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The steps to health employee weight management randomized control trial: Rationale, design and baseline characteristics ☆

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ABSTRACT

Background: The workplace can be an important setting for addressing obesity. An increasing number of employers offer weight management programs.
Purpose: Present the design, rationale and baseline characteristics of the Steps to Health study (STH), a randomized trial to evaluate the effectiveness of two preexisting employee weight management programs offered at Duke University and Medical Center.
Methods: 550 obese (BMI ≥30) employee volunteers were randomized 1:1 to two programs. Baseline data, collected between January 2011 and July 2012, included height/weight, accelerometry, workplace injuries, health care utilization, and questionnaires querying socio-cognitive factors, perceptions of health climate, physical activity, and dietary intake. In secondary analyses participants in the two programs will also be compared to a non-randomized observational control group of obese employees.
Results: At baseline, the mean age was 45 years, 83% were female, 41% white, and 53% black. Mean BMI was 37.2. Participants consumed a mean of 2.37 servings of fruits and vegetables per day (in the past week), participated in 11.5 min of moderate-to-vigorous physical activity, and spent 620 min being sedentary.
Conclusion: STH addresses the need for evaluation of worksite interventions to promote healthy weight. In addition to having direct positive effects on workers' health, worksite programs have the potential to increase productivity and reduce health care costs.

1. Introduction

Overweight and obesity are epidemic in the U.S., with 72% of men and 64% of women aged 20 or older having a body mass index (BMI) of 25 kg/m^2 or greater [1]. The consequences and cost of obesity to both individuals and society are substantial [2–9]. Efforts are clearly needed to prevent and decrease overweight and obesity.

Traditional obesity control efforts often do not reach large numbers of individuals, and few are able to sustain weight loss long-term [10–16]. Several review articles have assessed the effects of behavioral weight loss interventions, and while results vary somewhat, long-term weight loss does not occur for most [12–16]. An approach that has the potential to reach a large group of adults in the population is the provision of

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intervention and prevention programs offered through the worksite, as more than one hundred million Americans spend most of their waking hours at work [17]. Furthermore, worksites generally function as systems for communication, education and social support, and offer a unique recurring setting for repeated contacts with program participants as well as a social environment that can influence norms and expectations [17,18].

Reviews of worksite program studies addressing obesity prevention and weight loss show some evidence of success [17,19]. Unfortunately, few studies have followed up participants after the end of the intervention period. Additional studies have been conducted, but only a small number of these included long-term follow-up of outcomes or had strong methodological designs [18,20]. Available evidence indicates that there is value in worksite weight loss programs. In general, such programs reach individuals that otherwise may not have sought clinical intervention and yield short-term weight loss of 1–2 lb per week [17]. A few studies have been able to demonstrate a sustained effect over the course of 1–2 years [21–23]. but none of these have included a traditional, randomly assigned comparison group.

In terms of costs to employers, one large study concluded that obese workers had 21% higher health care costs than those of recommended weight [19] and that obesity, smoking, and stress were the costliest modifiable risk factors to the employer-sponsored health plan [20,21]. Of particular interest is the increased rate of workplace injuries related to obesity. Although the relationships between lifestyle factors, obesity, work, and injuries are complex [22] and span both work and the private sphere, BMI is strongly associated with rates of workplace injuries.

Numerous lifestyle interventions have applied social cognitive theory (SCT) to guide intervention development [24,25], and this has been the dominant theoretical model for many worksite obesity prevention programs as well [19]. SCT emphasizes the importance of reciprocal determinism—the notion that individual behavior is in a reciprocal relationship with a person's characteristics or beliefs and the environment. In lifestyle interventions targeting diet, physical activity or weight this often translates to a focus both on changing individual capabilities and beliefs (e.g., improving dietary skills or improving self-efficacy for physical activity) as well as aspects of the environment supportive of these (e.g., providing opportunities to practice new dietary/physical activity behaviors). Motivational Interviewing (MI) [26] has also been used in programs that target SCT constructs [27–29]. MI techniques can be useful in worksite interventions targeting lifestyle behaviors by helping individuals overcome barriers to participation in weight management [27,28]. While SCT has some limitations (e.g., it is so comprehensive and lacking in specificity that it is used to explain all types of phenomena), it remains a robust framework upon which to design health behavior interventions.

In this manuscript, we present the design, rationale and selected baseline characteristics of participants in the Steps to Health study (STH), a randomized trial to compare and evaluate the effectiveness of two existing employee health programs aimed at weight loss and management offered at Duke University and Medical Center.

2. Materials and methods

2.1. The Duke Health and Safety Surveillance System

Our research team previously developed and implemented a model health and safety surveillance system for the Duke University and Health System employee population: the Duke Health and Safety Surveillance System (DHSSS). It was created around ongoing health promotion programs, occupational safety and health programs, human resource data, and health benefits data systems [30]. A key feature of this system is its ability to link data from multiple systems at the individual level in order to define both health risk profiles [29] and health outcomes. DHSSS data elements are updated at least annually, more frequently if needed for specific projects, and allow for cross-sectional and longitudinal analyses to identify populations at risk and to evaluate intervention and prevention programs [31]. Duke is self-insured for employee medical coverage, and health insurance benefits include inpatient and outpatient, pharmacy, and mental health services provided through several vendors. Over 90% of eligible employees participate in one of the Duke health care plans. The DHSSS allows us to evaluate health insurance claims data for the current study.

