intake was assessed by the validated Dutch Fat List.[94] A total fat score was calculated (range 0 to 95), with one fat point representing a daily fat intake of between one and four grams of fat, two fat points representing five to eight grams of fat, et cetera. Vegetable intake in grams per day and fruit intake in pieces per day were determined from a validated short fruit and vegetable questionnaire.[95, 96] For adults a daily intake of at least 200 grams of vegetables and two pieces of fruit is regarded to contribute to weight management.[162]

Physical activity in the previous week was measured with the validated short questionnaire to asses health enhancing physical activity (SQUASH).[97] This questionnaire inquires about duration (minutes), frequency (days per week) and perceived effort (light, moderate or vigorous) spent on eight predefined activities and a maximum of four sports. MET-values (multiplications of basic metabolic rate) were assigned to each activity and effort level, based on the compendium of activities developed by Ainsworth et al.[163, 164] Assigned MET-values can be found in Additional file 1 (available at http://www.biomedcentral.com/1471-2458/9/6/additional). MET-minutes per week were calculated for total physical activity. Adherence to the guideline of accumulating a minimum of 30 minutes of moderate physical activity on at least five days a week was assessed with a single question, asking about the number of days on which the respondent did at least 30 minutes of bicycling, gardening, odd jobs and sports.

Possible confounders and effect modifiers were measured by questionnaire. These included age, sex, educational level, country of birth, marital status, smoking behavior, medication for certain health conditions and the number of previous weight loss attempts.[141]

Lastly, counselors tracked the content and number of counseling contacts in a web-based participant management system.

Statistical analysis

Analyses to determine effectiveness were performed using multiple linear and logistic regression, with the follow-up outcome measure as the dependent variable. Assumptions of linear and logistic regression were verified. All analyses were adjusted for baseline values, thus creating an adjusted follow-up score.[165] Differences in effectiveness between counseling by phone and e-mail were assessed. For this, two dummy variables were constructed and a simultaneous comparison with the control group was performed. Coefficients and confidence intervals in the phone group and the internet group were thereafter compared. If the confidence interval of the phone group included the coefficient of the internet group and/or vice versa, there was no significant difference.

All subjects, regardless of intervention adherence, were included in the analyses except respondents that became pregnant during the study. For the primary analysis on body weight, missing follow-up body weight was imputed. Body weight was considered missing if no follow-up weight measurement was performed and if self-reported body weight for both baseline and follow-up were unavailable. Five different data sets were created by applying multiple imputation using correlated variables such as baseline body weight, available body weight data from later follow-up measurements at 12 (self-reported), 18 (self-reported) and 24 months (measured or self-reported), age, sex and educational level in the imputation model.[166] These data sets were analyzed as specified above. The estimates were then pooled with methods described by Rubin.[167] Secondary analyses were performed on complete cases for body weight, waist circumference, diet and physical activity.

In the secondary analyses on body weight, confounding was checked by adding a possible confounder to the regression model. A variable was classified as a confounder if the coefficient of group allocation had changed by 10%, compared to the coefficient of group allocation in the model without the variable. To examine effect modification, interaction terms were constructed and added to the regression model. If there were significant interaction effects, groups were stratified according to the identified effect modifier.

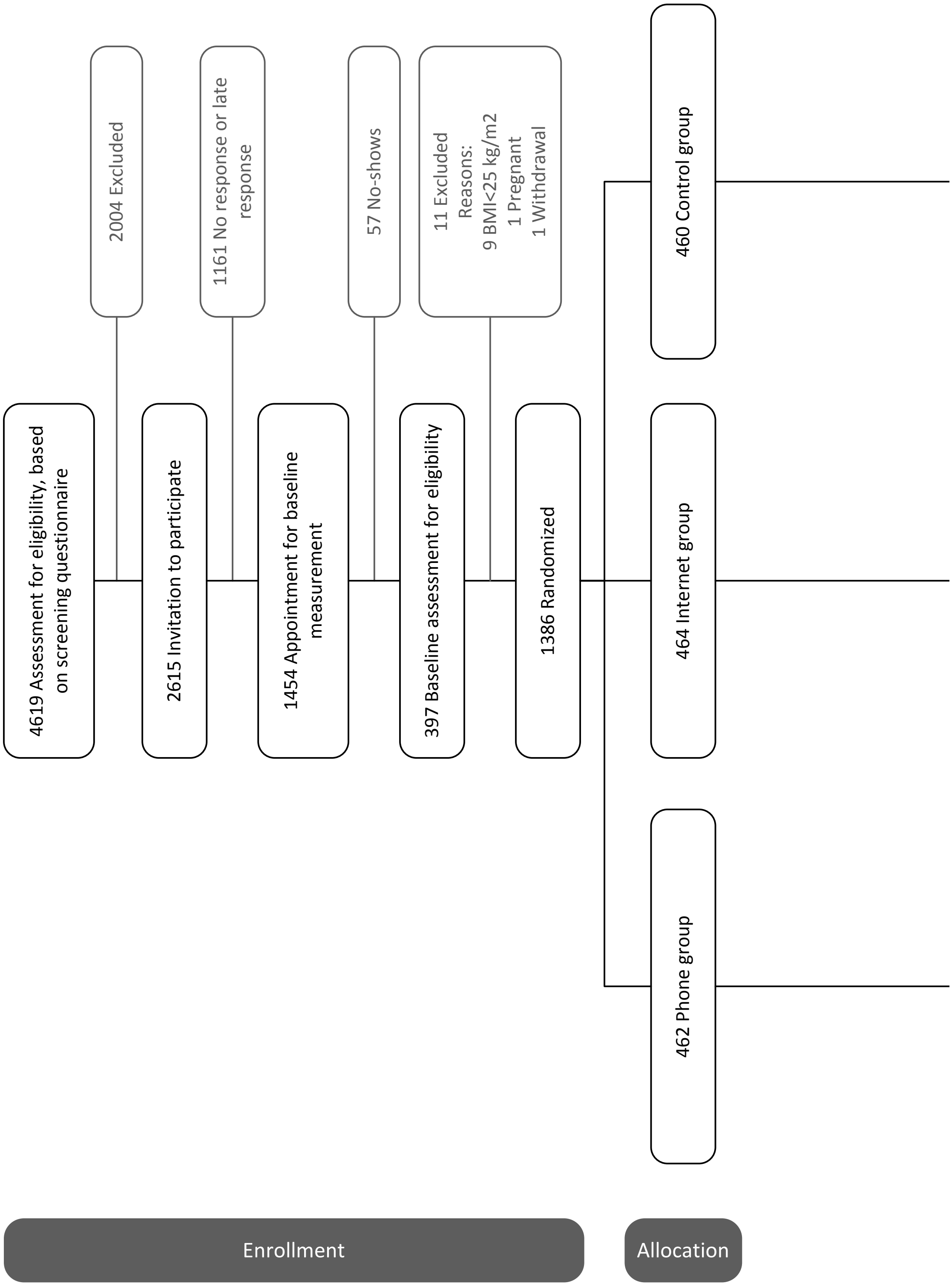
The multiply imputed datasets were generated using R version 2.7.1.[168] Inferences from the primary analysis were pooled using Excel 2003. All analyses were performed with SPSS version 15.0 and p-values < 0.05 were considered significant.

RESULTS

Participants

The screening questionnaire was returned by 4619 employees. Of these, 2615 were eligible to take part in the study. 1454 Employees were willing to participate and received an appointment for baseline measurement, which was kept by 1397 employees. At baseline 11 employees were excluded and 1386 employees were randomized to the phone group (N=462), internet group (N=464) and control group (N=460). Participation in the study as a percentage of estimated number of eligible employees varied between 20% and 32% per company. The participant flow is presented in Figure 4.1. This chart illustrates the flow of participants through the trial and the response to the measurements. Analyses were performed for participants with either complete objective or complete subjective baseline- and follow-up data. Therefore the number of participants that was analyzed in the completers-analyses is smaller than the number that responded to the follow-up measurements.

Between baseline and one month after scheduled follow-up 256 participants withdrew from the study. Self-reported body weight at time of withdrawal was obtained


4619 Assessment for eligibility, based on screening questionnaire
2004 Excluded
2615 Invitation to participate
1161 No response or late response
1454 Appointment for baseline measurement
57 No-shows
397 Baseline assessment for eligibility
11 Excluded
Reasons:
9 BMI<25 kg/m2
1 Pregnant
1 Withdrawal
1386 Randomized
460 Control group
464 Internet group
462 Phone group
Enrollment
Allocation

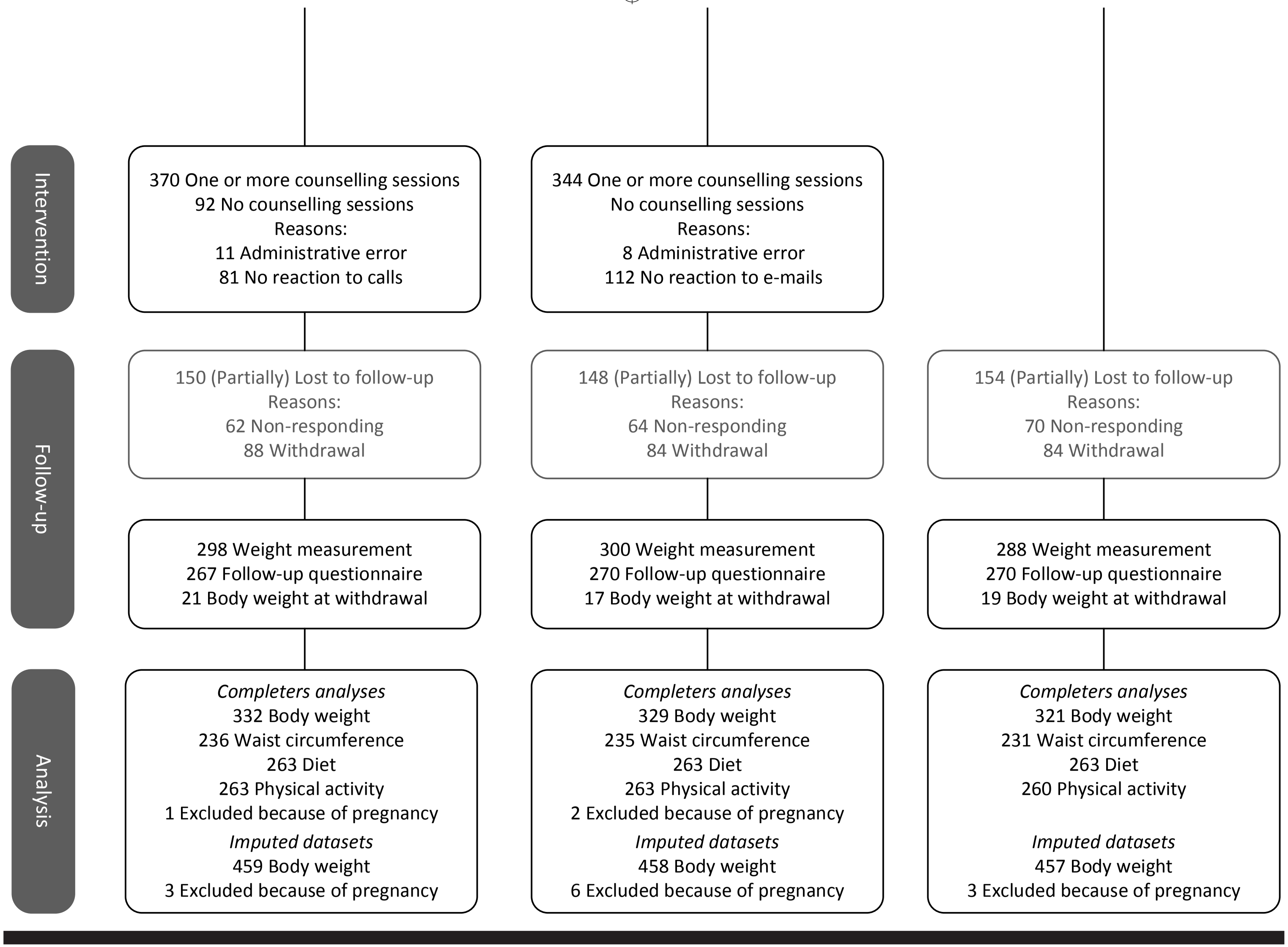


FIGURE 4.1 Participant flow

TABLE 4.1 Baseline characteristics for all subjects by treatment group

	Control n=460	Phone n=462	Internet n=464	All n=1386
Male, No. (%)	306 (66.5)	321 (69.5)	302 (65.1)	929 (67.0)
Age, mean (SD), y	43 (8.7)	43 (8.8)	43 (8.4)	43 (8.6)
BMI (SD), kg/m^2	29.6 (3.7)	29.5 (3.5)	29.6 (3.4)	29.6 (3.5)
Highly educated, No. (%)[1]	255 (58.8)	271 (60.1)	281 (62.2)	807 (60.4)
Married/cohabiting, No. (%)[1]	368 (84.8)	380 (84.3)	384 (85.1)	1132 (84.7)
Born in the Netherlands, No. (%)[2]	401 (94.1)	416 (92.7)	417 (93.3)	1234 (93.3)
Medication for certain conditions, No. (%)[3]	67 (16.5)	80 (18.6)	77 (17.8)	224 (17.7)
Smokes ≥ 1 unit/day, No. (%)[4]	65 (15.3)	73 (16.3)	59 (13.2)	197 (14.9)
Weight loss attempts previous 2 yrs, No. (%)[5]				
0 attempts	141 (33.2)	147 (32.9)	141 (31.6)	429 (32.5)
1 - 3 attempts	196 (46.1)	212 (47.7)	202 (45.3)	610 (46.3)
4 or more attempts	88 (20.7)	88 (19.7)	103 (23.1)	279 (21.2)
Tried to prevent weight gain in previous 2 yrs, No. (%)[5]	347 (81.5)	353 (79.1)	370 (83.0)	1070 (81.2)
At baseline wants to, No. (%)[5]				
Lose weight	363 (85.6)	386 (86.2)	373 (83.8)	1122 (85.2)
Prevent weight gain	55 (13.0)	56 (12.5)	67 (15.1)	178 (13.5)
Neither are important	5 (1.1)	6 (1.3)	4 (1.6)	17 (1.3)

SD, Standard Deviation; 1 n=1337, 2 n=1322, 3 n=1269, 4 n=1320, 5 n=1318.

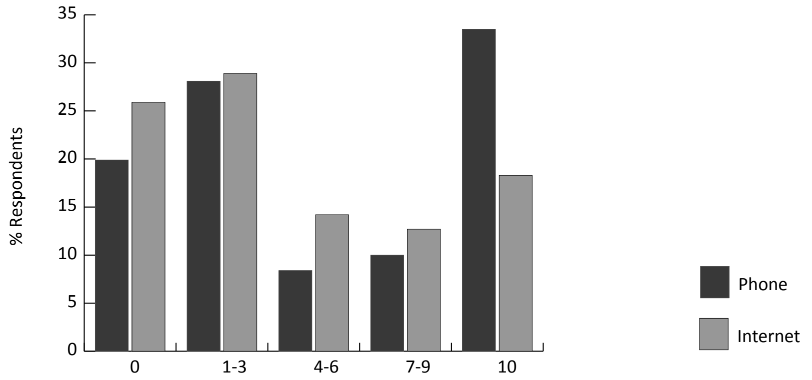


FIGURE 4.2 Participation in the intervention

The columns represent the proportions of participants in the phone and internet groups that received no counseling (0) or that were counselled on modules 1-3, 4-6, 7-9 or 10.

from 57 participants. Most employees withdrew because of lack of time or motivation for further participation in the study and/or program (30%), or because of personal and undisclosed reasons (34%). Nine participants withdrew because of pregnancy. These and three other pregnant participants were excluded from the analyses. Withdrawal was similar in the three groups. For 886/1386 (64%) participants measured body weight at follow-up was available. For 96/1386 (7%) directly measured follow-up weight was missing, but self-reported weight at baseline and follow-up were present and subsequently used in the analysis. Data on participation in the intervention were available for all participants.

Baseline characteristics for participants are shown in Table 4.1. The majority was male (67%) and had a high education level (60%). Mean age was 43 (SD 8.6) years, mean BMI 29.6 (SD 3.5) kg/m^2 and 34% was obese. Approximately one out of six used medication for certain co-morbidities (hypertension (10%), hypercholesterolemia (6%), depression (3%), diabetes (2%), myocardial infarct (1%) and angina (1%)). Around two-third of the study population had previously tried to lose weight, of which 6.3% had used a formal weight loss program. The majority wanted to lose weight.

We compared participants with complete body weight data with the participants who had incomplete data. There was no differential non-response between groups with regard to numbers. However, employees with missing data had a higher baseline BMI (0.9 kg/m^2, $p<0.001$) and were more often obese (40.6% vs. 31.5%, $p<0.001$). Furthermore, they had a lower education level (53.6% high vs. 62.9 high, $p<0.001$), contained more people that (tried to) quit smoking before or during the study (14.0% vs. 7.3%, $p<0.001$), more people wanting to lose weight (89.7% vs. 83.4%, p=0.01) and more people with 4 or more weight loss attempts (25.7% vs. 19.4%, p=0.01) than the complete cases. A comparison of participants with complete lifestyle behavior data with those with only baseline data showed equivalent differences. Additionally, employees with missing lifestyle follow-up consumed somewhat less vegetables (-9 gram/day, p=0.029) and were less likely to eat two pieces of fruit per day (30.4% vs. 36.4%, p=0.024).

Participation in the intervention

Erroneously 11 participants in the phone group and 8 participants in the internet group were never contacted by their counselor. Of the participants in the phone group, 81 did not return the initiating calls from the counseling team, and 370/462 (80%) had at least one counseling session. The web-based program was initiated by 400/464 (86%) employees and 344/464 (74%) employees were counseled on at least the first module. Figure 4.2 shows the attendance to the counseling sessions in each intervention group. The median number of counseled sessions for participants with complete body weight data was 9 (IQR = 2 to 10) modules in the phone group and 5 (IQR = 1 to 10) modules in the internet group. For participants with incomplete data this was 1 (IQR = 0 to 2) modules in the phone group and 0 (IQR = 0 to 2) modules in the internet group.

TABLE 4.2 Baseline and follow-up anthropometric outcomes by treatment group

	Control group		Phone group			Internet group		
	Baseline	Follow-up	Baseline	Follow-up	Change vs. control (95% CI)	Baseline	Follow-up	Change vs. control (95% CI)
Imputed datasets	n=457		n=459			n=458		
Body weight (SD), kg	92.9 (13.6)	91.7 (13.8)	93.4 (14.1)	90.7 (13.7)	-1.5*** (-2.2;-0.8)	92.8 (14.3)	91.0 (14.2)	-0.6* (-1.3;-0.01)
Completers	n=321		n=332			n=329		
Body weight (SD), kg	92.0 (13.2)	91.0 (13.4)	93.5 (14.3)	90.8 (14.0)	-1.6*** (-2.2;-1.0)	91.9 (14.2)	89.8 (14.1)	-1.1*** (-1.7;-0.5)
≥5% weight loss, No. (%)	-	34 (10.6)	-	91 (27.4)	-	-	71 (21.6)	-
≥3% weight gain, No. (%)	-	26 (8.1)	-	20 (6.0)	-	-	18 (5.5)	-
	n=231		n=236			n=235		
Waist circumference (SD), cm	101.5 (9.8)	99.5 (10.0)	102.6 (10.0)	98.6 (10.3)	-1.9*** (-2.7;-1.0)	101.5 (10.3)	98.2 (10.2)	-1.2** (-2.1;-0.4)

* $p<0.05$, ** $p<0.01$, *** $p<0.001$.

Body weight

As table 4.2 shows, in the main analysis the phone group had a significant weight loss of 1.5 kg (95% CI -2.2 ; -0.8) in comparison with the control group. For the internet group this was 0.6 kg (95% CI -1.3 ; -0.01). The difference between the intervention groups was not statistically significant as their coefficients were mutually included in their 95% confidence intervals. The secondary analysis gave somewhat different results. In the phone group a significant loss of 1.6 kg (95% CI -2.2 ; -1.0) was established and in the internet group 1.1 kg (95% CI -1.7 ; -0.5), compared with the control group. No interaction or confounding was found. Table 4.3 shows that in complete cases the phone and internet group were more likely to have a weight loss of at least 5% of initial weight than the control group. As presented in Table 4.2, in the control group the proportion achieving this result was 11%, in the phone and internet group it was 27% (OR 3.2 [95% CI 2.1 ; 4.9]) and 22% (OR 2.3 [95% CI 1.5 ; 3.6]) respectively. No significant results were found for likeliness to gain more than 3% of initial weight, with a proportion of 8% in the control group, 6% (OR 0.7 [95% CI 0.4 ; 1.3]) in the phone group and 5% (OR 0.7 [95% CI 0.4 ; 1.2]) in the internet group.

TABLE 4.3 Likeliness for meeting public health guidelines for weight control, waist circumference and lifestyle behaviors

	OR (95% CI)	p value
Body weight loss ≥ 5%		
Phone vs. control	3.2* (2.1 ; 4.9)	<0.001
Internet vs. control	2.3* (1.5 ; 3.6)	<0.001
Body weight gain >3%		
Phone vs. control	0.7 (0.4 ; 1.3)	0.30
Internet vs. control	0.7 (0.4 ; 1.2)	0.19
≥ 200 gram vegetables/day		
Phone vs. control	1.0 (0.7 ; 1.7)	0.85
Internet vs. control	0.9 (0.5 ; 1.4)	0.53
≥ 2 pieces fruit/day		
Phone vs. control	1.1 (0.7 ; 1.6)	0.80
Internet vs. control	0.9 (0.6 ; 1.4)	0.80
≥ 30 mins. PA/5 days a week		
Phone vs. control	1.8* (1.3 ; 2.6)	<0.001
Internet vs. control	1.4 (0.97 ; 2.1)	0.07

OR, odds ratio; PA, physical activity;
All analyses are based on complete data;
* significant difference: $p < 0.05$.

Waist circumference

Comparable results as for change in body weight were observed for reductions in waist circumference. Compared with the control group, the phone group significantly lost 1.9 cm (95% CI -2.7 ; -1.0) and the internet group 1.2 cm (95% CI -2.1 ; -0.4), as can be seen in table 4.2. No differences were found between counseling by phone and e-mail.

Dietary behavior and physical activity

Table 4.4 presents the behavioral outcomes. The comparison of the phone group with the control group showed statistically significant changes for fat intake and for physical activity. Fat intake decreased by 1.0 fat points (95% CI -1.7 ; -0.2), representing 1 to 4 grams per day, more in the phone group; no differences were seen between the phone and internet group. The phone group also showed a significant increase in physical activity by 866 MET-minutes (95% CI 203 ; 1530) and an odds ratio of 1.8 (95% CI 1.3 ; 2.6) for likeliness to adhere to the physical activity guideline (Table 4.3), compared with the control group, though no differences were found in the comparison of the phone group and the internet group.

	Control group		Phone group			Internet group		
	Baseline	Follow-up	Baseline	Follow-up	Change vs. control (95% CI)	Baseline	Follow-up	Change vs. control (95% CI)
Diet	n=261		n=263			n=263		
Fat (SD), score/day	18.6 (6.2)	16.7 (5.9)	18.6 (5.9)	15.7 (5.5)	- 1.0* (-1.7 ; -0.2)	18.0 (6.3)	15.6 (5.9)	-0.7 (-1.4 ; 0.04)
Vegetables[1] (IQR), g/day	143 (100 ; 193)	143 (100 ; 193)	136 (93 ; 193)	143 (100 ; 193)	9 (-1 ; 20)	129 (86 ; 171)	129 (100 ; 186)	-2 (-12 ; 9)
≥ 200 g veg/day, No (%)	54 (20.7)	56 (21.5)	50 (19.0)	56 (21.3)	-	47 (17.9)	48 (18.3)	-
Fruit[1] (IQR), pieces[2]/day	1.6 (1.0 ; 2.6)	1.9 (1.0 ; 2.9)	1.7 (0.9 ; 2.6)	2.0 (1.3 ; 2.6)	0.2 (-0.02 ; 0.4)	1.6 (0.9 ; 2.4)	1.7 (1.3 ; 2.4)	-0.04 (-0.2 ; 0.2)
≥ 2 pieces[2] fruit/day, No (%)	96 (36.8)	109 (41.8)	100 (38.0)	114 (43.3)	-	90(34.2)	104 (39.5)	-
Physical activity	n=260		N=263			n=263		
Total PA[1] (IQR), METmins./wk.	6114 (3273 ; 8755)	5940 (3596 ; 9141)	5895 (3250 ; 8690)	6875 (4645 ; 9483)	866* (203 ; 1530)	6060 (3240 ; 8355)	7080 (4260 ; 9145)	431 (-233 ; 1095)
≥ 30 min/5 days a week, No (%)	91 (35.0)	100 (38.5)	83 (31.6)	131 (49.8)	-	81 (30.8)	116 (44.1)	-

TABLE 4.4 Baseline and follow-up lifestyle behavior outcomes by treatment group

IQR, interquartile range; PA, physical activity;
All analyses based on complete data; a Median, b One piece or portion of fruit approximates 100 grams;
* p<0.05, ** p<0.01, *** p<0.001.