2.2. Study overview and objectives

The Steps to Health (STH) study is a randomized controlled trial designed to evaluate the effects of two different pre-existing employee health programs for weight management (Weight Management [WM] and Weight Management Plus [WM+]). These programs were based on employee health programs developed by Johnson & Johnson [32]. The programs aim to help employees achieve weight loss and maintain healthy weights. The two programs are grounded in current health promotion theories but differ in focus (educational vs. behavioral), intensity, frequency, and resource requirements. This study was approved by the Duke Medicine IRB and informed consent was obtained from all participants.

The primary aim of the study is to compare body mass loss between participants in the two programs. We hypothesize that employees enrolled in the WM+ program will demonstrate greater reductions in BMI than employees in WM (10% overall reduction in body mass for participants in WM+ compared to a 5% reduction for those in WM). Secondary aims are to compare the two programs on changes in social-cognitive factors, lifestyle behaviors, workplace injuries, health care utilization, absenteeism rates, and overall impact on program costs. The hypothesis is that participants in the WM+ program will demonstrate greater improvements in social-cognitive and lifestyle factors, greater health care utilization, and a larger decrease in absenteeism than those in the WM program. In secondary analyses, participants in both programs will also be compared to a non-randomized observational control group of employees on most of these outcomes. These are employees who would have met inclusion criteria but did not participate in the Steps to Health study. The study design is depicted in Fig. 1. We hypothesize that employees in either weight management program will demonstrate greater reductions in BMI than the employees in the observational control group.

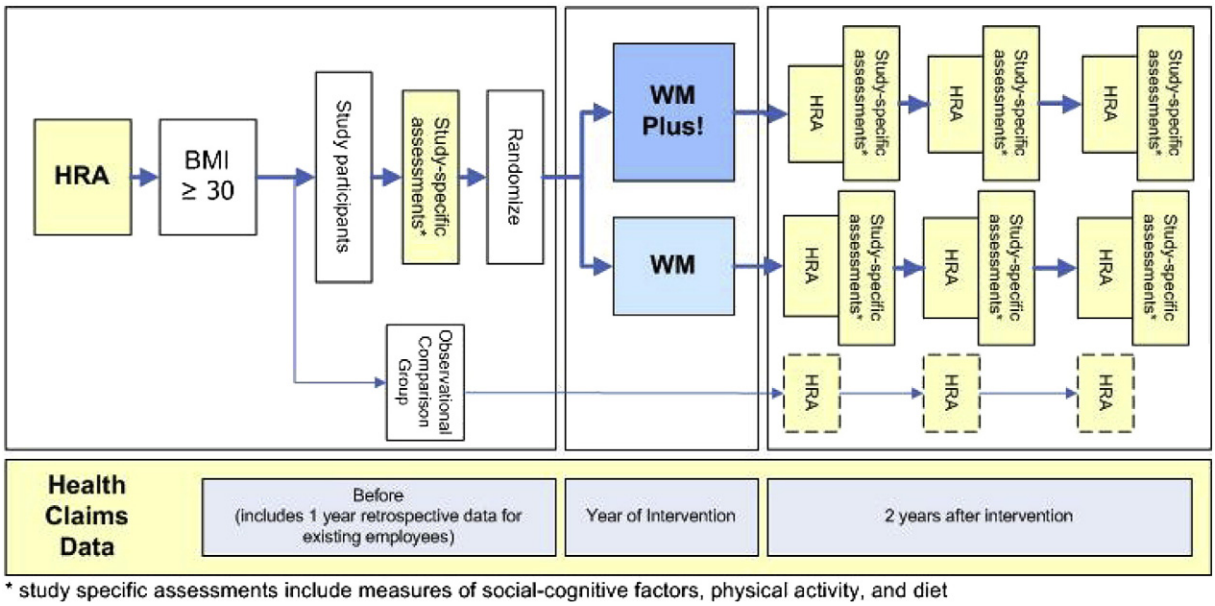

Fig. 1. Study design. WM, the Weight Management study arm; WM Plus! (WM+), the Weight Management Plus study arm. Data collected between January 2011 and July 2012 at Duke University and Medical Center, Durham, NC.

2.3. Participants

The target population consists of obese (BMI ≥ 30) employee volunteers at Duke University and Medical Center. To be eligible for the STH study, employees must be benefit-eligible (work at least 20 h per week) and be enrolled in one of the health insurance programs offered through Duke at the time of randomization. Additionally, they should not be planning to leave Duke during the 12 months following enrollment in the study. Current pregnancy is an exclusion criterion, as is enrollment in the weight management program as a means to qualify for bariatric surgery.

2.4. Screening and enrollment

Employees were screened for eligibility during annual Health Checks. Over 7,000 Duke employees complete a Health Check each year via three mechanisms: 1) at new employee orientation, 2) voluntarily, through a roving health screening unit, and 3) via appointment in the employee health offices. The Health Checks include the following domains: 1) measured height and weight, 2) total cholesterol, 3) blood pressure, 4) blood glucose, and 5) self-reported Health Risk Assessment questionnaires that include brief measures of diet and physical activity. The Health Check takes place during work hours, requires approximately 30 min to complete, and is facilitated by an RN. Enrollment and baseline data collection occurred between January 2011 and July 2012.

During this Health Check, employees with a measured BMI ≥ 30 were informed about their eligibility for one of the two existing weight management programs. They were also provided basic information about the study, which was available only to employees choosing to enroll in one of the programs. If the employee was interested, the employee was referred to study staff to obtain a detailed study description and provide written consent. Participants were randomized (1:1) by study staff to one of the two weight management programs (WM or WM+) once they completed all baseline measures. Randomization was done using a simple computer generated randomization scheme.

2.5. Intervention

This study evaluates two existing employee weight management programs offered at Duke: Weight Management and Weight Management Plus. Fig. 2 presents the details of the two programs, both of which were based on programs developed by Johnson & Johnson [32]. Previous research points toward the benefit of individualized counseling, embedded in a larger health promotion program, to affect the greatest amount of change in participants [33–37]. Also, multiple contacts over an extended period of time (6–12 months) have been shown to lead to better outcomes in participants [18,36]. Both programs being evaluated in the current study are approximately 12 months long, and are embedded in the larger employee wellness program at Duke, but the programs differ in intensity and degree of personalization.

2.5.1. Weight Management

Participants randomized to Weight Management (WM) receive an educational program targeting healthy lifestyle changes for weight loss. They receive 1 face-to-face meeting with a counselor in the first month, followed by monthly mailings of health education materials. They have two telephone counseling sessions (at months 6 and 12), that are coupled with feedback on self-reported weigh.

Feature	Detailed component		Frequency/mode	
	WM	WM+	WM	WM+
Counseling	• supportive	• Motivational Interviewing • stage-based plans • goal setting and skill building	• semi-annually • phone	• monthly • phone & in-person
Health education materials	• generic materials	• targeted materials	• monthly • e-mail	• monthly • phone & in-person
Resources within workplace environment	• provide written descriptions and contact info	• Provide information on resources specific to goals & interests • enroll in groups and programs • schedule to meet with nutritionist/exercise physiologist	• monthly • e-mail	• monthly • phone & in-person
Biometric feedback	• total cholesterol, blood glucose, weight, blood pressure	• total cholesterol, blood glucose, weight, blood pressure	• semi-annually	• quarterly
Social support networking	• encourage	• target existing networks • facilitate establishment of new social support networks	• monthly • email	• monthly • phone & in-person
Reward (token economy)	• STH dollars for assessments	• STH dollars for assessments • STH dollars for meeting intervention targets	• semi-annually	• monthly

Fig. 2. – Relative intensity of intervention components—WM vs. WM+. WM, the Weight Management study arm; WM+, the Weight Management Plus study arm. Data collected between January 2011 and July 2012 at Duke University and Medical Center, Durham, NC.

2.5.2. Weight Management Plus

Participants randomized to Weight Management Plus (WM+) receive an intensive behavioral intervention. The intervention is stage-based and works with the participant at his/her level of readiness to change using counseling based on motivational interviewing [38]. The program borrows structure and components from the Johnson & Johnson Health and Wellness Program [39] and, consistent with the Expert Panel on the Identification, Evaluation, and Treatment of Overweight in Adults, [40] has an overall goal of a 10% reduction in weight over the 12-month program. Participants in WM+ are offered 1) monthly counseling sessions (face-to-face in months 1, 4, 8, and 12, and the rest via telephone), 2) meetings with an exercise physiologist in months 2 and 5 to set goals and troubleshoot barriers related to physical activity, 3) quarterly biometric feedback, 4) targeted health education materials, and, 5) information and active linking with various Duke programs and wellness resources. Participants are also encouraged to make use of eHealth trackers for diet and weight.

2.6. Assessments

Assessments are completed at entry to the study (baseline), end-of-intervention (~12 months post-baseline, AKA "follow-up 1"), one year post-intervention (~24 months post-baseline, AKA "follow-up 2") and two years post-intervention (~36 months post-baseline, AKA "follow-up 3"). All participants receive monetary incentives (totaling $100) for completing study assessments (in addition to modest tokens for program participation).

2.6.1. Anthropometrics

Standardized, measured weights and heights are collected using a Seca portable stadiometer (baseline only) and a Tanita BWB-800 scale (at all time points). Participants are weighed and measured wearing minimal street clothing and without shoes.

2.6.2. Diet and activity

At all time points, participants complete a self-report questionnaire that includes items regarding daily intake of food items potentially related to obesity. The National Cancer Institute (NCI) fruit and vegetable screener estimates the daily intakes of both fruits and vegetables [41,42]. The NCI fat screener was used to estimate the percentage of energy intake derived from fat [43,44]. Additional questions ask participants to estimate intake of sodas, other sweetened beverages, and fast food meals per day.

At baseline and follow-up 1, time spent being physically activity or sedentary are measured using accelerometers [45]. The Actical accelerometer (model #198-0302, Mini-Mitter Co. Inc., Bend, Oregon) is a small, lightweight multi-axial accelerometer sensitive to movement in all directions. Participants are asked to wear the belted monitors on the right hip during waking hours for 7 consecutive days. Data reduction programs were used to determine the means number of minutes of MVPA and sedentary time per day. These programs were based off the National Health and Nutrition Examination Survey (NHANES) [46] using the cut-points of $\geq$1535 counts/epoch for MVPA and <100 counts/epoch for sedentary time [47]. Prior research has shown the Actical count [48] and step functions [49] to be reliable. Self-reported physical activity was also assessed by the International Physical Activity Questionnaire (IPAQ) (long last 7 days self-administered format) [50].