DISCUSSION

Our study shows that a lifestyle program combined with a maximum of 10 counseling sessions in six months, aimed at overweight workers, is effective for reducing body weight by 1.5 kg if counseling is done by phone and 0.6 kg if counseling is done by e-mail, compared to self help materials. Distance lifestyle counseling is also effective for producing clinically relevant weight loss. No effect was found for avoiding a 3% weight gain. The weight reduction from counseling by phone was higher than weight loss found at six months in two other studies.[48, 90] Nevertheless, results in both intervention groups seem lower than those seen in other distance counseling studies.[53, 54, 159] An explanation for the larger effect on weight loss in the studies by Tate et al. is their explicit recommendation of a maximum daily intake of 1500 kcal, while we focused on a healthy diet.[53, 54] Furthermore, these studies offered more frequent contact, ranging from daily to weekly phone calls or e-mails, than we did. Their effects are in line with results from a meta-analysis,[62] showing that increasing the counseling intensity significantly increases weight reduction. Increasing intensity also raises the costs of a behavioral intervention program. Future research should study the cost-effectiveness of different intensities.

We have also shown that the lifestyle program with distance counseling is effective for reducing waist circumference by 1.9 cm in the phone group and 1.2 cm in the internet group, compared with self help materials. Tate et al. found larger waist circumference reductions from e-mail counseling, but these reductions are probably associated with the higher weight loss that was produced in their study.[53]

Phone counseling resulted in an intra-group reduction of 2.7 fat points, representing 6-8 grams of fat and a reduction of 54-72 kcals per day. In an average diet of 2250 kcals per day this would constitute a 2.4-3.2% reduction in energy from fat. Another study, emphasizing much lower fat intakes than we did, showed less reduction,[159] while a second study showed a larger reduction in the intake of total fat than we achieved.[48] This study was performed in cardiac patients that were counseled to lower their blood cholesterol. Maybe they were more motivated to change fat intake than our overweight subjects. Nonetheless, the effect we find on fat consumption in the phone group is substantial and constitutes a meaningful contribution to weight management. We found no intervention effects on the consumption of vegetables or fruit at six months. With regard to vegetable consumption this could be explained by a ceiling effect. Mean intake at baseline was already close to the, in The Netherlands, recommended minimum intake of 150 g/day. Alternatively, in our program fruit and vegetables were recommended as 'healthy' choices, but their importance for weight regulation was not discussed. Whether emphasizing the role of fruit and vegetables for weight control increases their consumption should be further studied.

Physical activity levels increased as a result of the intervention, but only the phone group showed a significant difference compared with the control group. This is in agreement with studies that found increased physical activity from phone counseling,[169, 170] and no effect from internet counseling.[59] Attendance to the counseling sessions was satisfactory in individuals with complete data, but low in those with missing data. Attendance has been found to be associated with weight loss,[47, 53, 90] so improving attendance could increase weight loss. However, the question remains if attendance to counseling sessions is responsible for successful weight change, or rather if it is a representative of an underlying motivational construct that also influences behavior change.

A secondary aim of the study was to determine differences in the effects of phone counseling and e-mail counseling. With regard to fat intake and physical activity, the phone group appears to perform better than the internet group, because only in this group significant changes in comparison with the control group were seen. In addition, changes in the phone group are larger than in the internet group but direct comparisons between the phone and internet group showed no statistical differences.

Several potential limitations in this study need to be considered. First, for 29% of the participants no follow-up data on body weight at six months were available. This is comparable to other distance counseling studies,[53, 90, 159] and lower than in some studies in the work setting.[171, 172] Missing data has implications. Results from completers-analyses and from analyses for which the baseline value is carried forward, are only valid if data are missing completely at random.[173] The comparison between completers and non-completers showed that missingness was associated with observed data like baseline body weight and counseled modules. We therefore based our imputation model on missing at random (MAR) assumptions and included all variables that were related to the variables with missingness in our imputation model. An advantage of multiple imputation over single imputation methods is that it allows for the uncertainty of the values that are used to substitute the missing values.[173] The results we found after multiple imputation differed from the completers-analyses, especially for the internet group, but are more credible because of the MAR assumption and the use of multiply imputed datasets.

A second restriction is that analyses of waist circumference and of the behavioral outcomes were limited to complete cases. Loss to follow-up was non-differential. However, in the intervention groups, participants that completed follow-up measurements had also completed more modules compared to the participants with missing follow-up. As argued before, attendance to the sessions could be indicative of adherence to behavior change. Thus non-responders and dropouts in the intervention groups would have fewer or no change in their diet and physical activity behavior than responders. Although non-responders and dropouts in the control group can be assumed to be equally (non)adherent to these behavior changes, effects in all participants are probably attenuated compared to the complete-case-analysis.

A further consideration is whether the effects we found on body weight are meaningful. From the individual viewpoint additional weight loss of 1.5 kg or 0.6 kg (i.e. the mean weight losses in the phone and internet group compared to self-help materials) is not the amount wished for. However, as Rose has argued, small changes in a large group can have a huge impact on public health.[174] A modeling study showed that reducing BMI by 2 points in a moderate to high risk group (BMI ≥24) has considerable effect on the population burden of diabetes.[175] The type of program we studied can be used to reach a large group of overweight employees; we managed to engage about 25% of the overweight working population. We therefore consider our results to be of relevance for public health. Further research should elicit if they are sustainable and cost-effective.

Other limitations of our study are that behavioral outcomes are all based on self-report and that we only measured a few of the dietary changes associated with weight control. We found that an exhaustive food questionnaire increased our questionnaire to unacceptable length. For that reason we focused on fat, fruit and vegetable intake. More objective measurement of lifestyle behaviors was not feasible because of the trial size. Self-report is vulnerable to social desirability bias which especially at follow-up might have led to more favorable outcomes.

Lastly, the study population does not represent the general Dutch working population (40% high educated, 57% men). This is related to the fact that we mostly included companies that employ white collar workers. Also, self-selection of more health oriented workers probably took place judged by baseline adherence to public health guidelines which is higher than found in the general population and by the proportion of smokers which was lower than expected on the basis of education level and age. This is a common phenomenon in lifestyle interventions, demonstrating that it is hard to engage those who, from the public health perspective, are most in need of change. When an intervention like ours is implemented in the work setting, efforts should be made to recruit lower-educated and high-risk individuals, and effects from the intervention in this population should be evaluated.

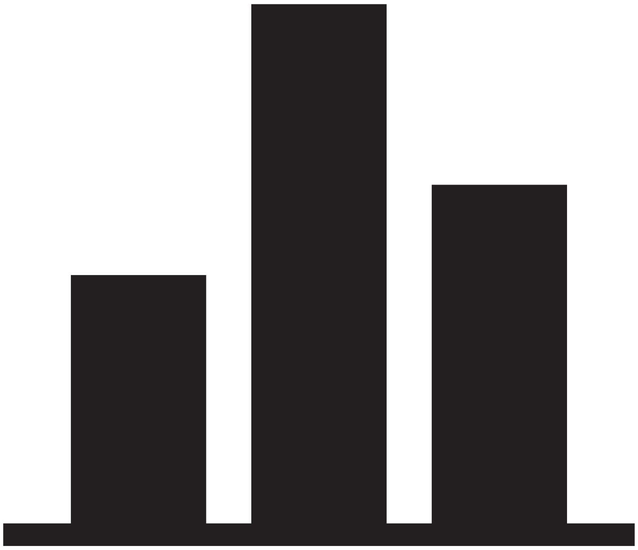
Strengths of our study include objective measurement of body weight, broad inclusion criteria, size of the group studied, use of multiple imputation for missing data, recruitment of individuals who previously had not been engaged in weight loss programs and the design of an intervention suitable for the occupational setting. We are therefore confident that the program we developed and the results we found are transferable to the occupational health practice.

CONCLUSION

Results showed that lifestyle counseling by phone and e-mail is effective for reducing body weight and waist circumference in a group of overweight employees at six months. Furthermore, counseling by phone is effective for reducing fat intake and increasing physical activity.

CHAPTER 5:

EFFECTIVENESS OF PHONE AND E-MAIL LIFESTYLE COUNSELING FOR LONG TERM WEIGHT CONTROL AMONG OVERWEIGHT EMPLOYEES



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ABSTRACT

Objectives: To determine the effectiveness of a weight-management program with personal counseling by phone or e-mail.

Methods: A randomized controlled trial of a six-month program comparing two modes of intervention delivery (phone, n=462; internet, n=464) with self-directed materials (control, n=460), among overweight employees. Change in body weight after two years was the main outcome.

Results: Among complete cases, weight loss in the internet group was 1.2 kg (95% confidence interval -1.9 to -0.4) and in the phone group 0.8 kg (-1.5 to 0.03), compared with the control group. Multiple imputation of missing body weight resulted in comparative weight losses of -0.9 kg (-2.0 to 0.3) and -0.4 kg (-1.4 to 0.7).

Conclusion: Among complete cases, the internet intervention showed modest long-term weight loss, but among all participants neither program version was more effective than self-help.

INTRODUCTION

The prevalence of overweight, defined as a Body Mass Index (BMI) of 25 kg/m^2 or more, has been rising in recent decades.[176] In the Netherlands, the prevalence of overweight among adults aged 20 years or older has increased from 35% in 1990 to 47% in 2009,[177] compared with a rise from 56% to 68% in the USA[178]. Overweight is associated with various diseases, most notably type 2 diabetes and cardiovascular diseases.[176] In addition, in comparison to employees with a BMI below 25 kg/m^2, overweight employees have longer sick leave spells[179] and are at increased risk for work disability.[16] In light of its consequences to individuals and to society, prevention and treatment of overweight are essential.

In a systematic review, the United States Task Force on Community Preventive Services found that worksite nutrition and physical activity interventions result in a mean weight loss of 1.3 kg compared with untreated controls at 6 to 12 months, and they recommend the use of these programs.[41] In this review, structured programs that offer multiple group or individual contacts appeared more effective than self-directed approaches. Consequently, these types of programs should preferably be adopted. However, it will be difficult and costly to provide programs with personal contact at all worksites. A solution could be found in telecommunication technology, like e-mail and phone. Individual counseling by e-mail or phone can take place at a convenient time and location, at a lower cost than face-to-face contacts. Despite this appeal, questions remain about the effectiveness of telecommunication interventions for weight control. Previous studies have shown short-term comparative weight loss from programs providing phone counseling,[47, 48] as well as lack of effect.[49-51] Weight loss programs with personal feedback by e-mail have also shown mixed results.[53-58] No studies providing only telecommunication feedback have been carried out among overweight employees. Likewise, the effectiveness of these interventions beyond cessation of the intervention and the superiority of either method is not known.

The purpose of the ALIFE@Work study was to address these issues. A six-month lifestyle program was developed, aimed at overweight employees and provided by means of a workbook with phone counseling in one group and through the internet with e-mail counseling in a second group. The primary aim was to determine the effects on body weight two years after baseline. Secondary aims were to compare the phone-based program with the internet-based program, and to determine the effects on self-reported waist circumference, diet and physical activity.

METHODS

Study design, setting and participants

Between January and August 2004, about 21,000 employees from seven Dutch service-sector companies received a screening questionnaire that assessed their eligibility for participation.[141, 180] Approximately 25% of the employees were expected to meet the criteria, i.e.: BMI (calculated as weight in kilograms divided by height in meters squared) ≥ 25 kg/m^2; paid employment ≥ 8 hours/week; able to read and write Dutch; access to internet (at work or at home); minimum age 18 years; not pregnant; no diagnosis or treatment for disorders that would make physical activity difficult. Eligible employees received further study information and were invited to participate. If they accepted the invitation, a personal appointment was made for baseline body height and weight measurements, at or near the workplace, during working hours. Employees with a BMI < 25 kg/m^2, as calculated from the measurements, were excluded. The eligible employees were randomly assigned to one of the three study groups.[141, 180] A statistician generated a random allocation scheme in blocks of 18. The allocations were put in sequentially numbered, opaque envelopes which were brought to the measuring locations. If a participant was found to be eligible for the study, the next envelope in the sequence was opened. Blinding of the participants and counselors was not possible, due to the nature of the intervention.

Follow-up body weight measurements were at six months and two years after baseline. Self-reported measurements were assessed at six-month intervals from baseline until the two-year follow-up by means of a questionnaire that was sent to the home address of the participant.

Participants who did not respond to the postal questionnaire received a maximum of five reminders (post, e-mail and phone). Participants who indicated that they wanted to withdraw from the study were asked to report their current weight and reason for withdrawal. Several weeks before the two-year follow-up measurements, the drop-outs received a once-only letter, asking them if they would take part in the final weight measurement. Participants who had withdrawn because of pregnancy or dissatisfaction were not approached.

The study design, procedures and informed consent procedure were approved by the Medical Ethics Committee of the VU University Medical Center, and all participants gave written informed consent.

Interventions

All groups received self-help brochures about overweight, healthy diet and physical activity. Additionally, the phone group and the internet group had access to a lifestyle intervention program, adapted from previous research carried out by HealthPartners in Minnesota, USA.[90] Based on principles of behavior modification,[40] it consisted of ten modules. These modules provided information on nutrition and physical activity, and explained behavior modification strategies (e.g. self-monitoring, goal-setting). The phone group received the program in the form of a workbook. The internet group accessed the program through an interactive website composed of personalized web pages. No diet or exercise prescription was given, but participants were encouraged to set their own behavioral goals towards the Dutch dietary and physical activity guidelines. After finishing each module, the participants were contacted by their personal counselor, depending on group allocation, either by phone or e-mail. The counseling was provided by four trained counselors (two dieticians and two physical activity scientists), according to a standardized protocol, for a maximum of six months.[141] Further details of the intervention can be found in earlier publications about the study.[141, 181]

Outcome measures

The primary outcome of the study was change in body weight between baseline and the two-year follow-up. Secondary outcomes were changes in waist circumference, dietary intake and physical activity between baseline and the two-year follow-up.

Trained research personnel measured body height and weight according to a standardized protocol.[141] Body height (cm) was measured at baseline with a portable stadiometer (Seca 214; Seca GmbH & Co, Hamburg, Germany). Body weight (kg) was measured with a digital scale (Seca 770; Seca GmbH & Co, Hamburg, Germany), with participants wearing light clothing and no shoes. Self-reported weight, collected at baseline and follow-up or drop-out (within ±3 months from planned follow-up) was used if there was no follow-up weight measurement. Three outcomes with regard to body weight were studied: 1) weight change at follow-up, 2) likeliness of achieving a decrease of at least 5% of initial weight,[182] and 3) weight change from six months to two years, adjusted for initial weight change at six months.[183]

Self-reported waist circumference was measured with a non-tearing paper tape.[141] The focus of dietary intake was on fat, fruit and vegetable intake. Fat intake was assessed with the validated Dutch Fat List.[94] A total fat score was calculated (range 0 to 95), with one fat point representing a daily fat intake between one and four grams of fat, two fat points representing five to eight grams of fat, etc. Vegetable intake in grams per day and fruit intake in pieces per day were determined from a validated short fruit and vegetable questionnaire.[95, 96] Physical activity was measured with the validated Short Questionnaire to Assess Health enhancing physical activity (SQUASH).[97] MET-minutes per week for total physical activity were calculated from this questionnaire.[180] Possible confounders were assessed by questionnaire. These included age, gender, level of education, country of birth, marital status, smoking behavior, medication for certain health conditions, and the number of previous attempts to lose weight.[141] Lastly, counselors recorded contacts with participants in a participant management system.

Sample size

An a priori power calculation to detect a weight loss of 1.4 kg (standard deviation [SD] 6.8 kg) between two groups with 90% power in two-tailed tests at a significance level of 0.05, determined the sample size for each group at 500. Thus, 1500 participants were needed for the study.[141] No allowance was made for drop-out.

Statistical analyses

Groups with complete and incomplete data were compared on baseline values by two-sided t-tests and Chi-square tests. Participants who became pregnant or died during the study were excluded from all further analyses. Analyses to determine effectiveness were based on group allocation, regardless of the actual intervention received or of adherence to the intervention.

Multiple linear regression analysis was performed, with the follow-up value as the dependent variable and adjustment for the baseline value. Assumptions of linear regression analysis were verified with residual analysis. Binary outcomes were analyzed with logistic regression.

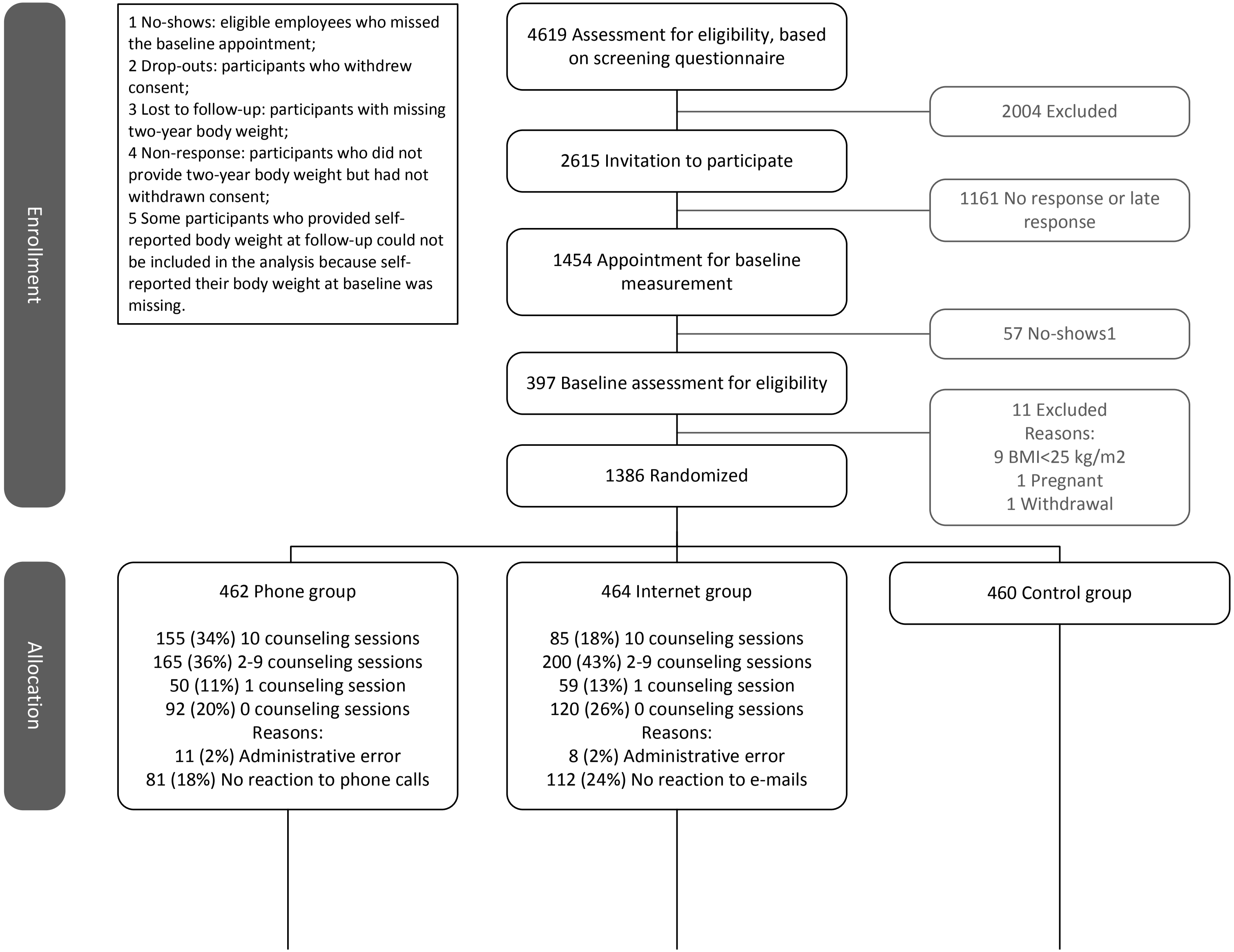
For the primary analysis of body weight, missing follow-up weight was multiply imputed. Five different data sets were created with Multivariate Imputation by Chained Equations (MICE).[166] Baseline weight, available mid-point (6, 12 and 18 months) and follow-up weight, group allocation, intervention adherence, age, gender and level of education were included as predictors in the imputation model. Each of the five datasets was analyzed as specified above. The estimates were pooled, using methods described by Rubin.[166]

Secondary analyses were performed for participants with complete baseline and follow-up data for body weight, waist circumference, diet and physical activity; i.e. complete-case analysis. In the secondary analyses of body weight, confounding was checked by adding a possible confounder to the regression model. A variable was classified as a confounder if the coefficient of group allocation had changed by 10%, compared to the unadjusted model. The multiply imputed datasets were generated with R version 2.7.1.[168] All analyses were performed with SPSS version 15.0 and p-values <0.05 were considered to be significant.

RESULTS

Participants

The majority of the participants were male (67%) and wanted to lose weight (85%), as shown in Table 5.1. About a third of participants (34%) were obese (i.e. BMI ≥ 30). Approximately one in six took medication for certain co-morbidities (hypertension (10%), hypercholesterolemia (6%), depression (3%), diabetes (2%), myocardial infarct (1%) and angina (1%)).


Enrollment
1 No-shows: eligible employees who missed the baseline appointment;
2 Drop-outs: participants who withdrew consent;
3 Lost to follow-up: participants with missing two-year body weight;
4 Non-response: participants who did not provide two-year body weight but had not withdrawn consent;
5 Some participants who provided self-reported body weight at follow-up could not be included in the analysis because self-reported their body weight at baseline was missing.
4619 Assessment for eligibility, based on screening questionnaire
2004 Excluded
2615 Invitation to participate
1161 No response or late response
1454 Appointment for baseline measurement
57 No-shows1
397 Baseline assessment for eligibility
11 Excluded
Reasons:
9 BMI<25 kg/m2
1 Pregnant
1 Withdrawal
1386 Randomized
Allocation
462 Phone group
155 (34%) 10 counseling sessions
165 (36%) 2-9 counseling sessions
50 (11%) 1 counseling session
92 (20%) 0 counseling sessions
Reasons:
11 (2%) Administrative error
81 (18%) No reaction to phone calls
464 Internet group
85 (18%) 10 counseling sessions
200 (43%) 2-9 counseling sessions
59 (13%) 1 counseling session
120 (26%) 0 counseling sessions
Reasons:
8 (2%) Administrative error
112 (24%) No reaction to e-mails
460 Control group

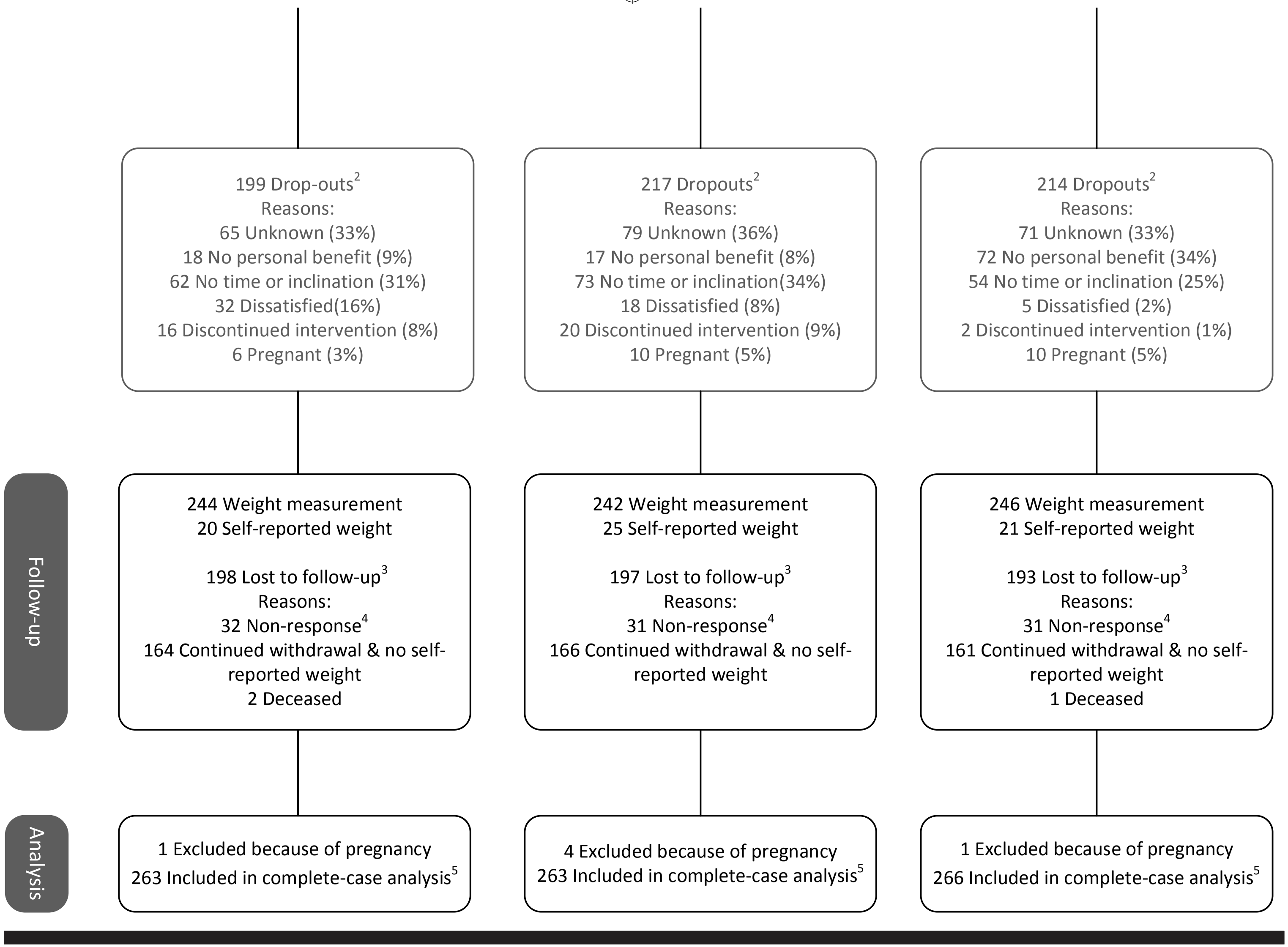


FIGURE 5.1 Flow of participants through the trial

TABLE 5.1 Baseline characteristics according to study group

	Control n=460	Phone n=462	Internet n=464	All n=1386
Male, No. (%)	306 (66.5)	321 (69.5)	302 (65.1)	929 (67.0)
Age, mean (SD), yrs	43 (8.7)	43 (8.8)	43 (8.4)	43 (8.6)
BMI, mean (SD), kg/m^2	29.6 (3.7)	29.5 (3.5)	29.6 (3.4)	29.6 (3.5)
Highly educated[1], No. (%)[2]	255 (58.8)	271 (60.1)	281 (62.2)	807 (60.4)
Married/cohabiting, No. (%)[2]	368 (84.8)	380 (84.3)	384 (85.1)	1132 (84.7)
Born in the Netherlands, No. (%)[3]	401 (94.1)	416 (92.7)	417 (93.3)	1234 (93.3)
Medication for co-morbidity, No. (%)[4]	67 (16.5)	80 (18.6)	77 (17.8)	224 (17.7)
Smoker ≥ 1 unit/day, No. (%)[5]	65 (15.3)	73 (16.3)	59 (13.2)	197 (14.9)
Weight loss attempts previous 2 yrs, No. (%)[6]				
0 attempts	141 (33.2)	147 (32.9)	141 (31.6)	429 (32.5)
1 - 3 attempts	196 (46.1)	212 (47.7)	202 (45.3)	610 (46.3)
4 or more attempts	88 (20.7)	88 (19.7)	103 (23.1)	279 (21.2)
Tried to prevent weight gain in previous 2 yrs, No. (%)[6]	347 (81.5)	353 (79.1)	370 (83.0)	1070 (81.2)
At baseline wants to: No. (%)[6]				
Lose weight	363 (85.6)	386 (86.2)	373 (83.8)	1122 (85.2)
Prevent weight gain	55 (13.0)	56 (12.5)	67 (15.1)	178 (13.5)
Neither are important	5 (1.1)	6 (1.3)	4 (1.6)	17 (1.3)

SD, standard deviation; BMI, Body Mass Index;
1 A minimum of five years of secondary education, 2 n=1337, 3 n=1322, 4 n=1269, 5 n=1320, 6 n=1318.