2.6.3. Social–cognitive factors

For this study we created a measure of social support with items assessing how much participants felt they could count on other people close to them to provide support, with response options from 1 ("Not at all") to 3 ("A lot"). Subscales of this measure included emotional (e.g., "How much could you count on people close to you to encourage you to eat health foods?" [3 items, $\alpha = 0.74$]), informational (e.g., "How much can you count on people close to you to tell you about ways to increase your physical activity?" [3 items, $\alpha = 0.92$]), and instrumental support (e.g., "How much can you count on people close to you to help you stick with weight management goals?" [3 items, $\alpha = 0.63$]). Self-regulation of physical activity was assessed using the Exercise Goal-Setting Scale [51] (10 items, $\alpha = 0.91$[in our sample]) and the Exercise Planning and Scheduling Scale (10 items, $\alpha = 0.69$) [51]. We created similar scales to measure goals and plans for healthy eating: items in our healthy eating goals measure (10 items, $\alpha = 0.90$) include "I usually set dates for achieving my healthy eating goals" and "If I do not reach a healthy eating goal, I analyze what went wrong" and directly mirror those in the physical activity goals scale. Items in the healthy eating plans scale (10 items, $\alpha = 0.65$) include "I plan my meals ahead of time" and "I keep a food journal and write down everything I eat and drink throughout the day". Self-efficacy was assessed using the Eating Habits Confidence Survey (EHCS) and Exercise Confidence Survey (ECS) [52]. Subscales of the EHCS used were "sticking to it" (5 items, $\alpha = 0.88$), "reducing calories" (5 items, $\alpha = 0.78$), and "reducing fat" (5 items, $\alpha = 0.80$). Subscales of the ECS are "sticking to it" (5 items, $\alpha = 0.88$), and "making time for exercise" (5 items, $\alpha = 0.51$). The Impact of Weigh on Quality of Life [53] scale was used to assess how much obesity effected physical functioning (11 items, $\alpha = 0.92$) and self-esteem (7 items, $\alpha = 0.94$).

2.6.4. Health risks/co-morbid disorders

During the annual Health Check a nurse measures blood pressure (BP), glucose, and cholesterol. As part of the self-reported HRA, employees report current illness diagnoses and medications they take. Based on this information we identified four co-morbid health conditions: diabetes, dyslipidemia, prehypertension, and hypertension. Diabetes was defined as either a blood glucose $\geq$ 200 mg/dl, self-report of a diagnosis of Type 2 diabetes, or taking a diabetes medication [54]. Dyslipidemia was defined as a cholesterol level $\geq$ 200 mg/dl, endorsing a diagnosis of high cholesterol, or taking cholesterol medications [55]. Prehypertension was defined as having a measured systolic BP between 120 and 139 mm Hg and/or a diastolic BP between 80 and 89 mm Hg [56]. Hypertension was defined as a systolic BP $\geq$ 140 mm Hg and/or a diastolic BP $\geq$ 90 mm Hg, endorsing a diagnosis of high blood pressure, or taking blood pressure medication [56].

2.6.5. Covariates

Demographic factors including racial/ethnic group, income, education, health insurance status, and marital status are assessed at baseline through the questionnaire or from DHSSS records. Work location (both physical location and department/unit), and full-time or part-time status are also assessed from DHSSS records.

2.7. Observational comparison group

Data from an observational comparison group, consisting of employees who are eligible for the main study (BMI $\geq$ 30) but do not take part, are also collected. In secondary analyses, data collected from all eligible employees (those participating in the RCT as well as those who are eligible for, but do not to take part in, the RCT) will be compared to the participants in the two WM programs. The data from the observational comparison group include a baseline HRA, any other HRAs they complete in the following 3 years, their workers' compensation claims (workplace injuries), and their health insurance claims. This will allow us to not only contrast the two programs in the RCT with one another, but also to control for any secular changes in HRA variables (including BMI), workers' compensation claims, and health claim reimbursements.

2.8. Statistical considerations

A total of 550 participants were randomized with equal allocation between the WM and WM+ programs. The program difference in BMI change from baseline to the 36-month follow-up, the primary endpoint, will be tested with a one-sided alpha of 0.025. With 275 participants per program, the t-test has 90% power when the true standardized mean arm difference is 0.29. According to Cohen [57], this effect size is "small" in size. We will use the method described by Senn [58] to select which covariates (age, race, gender, baseline BMI) to include when testing for the intervention effect. We will also test for program differences in change in psychosocial factors (social support, self-regulation, self-efficacy, and quality of life), physical activity, and dietary intake. Any participants lost to follow-up before the 36-month follow-up will be included in these analyses by imputing no change across time.

For each of the two programs, we will assess change in overall workplace injuries and health care utilization from the year before the intervention to the two years after the intervention. The programs will be compared to each other on these changes, and the changes of each program will be compared to changes in the observational control group. We will assess cost-effectiveness (cost of program plus workers compensation and other health claims reimbursement and absenteeism costs per BMI unit reduction) for the year of the intervention and the two following years. Prior to conducting analyses using the observational control group we will test for any baseline differences between the two intervention groups and this observational control group, and adjust for any significant differences in the analyses.

3. Baseline characteristics

Five hundred and fifty participants were randomized to the trial between January 2011 and July 2013, this represents 42% of people who attended a health screening during that time and had a measured BMI >30 (n = 1296). Participants had a mean age of 45 years (SD = 10.0), 83% were female (n = 457), and 53% were Black (n = 293). Obesity related comorbidities are common, especially dyslipidemia (20%, n = 111) and prehypertension/hypertension

(47%, n = 256). Baseline sociodemographic characteristics and co-morbid health risks for the study sample are presented in Table 1.

Table 2 presents the baseline psychosocial factors and health behaviors. Participants in the study consumed well below the 5 servings a day of fruits and vegetables recommended by the Centers for Disease Control and Prevention [59] (mean = 2.37, SD = 2.03). Intake of sugar sweetened beverages was high (mean = 29.02 ounces per day, SD = 36.94), as was the number of people reporting they ate fast food meals 2 or more times per week (41%, n = 223). The population was mostly sedentary (mean = 620.0 min per day, SD = 103.34), with MVPA well below the recommendations [60] (mean = 11.5 min per day, SD = 10.07). Table 3 presents the correlations for the primary outcomes and key secondary outcomes.