The flow through the trial of the 1386 employees randomized is presented in Figure 5.1. Between baseline and the two-year follow-up, 630 participants withdrew from the study and three participants died. Lack of time or loss of interest in the study and, in the control group, lack of personal benefit, were the main reasons for withdrawal (Figure 5.1). Of the approached drop-outs, 121 attended the follow-up weight measurement. Loss to follow-up was equal in all study groups. However, participants with missing follow-up weight measurements differed on several characteristics from complete cases. Most important was a mean 2.9 kg (95% confidence interval [CI] 1.4 to 4.4, p<0.001) higher baseline weight. Furthermore, incomplete cases in the phone group showed 1.6 kg (95% CI 0.3 to 2.9, p=0.01) less weight loss at six months. Adherence to the intervention also differed significantly. The median (inter-quartile range [IQR]) number of counseled sessions among incomplete cases in the phone group was 2 (0 to 4) and 10 (3 to 10, p<0.001) among completers. In the internet group this was 1 (0 to 4) and 5 (1 to 10, p<0.001), respectively.

Intervention adherence

The median (IQR) was 4 (1 to 10) sessions in the phone group and 3 (0 to 8) sessions in the internet group. Of participants in the phone group, 34% completed all counseling sessions, compared to 18% in the internet group (Figure 5.1).

Body weight outcomes

Table 5.2 presents the results for body weight at baseline and at the two-year follow-up. Figure 5.2 provides an overview of the weight change over time according to study group, including weight loss at six months. These results are based on the multiply imputed datasets created for the present study. The intervention groups experienced significant weight loss at six months, compared to the control group: 1.6 kg (95% CI -2.2 to -1.0) in the phone group and 0.7 kg (95% CI -1.2 to -0.1) in the internet group. At two years, weight loss within all groups was significant, as depicted in Figure 2. However, no significant differences were shown between groups (Table 5.3). Among complete cases a significant weight reduction of 1.2 kg was found in the internet group, as compared with the control group (Table 5.3). Conversely, the likelihood of a 5% weight loss among complete cases was significantly higher in the phone group than in the control group (OR 1.7, 95% CI 1.1 to 2.7, p=0.032), but not in the internet group (OR 1.6, 95% CI 0.99 to 2.5, p=0.053). No confounders were identified.

In the direct comparison between the intervention groups, participants in the internet group gained 1 kg less than participants in the phone group who experienced the same weight change at six months in both the primary and secondary analysis (Table 5.3).

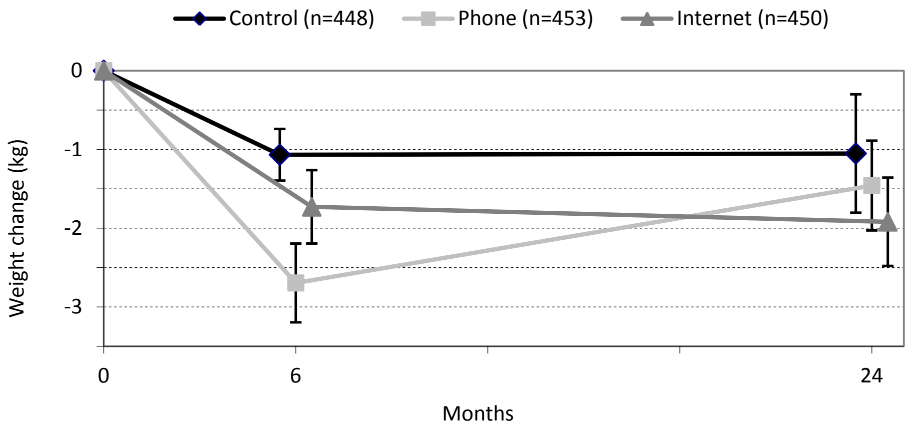


FIGURE 5.2 Weight change over time according to study group.

The data-points characterize mean weight changes at baseline (0), six months (6) and two years (24) within each study group, with the error bars representing the 95% confidence interval around that change.

	Control group		Phone group		Internet group	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
Multiply imputed datasets	n=448		n=453		n=450	
Body weight , mean (SD), kg	93.0 (13.4)	92.0 (13.2)	93.6 (14.0)	92.1 (13.7)	92.9 (14.4)	91.0 (14.4)
≥5% weight loss, No. (%)	-	71 (15.9)	-	100 (22.1)	-	101 (22.4)
Complete cases						
Body weight	n=266		n=263		n=263	
Body weight, mean (SD), kg	91.3 (12.4)	90.6 (12.9)	92.3 (13.0)	90.9 (13.3)	91.5 (13.7)	89.6 (13.9)
≥5% weight loss, No. (%)	-	35 (13.2)	-	53 (20.2)	-	51 (19.4)
Waist circumference	n=241		n=252		n=241	
Waist circumference, mean (SD), cm	101.3 (9.1)	99.5 (9.7)	102.4 (9.7)	99.8 (10.1)	101.5 (9.9)	99.4 (10.5)
Diet	n=174		n=197		n=167	
Fat, mean (SD), score/day	19.2 (6.0)	17.0 (6.1)	18.5 (5.9)	16.8 (6.0)	18.3 (6.1)	15.8 (6.0)
Vegetables, median (IQR), grams/day	139 (100 ; 193)	143 (100 ; 193)	129 (93 ; 186)	129 (89 ; 179)	129 (93 ; 171)	143 (100 ; 179)
Fruit, median (IQR), pieces/day	1.6 (1.0 ; 2.6)	1.8 (1.1 ; 2.6)	1.6 (0.9 ; 2.6)	1.9 (1.1 ; 2.6)	1.6 (0.9 ; 2.4)	1.7 (1.1 ; 2.4)
Physical activity	n=173		n=195		n=164	
Total physical activity, median (IQR), METminutes/week	6184 (3798 ; 8480)	7200 (4845 ; 9698)	5912 (3390 ; 8675)	7470 (5250 ; 9660)	6060 (3259 ; 8402)	7613 (5058 ; 9319)

TABLE 5.2 Baseline and two-year follow-up outcomes for body weight, waist circumference, diet and physical activity

SD, standard deviation; IQR, inter-quartile range; MET, metabolic equivalents.

Waist circumference, dietary behavior and physical activity outcomes

Results for waist circumference, fat and vegetable consumption, and physical activity can be found in Table 5.2. The comparison of these outcomes between groups showed no significant results, although the direction of the differences was generally in favor of the intervention groups (Table 5.3).

DISCUSSION

The main finding was that the six-month lifestyle program, either offered as a website with e-mail counseling or as a workbook with phone counseling, was not more effective for achieving weight loss, or improving diet and physical activity after two years, than self-directed materials, among all employees included in the study. In contrast, among the participants who provided follow-up data, the internet program resulted in significantly more weight loss than the self-help brochures, and participants from the phone intervention were more likely to achieve a 5% weight loss.

Adherence to the intervention was limited, with half of the participants completing less than three sessions (internet) or four sessions (phone). Weight control studies that select participants who are prepared to comply with all intervention features have shown much higher attendance rates.[184] Selecting employees for their interest in using fundamental elements of the program, such as self-monitoring and doing homework assignments, could increase adherence, and likely the effectiveness of the program. Further research should be directed towards other factors influencing participation, such as user preferences and needs. This information could be used to improve telecommunication programs, and to develop tailored formats for different user groups.

It is not possible to compare the results of this study with those from similar trials. Few weight control studies in the work setting have evaluated effects on body weight more than six months after baseline, and none have done so 18 months post-intervention.[23, 41, 185] The same applies to telecommunication lifestyle interventions.[52, 186] One trial evaluated the two-year effects of the lifestyle counseling program after which the current intervention was modeled, on body weight in a managed care setting at two years.[51] Counseling was provided either by phone or post and was available for the complete trial period. The present study confirms their finding of a non-significant weight difference between usual care and phone counseling.[51]

The result found in the complete-case analysis, a weight loss of 1.2 kg among the internet participants, is comparable to that found in a systematic review of worksite lifestyle programs, i.e. a mean incremental weight loss of 1.3 kg at 6 to 12 months.[41] However, this study finds this amount of weight loss at the longer follow-up of two years. It has to be noted that loss to follow-up in the pooled studies was lower (range 0-29%) than in the current study (43%). Thus, the present results could be more biased than those of the reviewed studies.

TABLE 5.3 Differences between study groups in body weight, waist circumference, diet and physical activity at the two-year follow-up

Variable	Difference (95% CI)	p-value
Multiply imputed datasets		
Body weight 0 - 24 months, kg		
Phone vs. control	-0.4 (-1.4 ; 0.7)	0.448
Internet vs. control	-0.9 (-2.0 ; 0.3)	0.112
Internet vs. phone	-0.5 (-1.2 ; 0.2)	0.142
Body weight 6 - 24 months[1], kg		
Phone vs. control	0.5 (-1.3 ; 2.3)	0.470
Internet vs. control	-0.7 (-1.7 ; 0.3)	0.162
Internet vs. phone	-1.0* (-1.7 ; -0.3)	0.009
Complete cases		
Body weight 0 - 24 months, kg		
Phone vs. control	-0.8 (-1.5 ; 0.03)	0.059
Internet vs. control	-1.2* (-1.9 ; -0.4)	0.004
Internet vs. phone	-0.4 (-1.2 ; 0.4)	0.314
Body weight 6 - 24 months[1], kg		
Phone vs. control[b]	0.4 (-0.4 ; 1.1)	0.360
Internet vs. control[c]	-0.6 (-1.4 ; 0.1)	0.096
Internet vs. phone	-1.0* (-1.7 ; -0.2)	0.009
Waist circumference, cm		
Phone vs. control	-0.7 (-1.7 ; 0.4)	0.199
Internet vs. control	-0.3 (-1.3 ; 0.8)	0.598
Internet vs. phone	0.4 (-0.6 ; 1.4)	0.424
Fat consumption, score/day		
Phone vs. control	0.2 (-0.7 ; 1.2)	0.623
Internet vs. control	-0.6 (-1.6 ; 0.4)	0.250
Internet vs. phone	-0.8 (-1.8 ; 0.2)	0.098
Vegetable consumption, g/day		
Phone vs. control	-5 (-17 ; 7)	0.421
Internet vs. control	1 (-12 ; 13)	0.931
Internet vs. phone	6 (-7 ; 18)	0.391
Fruit consumption, pieces/day		
Phone vs. control	-0.2 (-0.5 ; 0.1)	0.184
Internet vs. control	-0.3 (-0.6 ; 0.01)	0.059
Internet vs. phone	-0.1 (-0.3 ; 0.1)	0.392
Physical activity, METmin/week		
Phone vs. control	646 (-94 ; 1385)	0.087
Internet vs. control	415 (-358 ; 1188)	0.292
Internet vs. phone	-212 (-984 ; 561)	0.590

CI, confidence interval; MET, metabolic equivalents;
1 Adjusted for baseline body weight;
* significant difference, $p < 0.05$.

Selection bias in this trial is confirmed by differences detected between complete cases and incomplete cases, and by the results from the primary analysis in which missing data were multiply imputed. In the latter a smaller and non-significant weight loss was found in comparison to the control group. This could be related to the lower adherence to the counseling sessions among non-completers, as lesser program utilization is associated with poorer outcomes.[52, 186] On the whole, worksite nutrition and physical activity programs do not result in large weight losses, probably because they are not designed to do so.[41] They usually aim to decrease risk for cardiovascular disease, or achieve a healthy lifestyle, and do not offer the comprehensive, intensive and prolonged strategies needed for extensive weight loss.[41, 187] Similarly, the current intervention aimed for small, sustainable lifestyle changes, so large weight losses were not to be expected. Considering that 85% of the participants wanted to lose weight, in the future more emphasis could be placed on caloric restriction by providing diet plans. Other strategies could be employed to enhance further weight loss and to reduce weight regain, such as environmental changes,[188] prolongation of the program[187] and offering on-site exercise classes.

A secondary aim of the ALIFE@Work study was to compare the effects of counseling by phone with the effects of counseling by e-mail. Immediately after the intervention no difference was found between phone and e-mail counseling.[180] The mean weight loss at two years did not differ either, although, in complete cases, only e-mail counseling produced a significant weight loss compared with the control condition, whereas only phone counseling participants were more likely to achieve a 5% weight loss. In the direct comparison with phone counseling, e-mail counseling reduced weight gain between six months and two years, despite the fact that the internet group was counseled on fewer modules than the phone group. These results suggest that the internet-based program might be more effective for sustained weight loss and prevention of weight gain than the phone-based program, but other studies are needed to verify this.

Further aims of the study were to assess the effects of the intervention on waist circumference, diet and physical activity. This was evaluated in participants with complete data. Directly after the intervention, waist circumference decreased in both the phone group and the internet group, while the phone group significantly increased their physical activity, and decreased their consumption of fat, compared with the control group.[180] At two years, all groups showed a decrease in waist circumference and fat intake, and an increase in physical activity, but the differences between the groups had disappeared. This is in contrast with the finding that the complete cases in the internet group had a significantly lower weight at the two-year follow-up. It is possible that the small variations in behavior that would explain this difference could not be detected from the questionnaires that were used.[94, 96, 97]

An important limitation of the study is the rate of loss to follow-up; 29% at six months[180] and 43% at two years. This is in line with rates of attrition seen in other worksite weight-control studies.[41] At six to twelve months the mean attrition rate is 24%; mean rate at 24 months could not be established due to lack of studies. Missing body weight data were multiply imputed, to allow for an analysis of all participants. Variables that correlated with loss to follow-up were included as predictors in the imputation model, which makes the estimates resulting from this analysis plausible.[189] Additionally, in a recent study on missing data in obesity trials it was found that multiple imputation is superior to simple imputation methods (e.g. baseline carried forward).[190] Nevertheless, clear-cut conclusions cannot be drawn based on this study. Future trials in the work setting should look at methods to improve retention.

Noteworthy strengths of the study include the adaptation of a theory based intervention to the Dutch occupational setting; the broad selection criteria; the objective measurement of body weight for the majority of participants; the substantial sample size; and the long follow-up period.

In conclusion, the six-month lifestyle intervention, offered through a website with e-mail counseling, or as a workbook with phone counseling, was effective for weight loss at six months. Eighteen months after its cessation, no differences in weight control, diet or physical activity were seen in comparison with general lifestyle brochures, among all employees included in the study. Nonetheless, among employees with available follow-up data, modest long-term weight loss was seen in participants of the internet intervention. There are also indications that the internet intervention was more effective for sustained weight loss than the phone intervention. Internet programs such as the one studied show potential for use in the occupational health setting after improvement and when offered to selected employees, but more research is needed to confirm this.

CHAPTER 6:

COMPARATIVE EFFECTIVENESS OF LIFESTYLE INTERVENTIONS ON CARDIOVASCULAR RISK FACTORS AMONG A DUTCH OVERWEIGHT WORKING POPULATION

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ABSTRACT

Background: Overweight (Body Mass Index [BMI] ≥25 kg/m^2) and obesity (BMI ≥30 kg/m^2) are associated with increased cardiovascular risk, posing a considerable burden to public health. The main aim of this study was to investigate lifestyle intervention effects on cardiovascular risk factors in healthy overweight employees.

Methods: Participants were 276 healthy overweight employees (69.2% male; mean age 44.0 years [SD 9.2]; mean BMI 29.7 kg/m^2 [SD 3.1]). They were randomized to one of two intervention groups receiving a six month lifestyle intervention with behavior counseling by phone (phone group) or e-mail (internet group), or to a control group receiving usual care. Body weight, height, waist circumference, sum of skinfolds, blood pressure, total cholesterol level and predicted aerobic fitness were measured at baseline, at 6 and at 24 months. Regression analyses included the 141 participants with complete data.

Results: At 6 months a significant favorable effect on total cholesterol level (-0.2 mmol/l, 95%CI -0.5 to -0.0) was observed in the phone group and a trend for improved aerobic fitness (1.9 ml/kg/min, 95%CI -0.2 to 3.9) in the internet group. At two years, favorable trends for body weight (-2.1 kg, 95%CI -4.4 to 0.2) and aerobic fitness (2.3 ml/kg/min, 95%CI -0.2 to 4.8) were observed in the internet group.

Conclusion: The intervention effects were independent of the used communication mode. However short-term results were in favor of the phone group and long-term results in favor of the internet group. Thus, we found limited evidence for our lifestyle intervention to be effective in reducing cardiovascular risk in a group of apparently healthy overweight workers.

BACKGROUND

The prevalence of overweight (i.e. Body Mass Index [BMI] ≥ 25 kg/m^2) and obesity (BMI ≥30 kg/m^2) is high and still continues to increase. Overweight and obesity have become a worldwide epidemic, posing a considerable threat to public health.[191, 192] Overweight is associated with increased risk for cardiovascular diseases and other health problems.[191] In addition, it is responsible for high health care costs.[13] Therefore, early prevention of overweight and obesity is warranted.

It is now globally recognized that lifestyle modification aimed at improving dietary habits and physical activity is the first-line approach to reducing overweight and related cardiovascular risk.[193-195] The effect of lifestyle modification on cardiovascular risk is assumed to depend largely on weight loss.[194]

Three recent reviews have shown favorable effects of lifestyle modification on body weight and/or cardiovascular risk factors in overweight or obese subjects.[66, 193, 196] Most research concerning the effects of lifestyle intervention on cardiovascular risk factors included subjects suffering from one or more overweight-related health problem(s). As yet, relatively few lifestyle intervention studies on the effect on cardiovascular risk factors have been performed in overweight/obese adults that were not selected for known co-morbidities.[197-202] Of these studies, three included only (peri- to postmenopausal) women[198, 199, 202] and one only men.[197] We were interested in lifestyle intervention effects on cardiovascular risk factors in overweight adults not selected for known co-morbidities. In this article we refer to them as apparently healthy overweight adults.

Recently, both the telephone[52, 90, 203, 204] and the internet/e-mail[53, 54, 186, 205] have shown to be promising tools to deliver lifestyle interventions designed to enhance physical activity and/or nutrition behavior. Only a few of these studies investigated, apart from the effects on lifestyle, effects on cardiovascular risk factors in overweight subjects.[53, 54, 204] Furthermore, none of the distance-counseling studies used both the telephone and the internet as an intervention mode, which would have allowed for a direct comparison between these two communication methods.

As adults spend much of their time in the workplace, the worksite is regarded a suitable setting to promote healthy lifestyle changes to a large proportion of the population.[206] Moreover, the unfavorable changes in the worksite environment during the past decades (i.e. increase in vending machines and desk jobs), may have significantly contributed to unhealthier diet and sedentary behavior of employees.[207] We performed our study in an occupational setting. So far, only one Dutch high quality study regarding the effect of a lifestyle intervention program on health risk factors has been conducted among apparently healthy employees. However, the employees in that study were not overweight and the follow-up period was relatively short (9 months).[208]

To our knowledge, this is the first Dutch randomized controlled trial (RCT) to study the short- and long-term intervention effects of a distance-counseling lifestyle intervention program by phone and internet/e-mail on cardiovascular risk factors in apparently healthy overweight workers. The main objective of this study was to evaluate the lifestyle intervention effects on cardiovascular risk factors at 6 and at 24 months. A second aim was to study whether these effects differed between the phone and internet intervention modes and if adherence to the interventions was of influence on these effects.

METHODS

Participants

The 276 participants in this study were a random sub-sample of 1386 apparently healthy overweight (BMI ≥ 25 kg/m^2) subjects participating in a large-scale lifestyle intervention study, called ALIFE@Work.[141] In this randomized controlled trial (RCT) the effectiveness of a distance-counseling lifestyle intervention program, delivered by either phone or internet/e-mail, was investigated in overweight employees.

Participants were employees from seven different companies (two IT-companies, two hospitals, an insurance company, the head office of a bank and a police force) located in The Netherlands. Inclusion criteria were: 1) ≥18 yrs old, 2) BMI ≥ 25 kg/m^2, 3) access to internet (at home or at work) and knowledge how to use it, 4) paid employment for at least 8 hours a week; 5) being able to read and write Dutch. Subjects who were pregnant, or were diagnosed or treated for disorders that made physical activity difficult were excluded.

The Medical Ethics Committee of the VU University medical center reviewed and approved the study design, procedure and informed consent procedure (December 11, 2003). All participants provided written informed consent. All subjects participated voluntarily and were free to cancel their participation at any time throughout the course of the study.

Design and study procedures

A detailed description of the study procedures has been given elsewhere.[141] Briefly, the study procedure was as follows: all apparently eligible subjects received further study information and were invited to take part. Those who affirmed the invitation were invited to have their body weight and height measured near or at their worksite, in order to assess their BMI. Employees with a BMI < 25 kg/m^2 were subsequently excluded.

After baseline measurements (body weight and height), the 1386 employees subjects with a BMI ≥ 25 kg/m^2 were randomized to one of the three study groups and either to a group receiving basic weight measurements (80% of each study group) or to a group receiving additional measurements (i.e. waist circumference, sum of four skinfolds, blood pressure, total cholesterol level, and aerobic fitness) (20% of each study group). This two-step randomization meant that there were six groups an employee could be assigned to. Randomization to these six groups was done by block randomization, with each block containing 18 allocations. A computerized random number generator drew up an allocation schedule. An administrative assistant put the group allocation in opaque sealed envelopes, numbered 1 to 1500. These envelopes were taken to the locations of the baseline measurements and opened in the given order. The researchers were blinded for the allocation schedule, but were not blinded for allocation after randomization. The participants were, in consequence of the nature of the intervention, not blinded for allocation after randomization. Employees were not allowed to change groups after randomization.

Follow-up measurements were done six months and two years after baseline. In addition to the measurements, participants completed surveys regarding their physical activity level, dietary habits, education, smoking status and medication use at all three time points. The surveys were sent to the home address of the participant approximately two weeks prior to the measurements. Data were collected from February 2004 till November 2006 at or near the participant's worksite.

Interventions

All groups received self-help materials on overweight, physical activity and healthy diet by means of standard brochures issued by the Netherlands Heart Foundation, intended for the general public. Additionally, the phone and internet group received a distance-counseling lifestyle intervention program. This intervention program was an adapted version of previous work of HealthPartners (Minnesota, USA) that was designed according to principles of cognitive-behavioral therapy.[209] The adaptation had involved translation to Dutch and to a Dutch tone of voice, and adaptations of cultural elements such as food and calorie charts, cooking methods, options when eating out and opportunities for everyday physical activity. The Dutch intervention was called 'Leef je Fit' (in English: Live Yourself Fit).