4. Discussion

Worksite interventions have the power to improve both individual employee health risk profiles and overall health care costs to employers [39,61,62] and can reduce employee absenteeism [63–65]. Of particular interest is the increased rate of workplace injuries related to obesity. Although the relationships between lifestyle factors, obesity, work, and injuries are complex [66] and span both work and the private sphere, BMI is strongly associated with rates of workplace injuries. Further, in obese persons, such injuries are associated with dramatic increases in lost workdays and workers' compensation costs—both medical and wage replacement (indemnity) costs—when compared with those of normal weight [67].

Previous successful studies of worksite health behavior change demonstrate that individualized behavioral counseling is not only a critical success factor in such programs [33–37] but can also be cost-effective in generalized wellness programs and cardiovascular risk factor interventions [68–70]. Although these positive outcomes have been demonstrated in other types of intervention programs, few studies have examined the costs and benefits associated specifically with obesity reduction through the worksite. In particular, there have been no studies demonstrating that weight reduction can lead to a decrease in workplace injuries and associated workers' compensation costs.

The Steps to Health study evaluates two weight management programs, originally conceived at Johnson & Johnson, that had been offered to obese Duke employees for several years. Both programs include multiple contacts over the year-long program, [18,36] include some amount of individual counseling, [33–35,37] and offer incentives for participation [17,36]. The study is responsive to the recommendations of the Surgeon General and the Task Force on Community Preventive Services by using the existing DHSSS to evaluate employee health insurance claims data, and by assessing the effects of the weight management programs on multiple outcomes, including productivity and absenteeism.

Baseline data shows that participants are not meeting the government recommendations for dietary intake or physical activity, [59,60] but they report high levels of self-efficacy, which suggests a good target for weight management interventions [71,72]. Participants reported that their health problems had very little effect on productivity at work, but they did report that their weight had some impact on their physical functioning and self-esteem.

The advantages of evaluating existing health promotion interventions include a) the wide program recognition, b) a robust system for identification and recruitment of eligible employees, and c) the ability to more easily engage participants in other collaborative Duke employee health programs (like the walk/run club). Another benefit is the vested support from management for the employee health program. Overall, this support was high, but in practice has

Table 1
Baseline sample characteristics by arm.

Variable	Total (n = 550) % (n)		WM (n = 275) % (n)		WM + (n = 275) % (n)	
Gender						
Male	17	93	17	48	16	45
Female	83	457	83	227	84	230
Age						
<35	17	95	19	53	15	42
35–50	49	267	49	134	48	133
>50	34	188	32	88	36	100
Race						
White	41	227	42	115	41	112
Black	53	293	52	144	54	149
Other races	5	30	6	16	5	14
Ethnicity						
Hispanic	3	15	3	9	2	6
Baseline BMI (kg/m^2)						
Obese class I (30–34.9)	47	256	48	132	45	124
Obese class II (35–39.9)	26	145	25	70	27	75
Obese class III (40+)	27	149	27	73	28	76
Co-morbid health risks/diseases						
Diabetes	10	54	7	20	12	34
Dyslipidemia	35	195	35	95	36	100
Prehypertension	20	111	21	59	19	52
Hypertension	26	145	29	79	24	66

STH, the Steps to Health study arm; STH+, the Steps to Health+ arm; BMI, Body Mass Index.

Table 2
Baseline psychosocial factors and health behaviors by arm.

	Total			WM			WM+		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Psychosocial factors (range = 1 [low]–5 [high])									
Emotional support	546	1.22	0.66	273	1.22	0.75	273	1.23	0.55
Informational support	545	1.00	0.61	272	0.98	0.65	273	1.02	0.56
Instrumental support	543	0.85	0.62	272	0.87	0.71	271	0.82	0.52
Exercise Goals	543	2.13	0.90	271	2.10	0.89	272	2.16	0.92
Exercise Plans	543	2.28	0.72	271	2.26	0.64	272	2.29	0.78
Healthy Eating Goals	544	2.25	0.93	272	2.20	0.95	272	2.29	0.92
Healthy Eating Plans	544	2.27	0.70	271	2.36	0.78	272	2.37	0.62
Exercise self-efficacy—sticking to it	545	3.40	0.90	272	3.43	0.89	273	3.37	0.91
Exercise self-efficacy—making time	545	3.81	1.03	272	3.92	1.18	273	3.70	0.86
Eating habits self-efficacy—sticking to it	545	3.57	0.88	272	3.62	0.88	273	3.52	0.87
Eating habits self-efficacy—reducing calories	545	3.81	0.96	272	3.89	1.07	273	3.73	0.82
Eating habits self-efficacy—reducing fat	545	3.97	0.84	272	3.99	0.85	273	3.94	0.83
Impact of weight on quality of life									
Physical functioning (range = 11 [low impact]–55 [high impact])	542	23.01	9.43	270	22.52	9.32	272	23.50	9.54
Self-esteem (range = 7 [low impact]—35 [high impact])	540	18.48	8.18	268	18.83	8.29	272	18.14	8.06
Presenteeism (range = 0 [none]–10 [completely])									
How much did your health problems affect your productivity	496	1.08	1.98	245	1.03	1.86	251	1.12	2.09
Dietary intake									
Fruit and vegetable servings	548	2.37	2.03	274	2.52	2.14	274	2.22	1.92
% energy from fat	530	33.36	5.35	266	32.97	4.91	264	33.76	5.75
Ounces of sugar sweetened beverages	539	29.02	36.94	268	29.47	37.77	271	28.70	36.17
Physical activity and inactivity									
Mean minutes moderate/vigorous activity/day	492	11.53	10.07	249	11.31	9.7	243	11.74	10.42
Mean minutes sedentary time/day	492	620.03	103.34	249	614.59	104.38	243	624.86	102.16