Leef je Fit, based on cognitive behavioral approach, consisted of ten educational modules that addressed physical activity and nutrition and taught lifestyle modification strategies (e.g. self-monitoring and goal-setting). Physical activities that could easily be fitted in daily life were encouraged (e.g. lunch-walking, active commuting), as well as a healthy diet with less fat, sugar and alcohol, and sufficient intake of fruit and vegetables. On the whole, the program emphasized sustainable lifestyle changes rather than weight loss. In each module, subjects were asked to complete several assignments related to the specific educational and behavioral foci of that module. The design of the program was such that subjects were able to finish any module within two weeks. The program was self-paced, but subjects had to finish the entire program within six months. All intervention subjects received personal tailored counseling support while working through the program. Counselors contacted participants in the phone group by phone to go through a module and to discuss the assignments. At the end of each call, an appointment for the next call in about two weeks was scheduled. When participants in the internet group had completed a module their counselor received an automated e-mail about this. Thereafter the counselor checked the information the participant had provided and responded by e-mail within five working days. By way of automated e-mail reminders and, if the participant had selected this option, automated mobile phone text-messages, internet participants were encouraged to start and finish modules within two weeks. Thus, all participants had a maximum of ten counseling contacts during the intervention program. Counseling was done by four trained counselors (two dieticians, two movement scientists) and according to two comparable standardized counseling protocols, one for each communication method.[141] Two weeks after randomisation, the counselor initiated the intervention by contacting the employees. Participants could also contact the counselor centre themselves.

Outcome measures

All cardiovascular risk factors and body weight and height were measured according to protocols by trained research personnel.[141] Waist circumference (in cm) was measured twice with a tape measure (Gulick; Creative Health Products, Ann Arbor, MI, USA; range 0-150 cm) at the midpoint between the lower border of the ribs and the upper border of the iliac crest. Next, the two measurements were averaged. Skinfold thicknesses (in mm; subscapular, suprailiac, triceps and biceps) were measured twice on the right side of the body with a Harpenden caliper (HSK-BI; Baty International, Burgess Hill, UK; range 0-50 mm, graduation 0.2 mm). In case two measurements differed more than 1.0 mm, the skinfold was measured a third time. The value of the two (or three) obtained values was averaged. Next, the sum of the skinfolds at the four loci was computed.

Blood pressure (in mmHg) was measured twice with a fully automated blood pressure monitor (Omron HEM 757 E [M5-I]; Omron Healthcare Europe BV, Hoofddorp, The Netherlands) after the participant had rested for 5 minutes in sitting position. This blood pressure monitor is validated and recommended for clinical use.[99] Approximately two minutes separated the two measurements during which the participant remained seated comfortably. Next, the mean value of the two measurements was computed. In case elevated (>140/90 mmHg) blood pressure levels were found, subjects were advised to visit their general practitioner.

Total cholesterol level (TC) was assessed in non-fasting capillary blood collected by finger stick. Blood was analyzed using a Reflotron® Plus (Roche Diagnostics GmbH, Mannheim, Germany), which provides a good risk classification.[100] When a low (≤3.0 mmol/l) or elevated (≥6.5 mmol/l) TC level was found, a second assessment was completed and the two measurements averaged. Subjects with low or elevated TC level were advised to visit their general practitioner.

Aerobic fitness level was assessed by means of the submaximal Chester Step Test (CST) that has been shown to be a valid and reliable predictor of VO_2 max.[102] During the CST subjects were required to step on and off an adjustable gym bench. The height of the gym bench depended on the participant's age and current fitness level.[103] The test started at a relatively slow pace of 15 steps per minute. The pace increased every two minutes to respectively 20, 25, 30 and 35 steps per minute. A metronome was used to set the stepping rate. The test-instructor gave instructions throughout the test when necessary. Subject's heart rate was monitored continuously with a heart rate monitor (Polar S610; Polar Electro Oy, Kempele, Finland). Also, the subject was asked to report his subjective rate of exertion at each increase in pace using a Borg scale.[104] The test was terminated at the end of a stage at which the subject's heart rate had reached 80% of his predicted maximal heart rate (220 minus age), or when the reported rate of perceived exertion exceeded 14 (hard).[103] The estimated VO_2 max was calculated with software that came with the Chester step test (ASSIST creative resources Limited, Redwither Business Park, UK). The step test was chosen because of low cost, portability and ease of operation.

Body weight (kg) was measured using a digital scale (Seca 770; Seca GmbH & Co, Hamburg, Germany) with participants wearing light clothing and no shoes. Body height (cm) was measured with a portable stadiometer (Seca 214, Leicester Height Measure; Seca GmbH & Co, Hamburg, Germany). Weight and height were measured twice, and the mean value of the two measurements was computed. Next, the Body Mass Index (BMI) was calculated by dividing body weight (kg) by height squared (m^2).

Power calculation

A priori power calculations were done for diastolic blood pressure (DBP) and for total cholesterol. The standard deviations (SD) were based on unpublished data from the

Amsterdam Growth and Health Longitudinal study. The calculation to detect a change in DBP of 4.5 mmHg (SD 10.6 mmHg) with 80 % power in two-tailed tests at a significance level of 0.05, determined the sample size for each study group at 87. The calculation to detect a change in total cholesterol of 0.4 mmol/l (SD 0.9 mmol/l) with 80 % power in two-tailed tests at a significance level of 0.05, determined the sample size for each study group at 80. The sample size for this study was therefore set at 300. Loss to follow-up was not taken into account.

Statistical analyses

Linear regression analysis was used to evaluate the intervention effects on the cardiovascular risk factors. The cardiovascular risk factor level at six months or at 24 months was taken into the model as dependent variable and study group (phone, internet and control) and baseline level of the risk factor as independent variables. Two dummy variables were created and coded such that the phone and internet groups were compared with the control group. Subsequently, the phone and internet groups were compared: if the confidence interval of the phone group included the regression coefficient of the internet group and/or vice versa, the difference between the groups was not significant. To test whether adherence to the program influenced the intervention effects, number of counseled modules X study group was added to the model as interaction term.

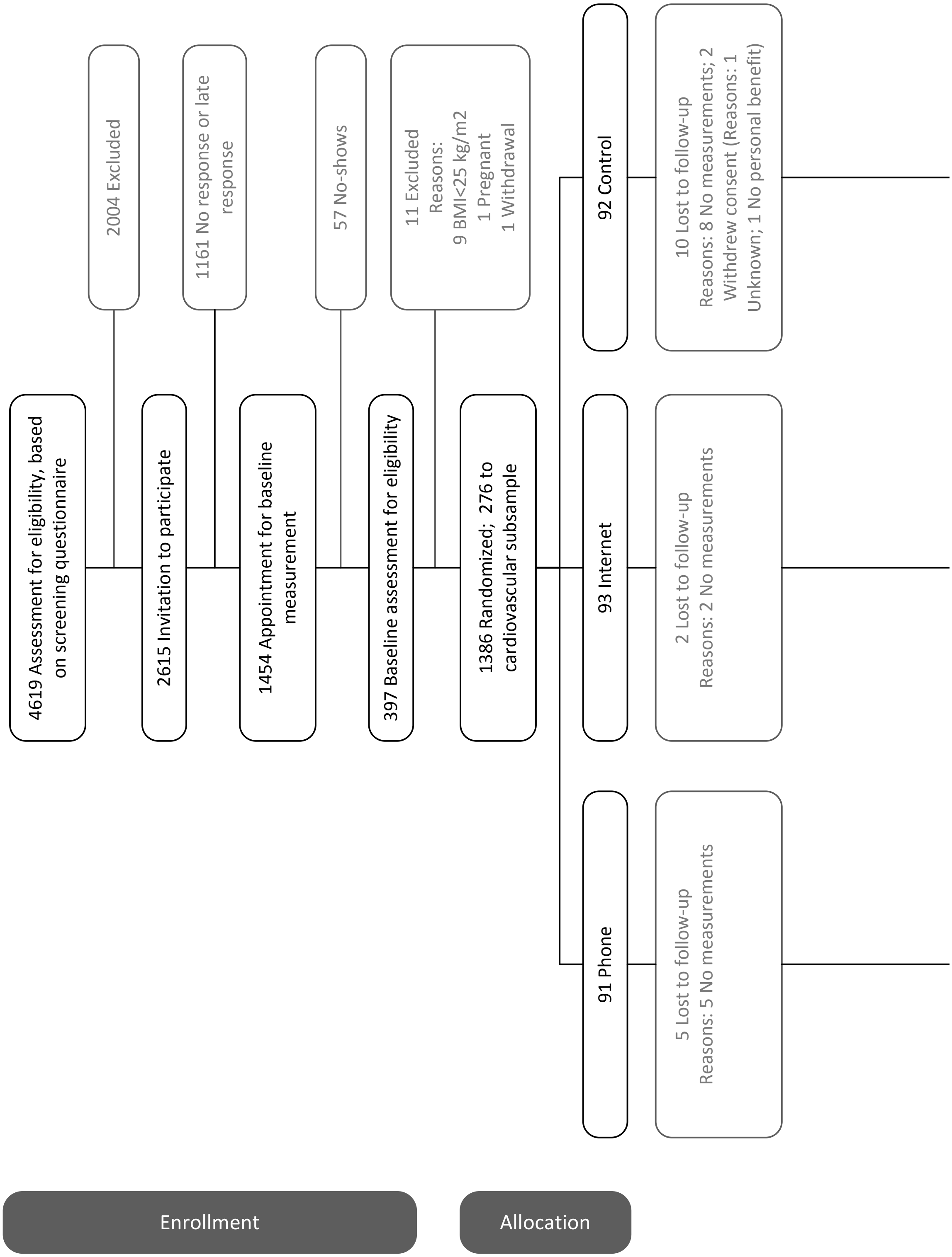
All analyses were performed using SPSS software (version 12.0.1). P-values <0.05 were considered to be significant.

RESULTS

Subjects

Figure 6.1 shows the participant flow through the trial. It can be observed that 276 subjects (phone group: n=91; internet group: n=93; control group: n=92) of the 1386 eligible subjects were randomly assigned to the group in which cardiovascular risk factors were measured. Participants were predominantly male (69.2%), highly educated (56.9%) and non-smoking (87.2%) (Table 6.1). They had a mean BMI of 29.7 (SD 3.1) kg/m^2 and 36% was considered (i.e. BMI ≥ 30). Forty subjects (14.5%) were on medication for co-morbidities (hypertension [N=26], hypercholesterolaemia [N=13], diabetes mellitus [N=10], depression [N=7], heart infarction [N=3], angina pectoris [N=1]). As shown in Table 6.1, no significant differences between the baseline characteristics existed between the three study groups.

Between baseline and two year follow-up, 47 participants were lost in the phone group, 45 participants in the internet group, and 43 participants in the control group. Reasons for the loss to follow-up were (mainly) the lack of measurements and withdrawal of consent (Figure 6.1). The 141 subjects included in the study did not significantly differ from the 135 subjects that were lost to follow-up, except from being older and being more frequently highly educated (Table 6.2).


4619 Assessment for eligibility, based on screening questionnaire
2004 Excluded
2615 Invitation to participate
1161 No response or late response
1454 Appointment for baseline measurement
57 No-shows
397 Baseline assessment for eligibility
11 Excluded Reasons: 9 BMI<25 kg/m2 1 Pregnant 1 Withdrawal
1386 Randomized; 276 to cardiovascular subsample
91 Phone
93 Internet
92 Control
5 Lost to follow-up Reasons: 5 No measurements
2 Lost to follow-up Reasons: 2 No measurements
10 Lost to follow-up Reasons: 8 No measurements; 2 Withdrew consent (Reasons: 1 Unknown; 1 No personal benefit)
Enrollment
Allocation

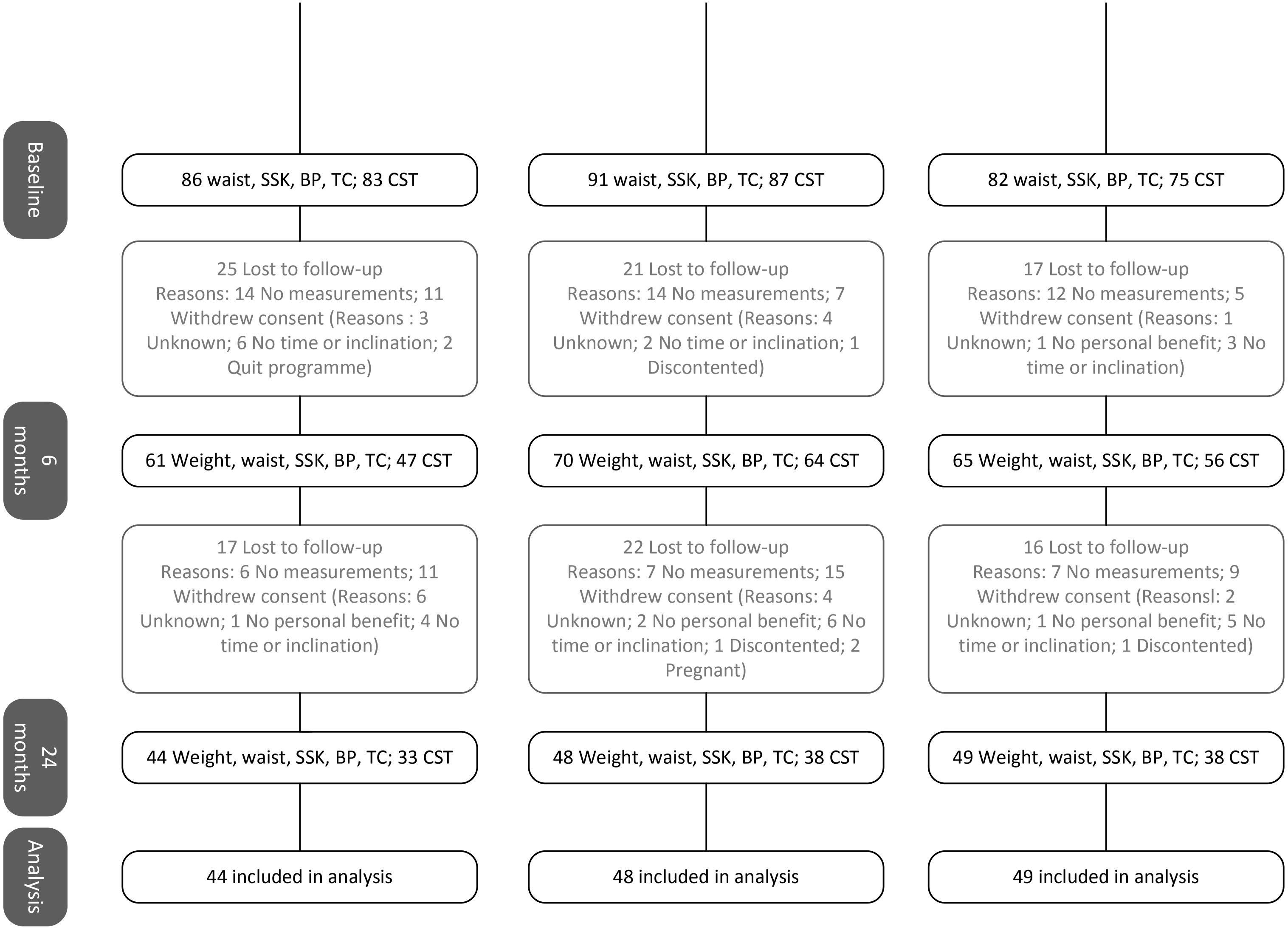


FIGURE 6.1 Flow of subjects through the trial – BP, blood pressure; CST, Chester Step Test; SSK, sum of skinfolds; TC, total cholesterol; waist, waist circumference.

TABLE 6.1 Baseline characteristics according to study group

	Control (n=92)	Phone (n=91)	Internet (n=93)	All(n=276)	p-value
Demographics					
Male, %	70.7	68.1	68.8	69.2	0.930
Age (SD), yrs	43.8 (9.4)	43.2 (9.6)	44.9 (8.5)	44.0 (9.2)	0.410
Highly educated, %	59.8	53.8	57.0	56.9	0.720
Smoking ≥ 1 unit/day, %	16.3	13.2	11.8	13.8	0.664
Medication for co-morbidity, %	15.2	15.4	12.9	14.5	0.907
Anthropometric measures					
Body weight (SD), kg	92.3 (11.3)	94.4 (15.6)	94.0 (13.7)	93.5 (13.6)	0.540
Height (SD), cm	177.8 (9.0)	177.6 (10.1)	176.7 (8.4)	177.4 (9.2)	0.664
BMI (SD), kg/m^2	29.2 (2.7)	29.8 (3.3)	30.0 (3.4)	29.7 (3.1)	0.141
Cardiovascular risk factors	n=82	n=86	n=91	n=259	
Waist (SD), cm	101.4 (8.9)	102.1 (10.9)	102.6 (9.7)	102.0 (9.9)	0.696
SSK (SD), mm	80.9 (24.1)	88.6 (28.8)	90.5 (29.8)	86.8 (28.0)	0.062
SBP (SD), mmHg	135.9 (15.0)	135.1 (15.3)	135.9 (16.6)	135.6 (15.6)	0.940
DBP (SD), mmHg	87.9 (10.8)	88.4 (9.9)	90.0 (10.0)	88.8 (10.2)	0.345
TC (SD), mmol/l[1]	5.0 (0.8)	4.9 (0.9)	4.9 (0.9)	4.9 (0.8)	0.769
Predicted VO_2max (SD), ml/kg/min[2]	38.9 (5.6)	37.6 (6.9)	36.7 (6.3)	37.7 (6.4)	0.092

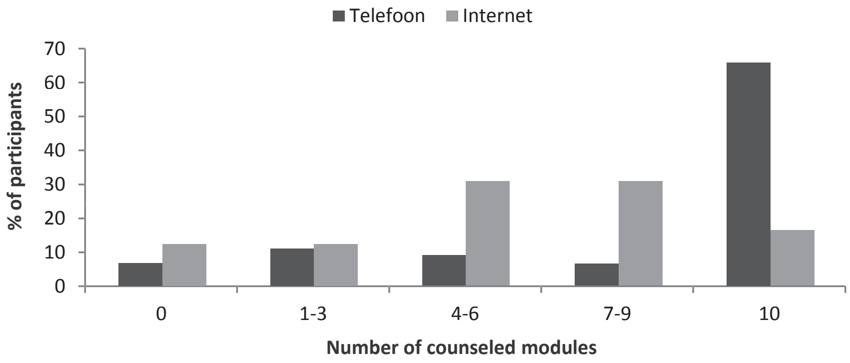
SD, standard deviation; BMI, Body Mass Index; Waist, waist circumference, SSK, sum of skinfolds; SBP, systolic blood pressure; DBP, diastolic blood pressure; TC, total cholesterol; VO_2 max, maximal oxygen uptake;
1 n= 253 (control: n=79, phone: n=85, internet: n=89);
2 n= 245 (control: n=75, phone: n=83, internet: n=87).

TABLE 6.2 Baseline differences between participants included[1] in and excluded[2] from the analyses

	Included (n=141)	Excluded (n=135)	Difference (95% CI)	p-value
Demographics				
Male, %	70.2	68.1	-	0.794
Age (SD), yrs	45.2 (9.1)	42.6 (9.1)	-2.6 (-4.8 ; 0.4)	0.018
Highly educated, %	63.1	50.4	-	0.039
Smoking ≥ 1unit/day, %	12.1	15.6	-	0.485
Medication for co-morbidity, %[3]	13.5	15.6	-	0.607
Anthropometric measures				
Body weight (SD), kg	92.2 (13.1)	94.9 (14.0)	2.8 (-0.4 ; 6.0)	0.091
Height (SD), cm	176.9 (8.4)	177.8 (9.9)	0.9 (-1.3 ; 3.1)	0.411
BMI (SD), kg/m^2	29.4 (3.1)	30.0 (3.1)	0.6 (-0.2 ; 1.3)	0.091
Cardiovascular risk factors	n=141	n=118		
Waist (SD), cm	101.5 (10.0)	102.7 (9.8)	1.1 (-1.3 ; 3.6)	0.357
SSK (SD), mm	84.8 (29.7)	89.3 (25.7)	4.5 (-2.4 ; 1.4)	0.198
SBP (SD), mmHg	137.1 (16.0)	133.8 (15.1)	-3.3 (-7.2 ; 0.5)	0.087
DBP (SD), mmHg	89.5 (10.6)	88.0 (9.7)	-1.4 (-3.9 ; 1.1)	0.259
TC (SD), mmol/l[4]	5.0 (0.9)	4.9 (0.8)	-0.1 (-0.3 ; 0.1)	0.334
Predicted VO_2max (SD), ml/kg/min)[5]	37.4 (6.1)	38.1 (6.6)	0.7 (-0.9 ; 2.3)	0.395

SD, standard deviation; BMI, Body Mass Index; Waist, waist circumference, SSK, sum of skinfolds; SBP, systolic blood pressure; DBP, diastolic blood pressure; TC, total cholesterol; VO_2 max, maximal oxygen uptake;
1 participants with complete measurements;
2 participants lost to follow-up due to the lack of measurements or withdrawal from the study;
3 n= 138 vs. n=126;
4 n= 140 vs. n=113;
5 n= 137 vs. n=108.

FIGURE 6.2 Participation in the intervention



The columns represent the proportion of participants in the phone and internet groups that received no counseling (0) or that were counseled on 1-3, 4-6, 7-9 or 10 modules.

Adherence to intervention

Figure 6.2 shows participation in the intervention for the study groups. In the phone group 6.8% never started the intervention (0 counseled modules) compared to 12.5% in the internet group. The proportion of subjects that was counseled on all modules was 64% in the phone group and 17% in the internet group. The median number of counseled modules was 4 (IQR= 2 to 4) in the phone group and 2 (IQR=1.25 to 3) in the internet group. Analyses showed no significant interaction effects between the number of counseled modules and study group, indicating that the effect of the number of counseled modules was independent of the intervention group.

At 6 months, the number of counseled modules significantly affected body weight (-0.7 kg, 95%CI -0.9 to -0.4), waist (-0.6 cm; 95%CI -0.9 to -0.3), SBP (-0.8 mmHg; 95%CI -1.4 to -0.1), DBP (-0.6 mmHg; 95%CI -1.0 to -0.2) and SSK (-1.0 mm; 95%CI -1.9 to -0.1). At 24 months, no such significant effects were observed.

Intervention effect on body weight and cardiovascular risk factors at 6 and 24 months

Table 6.3 shows the baseline, 6-months and two-year follow-up outcomes and differences between the study groups. Both at 6 and 24 months (Table 6.3), the intervention effects were not significant, except for total cholesterol in the phone group. This significant effect (-0.2 mmol/l, 95% CI -0.5 to -0.0) indicates that at 6 months TC level in the phone group was 0.2 mmol/l lower than in the control group. In addition, in the internet group favorable trends were observed for aerobic fitness at 6 and 24 months (6 months: 1.9 ml/kg/min, 95%CI -0.2 to 3.9; 24 months: 2.3 ml/kg/min, 95%CI -0.2 to 4.8) and for body weight (-2.1 kg, 95%CI -4.4 to 0.2) at 24 months. Evaluation of the internet group against the phone group showed no significant differences.

	Controls (n=49)			Phone (n=44)			Internet (n=48)			Phone T6	Phone T24	Internet T6	Internet T24
	T0	T6	T24	T0	T6	T24	T0	T6	T24	Change vs. control (95% CI)			
Body weight (SD), kg	91.5 (10.6)	89.8 (10.4)	90.3 (10.8)	91.7 (13.6)	89.3 (13.7)	90.3 (14.8)	93.3 (15.0)	90.5 (15.3)	90.0 (15.4)	-0.7 (-2.7;1.2)	-0.3 (-2.6;2.0)	-1.0 (-2.9;0.9)	-2.1 (-4.4;0.2)
Waist (SD), cm	101.7 (8.5)	99.2 (9.3)	99.3 (9.7)	99.9 (10.2)	96.4 (11.0)	97.9 (11.0)	102.9 (11.1)	99.4 (11.4)	99.3 (11.9)	-1.1 (-3.1;0.9)	0.3 (-2.0;2.6)	-1.0 (-2.9;0.9)	-1.1 (-3.3;1.1)
SSK (SD), mm[1]	77.8 (24.8)	72.5 (25.5)	75.6 (19.1)	82.3 (24.5)	73.5 (30.4)	81.0 (25.7)	94.1 (36.0)	89.2 (41.8)	83.7 (28.7)	-2.4 (-8.4;3.7)	0.1 (-5.3;8.1)	0.1 (-6.0;6.2)	-3.3 (-10.1;3.5)
SBP (SD), mmHg	135.2 (11.4)	134.2 (14.2)	133.7 (15.3)	138.2 (15.6)	136.4 (17.0)	136.4 (15.9)	138.2 (19.9)	137.7 (15.2)	135.4 (16.5)	0.14 (-4.3;4.6)	0.7 (-4.2;5.7)	1.5 (-2.9;5.8)	-3.0 (-5.1;4.5)
DBP (SD), mmHg	87.0 (9.5)	85.5 (9.9)	84.6 (9.8)	89.6 (10.4)	88.4 (11.2)	86.9 (12.0)	91.8 (11.4)	90.2 (9.8)	88.1 (10.5)	1.0 (-2.0;4.0)	0.5 (-2.8;3.8)	1.3 (-1.7;4.2)	0.2 (-3.1;3.5)
TC (SD), mmol/l	4.9 (0.8)	5.1 (0.6)	4.9 (0.8)	4.9 (0.9)	4.9 (0.9)	4.8 (1.0)	5.1 (0.9)	5.2 (0.9)	5.0 (1.0)	-0.2 (-0.5; -0.0)	-0.0 (-0.3;0.3)	-0.1 (-0.3;0.1)	-0.1 (-0.4;0.2)
VO_2max (SD), ml/kg/min	n= 49 38.8 (5.7)	n= 45 39.2 (4.8)	n= 39 39.7 (7.6)	n= 44 37.6 (6.6)	n= 37 38.7 (7.8)	n= 37 38.8 (8.5)	n= 48 36.3 (5.0)	n= 45 39.1 (6.4)	n= 40 39.6 (7.2)	0.5 (-1.6;2.6)	0.2 (-2.3;2.8)	1.9 (-0.2;3.9)	2.3 (-0.2;4.8)

TABLE 6.3 Baseline, 6-months and two-year follow-up outcomes and differences between the study groups

SD, standard deviation; Waist, waist circumference; SSK, sum of skinfolds; SBP, systolic blood pressure; DBP, diastolic blood pressure; TC, total cholesterol; VO_2 max, maximal oxygen uptake.

1 For seven subjects (control: n=2, phone: n=2, internet: n=3) one or more skinfolds were outliers, apparently due to measurement errors. These subjects were excluded from the analyses.

DISCUSSION

The main aim of this study was to evaluate lifestyle intervention effects on cardiovascular risk factors at 6 and at 24 months in a Dutch overweight working population. Two features of our RCT were that 1) we included apparently healthy overweight workers and that 2) we examined simultaneously the efficacy of two intervention modes, i.e. phone and Internet, to deliver the intervention. Our results indicate limited effectiveness of the lifestyle intervention in modifying cardiovascular risk in overweight subjects. This contrasts with significant lifestyle intervention effects on cardiovascular risk factors observed in overweight adults in other studies.[193, 196] It has been reported that intervention effects on cardiovascular risk factors occur mainly in overweight subjects with cardiovascular risks.[66] In the majority of the studies the overweight subjects were at increased cardiovascular risk, whereas our overweight subjects were apparently healthy without increased cardiovascular risk. This may explain the absence of intervention effects in our study. Lifestyle intervention studies including apparently healthy overweight/obese subjects and overweight/obese subjects with one or more co-morbidities are needed to confirm this hypothesis.

Another explanation for the limited effectiveness may be that the lifestyle intervention was not intense enough to establish and maintain significant changes in the cardiovascular risk factors. Our intervention program aimed at promoting a healthy lifestyle by stimulating subjects to meet the Public Health guideline of PA and to consume a healthy diet, i.e. at least two pieces of fruit and 150-200 grams of vegetables per day. Vegetable and fruit intake in our subjects was already close to the public health guidelines,[180] and thus no lifestyle change could be expected due to a ceiling effect.

Also, the ten counseling sessions on a two-weekly basis may have formed an inadequate level of guidance compared to the number of counseling sessions in other studies.[54, 210] Furthermore, no additional significant intervention was provided following the initial active treatment phase during the first 6 months. The absence of continued contact over the remaining 18 months may have eroded initially adopted changes and reduced the likelihood for retention of short-term effects. More information is needed on the optimal number of contacts necessary to enhance and maintain lifestyle modification.

Although most results at 6 months were not significant or clinically meaningful, most effects on cardiovascular risk factors were in the expected direction and, except for aerobic fitness, in favor of the phone group. Interestingly, at 24 months the intervention effects were in favor of the internet group. This may be explained by the fact that from 6 to 24 months the internet group lost another 1.1 kg of weight (-2.1 minus -1.0) compared to the control group, whereas the phone group gained 0.5 kg of weight (-0.3 minus -0.7) in the same period. This finding provides support for the assumption that the effect of lifestyle modification on cardiovascular depends on weight loss.[194] The lack of significant intervention effects may be caused by the limited statistical power of our study due to the high loss to follow-up.

A second aim of our study was to evaluate whether the intervention effects on cardiovascular risk factors depended on the communication mode used to deliver the program. As so far, no direct comparison between phone- and e-mail counseling had taken place, evidence to support a hypothesis about the superiority of either mode of counseling was not available. We found no evidence for one of the two communication modes to be more effective than the other. However, effects at six months were in favor of counseling by phone and at 24 months in favor of e-mail counseling. As e-mail counseling lacks contact with a person, it may have been perceived as being more impersonal or having a lack of social support.[211] Also, e-mail contacts contain no emotional cues, which make it less easy to establish a bond than phone counseling. Consequently, e-mail counseling may have been less effective for supporting behavior change than counseling by phone, resulting in more favorable intervention effects in the phone group at six months.

However, counseling stopped after these six months. Due to the cessation of personal contact the phone group may have experienced more difficulties in continuing to adopt a healthy lifestyle than the internet group, resulting in more favorable results in the internet group at 24 months. Also, participants in the internet group were able to read their email conversations again and again, whereas verbal conversations in the phone group could have been easily forgotten. Further lifestyle intervention studies that involve both phone and internet to deliver the lifestyle intervention are needed to increase the understanding of these communication modes to deliver interventions.

We also found that independent of the communication mode, the more modules completed, the stronger the intervention effects on the cardiovascular risk factors. Adherence has been reported to be positively associated with weight loss.[203] Thus, it is conceivable that a higher adherence in our subjects would have resulted in greater weight loss and, consequently, in stronger intervention effects. Effort should be taken to get insight into ways to increase adherence in long-term lifestyle studies aimed at reducing weight and cardiovascular risk. Future studies should improve the adherence of participants to the trial.

Several limitations in this study need consideration. First, as has been found in other lifestyle modification long-term studies,[66] we had a high proportion (135/276) of subjects lost to follow-up, which may have considerably affected our results. However, as reported earlier, the 135 subjects lost to follow-up did not significantly differ from the 141 subjects in the study regarding demographics, anthropometrics and cardiovascular risk factors, except from being younger and less often highly educated. Despite this, intervention effects may have been overestimated because the 141 subjects we based our results on may have experienced greater weight loss than subjects lost to follow-up. Therefore the results should be interpreted with caution. The main reason why participants were lost to follow-up in our study was the missing of one ore more measurements (see Figure 6.1), which may have been partly due to the fact that it appeared hard to schedule an appointment for the extra measurements in between liabilities at work. The other reason for the (high) loss to follow-up was withdrawal from the study. Several reasons for withdrawal were reported, among which no personal benefit and lack of time. Restricting the outcomes of interest to decrease the burden for participants and stressing the need of commitment to complete the trial could help to reduce the high loss to follow-up.

A second limitation is that we limited our analyses to participants with complete data. Additional analyses (results not shown) indicated that, in the intervention groups, participants that completed follow-up measurements had also completed more modules compared to participants that were excluded from the analyses due to missing follow-up measurements. As argued before, this may have resulted in greater weight loss and consequently in more favorable changes in CV risk factors in participants included in the study than in those excluded from the analyses. Therefore the results should be interpreted with caution.

Third, the voluntary participation in this study may have resulted in selection bias. It is conceivable that the overweight subjects taking part in our study were more willing to change their lifestyles, were more interested in PA and healthy eating and were more conscious about their health than overweight subjects that did not participate in the study. Despite this possible selection bias, the voluntary participation may have contributed to high external validity.

Fourth, our subjects are not representative of the Dutch working population of which 57% is male and 40% highly educated.[212] This is due to the fact that the majority of companies that participated in this study employ predominantly men and white collar workers. Consequently, the generalizability of the study is limited.

Fifth, some of our subjects used medication for hypertension and hypercholesterolaemia, which may have affected the intervention effects on blood pressure and cholesterol level. Due to the relatively small number of subjects using medication for the different co-morbidities, we could not reliably check whether medication use has influenced the intervention effects.

These limitations should be balanced against several strengths of the study. First, subjects were recruited from a variety of companies making the population studied a more heterogeneous group than solely relying on recruitment from a single employer group. Next, the random selection of a subset of subjects in each of the study groups allowed for an in-depth investigation of the intervention effects on measured, as opposed to self-reported, cardiovascular outcomes. This novel approach to risk factor modification in a sample of apparently healthy workers allowed for robust conclusions to be drawn from this investigation.

CONCLUSION

The results of this study provide limited evidence for lifestyle interventions being effective in establishing favorable short- and long-term changes in cardiovascular risk factors in a group of apparently healthy overweight workers. Although the majority of effects were not significant or clinically meaningful, they were all in the expected direction and are therefore likely of significance and interest to public health. The intervention effects were independent of the communication mode deployed, although short-term results were in favor of the phone group and long-term results in favor of the internet group. Additional research, especially long-term trials, involving apparently healthy overweight subjects as well as different communication modes to deliver lifestyle modification, are needed to improve our understanding of lifestyle intervention effects on cardiovascular risk factors in apparently healthy overweight subjects.

CHAPTER 7:

ECONOMIC EVALUATION OF A WEIGHT CONTROL PROGRAM WITH E-MAIL AND TELEPHONE COUNSELING AMONG OVERWEIGHT EMPLOYEES

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ABSTRACT

Background: Distance lifestyle counseling for weight control is a promising public health intervention in the work setting. Information about the cost-effectiveness of such interventions is lacking, but necessary to make informed implementation decisions. The purpose of this study was to perform an economic evaluation of a six-month program with lifestyle counseling aimed at weight reduction in an overweight working population with a two-year time horizon from a societal perspective.

Methods: A randomized controlled trial comparing a program with two modes of intervention delivery against self-help. 1386 Employees from seven companies participated (67% male, mean age 43 (SD 8.6) years, mean BMI 29.6 (SD 3.5) kg/m^2). All groups received self-directed lifestyle brochures. The two intervention groups additionally received a workbook-based program with phone counseling (phone; n=462) or a web-based program with e-mail counseling (internet; n=464). Body weight was measured at baseline and 24 months after baseline. Quality of life (Euro-Qol-5D) was assessed at baseline, 6, 12, 18 and 24 months after baseline. Resource use was measured with six-monthly diaries and valued with Dutch standard costs. Missing data were multiply imputed. Uncertainty around differences in costs and incremental cost-effectiveness ratios was estimated by applying non-parametric bootstrapping techniques and graphically plotting the results in cost-effectiveness planes and cost-effectiveness acceptability curves.

Results: At two years the incremental cost-effectiveness ratio was €1009/kg weight loss in the phone group and €16/kg weight loss in the internet group. The cost-utility analysis resulted in €245,243/quality adjusted life year (QALY) and €1337/QALY, respectively. The results from a complete-case analysis were slightly more favorable. However, there was considerable uncertainty around all outcomes.

Conclusion: Neither intervention mode was proven to be cost-effective compared to self-help.

INTRODUCTION

Globally the number of people who are overweight, defined as having a Body Mass Index (BMI) of 25 kg/m^2 or higher, is increasing. In the Netherlands, almost half of the population is overweight.[213] Overweight is linked to the development of chronic diseases like type 2 diabetes, cardiovascular disease and certain types of cancer and has a considerable impact on public health.[6] The increased prevalence of overweight also has an impact on the work setting. In comparison with employees with a BMI below 25 kg/m^2, overweight employees have longer sick leave spells[214] and are at increased risk for work disability.[16] Treating and preventing overweight among employees could result in health gains and possible cost reductions due to decreased health care use and absenteeism. Implementation of weight control programs in the occupational health care setting may be advantageous from both a company and a societal perspective. However, economic evaluations of interventions are needed to guide implementation decisions. The motivation behind health economic evaluations is getting the most benefit from the scarce resources available to society. Economic evaluations should therefore take a societal perspective.[215] This societal perspective implies inclusion of all relevant costs and effects, regardless of who pays the costs or who receives the benefits.[216] The societal costs are weighed against health benefits. An advantage of the societal perspective over narrower perspectives is that it shows the distribution of costs and benefits over societal payers and allows for bargaining between them.[215] In the Netherlands, companies pay for occupational health care and prevention. They have to make decisions within a tight budget regarding allocation of resources. Therefore, the narrower perspective of the company, weighing the costs and benefits to employers, may also be relevant in economic evaluations of workplace health promotion.

Interventions for weight control in the clinical setting are usually based on behavior modification and comprise several face-to-face meetings, either individually or in a group. Several modeling studies have shown that these interventions may be cost-effective from a societal perspective.[217] Yet, face-to-face interventions could be impractical in the work setting. Employees mention constraints of time and location as barriers for participation in them.[45] Programs that make use of distance communication technology for person-to-person counseling, like e-mail and telephone, have the potential to be more accessible to employees. Limited evidence is available of the cost-effectiveness of these methods in addressing body weight and weight-related behaviors. Economic evaluations in healthy working-age adults concluded superior cost-effectiveness for a mix of e-mail and phone counseling[218-220] and inferior cost-effectiveness for phone counseling alone,[221, 222] compared with usual care, an alternative intervention or no intervention. The purpose of this study was to investigate the cost-effectiveness for weight reduction and cost-utility of a lifestyle program utilizing e-mail or phone counseling in comparison with self-help among overweight employees, from a societal perspective and with a time horizon of two years.

METHODS

Study design

An economic evaluation was conducted alongside a randomized controlled trial (RCT) with three study-arms, carried out in the Netherlands from 2004 to 2007. Details of the study design, the intervention and its effectiveness on body weight and cardiovascular risk factors after six months and two years have been published before.[141, 180, 223, 224] The study was approved by the Medical Ethics Committee of the VU University Medical Center and all participants provided written informed consent. The trial has been registered at isrctn.org as ISRCTN04265725.

Participants and setting

Seven different service-sector companies in the Netherlands participated in this study. Employees of these companies were eligible if they met the following criteria:

BMI ≥ 25 kg/m², paid employment for at least 8 hours a week, able to read and write Dutch, access to and making regular use of the internet, age 18 years and older, not pregnant and no diagnosis or treatment for disorders that would make physical activity difficult (for example knee osteoarthritis). Employees who were willing to participate were randomized using a blinded allocation schedule. The participants and counselors were, in consequence of the nature of the intervention, not blinded for the intervention.

Interventions

According to two reviews from 2006, information on diet and physical activity is only incidentally given in the Dutch occupational healthcare setting.[225, 226] Thus, usual occupational care for overweight employees likely consists of no care at all. However, having a no-care group was thought to hamper recruitment to the study. For that reason, all groups including the control group, received self-help brochures on lifestyle change. Additionally, participants in the two intervention groups received a lifestyle intervention program consisting of ten modules.[141] These modules gave information on nutrition and physical activity, and taught behavior modification strategies (e.g. self-monitoring, goal setting). After finishing each module, participants were contacted by their personal counselor. The phone group received the program in written form and was contacted by phone. The internet group had access to an interactive and individualized program website and was counseled by e-mail. Participants in the internet group received automated twice-weekly e-mails to encourage them to start and finish modules. Counselors made an appointment with participants in the phone group for the next phone session. If a participant could not be reached at the set date and time, one more phone call was made. If this was unsuccessful, an e-mail was sent asking the participant to contact the counselor. Counseling was provided for a period of six months and discontinued if the participant declined further contact. A step counter was given to the phone and internet group, as a motivational aid for increasing physical activity.

Study measures

Measurements consisted of a mixture of physical measurements and questionnaires, as explained below. Research-related follow-up, including follow-up of participants who discontinued their allocated intervention, was pursued with up to five reminders by mail, e-mail and telephone.

Health outcomes

The primary outcome of the study was change in body weight from baseline to 24 months. Baseline and 24-month follow-up body weight measurements were done at or near the workplace.[141] Body weight was measured using a digital scale (Seca 770; Seca GmbH & Co, Hamburg, Germany) with participants wearing light clothes and no shoes. Body weight was also measured at 6 months, and self-reported body weight was collected by questionnaire at baseline, 6, 12, 18 and 24 months. Current body weight was asked from participants who decided to withdraw from the study. When weight measurements at the 24-month follow-up were missing, but self-reported weight at baseline and 24-month follow-up or at dropout (within ± 3 months of planned follow-up) were available, these were used in the analyses.

The EuroQol-5D (EQ-5D) was used to assess quality of life at baseline, and at 6, 12, and 24 month follow-up.[227] Health utilities were estimated with the Dutch tariff.[228] Quality adjusted life years (QALYs) were calculated by the area under the curve method. Utilities were multiplied with the amount of time a patient spent in a particular health state. Transitions between health states were linearly interpolated.

Costs

Information on medical resource use, medication use and sickness absenteeism from paid work was obtained through prospective 6-month diaries provided to the participants at baseline, and at the 6, 12 and 18 month follow-up. Participants were asked to keep this diary for the next six months and to fill in frequency of use of each cost category per month. If no use was made of a cost category, the answer box could be left empty.

As recommended in Dutch guidelines, standard costs were used to value health care utilization such as costs of general practitioner care, allied health care, medical specialist care, complementary medicine and hospitalization.[229] When these were not available, prices reported by professional associations were used. The costs of drugs were estimated on the basis of prices charged by the Royal Dutch Society for

TABLE 7.1 Price weights and mean (SD) health care utilization for participants with complete cost and body weight data

Type of utilization	Price weight[1]
Intervention	
Counseling (minute)	1.14
Primary care	
General practitioner	20.44[2,3]
Occupational physician	21.50
Physical therapist	23.02
Dietitian	30.12
Dentist	17.47
Complementary therapists	23.51 – 63.95[4]
Other primary care	23.02 – 77.51[2, 4]
Secondary care	
Outpatient	56.66
Admission general hospital (days)	340.99
Production losses	
Sick leave (hour)	20.31 – 48.39[2]

1 Euros, corrected to the year 2004;
2 Dutch standard costs;[229]
3 Price for consultation at the practice;
4 Range of price weights for different therapists, obtained from professional organizations;
5 Range of possible price weights for sick leave, depending on age and sex.

Pharmacy.[230] Costs of production losses based on self-reported sick leave from work were estimated with the friction cost approach (friction period 154 calendar days and an elasticity of 0.8), using the mean income of the Dutch population according to age and gender.[229] Cost categories and prices used in the economic evaluation are given in Table 7.1. Prices were adjusted for the year 2004, the first year of measurement, using consumer price indices.[231]

Costs for the self-help materials provided to all groups were not included, as these were similar in each group. Intervention costs were based on charges paid during the development and implementation of the intervention. Intervention costs consisted of fixed (annual) costs and of counseling costs that varied per participant. The fixed costs covered costs of the development of materials and the website, printing costs, step counter costs and costs for maintaining a counseling center. Total fixed costs per participant of the phone intervention were €69 and of the internet intervention €65. During implementation of the intervention, counselors recorded the time they spent on counseling, attempts to contact the participant for counseling and administrative activities for each contact. Based on these records, counseling costs per participant were computed. Total intervention costs per participant were estimated by adding the fixed costs and counseling costs. A detailed description of the costing of the intervention can be found in Appendix 7.1 (accessible at http://www.ijbnpa.org/content/supplementary/1479-5868-9-112-s1.pdf). Research-related costs were excluded from the cost calculations.

Analyses

Intention-to-treat analyses were conducted based on group allocation, regardless of actual intervention received or adherence to the intervention. However, participants who died or became pregnant during the study were excluded from all analyses. In the main analyses, missing total direct costs, indirect costs, body weight and health utilities, were multiply imputed. Five different data sets were created with the Multivariate Imputation by Chained Equations procedure.[166] Group allocation, age, sex, educational level, baseline weight, available body weight at 6, 12 and 18 months (collected by questionnaires) and 24-month follow-up weight, intervention costs, and available direct and indirect costs at 6, 12, 18 and 24 months were included in the imputation model. The five data sets were analyzed separately. The estimates were then pooled using a formula described by Rubin.[166] This method does not allow for an estimation of standard deviations, so the standard error of the mean (SEM) is presented in the tables.

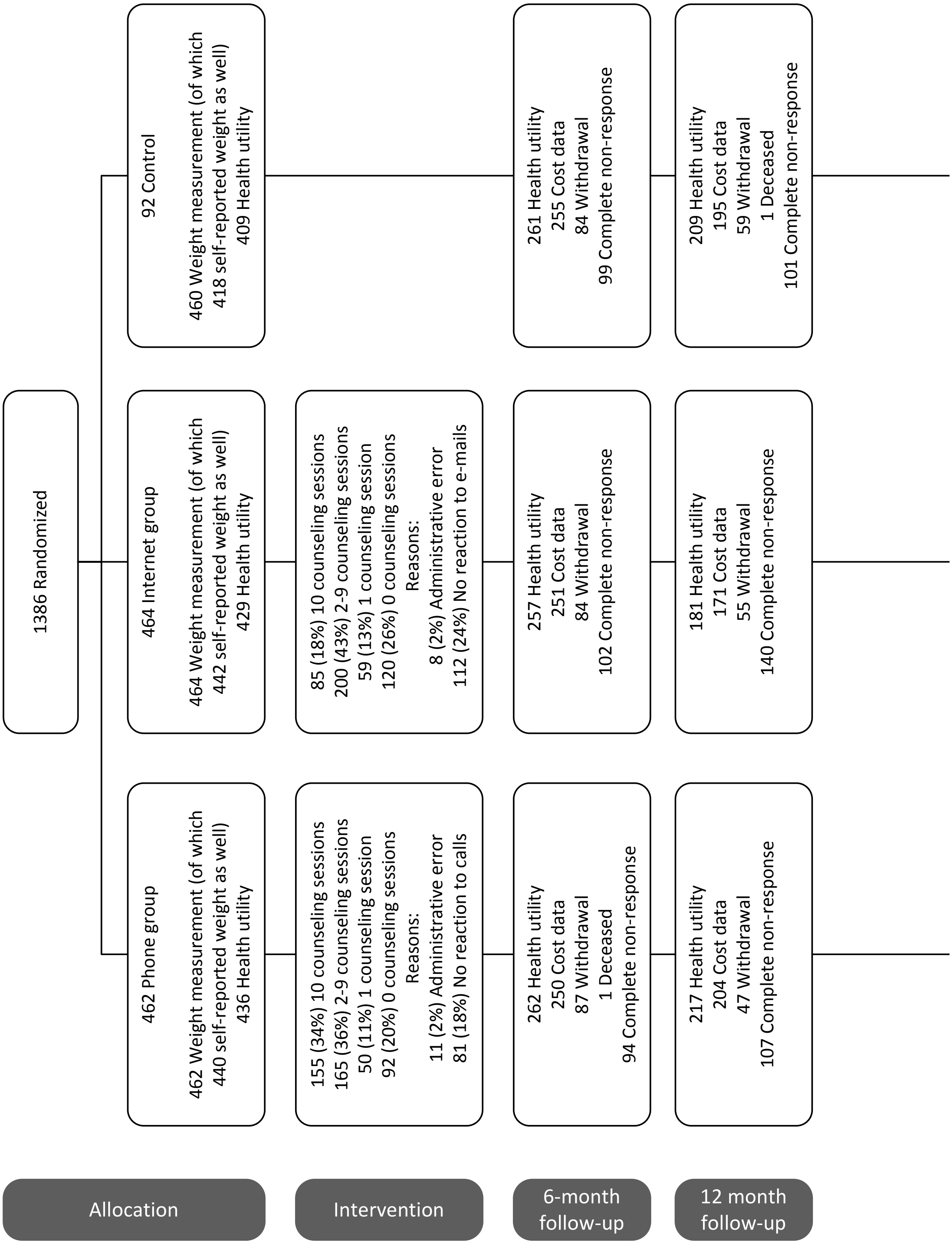
Regression analysis was used to compare differences in follow-up body weight between groups (i.e. phone vs. control and internet vs. control), while adjusting for baseline weight. Two-sided T-tests were used to compare QALYs gained.

To compare costs between groups, confidence intervals around the mean differences in costs were estimated using the bias-corrected and accelerated bootstrap method (BCA) with 2000 replications. Incremental cost-effectiveness ratios (ICER) and incremental cost-utility ratios (ICUR) were estimated by dividing the difference in total costs between the treatment groups by the difference in outcomes at 24 months. To graphically present uncertainty around the ratios, bootstrapped cost-effect pairs (2000 replications) were plotted on cost-effectiveness planes (CE-planes).[216] Cost-effectiveness acceptability curves (CEACs) were used to present the probability that each of the interventions is more cost-effective than the others for a range of willingness-to-pay thresholds.[232] The willingness-to-pay threshold represents the maximum amount of money a decision maker is willing to spend to obtain a unit of health outcome (e.g. QALYs). The Netherlands lack a formal threshold for societal cost-per-QALY.[233] For the current study a threshold of €20,000/QALY is applied, in line with a review of preventive interventions in the Netherlands.[234]

Four sensitivity analyses were conducted to test the robustness of the results. In the first sensitivity analysis costs for the second year were discounted with 4% and QALYs achieved in this year were discounted with 1.5%, according to Dutch guidelines.[235] The second sensitivity analysis was restricted to participants with complete cost and effect data, i.e. complete case analysis. The third sensitivity analysis was done from the perspective of a Dutch company. The costs concern those that the company pays, i.e. intervention costs and absenteeism costs. Since employers want interventions that are cost-saving, the willingness-to-pay threshold is €0 for all health effects.[25] In the fourth sensitivity analysis, QALYs were estimated using the UK EQ-5D tariff.[236]

The statistical significance level was set at 5%, meaning that if a 95% confidence interval does not include the value of no difference statistical significance is present.[237] Analyses were performed with SPSS version 15.0 and R version. 2.7.1.[168] CEACs were constructed using MS Excel 2007.