STH, the Steps to Health study arm; STH +, the Steps to Health + arm.

been somewhat variable for participants across Duke. The primary disadvantage of evaluating existing interventions was that participants were confused about the distinction between the health promotion programs and our evaluation of the programs. Participants also exhibited a reluctance to be randomized, since prior to our study, they were able to select their program of choice: WM or WM+. The study staff also found that in spite of employees being a captive population, they were often hard to reach for completion of baseline measures. The gender imbalance in our study sample (overall 83% female) is also notable, and similar to the gender distributions in other weight management trials [73]. This distribution is consistent between the two weight management programs in this study, and we plan to take this imbalance into consideration in the analyses. Changes in physical activity levels, as measured by accelerometry, between the two intervention groups is one of the secondary aims of this study. Participants may react to wearing a monitor by changing their behavior, but this concern is minimal for this project as we plan to compare overall mean changes in activity from baseline and follow-up for each intervention group, and control for baseline level of activity.

For analysis of secondary aim outcomes related to health care utilization and absenteeism and presenteeism, participants in the two programs will be compared to an observational control group. These analyses may be limited by the fact that only participants in the two intervention groups were paid for their participation.

Evaluating established programs allows the results to be immediately applicable and relevant to employee health promotion programs at other institutions. Although all data are from the Duke University Health System and Duke

Table 3
Correlation matrix for key outcome variables.

	Age	BMI	Fruit and vegetable servings	% energy from fat	Activity counts from accelerometer	Emotional support	Informational support	Instrumental support	QOL—physical functioning
BMI	0.01								
Fruit and vegetable servings	0.07	−0.02							
% energy from fat	−0.11*	0.11*	−0.09*						
Activity counts from accelerometer	−0.02*	−0.14*	0.05*	−0.11*					
Emotional support	0.03	−0.06	0.08*	−0.11*	0.09*				
Informational support	−0.02	−0.05	0.05	−0.08	0.07	0.61*			
Instrumental support	−0.03	−0.09*	0.06	−0.09*	0.15*	0.48*	0.57*		
QOL—Physical functioning	0.14*	0.45*	−0.03	0.21*	−0.15*	−0.17*	−0.16*	−0.16*	
QOL—Self-esteem	−0.18*	0.14*	−0.03	0.03	0.06	−0.11*	−0.13*	−0.15*	0.46

* $p < .05$.

University, this employer is the second largest in North Carolina (33,705) [74], and the results should be generalizable given the breadth and diversity of the study sample in terms of sex, income, race/ethnicity, and occupational group - ranging from low-risk university jobs to more "dangerous" hospital jobs [30].

5. Conclusion

The National Institute for Occupational Safety and Health has traditionally targeted occupational safety issues. This focus has recently been complemented by increased attention to the overall health of workers, namely, health protection combined with health promotion [65,68–70,72,73,75]. Several ongoing initiatives target lifestyle issues, including tobacco control, alcohol and substance use, prevention of chronic disease, and (most relevant from the point of view of our study) obesity reduction through improved nutrition and increased physical activity. The Steps to Health study addresses the need for evaluation of worksite interventions to improve workers' health, in particular to promote healthy weight.

Conflicts of interest

None.