Caption for Figure 7.1, displayed on pages 118-119: Costs and Quality Adjusted Life Years (QALYs) are complete when cost data and health utility data are available at each measurement. Participants were approached at each measurement, unless they had dropped out from the study. Participants showed intermittent non-response (e.g. providing data at baseline, 12 and 24 months but not at 6 and 18 months,) and also partial non-response (e.g. providing complete body weight data, but not complete cost data). The number of participants with complete data therefore cannot be calculated from this participant flow.


1386 Randomized
462 Phone group
462 Weight measurement (of which 440 self-reported weight as well)
436 Health utility
464 Internet group
464 Weight measurement (of which 442 self-reported weight as well)
429 Health utility
92 Control
460 Weight measurement (of which 418 self-reported weight as well)
409 Health utility
155 (34%) 10 counseling sessions
165 (36%) 2-9 counseling sessions
50 (11%) 1 counseling session
92 (20%) 0 counseling sessions
Reasons:
11 (2%) Administrative error
81 (18%) No reaction to calls
85 (18%) 10 counseling sessions
200 (43%) 2-9 counseling sessions
59 (13%) 1 counseling session
120 (26%) 0 counseling sessions
Reasons:
8 (2%) Administrative error
112 (24%) No reaction to e-mails
262 Health utility
250 Cost data
87 Withdrawal
1 Deceased
94 Complete non-response
257 Health utility
251 Cost data
84 Withdrawal
102 Complete non-response
261 Health utility
255 Cost data
84 Withdrawal
99 Complete non-response
217 Health utility
204 Cost data
47 Withdrawal
107 Complete non-response
181 Health utility
171 Cost data
55 Withdrawal
140 Complete non-response
209 Health utility
195 Cost data
59 Withdrawal
1 Deceased
101 Complete non-response
Allocation
Intervention
6-month follow-up
12 month follow-up

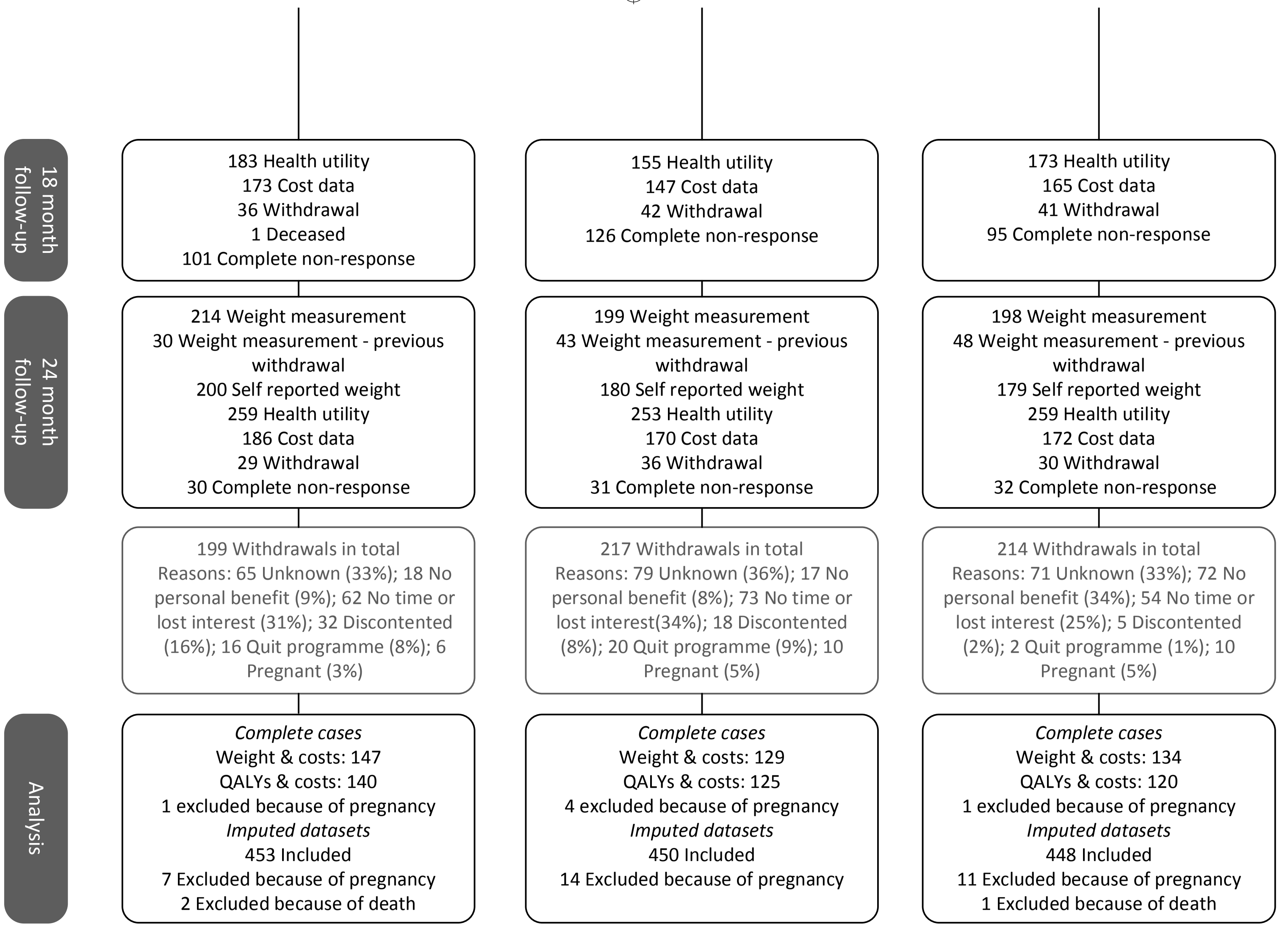


FIGURE 7.1 Participant flow after randomization. The participant flow up to randomization can be found in chapter 4 (page 66-67).

RESULTS

Participant flow and baseline characteristics

The participant flow of the 1386 employees randomized to the phone group (N=462), internet group (N=464) and control group (N=460) is presented in Figure 7.1. A total of 630 participants (45%) dropped out from the study and three participants died of unknown causes. Lack of time or loss of interest in the study and, for the control group, lack of personal benefit, were mostly given as reason for leaving the study (Figure 7.1). To increase the follow-up rate, dropouts (except those that dropped out because of pregnancy or disappointment in the study) were approached and asked if they were willing to attend the 24-month measurements. Out of the 549 approached, 121 were willing to do so.

Because utilities and costs had to be available at all measurement times to be complete and most participants missed at least one measurement, body weight and costs were complete for 410 (30%) participants. Utilities and costs were complete for 385 (28%) participants. For the main analysis, 43% of follow-up body weight, 41% of health utilities, and 57% of cost data were imputed.

Baseline characteristics of all randomized participants are given in Table 7.2. Over half of the participants were male, mean age was 43 years and mean BMI was 29.6 kg/m^2.

Loss to follow-up (i.e. missing data due to discontinuation and non-response) was equal in each study group. However, participants with missing data had a 3.4 kg higher baseline body weight (94.0 vs. 90.5 kg, 95% CI 1.9 to 4.9; results not tabulated). For those participants with missing cost data but available follow-up weight, a 2.9 kg higher two-year follow-up weight (91.8 vs. 89.0 kg, 95% CI 1.0 to 4.7) was observed compared with participants with full data. Furthermore, participants with missing data completed less counseling sessions. Participants in the phone group who had missing data completed 5.1 counseling sessions, while participants with complete data had 8.4 sessions (3.3; 95% CI 2.4 to 4.1). In the internet group this was 3.2 and 7.5 sessions respectively (4.3; 95% CI 3.5 to 5.1).

Outcomes

The main analysis showed no significant differences in change in body weight between the intervention groups and control group. Mean QALYs achieved over two years were similar in each group (Table 7.3).

Costs

Table 7.4 presents the mean two-year costs of each group and the mean incremental costs of the intervention groups in each main cost-category. Mean costs for the intervention were €201 for the phone version and €177 for the internet version. There were no statistically significant cost differences between the groups, except for higher healthcare costs in the internet group compared with the control group.

TABLE 7.2 Baseline characteristics of the control, phone and internet group, and of all subjects at baseline, values are mean (standard deviation), unless otherwise mentioned

	Control n=460	Phone n=462	Internet n=464	All n=1386
Male, n (%)	306 (66.5)	321 (69.5)	302 (65.1)	929 (67.0)
Age (years)	43.2 (8.7)	43.2 (8.8)	43.4 (8.4)	43.3 (8.6)
Body weight (kg)	92.8 (13.6)	93.3 (14.1)	92.7 (14.3)	92.9 (14.0)
BMI (kg/m^2)	29.6 (3.7)	29.5 (3.5)	29.6 (3.4)	29.6 (3.5)
Health utility[1, 2]	0.908 (0.136)	0.917 (0.129)	0.915 (0.117)	0.913 (0.128)
Sick leave in previous 3 months, (days)[3]	1.9 (6.0)	3.4 (11.1)	2.6 (9.6)	2.7 (9.2)
0 days, n (%)	267 (63.1)	291 (62.5)	315 (70.6)	873 (66.4)
1 - 7 days, n (%)	130 (30.7)	114 (25.6)	95 (21.3)	339 (25.8)
8 - 30 days, n (%)	24 (5.7)	28 (6.3)	28 (6.3)	80 (6.1)
> 30 days, n (%)	2 (0.5)	13 (2.9)	8 (1.8)	23 (1.7)

1 n=1261;
2 Health utilities in the EuroQol are expressed on a scale from 0 (death) to 1 (perfect health);
3 n=1315.

TABLE 7.3 Pooled outcomes for body weight and QALYs[1] achieved between baseline and two year follow-up

Clinical outcome	Control n=448	Phone n=453	Internet n=450	Phone vs. control	Internet vs. control
	Mean (SEM)	Mean (SEM)	Mean (SEM)	ΔE[2] (95% CI)	ΔE[2] (95% CI)
Weight reduction (kg)	1.1 (0.33)	1.5 (0.29)	1.9 (0.27)	0.3 (-0.6; 1.3)	0.9 (-0.1; 1.9)
QALYs achieved[3]	1.85 (0.008)	1.85 (0.011)	1.86 (0.009)	0.001 (-0.03; 0.03)	0.01 (-0.01; 0.04)

1 QALY, Quality Adjusted Life Year;
2 ΔE, mean difference in clinical outcome;
3 The maximum amount of QALYs that can be achieved in two years is 2.0.

TABLE 7.4 Pooled costs and cost differences in Euros between baseline and two year follow-up

	Control n=448	Phone n=453	Internet n=450	Phone vs. control	Internet vs. control
	Mean (SEM)	Mean (SEM)	Mean (SEM)	ΔC (95% CI)[1]	ΔC (95% CI)[1]
Intervention	0	201 (5)	177 (5)	201 (NA[2])	177 (NA[2])
Health care	656 (46)	739 (61)	819 (90)	83 (-56; 219)	163* (10; 344)
Sick leave	1824 (249)	1893 (296)	1498 (305)	69 (-731; 765)	-326 (-1019; 419)
Total	2480 (273)	2832 (295)	2494 (360)	352 (-462; 1095)	14 (-790; 817)

1 ΔC, mean difference in total costs; 2 NA, not applicable.

Cost-effectiveness for weight loss

Mean incremental societal costs, incremental effects, ICERs and the distribution of cost-effectiveness pairs in the cost-effectiveness planes for the phone group are presented in Table 7.5 and for the internet group in Table 7.6. The ICERs suggest that the interventions were more effective than self help, but also more costly. The ICER for weight loss in the phone group compared with the control group was €1009 per kg weight loss, whereas it was €16 per kg weight loss in the internet group compared with the control group. The CE-planes are shown in Appendix 7.2 (accessible at http://www.ijbnpa.org/content/supplementary/1479-5868-9-112-s2.pdf). At a societal willingness-to-pay (WTP) of €0/kg, self help and the internet intervention had an equal probability of cost-effectiveness, but at higher WTP values the probability increased for the internet intervention and decreased for self help (Figure 7.2). The probability that the phone intervention was more cost-effective was below 5%, regardless of WTP.

Cost-utility

The ICUR of the phone group compared with the control group was €245,243 per QALY (Table 7.5). For the internet group compared with the control group the ICUR was €1337 per QALY (Table 7.6). Both ICURs implied higher effectiveness at greater costs. The CE-planes are displayed in Appendix 2, with the distribution of the cost-effectiveness pairs given in Tables 7.5 and 7.6. Cost-utility probabilities at a WTP of €20,000/QALY were 8% for the phone intervention, 60% for the internet intervention and 32% for self help (Figure 7.3).

Sensitivity analyses

Results from the sensitivity analysis with discounted data were comparable with the results from the main analysis (results not shown). However, results from the complete case analysis, as presented in Table 7.5 for the phone group and in Table 7.6 for the internet group, differed from those found in the main analysis, most notably so in the internet group. Compared with self help, the internet intervention resulted in significant weight loss while societal costs were (non-significantly) lower (Table 7.6). An ICER of €-62 (i.e. a reduction in societal costs of €62 for each kg lost) and an ICUR of €-27,908 (i.e. a reduction in societal costs of €27,908 for each QALY gained), as compared with self help, were found (Table 7.6). The probability that the internet intervention was cost-effective at a WTP of €0/kg weight loss was 57% and reached a maximum of 89% at a WTP of €550. The probability of its cost-utility was 86% at €20,000/QALY.

Results from the analysis from the perspective of a Dutch company were similar to the main analysis for the phone group (Table 7.5). Results of the internet group showed a saving of €149 Euros (Table 7.6). At a WTP of €0 per unit of health effect, the likelihood that the intervention was cost-effective was 66% for both weight loss and QALYs gained.

The analysis in which QALYs were estimated according to the UK tariff also resulted in different outcomes. The ICUR in the phone group was €52,496, which was lower than in the main analysis (Table 7.5). The probability of cost-utility at €20,000/QALY was 8%. Similarly, the ICUR of the internet group was lower, €702 (Table 7.6). The probability of cost-utility was 71% at €20,000/QALY.

Analysis[1]	Sample size per group		ΔC (95% CI)	ΔE (95% CI)		Distribution in CE plane (%)			
Weight loss	*Control*	*Phone*	*Euros*	*Weight loss (kg)*	*ICER*	*NE*[2]	*SE*[3]	*SW*[4]	*NW*[5]
Main	448	453	352 (-462; 1095)	0.3 (-0.6; 1.3)	1009	65	14	6	16
Complete cases	134	147	593 (-157; 1458)	1.1 (-0.02; 2.2)	543	91	7	0	2
Company perspective	448	453	270 (-525; 997)	0.3 (-0.6; 1.3)	772	62	17	7	13
QALY				*QALY*	*ICUR*				
Main	448	453	352 (-490; 1099)	0.001 (-0.03; 0.03)	245,242	41	14	5	40
Complete cases	120	140	423 (-458; 1250)	0.006 (-0.04; 0.05)	131,863	50	13	3	34
Company perspective	448	453	270 (-525; 997	0.001 (-0.03; 0.03)	187,545	37	17	8	38
UK tariff	448	453	352 (-490; 1099)	0.007 (-0.04;0.05)	52,496	50	13	7	30

TABLE 7.5 Incremental cost-effectiveness ratios and distribution of the joint cost-effect pairs in the cost-effectiveness planes of the phone group resulting from the main analyses and the sensitivity analyses

1 In the analysis ΔC= mean difference in total costs, ΔE= mean difference in outcome, ICER (ICUR) =incremental cost-effectiveness (utility) ratio calculated as ΔC/ ΔE. In the main analysis missing data were multiply imputed. The complete cases analysis was restricted to participants with complete cost and effect data; 2 Northeast quadrant of the CE-plane: the intervention is more effective and more costly than self-help brochures; 3 Southeast quadrant of the CE-plane: the intervention is more effective and less costly than self-help brochures; 4 Southwest quadrant of the CE-plane: the intervention is less effective and less costly than self-help brochures; 5 Northwest quadrant of the CE-plane: the intervention is less effective and more costly than self-help brochures.

Analysis[1]	Sample size per group		ΔC (95% CI)	ΔE (95% CI)		Distribution in CE plane (%)			
Weight loss	*Control*	*Internet*		*Weight loss (kg)*	*ICER*	*NE*[2]	*SE*[3]	*SW*[4]	*NW*[5]
Main	448	450	14 (-790; 867)	0.9 (-0.1; 1.9)	16	50	48	1	1
Complete cases	134	129	-82 (-838 to 633)	1.3* (0.3; 2.4)	-62	41	58	0	0
Company perspective	448	450	-149 (-858; 618)	0.9 (-0.1; 1.9)	-171	33	65	2	1`
QALY				*QALY*	*ICUR*				
Main	448	450	14 (-774; 887)	0.01 (-0.01; 0.04)	1337	35	47	5	14
Complete cases	120	125	-307 (-1179; 315)	0.02 (-0.02; 0.06)	-27,908	17	71	8	5
Company perspective	448	450	-149 (-858; 618)	0.01 (-0.01; 0.04)	-14,181	23	58	8	11
UK tariff	448	450	14 (-774; 887)	0.02 (-0.02;0.06)	702	41	47	4	9

TABLE 7.6 Incremental cost-effectiveness ratios and distribution of the joint cost-effect pairs in the cost-effectiveness planes of the internet group resulting from the main analyses and the sensitivity analyses

1 In the analysis ΔC= mean difference in total costs, ΔE= mean difference in outcome, ICER (ICUR) =incremental cost-effectiveness (utility) ratio calculated as ΔC/ ΔE. In the main analysis missing data were multiply imputed. The complete cases analysis was restricted to participants with complete cost and effect data; 2 Northeast quadrant of the CE-plane: the intervention is more effective and more costly than self-help brochures; 3 Southeast quadrant of the CE-plane: the intervention is more effective and less costly than self-help brochures; 4 Southwest quadrant of the CE-plane: the intervention is less effective and less costly than self-help brochures; 5 Northwest quadrant of the CE-plane: the intervention is less effective and more costly than self-help brochures.

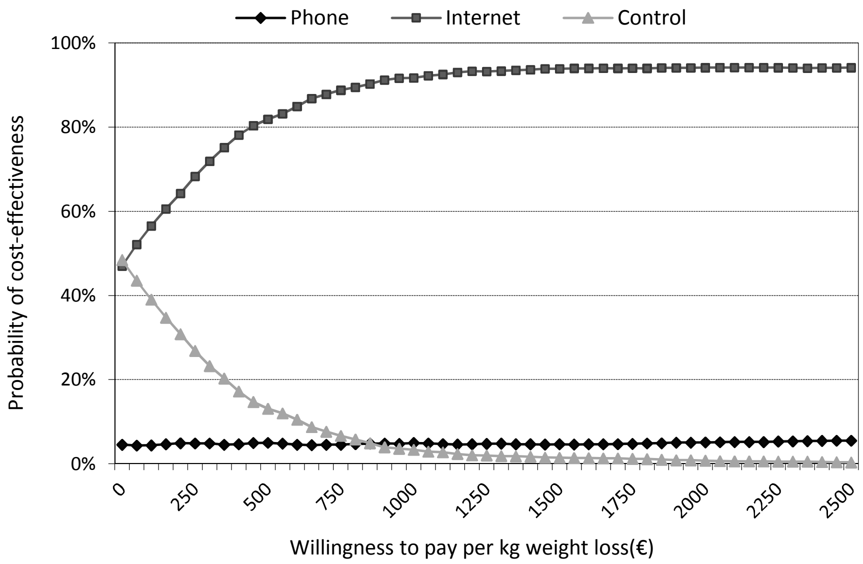


FIGURE 7.2 Cost-effectiveness acceptability curves for weight loss from self help (control) and two lifestyle programs with counseling by phone (phone) or e-mail (internet)

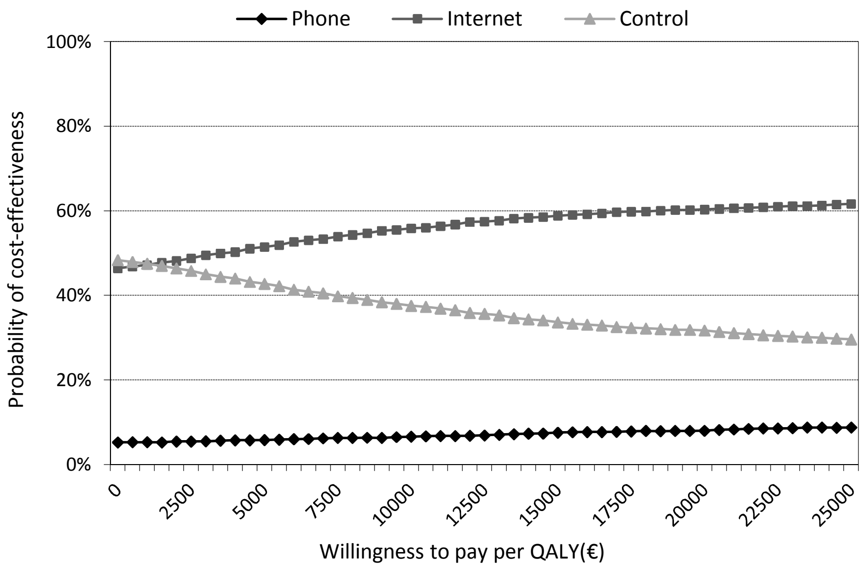


FIGURE 7.3 Cost-effectiveness acceptability curves for QALYs gained from self help (control) and two lifestyle programs with counseling by phone (phone) or e-mail (internet)

DISCUSSION

We set out to investigate the cost-effectiveness for weight reduction and cost-utility of a lifestyle program utilizing e-mail or phone counseling in comparison with self-help among overweight employees. Adherence to both interventions was limited. ICERs and ICURs implied that both interventions were more effective but also more costly than self help. However, the ICER and ICUR of the internet group were lower (respectively, €16/kg and €1337/QALY) than those of the phone group (respectively, €1009/kg and €245,243/QALY) and quite favorable. The phone group had the lowest probability of cost-effectiveness and cost-utility of all groups, whereas the internet group had the highest probability of cost-effectiveness at most willingness to pay thresholds, ranging from 47% at €0/kg to 80% at €450/kg, and 60% at €20,000/QALY. The sensitivity analyses generally confirmed the results from the main analysis, with some showing results that favored the internet group more than in the main analysis. The internet-based program therefore appears to be the preferred intervention.

Participants finished about half of the ten modules, with lower adherence in the internet group. The latter may be related to satisfaction with the different formats. At six months after baseline we conducted a process evaluation in which we asked the participants how satisfied they were with their group allocation: 91% of the phone group participants were satisfied compared with 78% of the internet group. The general appreciation, on a scale of 0 (lowest) to 10 (highest), was 7.4 for the phone format and 6.9 for the internet format.

In the main analyses we found no significant differences in body weight and QALYs gained, in comparison with the control group. Conversely, the complete case analysis showed significant weight loss in the internet group, and a trend towards significant weight loss in the phone group, compared with the control group. However, self-selection seems to have played a role in this result, judged by the differences in baseline and follow-up body weight between complete and incomplete cases. In addition, compared to the imputed cases, within-group weight loss in the complete cases of the internet group was similar, while weight loss decreased in the control group and increased in the phone group. This is surprising as we expected selection effects in the complete cases to result in higher within-group weight losses among all groups. The significant result among complete cases should be treated with caution.

Baseline health utility values were, on a scale from 0.00 (representing death) to 1.00 (representing perfect health), already high with values around 0.91. A problem of the EQ-5D utility index is that it does not discriminate between health states at the high end of the healthy utility range.[238] It is therefore not surprising that, in our relatively healthy population, differences in QALYs gained were small and not statistically significant. Research is going on to develop quality-of-life outcomes that are more sensitive to the immediate effects associated with preventive interventions.[239]

When the UK tariff was applied, somewhat more QALYs were gained than with the NL tariff. Dutch respondents ascribe less weight than UK respondents to most dimensions on the EQ-5D.[240] This could mean that the UK-tariff is more sensitive to improvements in the EQ-5D dimensions than the NL tariff. Nevertheless, incremental gains remained small.

Health care costs in the internet group differed significantly from controls. Otherwise, no significant differences were found. Like most economic evaluations conducted alongside a RCT, our study was not powered to detect statistically significant differences in costs.[241]

Results of the current study confirm those of two other studies that compared phone counseling of healthy adults on weight-related behaviors and concluded that it was not cost-effective compared with no intervention.[221, 222] Both studies did not include societal costs nor had follow-up beyond the duration of the intervention. Regarding e-mail counseling interventions, no economic evaluations of these were identified. However, three trials found a combination of e-mail and phone counseling to be cost-effective in comparison usual care[218, 219] or another intervention.[242] This suggests that a combination might be more cost-effective than each intervention separately. Another explanation might lie in the methodological differences. First, conclusions in the three studies were based on complete cases (29% to 82% of all randomized participants) instead of imputed data sets, possibly leading to inflated effectiveness. Second, two of the studies[219, 243] based their conclusion on the ICER but did not explore uncertainty around these outcomes.[244] Third, these studies did not include costs of productivity loss or all health care costs. Finally, all three studies reported post-intervention outcomes, as opposed to 18-months post-intervention in the current study. Weight rebound after initial weight loss is common, and was also seen in our sample.[224, 245]

The main purpose of the current economic evaluation was to identify which counseling mode produced the greatest amount of additional health at acceptable costs. It is not clear how much societal decision makers (i.e. the Netherlands Ministry of Health, Welfare and Sport) are willing to pay for a kg of body weight lost. Furthermore, in the Netherlands, no maximum societal ceiling ratio per QALY gained is defined. A recent review commissioned by the Dutch government used a threshold of €20,000/QALY for preventive interventions,[234] but higher thresholds have been proposed for both curative and preventive interventions, depending on the burden of disease.[246] Uncertainty about the cost-utility of the internet-based weight control program was appreciable, i.e. 40% at the €20,000/QALY threshold. The probability of its cost-effectiveness was a respectable 80% at €450/kg, but it seems unlikely that society is willing to pay this much. In addition, from the perspective of a Dutch company cost-effectiveness of this intervention was fairly uncertain, with a probability of 66% at zero WTP, for both QALYs and kg weight loss.

A limitation of this study is the rate of missing data. Missing data were multiply imputed for the main analysis. This method gives more valid results than complete case analysis and simple imputation methods such as baseline value carried forward.[190, 247] Multiple imputation assumes that the available data are sufficient to predict missing costs and clinical outcomes, and that the costs and outcomes of those who provided data are similar to those who did not provide data. The latter assumption may not necessarily hold true, but cannot be tested. This makes it impossible to draw firm conclusions about the cost-effectiveness of the studied interventions.

Retention to the study is challenging in behavioral weight control studies. In the current study 45% of participants had dropped out after two years. Few previous studies in this field had a follow-up beyond one year. A modeling study estimated that 50% of participants in weight control studies will have dropped out after two years, which is comparable to the dropout we found.[190] This indicates that conclusions regarding efficacy and (cost-)effectiveness in the weight control field are seriously hampered. Future studies should prevent loss to follow-up. Upcoming technologies, like weighing scales that are connected to the internet, could make measurement of body weight for study-purposes less burdensome.[248] Research is needed to optimize cost diary and questionnaire design.[249] Finally, participants should be selected on motivation for continued participation in the trial[184] and motivation for completion of the study could be enhanced.[250]

Another possible limitation of the study is that all cost data, except the costs of the intervention, were self-reported and that the cost diaries covered a relatively long period. More objective data, such as health claims data, are practically inaccessible in the Netherlands, so self-report of resource utilization is the common method. However, it is possible that participants completed the diaries retrospectively at the moment they had to return them instead of completing them prospectively. This could have resulted in recall bias. Contradictory results on the influence of (period of) recall on the precision of self-reported sick leave and health care and medication use have been reported,[251-254] but under-reporting of utilization seems likely. Nevertheless, we do not expect under-reporting to systematically differ between the intervention groups.

Strong points of the study are the randomized controlled design, the large study population of nearly 1400 participants, the relatively long follow-up period of two years, and the thorough presentation of uncertainty around the outcomes.

CONCLUSION

The lifestyle program with phone counseling was not proven to be cost effective. The program with e-mail counseling showed some promising results but its cost-effectiveness was uncertain. Due to high loss to follow-up firm conclusions cannot be drawn. Future economic evaluations of weight control interventions should ensure that dropout is limited.

CHAPTER 8:

GENERAL DISCUSSION

Prevention and treatment of overweight are important to reduce the burden of overweight on public health. The work setting presents an opportunity to offer weight loss and weight maintenance programs to a large number of people. Programs making use of distance counseling, by internet and telephone, seem especially promising in this setting. However, the short- and long-term effectiveness and cost-effectiveness of distance counseling for weight management in overweight workers, and differences in effectiveness between the two counseling modes, are not known. The general aim of this PhD dissertation was to address these issues. To that end, a randomized controlled trial, ALIFE@Work, was conducted among overweight employees from seven organizations in the Netherlands. The effectiveness and cost-effectiveness of a lifestyle program called 'Leef je Fit' with two modes of counseling, i.e. phone and e-mail, was studied in this trial.

In this general discussion, we first present the main findings of the study. Secondly, methodological considerations regarding the study and its findings will be discussed. Thirdly, suggestions for future research will be proposed and the public and occupational health implications of the main findings will be addressed.

MAIN FINDINGS

Accuracy of self-reported body weight, body height and waist-circumference

The accuracy of self-reported measures for body weight, body height and waist circumference were reported in chapter 3. We found that body weight was under-reported, on average by 1.4 kg. Conversely, body height was over-reported by 0.7 cm. As Body Mass Index (BMI) is calculated from the ratio of body weight relative to body height, an average under-reporting of BMI was found by 0.7 kg/m^2. For waist circumference over-reporting by 1.1 cm was observed. Intra Class Correlation showed high concordance between measured and self-reported values. Also, substantial agreement existed between the prevalences of BMI status and increased waist circumference based on measured and self-reported data. We concluded that self-reported BMI and waist circumference are satisfactorily accurate for the assessment of the prevalence of overweight/obesity and increased waist circumference in large scale studies among a middle-aged overweight working population. Thus, self-report can be used to assess the distribution of overweight and obesity in similar populations as we studied. Nevertheless, limits of agreements showed considerable individual differences in the accuracy of self-reported anthropometrics. Consequently, self-reported anthropometrics are less suitable to classify an individual as overweight or obese. For this, direct measurements are recommended.

Effects on body weight and waist circumference

Effectiveness of the program was studied at six months, as described in chapter 4, and at two years, which was reported in chapter 5. Based on analyses in which missing body weight data were imputed with multiple imputation techniques, we found that the lifestyle program was effective for weight loss at six months as the phone group reduced body weight by 1.5 kg (95% CI -2.2 to -0.8), and the internet group did so by 0.6 kg (95% CI -1.3 to -0.01), compared with the control group. These effects were more pronounced among study-participants for whom body weight data were available at both measurements, i.e. the complete cases. Among them, weight loss was 1.6 kg (95% CI -2.2 to -1.0) and 1.1 kg (95% CI -1.7 to -0.5), respectively, compared with the controls. Waist circumference in the phone group was reduced with 1.9 cm (95% CI -2.7 to -1.0) while the reduction was 1.2 cm (95% CI -2.1 to -0.4) in the internet group, compared with the control group.

At two years some of the effect on body weight remained in both groups, but failed to reach a level of statistical significance in the multiply imputed samples. Among complete cases, weight loss in the internet group was 1.2 kg (95% CI -1.9 to -0.4) and the phone group was more likely to reduce body weight by 5% (OR 1.7, 95% CI 1.1 to 2.7), compared with the control group. Differences in waist circumference between the groups were not found after two years.

We concluded that the program was effective for reducing body weight and waist circumference, but that these reductions were not sustained after discontinuation of the program.

Effects on diet and physical activity

Effects on behavioral outcomes at six months and two years were also reported in chapter 4 and 5. For these outcomes, only complete cases were included in the analyses. Relative to the control group, participants who had been counseled by phone decreased their fat intake with 1 to 4 grams/day (95% CI -1.7 to -0.2) and increased their physical activity with 866 MET-minutes/week (95% CI 203 to 1530) after six months. No effects on behavioral outcomes were seen in participants from the internet group. At two years effects in the phone counseling group had disappeared and again no effects were found in the internet group. This may indicate that no behavioral effects were present, but this contradicts the significant weight loss we found in the same participants from the internet group. Thus, we concluded that it is possible that the program changed lifestyle behavior outcomes but that inaccurate measurement may have limited detection of this change.

Effects on blood pressure, total cholesterol level, sum of skinfolds and cardiovascular fitness

The results with regard to cardiovascular risk factors are reported in chapter 6. These outcomes were studied in a random subset of 141 employees. At six months a significant reduction in total cholesterol by 0.2 mmol/l (95% CI -0.5 to -0.0) was observed in the phone group and a trend for an increase in aerobic fitness by 1.9 ml O_2/kg/min (95% CI -0.2 to 3.9) in the internet group. At two years, a trend for an increase in aerobic fitness (2.3 ml O_2/kg/min, 95% CI -0.2 to 4.8) was observed in the internet group. No differences were found between the phone group and the internet group. In conclusion, we found little evidence that the lifestyle intervention was effective in reducing cardiovascular risk factors in a group of overweight workers that were not selected on a cardiovascular risk profile aside from being overweight.

Effectiveness of phone-counseling compared with counseling by e-mail

Direct comparison of the phone with the internet group only resulted in significant differences in weight regain at two years (chapter 5). Adjusted for weight change at six months, internet participants gained 1 kg less (95% CI -1.7 to -0.3), as compared with phone participants. Other differences between the groups did not reach statistical significance. The results suggest that the internet version is more effective than the phone version for preventing weigh regain. Further research of other differential effects is warranted.

Cost-effectiveness for body weight and QALYs gained

Chapter 7 gives the cost-effectiveness outcomes. Two years after baseline, small and statistically non-significant differences in effects and societal costs were found. The direction of the differences implied that both interventions were more effective but also more costly than self help. The incremental cost-effectiveness ratios of the internet group were lower (€16/kg and €1337/QALY) than those of the phone group (€1009/kg and €245,243/QALY) and quite favorable. The phone group had the lowest probability of cost-effectiveness and cost-utility of all groups, whereas the internet group had the highest probability at most willingness to pay thresholds, ranging from 47% at €0/kg to 80% at €450/kg, and 60% at €20,000/QALY. Similar as before, more effect was seen in participants with complete data. Consequently, in complete cases the probability of cost-effectiveness of the internet intervention was approximately 86% at a ceiling ratio of €20,000/QALY. In conclusion, the phone intervention was not cost-effective compared with usual care. The internet program with e-mail counseling showed some promising results but firm conclusions cannot be drawn due to large numbers of missing data.

METHODOLOGICAL CONSIDERATIONS

The randomized controlled trial (RCT) is the acknowledged method for incurring valid conclusions about the efficacy and effectiveness of interventions. It was therefore the type of trial we selected to study the effectiveness of the lifestyle counseling intervention. Nevertheless, implementing a RCT of a behavioral intervention in a real-world setting is a challenge. Our design exhibits a number of strengths, but also has some drawbacks, as will be explained in this section.

Main strengths of the study

As mentioned, the RCT is a strong design to study efficacy and effectiveness. Randomization to study groups minimizes the chance of baseline differences influencing the results. Furthermore, the use of a control group that differs only with regard to the intervention received makes it possible to distinguish intervention effects from the effects of other influences. Few worksite weight management interventions have been studied using a control group and using a truly randomized allocation procedure.[23, 185] By using this type of design, our study has added to the strength of evidence concerning the effect of weight management at the worksite. Performing the trial in a real-world setting gave us the opportunity to draw conclusions about the effectiveness of the intervention rather than its efficacy. The external validity was also strengthened by having few exclusion criteria.

A further strong point was the objective measurement of the main outcome, i.e. body weight, for the majority of the study population. Moreover, we used multiple imputation for handling missing data. While having complete data is of course preferred, multiple imputation is considered to be one of the best methods when data are missing.[255] Yet, very few weight control studies choose this method.[173, 190] The majority of studies analyzed only the available data, or used simple imputation methods such as imputing missing data with data from a previous measurement. A major weakness of these imputation methods is that they underestimate the true variability in the data and therefore increase the probability of making a type 1 error, i.e. observing a statistically significant difference when in reality there is none.[173] Multiple imputation uses available information to produce estimates (e.g. means, standard errors) that, under the assumption that the data are missing at random (MAR) and the imputation model is correct, are more reliable than those derived from a complete-case analysis.[173, 256]

Another strong point of the study is that we performed the economic evaluation of the lifestyle program from a societal perspective. This perspective is the most suitable to judge the value and costs an intervention has for public health or, in a broader sense, public welfare. The societal perspective makes it possible to assess possible transfers of costs between stakeholders.[257] Furthermore, payers interested in a narrower perspective can extract the costs and benefits they are interested in from those included in the societal perspective.

Finally, our study is the first to report about the sustainability of the effects of distance counseling on weight management,[52, 258] and the first to report the effects of a weight management program in the work setting at 18 months post-intervention.[23, 185]

Limitations in the internal validity

Internal validity refers to the strength of a study design to draw true conclusions about causes and effects.

Comparison intervention

In economic studies, the comparison intervention has to be relevant for the policy question being addressed.[216] Typically this involves a comparison with usual care. At the time the study was initiated, structured efforts to identify overweight employees were not part of standard Dutch occupational health care. Moreover, no standard care existed for employees that were found to be overweight during voluntary health examinations. Maybe these employees received lifestyle advice from their occupational physician and information in the form of brochures, or a referral to a dietitian, but it is quite likely that they received no help at all. That is why we chose to compare the experimental intervention with widely available self-help brochures. All groups received brochures on overweight, physical activity and diet. These self-help materials were briefly explained to the control participants during the baseline appointment. Other research has shown that self-help materials may be more effective for weight control than no-treatment.[157] As a consequence of this choice, the (cost-) effectiveness of the weight management program could be somewhat underestimated, compared with the state-of-affairs at the time the study started.

Blinding

Blinding is the masking of treatment allocation and other aspects of the study following randomization. It is critical to minimize bias.[259] However, blinding is not always feasible in non-pharmacological interventions. Due to the nature of the intervention we studied, it was not possible to blind participants for group assignment. Prior information about the intervention was brief, but enough for participants to distinguish between the experimental and control conditions.

Lack of blinding of group allocation could lead to several biases. First, knowledge of group assignment could influence participants' participation. This would have been observable in differences in dropout between groups. To gain insight in the influence of knowledge of group assignment, we asked the participants at six months how content they were with the group they were randomized to. Of the control group 68/215 (32%) participants were content, whereas this was 205/223 (91%) in the phone group and 166/207 (80%) in the internet group. Despite these differences in satisfaction, we found no differential dropout. Another concern about failure to blind participants for group allocation is that participants in the perceived to be inactive (control) group might seek alternative treatment that would interfere with the outcome of the study. We found no evidence for this. At six months 30/268 (11%) of controls, 23/264 (9%) of phone-participants and 18/269 (7%) of internet-participants said they had initiated co-interventions like a slimming course, consulting a dietician or taking weight-loss medication. A test for differences in proportions reached no significance (X^2=3.38, p=0.184).

Participation rate

Out of the 5250 (25% of 21,000) employees expected to be eligible for the study, one-fourth participated. This shows that considerable numbers of Dutch employees are interested in lifestyle counseling, a finding that is confirmed in other studies.[260, 261] Yet, the majority of eligible employees did not take part in the study. We could not study differences between participants and non-participants, and only limited information is available from other studies. These studies show that participation is more likely among female employees,[43, 262-264] low risk and healthier employees,[262, 265] and older employees.[43, 265] In men, perceptions of already being healthy play a role in choosing not to participate in lifestyle programs.[260]

In general, women are more health conscious and worried about their body weight. A recent review concluded that incentives and multi-component programs result in higher participation levels.[43] More research is needed to elicit what drives differences in participation, to enable development of tailored recruitment strategies and more fitting programs.

Intervention

Some possible shortcomings of the intervention have to be discussed: its content and duration, number and frequency of counseling sessions, and participants' adherence to the intervention. In conclusion the need for an intervention mix is discussed.

Intervention content

First off, due to time constraints we could not pretest the intervention. Process evaluation data collected during the study showed that some parts of the intervention were experienced as less engaging. In general the information in both the workbook and on the website was appraised positively, but only 50% of the participants said the information applied to them personally. The evaluation of the assignments was less positive. Around 60% of participants valued them as helpful in changing their dietary and physical activity habits and only 21% (internet group) and 38% (phone group) found them enjoyable. Opinions of the website were fairly positive, as 76% found it easy-to-use and 89% judged the navigation on the site to be straightforward. Not all elements of the website were valued favorable. Specifically, only 41% thought the calorie intake, calorie expenditure and body weight trajectory graphs were useful. The appraisal of the program most likely affected its uptake, and the adherence to the modules.

With respect to the self-monitoring materials we supplied, 73% of the participants of the phone group said that they had used the food and activity logs, against 57% of the internet groups. Conversely, 36% of the phone group and 48% of the internet group had used the provided step counter on a regular basis. These numbers are of concern because self monitoring has been shown to be an important factor for weight control success.[266, 267] It is unclear why not all participants used these materials. This requires further study, so the intervention can be adjusted accordingly.

Number and frequency of counseling sessions

In the phone group 87% of respondents said their counselor contacted them a sufficient number of times. This was 56% in the internet group. As the offered number and frequency of sessions were the same in each group, this difference probably reflects a need for scheduled contact moments and a more personal approach. The latter is confirmed by the appraisal of the counseling, which was more positive in the phone group than in the intervention group. That is, 76% of the phone group said that the contact with the counselor was personal and individual, while this was 22% in the internet group.

Level of satisfaction aside, several reviews show that frequent and many sessions enhance lifestyle change and weight loss, but the optimal dose is unknown and could be more frequent than ten sessions in six months.[266, 268]

Duration of the intervention

After completion of all modules, contact with the counselor ended. A recent review concluded that weight loss was better maintained if there was ongoing communication with the participant after the active weight loss phase of in-person counseling interventions, provided this was with the same counselor.[245] This suggests that our intervention could have been more effective in maintaining initial changes if it had been prolonged. The development of maintenance strategies for lifestyle programs with distance counseling warrants further attention.

Adherence to the intervention

Adherence to the intervention was far from optimal, as was described in chapters 4 and 5 of this thesis. In the phone group 20% of the participants did not start the program, whereas 34% finished all counseling sessions. In the internet group 26% did not start the program, and 18% was counseled on all modules. An explanation for the high number of participants that did not start their allocated intervention could be that the pre-trial information (i.e. before randomization) about the intervention was quite general. Participants who did not commence the intervention were possibly expecting something different. Another reason could be that participants reconsidered their intention to change their lifestyle habits. Unfortunately, hardly any of the participants who did not start the intervention filled out the process evaluation questionnaire, so we cannot verify reasons for not initiating the program. Nevertheless, if the intervention would be implemented in occupational health care, it seems sensible to give detailed information about the program, assess participants' willingness to make behavioral changes and willingness to invest time and effort in this, and offer a trial session.

Differences in adherence to the two intervention modes might be explained from the way participants were contacted. To start the program, participants in the phone group were contacted by their counselor. Thereafter participants had prescheduled biweekly appointments for reviewing the modules. Internet participants received automated e-mail reminders to start the program and to start and finish modules. This was probably less stimulating than the scheduled in-person contact that was offered to phone participants. This is supported by results from the process-evaluation. Among the phone group participants 81% found the counseling motivating against 46% in the internet group. Adherence to the internet program could probably be enhanced by additional in-person contact.

Intervention mix

The intervention aimed at changing lifestyle behavior by efforts of the employees themselves. However, specifically for dietary behaviors, systematic reviews have shown that physical aspects of the working environment, such as the assortment of food in the cafeteria, are important in changing these behaviors.[75, 188] There is some evidence that social support at the worksite is also of influence on diet and physical activity.[269] It is plausible that individual lifestyle counseling and environmental changes support each other, to make their combined effect larger than that of each of these interventions alone. Changing the physical and social environment in conjunction with distance lifestyle counseling could be important to achieve better and sustained results.

Finally, it is unlikely that 'one size fits all'. Weight loss can be accomplished through a multitude of approaches. A single magic bullet that achieves adherence to a healthy lifestyle in all at whom it is aimed does not exist. There is a need for a more varied and personalized approach.

Study outcomes

Body weight

There is no consensus on the outcomes that are relevant for evaluating the effectiveness of weight control lifestyle interventions in large field studies. Effects are usually reported as mean body weight difference or BMI difference.[270, 271] Most trials in obese subjects also report the proportion of people that experience a weight loss of 5% or more. This threshold has long been considered clinically relevant, based on trials in obese subjects with impaired glucose tolerance (IGT), a precursor for Type 2 Diabetes Mellitus type 2 (T2DM). Recent research among subjects with a BMI ≥ 24 and IGT, showed that the risk for T2DM reduced with 16% for each kg of body weight that was lost.[272] This effect was already discernible at a weight loss of 2%. No evidence is available for thresholds of clinical effectiveness for obese subjects without co-morbidities or subjects with a BMI between 25 and 30 kg/m^2. However, the previous research suggests that all weight loss should be considered relevant.

As explained in the introduction, the real health problem is an excess of fat mass, specifically of visceral fat. BMI correlates with fat mass, but is not sensitive to a decrease in fat mass if this is accompanied by an increase in muscle tissue. The latter is possible in lifestyle programs that endorse physical activity. Moreover, BMI gives no indication of the distribution of fat mass.[270] A proxy measure for visceral fat is waist circumference.[273] Some have argued that this should be the main outcome of lifestyle interventions aimed at weight control.[274] Our results show that there is considerable variation in the self-report of waist circumference and the consistency of misreport is not known. Therefore, if waist circumference is used as the main study outcome, we recommend it to be measured by research personnel.

In conclusion, the most relevant outcome to judge the effect of lifestyle interventions for weight control in large field studies has not been identified so far. We recommend the development of uniform standards in the report of these studies.

Quality Adjusted Life Years

For the cost-utility analysis we used the EuroQol-5D (EQ-5D) to estimate the amount of Quality Adjusted Life Years (QALYs) gained. The EQ-5D consists of five health domains: mobility, self care, usual activity, pain/discomfort, and anxiety/depression. Each domain has three possible states: no problems or limitations, some problems or limitations and extreme problems or limitations. From the EQ-5D, 243 health states can be derived. Important advantages of the EQ-5D are that the questionnaire is short, easy to fill out and translations to utility scores are available.

The mean health utility at baseline was 0.91, which is in the upper limit of all possible preference scores of the EQ-5D. Only 'perfect health' scores higher than 0.9. This ceiling effect causes the EQ-5D to be unresponsive to an improvement in the health of people with few and limited problems. It is therefore not surprising that hardly any QALYs were gained. As preventive interventions such as ours are aimed at still-healthy individuals, no immediate impact on QALYs gained is to be expected. Nevertheless, lifestyle programs may have an impact on other well being outcomes besides health.

For example, having more control over your own lifestyle behavior increases empowerment. Currently attempts are undertaken to conceptualize these non-health benefits and to develop a questionnaire that measures them.[239] This type of questionnaire might be more suitable to judge the immediate cost-utility of preventive interventions than the EQ-5D. Furthermore, as the effects of lifestyle programs on morbidity and mortality, and hence QALYs, occur after a longer time than intervention studies permit, modeling studies should be performed to judge their long term cost-effectiveness.

Accuracy of self-reported diet and physical activity

We measured dietary intake and physical activity because these are important mediators for weight loss, as well as independent risk factors for cardiovascular disease. Studies show that food intake is usually under-reported,[76] whereas physical activity (PA) is both over- and under-reported.[80] With regard to diet and PA, some evidence exists that exposure to an intervention influences the self-report of these behaviors to match the goals of the intervention program.[275, 276] This implies that the significant changes in fat intake and PA we found in the intervention groups at six months, could have resulted from bias in the self-reported data. We asked participants in our intervention to record their diet and PA for the duration of intervention. It is also possible that, as a consequence of this, accuracy of self-reporting of lifestyle behaviors increased in comparison to baseline. In the absence of objective lifestyle behavior data, presence and direction of self-report bias cannot be determined in our study. The observed differences in PA do however seem rather large. At six months a significant comparative difference of 866 MET-minutes/week was found in the phone group, equivalent to cycling at a speed of 18 km/hour for two-and-a half hours each week or walking at 4 km/hour for about five hours. The questionnaire we used to measure PA has been developed to measure PA in minutes of moderate and vigorous physical activity to judge adherence to national guidelines, and not to measure MET-minutes of PA, including those from light intensity activities.[97] This could have resulted in over-reporting of PA, in conjunction with bias due to self-report. Future large scale studies would do well to include more objective PA measurements in a sample of the study-population.

Time horizon of the economic evaluation

The time horizon of the economic evaluation was two years, equal to the length of the trial. Analyses were based on cost data that were collected alongside the effectiveness study. The two-year period is too short, because health benefits of a preventive intervention such as ours are likely to lie further in the future. A solution for this is to model costs and effects for a time period that extends that of the study. To do so, we would have had to make assumptions about the sustainability of weight loss from the intervention. These assumptions could not have been corroborated with other data from similar interventions, making the model very tentative. Because of this limitation, and for reasons of feasibility, we decided to limit the time horizon to the study length. We do acknowledge that a modeling study with different scenarios for sustainability of the results could shed more light on the long term cost-effectiveness of the intervention.

Loss to follow-up

A serious limitation of this study is the amount of loss to follow-up. Loss to follow-up occurred due to considerable participant dropout, but also because the participants who remained in the study did not take part in all measurements. Specifically, there was a very low response to the cost diaries.

Most weight control trials suffer from considerable loss of data; average dropout is 37% at one year after baseline. According to a prediction algorithm, dropout increases to around 60% at two years.[190] These numbers indicate that conclusions regarding efficacy and effectiveness in the weight control field are seriously hampered and that our study is no exception. Future studies must improve retention of participants to the trial.