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References

[1] Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. JAMA 2010;303:235–41.
[2] Brown CD, Higgins M, Donato KA, Rohde FC, Garrison R, Obarzanek E, et al. Body mass index and the prevalence of hypertension and dyslipidemia. Obes Res 2000;8:605–19.
[3] Field AE, Coakley EH, Must A, Spadano JL, Laird N, Dietz WH, et al. Impact of overweight on the risk of developing common chronic diseases during a 10-year period. Arch Intern Med 2001;161:1581–6.
[4] Finkelstein EA, Fiebelkorn IC, Wang G. National medical spending attributable to overweight and obesity: how much, and who's paying? Health Aff; 2003 [Suppl. Web Exclusives].
[5] Finkelstein EA, Fiebelkorn IC, Wang G. State-level estimates of annual medical expenditures attributable to obesity*. Obes Res 2004;12:18–24.
[6] Finkelstein EA, Strombotne KL. The economics of obesity. Am J Clin Nutr 2010;91:1520S–4S.
[7] Quesenberry Jr CP, Caan B, Jacobson A. Obesity, health services use, and health care costs among members of a health maintenance organization. Arch Intern Med 1998;158:466–72.
[8] Renehan AG, Tyson M, Egger M, Heller RF, Zwahlen M. Body-mass index and incidence of cancer: a systematic review and meta-analysis of prospective observational studies. Lancet 2008;371:569–78.
[9] Tsai AG, Williamson DF, Glick HA. Direct medical cost of overweight and obesity in the USA: a quantitative systematic review. Obes Rev 2011;12:50–61.
[10] Turk MW, Yang K, Hravnak M, Sereika SM, Ewing LJ, Burke LE. Randomized clinical trials of weight-loss maintenance: a review. J Cardiovasc Nurs 2009;24:58.
[11] Caplan W, Bowman JD, Pronk NP. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. J Am Diet Assoc 2007;107:1755–67.
[12] Anderson JW, Konz EC, Frederich RC, Wood CL. Long-term weight-loss maintenance: a meta-analysis of US studies. Am J Cli Nutr 2001;74:579–84.
[13] Franz MJ, VanWormer JJ, Crain AL, Boucher JL, Histon T, Caplan W, et al. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. J Am Diet Assoc 2007;107:1755–67.
[14] Brownell KD, Jeffery RW. Improving long-term weight loss: pushing the limits of treatment. Behav Ther 1987;18:353–74.
[15] Curioni CC, Lourenco PM. Long-term weight loss after diet and exercise: a systematic review. Int J Obes Relat Metab Disord 2005;29:1168–74.
[16] Kramer FM, Jeffery RW, Forster JL, Snell MK. Long-term follow-up of behavioral treatment for obesity: patterns of weight regain among men and women. Int J Obes 1989;13:123–36.
[17] Hennrikus DJ, Jeffery RW. Worksite intervention for weight control: a review of the literature. Am J Health Promot 1996;10:471–98.
[18] Pelletier KR. A review and analysis of the clinical and cost-effectiveness studies of comprehensive health promotion and disease management programs at the worksite: update VI 2000–2004. J Occup Environ Med 2005;47:1051–8, doi:10.1097/01.jom.0000174303.85442.bf.
[19] Anderson LM, Quinn TA, Glanz K, Ramirez G, Kahwati LC, Johnson DB, et al. The effectiveness of worksite nutrition and physical activity interventions for controlling employee overweight and obesity: a systematic review. Am J Prev Med 2009;37:340–57.
[20] Pelletier KR. Clinical and cost outcomes of multifactorial, cardiovascular risk management interventions in worksites: a comprehensive review and analysis. J Occup Environ Med 1997;39:1154–69.
[21] Kelly KL. Evaluation of a group nutrition education approach to effective weight loss and control. Am J Public Health 1979;69:813–4.
[22] Kneip JK, Fox HM, Fruehling JK. A weight-control program for bank employees. J Am Diet Assoc 1985;85:1489–91.
[23] Perin LA. Behavior modification for weight control. J Occup Environ Med 1982;24:935–7.
[24] Anderson E, Winett R, Wojcik J. Self-regulation, self-efficacy, outcome expectations, and social support: social cognitive theory and nutrition behavior. Ann Behav Med 2007;34:304–12.
[25] Bélanger-Gravel A, Godin G, Vézina-Im LA, Amireault S, Poirier P. The effect of theory-based interventions on physical activity participation among overweight/obese individuals: a systematic review. Obes Rev 2011;12:430–9.
[26] Hettema J, Steele J, Miller WR. Motivational interviewing. Annu Rev Clin Psychol 2005;1:91–111.
[27] Butterworth S, Linden A, McClay W, Leo MC. Effect of motivational interviewing-based health coaching on employees' physical and mental health status. J Occup Health Psychol 2006;11:358–65.
[28] Martins RK, McNeil DW. Review of motivational interviewing in promoting health behaviors. Clin Psychol Rev 2009;29:283–93.
[29] Olsen S, Smith SS, Oei TPS, Douglas J. Motivational interviewing (MINT) improves continuous positive airway pressure (CPAP) acceptance and adherence: a randomized controlled trial. J Consult Clin Psychol 2012;80:151–63.
[30] Dement JM, Pompeii LA, Østbye T, Epling C, Lipscomb HJ, James T, et al. An integrated comprehensive occupational surveillance system for health care workers. Am J Ind Med 2004;45:528–38.
[31] Dement JM, Epling C, Østbye T, Pompeii LA, Hunt DL. Blood and body fluid exposure risks among health care workers: results from the Duke Health and Safety Surveillance System. A J Ind Med 2004;46:637–48.
[32] Blair SN, Piserchia PV, Wilbur CS, Crowder JH. A public health intervention model for work-site health promotion: impact on exercise and physical fitness in a health promotion plan after 24 months. JAMA 1986;255:921–6.
[33] Erfurt JC, Foote A, Heirich MA. Worksite wellness programs: incremental comparison of screening and referral alone, health education, follow-up counseling, and plant organization. Am J Health Promot 1991;5:438–48.
[34] Gomel M, Oldenburg B, Simpson JM, Owen N. Work-site cardiovascular risk reduction: a randomized trial of health risk assessment, education, counseling, and incentives. Am J Public Health 1993;83:1231–8.
[35] Gomel MK, Oldenburg B, Simpson JM, Chilvers M, Owen N. Composite cardiovascular risk outcomes of a work-site intervention trial. Am J Public Health 1997;87:673–6.
[36] Heaney CA, Goetzel RZ. A review of health-related outcomes of multi-component worksite health promotion programs. Am J Health Promot 1997;11:290–307.