Limitations in the external validity

External validity refers to the application of results to other populations and other contexts than those in the study. We placed few restrictions on the eligibility of companies and employees. The study was also performed in the 'real world', thus enhancing generalization of the results to practice. However, there are some limitations on the generalization of the results to other companies and employees than those taking part in the study.

No specific inclusion criteria were devised for the companies of which the employees could take part. However, for logistic reasons, we only included companies that had more than 1000 employees working at the same location and who could facilitate measurements at the worksite. We did not document which and how many companies we approached, or why companies were not willing to participate. Companies that joined the study mostly employed white collar employees and all companies belonged to the service industry. This limits the generalization of our results to larger service sector companies.

RECOMMENDATIONS FOR FUTURE RESEARCH

Measurement and analysis

- More research is needed to develop methods for collecting anthropometric and lifestyle behavior data that are more valid than the current self-report methods, and appropriate for use in large-scale studies. Minimizing the burden that data collection places on study participants should be an important consideration in the development of these instruments.
- A broader set of well-being outcomes should be considered to assess the immediate cost-utility of lifestyle programs. More research is therefore needed to identify these outcomes and on how to value them.
- Modeling studies are needed to judge the long term cost-effectiveness of lifestyle programs.

Dropout

- It is important to prevent dropout in future weight control studies, particularly those with follow-up beyond one year. In that light, researchers should practice restraint in the number of outcomes they wish to examine, to reduce the burden to participants. Upcoming technologies, such as weighing scales that are connected to the internet, could make measurement less burdensome. Participants should be selected on motivation to complete the trial and their motivation could be further enhanced. Research is needed to discover other ways to increase retention to weight control trials.
- The collection of cost data deserves more attention.
- Researchers should make use of proper methods such as multiple imputation to handle missing data.

Mediators for effectiveness of distance counseling

- With regard to lifestyle programs using distance counseling, questions remain about the elements that influence their effectiveness and (continued) use. This should be subject of further study. Additionally, participant characteristics that determine initial and continued participation should be studied. Results from such research could be used to improve the effectiveness of distance counseling programs and to selectively offer them to those who are more likely to use these programs and benefit from them.
- Research is needed to develop a follow-up intervention aimed at maintenance of initial results of distance counseling.

Generalization of results

- The effectiveness of the studied intervention in employees in other sectors than the service industry is uncertain. Further research could be done to assess if distance counseling is effective among employees from these companies. Small companies should be included in that research as well.
- The intervention developed for this study could be used in other settings than

occupational health care. Because the companies were not involved in the implementation of the intervention it would be easy to transfer the program to other settings and populations. It is important to study the effectiveness of the program when doing so.

RECOMMENDATIONS FOR PUBLIC AND OCCUPATIONAL HEALTH

Achieving the promise of workplace health promotion

- Interventions at the worksite have the potential to reach a large part of the population. This study confirmed that a considerable number of employees have an interest in lifestyle programs at the workplace. Yet, few Dutch companies offer them. More effort should be placed towards this end by the companies themselves, but other stakeholders such as the employees (by way of the employees' council), health care and sickness absenteeism insurance companies, and the Dutch government could take steps to stimulate work health promotion as well.
- The initial interest did not always lead to taking part in the program, or in following it through. Considering the complex causality of overweight and the difficulties in achieving lifestyle change, it is doubtful that 'one size fits all' in realizing weight control among Dutch employees. We propose to offer a variety of programs, to increase overall participation in workplace health promotion and to create a better match between participant and program.

Implementation of distance lifestyle counseling

- After six months, both the program with counseling by phone and the program with counseling by e-mail resulted in modest average weight loss. After adjustments as explained below, we believe that the program is a worthwhile addition to the variety of programs that should be on offer.
- It is a promising strategy to embed the program in a wider intervention in which the physical environment and company culture are conducive to a healthier lifestyle.
- The adherence to the program and subsequent weight loss could be improved by giving detailed information about the content and the counseling methods, and to only offer it to those employees who like the format and think they will be able to commit themselves to the program and the time investment needed.
- The content of the program, especially the interactive website, could be improved.
- Adherence to the internet version could be enhanced by adding phone contact with the counselor.
- Follow-up interventions should be provided, to increase the chance of a long-lasting outcome.
- The adjusted intervention should be accompanied by a study of its effectiveness and cost-effectiveness, as well as its impact on the company's bottom line.

CONCLUSION

This study has shown that a program with six months of distance counseling by e-mail and phone can produce short-term weight loss. This weight loss was not preserved at the two-year mark. After some adjustments in format and recruitment, the program could form a useful addition to workplace health promotion programs aimed at energy balance and modest weight loss, but the effectiveness of this adjusted program should be evaluated.

SUMMARY

BACKGROUND

Overweight and obesity in particular, are major public health problems. Having excess weight is associated with disorders like high blood pressure, high blood cholesterol and other dyslipidaemias, cardiovascular diseases, diabetes type 2, various types of cancer, osteoarthritis and fatty liver disease. Globally the number of people that is overweight has severely increased. Therefore, overweight should be treated and prevented, to avoid a rise in overweight-related diseases.

The work setting is a viable place for population-based interventions for weight management. However, weight management programs are not routinely offered in the Dutch work setting and evidence of their effectiveness is mixed. Furthermore, participation from employees in worksite programs is hampered by constraints of time and location. Worksite programs offered by e-mail and phone could overcome these barriers. In other settings, e-mail and phone interventions have shown potential to change lifestyle behaviors and reduce body weight.

In the ALIFE@Work study a lifestyle program with distance counseling by phone and e-mail, called 'Leef je Fit', was developed for overweight employees. This thesis describes the effectiveness, cost-effectiveness and cost-utility of this distance counseling lifestyle program as compared with the provision of general lifestyle brochures.

DESIGN OF THE STUDY

Chapter 2 explains the design of the ALIFE@Work study. The study population consisted of 1386 employees with a Body Mass Index (BMI) $\geq$ 25 kg/m^2. The study was a controlled trial, with randomization to three arms: a control group (460 participants), a phone based intervention group (462 participants) and an internet based intervention group (464 participants).

The intervention was based on a cognitive behavioral approach, addressing physical activity and diet. Ten modules guided the participants through the process of lifestyle behavior change. The modules contained educational content combined with behavior change strategies. Assignments in each module helped participants to apply these strategies to everyday life. The phone group received the materials in written form. The internet group accessed the modules on a website. Between each module, participants received feedback from a trained personal counselor. Depending on the group they were randomized to, counseling was either by phone or by e-mail. The intervention lasted six months. All groups, including the control group, received general brochures on lifestyle and overweight, but participants in the control group were not counseled.

The primary outcome of the study was body weight. Other outcomes were diet and physical activity, waist circumference, sum of skin folds, blood pressure, total blood cholesterol level and aerobic fitness. Furthermore, cost-utility and cost-effectiveness were secondary outcomes of the study. Physiological outcomes were measured at baseline and after 6 and 24 months. Other outcomes, as well as cost measurements necessary for the economic evaluation, were assessed by questionnaire at baseline and after 6, 12, 18 and 24 months.

ACCURACY OF SELF-REPORTED ANTHROPOMETRICS

In chapter 3, we present the answer to a secondary question of the study: what is the accuracy of self-reported body weight, body height and waist-circumference in a sample of the Dutch working population? To address this question, self-reported outcomes were compared with outcomes that were directly measured by research personnel. We found that body weight was under-reported, on average by 1.4 kg. Conversely, body height was over-reported by 0.7 cm. As Body Mass Index (BMI) is calculated from the ratio of body weight relative to body height, an under-reporting of BMI was found by 0.7 kg/m^2. For waist circumference over-reporting by 1.1 cm was observed. Despite the mean misreport, agreement between measured and self-reported values was satisfactory. We recommend the use of self-reported body weight, height and waist circumference to assess of the prevalence of overweight/obesity and increased waist circumference in overweight working populations. However, there were considerable individual differences in the accuracy of self-reported anthropometrics. Direct measurements should therefore be used to correctly classify individuals as overweight or obese.

EFFECTIVENESS OF THE INTERVENTION

Chapter 4 considers the results on body weight, waist circumference, diet and physical activity, directly after conclusion of the intervention at six months. Because of missing data, multiply imputed datasets were created for the main analyses of changes in body weight. We found that body weight reduced by 1.5 kg in the phone group and by 0.6 kg in the internet group, compared with the control group. In study participants who had complete data, weight and waist circumference in the phone group were reduced with 1.6 kg and 1.9 cm respectively, 27% vs. 11% had lost at least 5% of their body weight, fat intake decreased with 1 fat point (representing 1 to 4 grams of fat) per day and physical activity increased with 866 MET-minutes (equivalent to 108 minutes cycling at 19-22 km/hour or 289 minutes walking at 4 km/hour) per week, compared with the control group. The internet intervention resulted in a weight loss of 1.1 kg, a reduction in waist circumference of 1.2 cm, and 22% vs. 11% losing at least 5% of their body weight in comparison with the control group. No statistically significant differences between the intervention groups and the control group were seen for the consumption of fruit and vegetables. The phone group appeared to have more and larger changes than the internet group, but direct comparisons between these groups revealed no differences. Consequently, we concluded that at six months lifestyle counseling by phone and e-mail is effective in producing small average weight losses in overweight employees.

In chapter 5 we examined the effectiveness of the intervention with regard to the same outcomes two years after baseline. In the main analyses, in which missing body weight data were multiply imputed for 43% of the participants, no differences in weight control were observed between the intervention groups and the control group. However, in participants with complete data, a weight reduction of 1.2 kg in the internet group compared to the control group was seen. Also, in participants with complete data, phone group participants were more likely to lose 5% of their body weight than control group participants. Participants who completed the study had been counseled on more modules than participants for whom data was missing. The comparison of waist circumference, fat and vegetable consumption, and physical activity between groups showed no statistically significant differences, although the direction of the differences was generally in favor of the intervention groups. Again, no differences were found between the two counseling modes except for weight gain following the intervention period. Corrected for weight loss during the intervention phase, participants in the internet group gained 1 kg body weight less than participants in the phone group. In conclusion, the internet intervention could be effective for small, but sustained long term weight losses in those participants who engaged in the program with a median of five (out of ten) counseling sessions. The results further suggest that the internet intervention is more effective in preventing weight regain than the phone intervention. However, due to large amounts of missing data, no robust conclusions can be drawn.

We also studied the effectiveness of the intervention on the cardiovascular risk factors body weight, waist circumference, sum of skinfolds (a measure of body fatness), blood pressure, total blood cholesterol and aerobic fitness in a subsample of each study group, after six months and two years. These results are reported in chapter 6. Analyses were done for 141/276 participants randomized to the subsample. No differences were found between the study groups, except for lowered total blood cholesterol, -0.23 mmol/l, between the phone and control group at six months. These results indicate limited effectiveness of the lifestyle intervention in modifying cardiovascular risk in overweight employees not selected for known comorbidities.

ECONOMIC EVALUATION OF THE INTERVENTION

Chapter 7 concerns the economic evaluation of the lifestyle intervention from a societal perspective, after two years. We assessed cost-effectiveness for body weight loss and the cost-utility of the two versions as compared with the control intervention. Missing data were multiply imputed; 976/1386 (70%) had (partially) missing data on body weight or costs. The phone intervention did not appear cost-effective. The mean incremental cost-effectiveness ratios (ICERs) of the internet intervention were €16/kg weight loss and €1337/QALY gained. The probability that the internet intervention was cost-effective at a ceiling ratio of €20,000 per QALY was 60%. In conclusion, the internet program with e-mail counseling showed promising results, but firm conclusions cannot be drawn due to high loss to follow-up.

DISCUSSION AND CONCLUSION

The final chapter, chapter 8, presents a summary of the main findings of this thesis. We discuss methodological considerations; make recommendations for further research and consider implications for public and occupational health.

Strengths of the study include the design: a randomized controlled trial in a real-world setting; the use of multiple imputation for missing data; and the long follow-up period after discontinuation of the intervention. Some limitations of the study concern poor adherence to the intervention; the use of self-reported behavioral outcomes; and high loss to follow-up, in particular at two years after baseline.

Future research should be directed towards developing methods for collecting anthropometric and lifestyle behavior data that are more valid than the current self-report methods, and appropriate for use in large-scale studies. More emphasis should be placed on preventing dropout from weight-control studies and approaches to increase retention to trials should be sought. With regard to distance-counseling programs, further study should elucidate which elements influence their effectiveness and continued use. Furthermore, personal characteristics of users that determine initial and continued engagement should be studied.

The study showed that programs initiated in the work setting can attract substantial numbers of employees and therefore can have an impact on public and occupational health. It is unlikely that one intervention will fit everybody who wants to change their lifestyle habits. A variety of programs and methods is needed. The 'Leef je Fit' intervention is a candidate to add to this assortment of programs in occupational health care.

SAMENVATTING

ALIFE@WORK
DE EFFECTEN VAN EEN LEEFSTIJLPROGRAMMA MET BEGELEIDING OP AFSTAND VOOR GEWICHTSCONTROLE BIJ WERKNEMERS

ACHTERGROND

Overgewicht, waarvan obesitas in het bijzonder, is een belangrijk probleem voor de volksgezondheid. Overmatig gewicht is geassocieerd met afwijkingen zoals hoge bloeddruk, verhoogd cholesterolgehalte en afwijkingen in de andere bloedvetten, hart- en vaatziekten, diabetes type 2, diverse soorten kanker, artrose en leververvetting. Wereldwijd is het aantal mensen met overgewicht sterk gestegen. Preventie en behandeling van overgewicht zijn daarom van belang, om een toename in overgewichtgerelateerde aandoeningen te voorkomen.

De werkplek is een aantrekkelijke setting om overgewicht bij een grote groep mensen aan te pakken. Toch is het in Nederland niet gebruikelijk om werknemers met overgewicht een leefstijlprogramma aan te bieden. In het buitenland zijn eerder wel programma's voor te zware werknemers ontwikkeld en onderzocht. De verschillende programma's gebruikten verschillende methoden en het effect ervan was ook niet eenduidig. Bovendien bleek dat werknemers moeite hebben met deelname, omdat ze geen tijd hebben of niet naar de locatie waar het programma plaatsvindt kunnen komen. Programma's die worden aangeboden via telefoon en internet zouden deze laatste barrière kunnen slechten. Bij andere doelgroepen hadden dergelijke programma's veelbelovende resultaten op leefstijlverandering en gewichtafname.

In de ALIFE@Work studie werd een leefstijlprogramma voor werknemers met overgewicht ontwikkeld: 'Leef je Fit'. Het programma voorzag in begeleiding op afstand via telefoon of e-mail. Dit proefschrift beschrijft de effectiviteit, kosteneffectiviteit en kostenutiliteit van dit programma, in vergelijking met het aanbieden van algemene leefstijlbrochures.

OPZET VAN DE STUDIE

In hoofdstuk twee wordt de opzet van de ALIFE@Work studie toegelicht. Het was een gerandomiseerd onderzoek met een controlegroep. De onderzoekspopulatie bestond uit 1386 werknemers van zeven Nederlandse bedrijven, allen met een Body Mass Index (BMI) van 25 kg/m^2 of hoger. Deelnemers werden naar drie studiegroepen gerandomiseerd: een controlegroep bestaande uit 460 deelnemers, een telefoongroep met 462 deelnemers en een internetgroep met 464 deelnemers.

De Leef je Fit interventie was gebaseerd op strategieën uit de cognitieve gedragstherapie. In tien modules werden de deelnemers door het proces van verbetering van hun voeding en lichamelijke activiteit geleid. Opdrachten in iedere module hielpen de deelnemer om de strategieën toe te passen in het dagelijks leven. De telefoongroep ontving de modules in schriftelijke vorm. De internetgroep had toegang tot een website. Na afronding van een module ontvingen de deelnemers feedback van hun persoonlijke counselor, per telefoon of per e-mail, afhankelijk van de groep waarbij ze waren ingedeeld. Deze begeleiding was zes maanden beschikbaar. Daarnaast ontvingen alle deelnemers algemene brochures over leefstijl en overgewicht. De controlegroep kreeg geen begeleiding.

De belangrijkste uitkomstmaat van het onderzoek was lichaamsgewicht. Andere uitkomstmaten waren: voeding en lichamelijke activiteit, middelomtrek, de som van vier huidplooien, bloeddruk, cholesterolgehalte en fitheid. Secundaire uitkomstmaten van de studie waren kostenutiliteit en kosteneffectiviteit. Lichaamsmaten werden bij de nulmeting en na 6 en 24 maanden door onderzoekspersoneel bepaald. Zelfgerapporteerde gegevens werden via vragenlijsten gemeten bij de nulmeting en na 6, 12, 18 en 24 maanden.

NAUWKEURIGHEID VAN ZELFGERAPPORTEERDE LICHAAMSMATEN

In hoofdstuk 3 presenteren we het antwoord op een secundaire vraag van dit onderzoek, namelijk: hoe nauwkeurig rapporteert een steekproef van werkende Nederlandse volwassenen hun lichaamsgewicht, lichaamslengte en middelomtrek? Om deze vraag te beantwoorden vergeleken we zelfgerapporteerde gegevens met metingen die door het onderzoekspersoneel waren uitgevoerd.

We vonden dat lichaamsgewicht gemiddeld 1,4 kg lager werd gerapporteerd dan was gemeten. Deelnemers meldden daarnaast dat ze 0,7 cm langer waren dan gemeten. Omdat de BMI berekening gebaseerd is op gewicht ten opzichte van de lengte, leverden de zelfgerapporteerde gegevens dan ook een lagere BMI op dan de gemeten gegevens. Het verschil was 0,7 kg/m^2. De middelomtrek werd 1,1 cm hoger gerapporteerd. Ondanks deze verschillen was de overeenkomst tussen de zelfrapportage en de metingen voldoende om zelfgerapporteerde lengte, gewicht en middelomtrek te gebruiken om de prevalentie van overgewicht c.q. obesitas en een te grote middelomtrek te bepalen in werkende volwassenen. Wel waren er aanmerkelijke individuele verschillen in de nauwkeurigheid van de zelfrapportage. Om te bepalen of een individu te zwaar is en een te grote middelomtrek heeft, bevelen we daarom metingen in de spreekkamer en door getraind personeel aan.

EFFECTIVITEIT VAN HET LEEFSTIJLPROGRAMMA

Effecten op lichaamsgewicht, middelomtrek, voeding en lichamelijke activiteit die direct na afloop van de zes maanden durende interventie optraden, worden gepresenteerd in hoofdstuk 4. Voor deelnemers die niet aan de vervolgmeting hadden deelgenomen, werd het missende lichaamsgewicht bepaald met multipele imputatie. Ten opzichte van de controlegroep was in de telefoongroep het lichaamsgewicht met 1,5 kg afgenomen en in de internetgroep met 0,6 kg. Verder keken we naar de effecten onder de deelnemers die aan alle metingen hadden deelgenomen en die alle vragenlijsten hadden ingevuld. In de telefoongroep was de gewichtsafname onder deze deelnemers 1,6 kg, 27% (t.o.v. 11% in de controlegroep) was 5% of meer van het startgewicht verloren, de middelomtrek nam met 1,9 cm af, de vetconsumptie nam met 1 tot 4 gram af en de lichamelijke activiteit nam toe met 866 MET-minuten per week (dit komt overeen met 108 minuten fietsen met een snelheid van 19-22 km/uur of 289 minuten wandelen met 4 km/uur), vergeleken met de controlegroep. De internetmethode resulteerde in een gewichtsverlies van 1,1 kg waarbij 22% van de deelnemers 5% of meer gewicht verloren en de middelomtrek was 1,2 cm afgenomen. In beide interventiegroepen werden geen effecten gevonden op fruit- en groenteconsumptie. Een directe vergelijking tussen de telefoongroep en de internetgroep leverde geen verschillen op. Onze conclusie is dat een programma met zes maanden leefstijlcounseling per telefoon of e-mail resulteert in een kleine gewichtsafname onder werknemers met overgewicht.

Hoofdstuk 5 betreft de lange termijnresultaten. In de analyse waarin voor 43% van de deelnemers missende gewichtsgegevens werden geïmputeerd, werden geen verschillen tussen de groepen gezien. Echter, onder deelnemers met complete uitkomsten had de internetgroep 1,2 kg meer gewicht verloren en in de telefoongroep waren meer deelnemers die 5% of meer gewichtsafname hadden, vergeleken met de controlegroep. Wel volgden deelnemers met complete uitkomsten meer counselingsessies dan deelnemers met missende metingen. Er waren geen statistisch significante verschillen in de andere uitkomstmaten hoewel de richting van de verschillen vaak ten gunste van de interventiegroepen uitviel. De twee interventiegroepen verschilden in gewichtstoename van elkaar: gecorrigeerd voor de gewichtsveranderingen tijdens de interventieperiode, namen deelnemers in de internetgroep 1 kg minder toe in gewicht dan de deelnemers uit de telefoongroep. In conclusie: voor werknemers die het internetprogramma redelijk actief volgen zou dit een geschikte methode kunnen zijn om blijvend een kleine gewichtsafname te bewerkstelligen. Ook lijkt het internetprogramma effectiever in het voorkomen van gewichtstoename dan het telefoonprogramma. Doordat veel deelnemers niet aan alle metingen deelnamen zijn echter geen harde conclusies te trekken.

Ook onderzochten we cardiovasculaire effecten in een subgroep waarbij we extra lichaammaten hadden gemeten, namelijk de som van vier huidplooien (indicatief voor het lichaamsvetpercentage), bloeddruk, cholesterolgehalte en fitheid, te vinden in hoofdstuk 6. Analyses werden uitgevoerd voor de 141/276 deelnemers die aan alle metingen (0, 6 en 24 maanden) hadden deelgenomen. Er werden geen verschillen gevonden tussen de groepen, met uitzondering van een -0,23 mmol/l lager cholesterolgehalte in de telefoongroep dan in de controlegroep, meteen na de interventie. De leefstijlinterventie verbetert het cardiovasculair risico daarom niet onder werknemers met overgewicht die niet wegens andere risicofactoren zijn geselecteerd.

ECONOMISCHE EVALUATIE VAN HET LEEFSTIJLPROGRAMMA

Hoofdstuk 7 betreft de economische evaluatie van de interventie. Deze werd uitgevoerd vanuit het perspectief van de maatschappij. De kosteneffectiviteit voor gewichtsverlies en de kostenutiliteit van beide varianten werd vergeleken met het alleen verstrekken van leefstijlbrochures (controlegroep). 976/1386 (70%) van de deelnemers had gedeeltelijk missende waarden voor lichaamsgewicht of voor kosten. Missende waarden werden multipel geïmputeerd. Er waren geen verschillen in kosten tussen de groepen. Het telefoonprogramma was niet kosteneffectief. Voor het internetprogramma waren de maatschappelijke meerkosten om 1 kg extra gewichtsafname te bewerkstelligen ten opzichte van de controle-interventie €16/kg, terwijl het €1337 extra kostte om één voor de kwaliteit van het leven gecorrigeerd levensjaar (QALY) te winnen. Wanneer maatschappelijke beslissers bereid zijn om €20.000 te betalen per QALY, is de kans dat het internetprogramma kosteneffectief is 60%. Dit zijn veelbelovende resultaten, maar doordat er veel missende waarden waren zijn harde conclusies niet te trekken.

DISCUSSIE

In het laatste hoofdstuk worden de methodologische sterktes en zwaktes van het onderzoek besproken, doen we aanbevelingen voor verder onderzoek en bespreken we de implicaties van de onderzoeksresultaten voor de volksgezondheid en de bedrijfsgezondheidszorg.

Een sterke kant van het onderzoek was de opzet; een gerandomiseerde studie met controlegroep. Andere goede punten waren het gebruik van multipele imputatie om missende waarden aan te vullen en de lange follow-up duur na afloop van het programma. Beperkingen betroffen onder andere de matige deelname aan het leefstijlprogramma, het gebruik van zelfgerapporteerde uitkomsten en de grote hoeveelheid missende waarden, vooral na twee jaar.

Toekomstig onderzoek zou zich moeten richten op methoden om lichaamsmaten en leefstijlgedrag te meten die meer valide zijn dan zelfrapportage en die toepasbaar zijn in grootschalig onderzoek. In onderzoek naar het effect van gewichtsprogramma's zou meer nadruk moeten liggen op het voorkomen van uitval uit de studie en er zou moeten worden onderzocht hoe dit te voorkomen is. Er zou ook onderzoek gedaan moeten worden naar de interventie-elementen die het gebruik van counseling op afstand stimuleren en die de effectiviteit ondersteunen. Daarnaast dient onderzoek te worden gedaan naar de persoonskenmerken die van invloed zijn op deelname aan dergelijke programma's.

Deze studie toont aan dat leefstijlprogramma's op de werkplek aantrekkelijk zijn voor grote aantallen werknemers en dat deze programma's daardoor invloed kunnen hebben op de gezondheid van werknemers en op de volkgezondheid. Het is echter niet waarschijnlijk dat één soort programma iedereen zal aanspreken of bij iedereen zal werken. Een verscheidenheid van programma's en methoden is nodig. Het Leef je Fit programma zou een geschikte toevoeging kunnen zijn.