[37] Proper KI, Hildebrandt VH, Van der Beek AJ, Twisk JWR, Van Mechelen W. Effect of individual counseling on physical activity fitness and health: a randomized controlled trial in a workplace setting. Am J Prev Med 2003;24:218–26.
[38] Miller WR, Rollnick S. Motivational interviewing: preparing people to change addictive behavior: New York. NY, US: Guilford Press; 1991.
[39] Goetzel RZ, Ozminkowski RJ, Bruno JA, Rutter KR, Isaac F, Wang S. The long-term impact of Johnson & Johnson's Health & Wellness Program on employee health risks. J Occup Environ Med 2002;44:417–24.
[40] Obesity Education Initiative Expert Panel, National Heart Lung and Blood Institute. Clinical guidelines on the identification, evaluation and treatment of overweight and obesity in adults. Bethesda MD: National Institutes of Health; 1998.
[41] Thompson FE, Midthune D, Subar AF, Kahle LL, Schatzkin A, Kipnis V. Performance of a short tool to assess dietary intakes of fruits and vegetables, percentage energy from fat and fibre. Public Health Nutr 2004;7:1097–105.
[42] National Cancer Institute Fruit and vegetable screener; 2000.
[43] National Cancer Institute. Fat screener; 1996.
[44] Thompson FE, Subar AF, Smith AF, Midthune D, Radimer KL, Kahle LL, et al. Fruit and vegetable assessment: performance of 2 new short instruments and a food frequency questionnaire. J Am Diet Assoc 2002;102:1764–72.
[45] Klippel NJ, Heil DP. Validation of energy expenditure prediction algorithms in adults using the Actical electronic activity monitor. Med Sci Sports Exerc 2003;35:S284.
[46] Centers for Disease Control and Prevention. National Health and Nutrition Examination Survey. Atlanta, GA: Centers for Disease Control. http://www.cdc.gov/nchs/nhanes.htm. (Accessed September 15, 2012.).
[47] Colley RC, Garriguet D, Janssen I, Craig CL, Clarke J, Tremblay MS. Physical activity of Canadian adults: accelerometer results from the 2007 to 2009 Canadian Health Measures Survey. Health Rep 2011;22: 7–14.
[48] Heil DP. Predicting activity energy expenditure using the Actical activity monitor. Res Q Exerc Sport 2006;77:64–80.
[49] Esliger DW, Probert A, Connor Gorber S, Bryan S, Laviolette M, Tremblay MS. Validity of the Actical accelerometer step-count function. Med Sci Sports Exerc 2007;39:1200–4.
[50] Craig CL, Marshall AL, Sjostrom M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc 2003;35:1381–95.
[51] Rovniak L, Anderson E, Winett R, Stephens R. Social cognitive determinants of physical activity in young adults: a prospective structural equation analysis. Ann Behav Med 2002;24:149–56.
[52] Sallis JF, Pinski RB, Grossman RM, Patterson TL, Nader PR. The development of self-efficacy scales for healthrelated diet and exercise behaviors. Health Educ Res 1988;3:283–92.
[53] Kolotkin RL, Crosby RD, Kosloski KD, Williams GR. Development of a brief measure to assess quality of life in obesity. Obe Res 2001;9: 102–11.
[54] Executive summary: standards of medical care in diabetes—2012. Diabetes Care 2012;35:S4–S10.
[55] Expert Panel on Detection E, Treatment of High Blood Cholesterol in A. Executive summary of the third report of the national cholesterol education program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (adult treatment panel III). JAMA 2001;285:2486–97.
[56] Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, et al. Seventh report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. Hypertension 2003;42:1206–52.
[57] Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
[58] Senn S. Testing for baseline balance in clinical trials. Stat Med 1994;13: 1715–26.
[59] Centers for Disease Control and Prevention. Nutrition for everyone; 2012.
[60] Centers for Disease Control, Prevention. Physical activity; 2011.
[61] Aldana SG. Financial impact of health promotion programs: a comprehensive review of the literature. Am J Health Promot 2001;15: 296–320.
[62] Ozminkowski RJ, Ling D, Goetzel RZ, Bruno JA, Rutter KR, Isaac F, et al. Long-term impact of Johnson & Johnson's Health & Wellness Program on health care utilization and expenditures. J Occup Environ Med 2002;44:21–9.
[63] Aldana SG, Merrill RM, Price K, Hardy A, Hager R. Financial impact of a comprehensive multisite workplace health promotion program. Prev Med 2005;40:131–7.
[64] Bertera RL. Behavioral risk factor and illness day changes with workplace health promotion: two-year results. Am J Health Promot 1993;7:365–73.
[65] Schultz AB, Lu C, Barnett TE, Yen LT-c, McDonald T, Hirschland D, et al. Influence of participation in a worksite health-promotion program on disability days. J Occup Environ Med 2002;44:776–80.
[66] Schulte PA, Wagner GR, Ostry A, Blanciforti LA, Cutlip RG, Krajnak KM, et al. Work, obesity, and occupational safety and health. Am J Public Health 2007;97:428–36.
[67] Ostbye T, Dement JM, Krause KM. Obesity and workers' compensation: results from the Duke Health and Safety Surveillance System. Arch Intern Med 2007;167:766–73.
[68] Erfurt JC, Foote A, Heirich MA. The cost-effectiveness of work-site wellness programs for hypertension control, weight loss, and smoking cessation. J Occup Environ Med 1991;33:962–70.
[69] Goetzel RZ, Jacobson BH, Aldana SG, Vardell K, Yee L. Health care costs of worksite health promotion participants and non-participants. J Occup Environ Med 1998;40:341–6.
[70] Oldenburg B, Owen N, Parle M, Gomel M. An economic evaluation of four work site based cardiovascular risk factor interventions. Health Educ Behav 1995;22:9–19.
[71] Bernier M, Avard J. Self-efficacy, outcome, and attrition in a weight-reduction program. Cogn Ther Res 1986;10:319–38.
[72] McAuley E, Jacobson L. Self-efficacy and exercise participation in sedentary adult females. Am J Health Promot 1991;5:185–207.
[73] Pagoto SL, Schneider KL, Oleski JL, Luciani JM, Bodenlos JS, Whited MC. Male inclusion in randomized controlled trials of lifestyle weight loss interventions. Obesity 2012;20:1234–9.
[74] Duke Office of News & Communications. Quick facts about Duke. http://www.cdc.gov/nchs/nhanes.htm. (Accessed September 15, 2012.).
[75] National Institute for Occupational Safety and Health. Steps to a healthier US workforce initiative: history of the WorkLife Initiative. http://www.cdc.gov/niosh/worklife/steps/default.html. (Accessed December 27, 2011.).