

## Chapter 6

### **Long-term effects of an occupational health guideline on employees' body weight-related outcomes, CVD risk factors and quality of life: results from an RCT**



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## **Abstract**

**Objective** To evaluate the effectiveness of a draft occupational health guideline aimed at preventing weight gain on employees' body weight-related outcomes, cardiovascular disease (CVD) risk factors and quality of life.

**Methods** In a randomized controlled trial including 16 occupational physicians (OPs) and 523 employees, guideline-based care was compared to usual care by OPs between 2009 and 2011 in the Netherlands. Guideline-based care consisted of 1) providing advice to employers on how to assess and intervene on the obesogenic work environment, 2) conducting five face-to-face behavioral change counseling sessions with employees to improve their lifestyle, and 3) evaluation and maintenance. Data were collected at baseline, 6, 12 and 18 months follow-up. To evaluate the effects of the intervention, multilevel analyses were performed.

**Results** No significant differences were found between the intervention and control group on body weight-related outcomes, CVD-risk factors or quality of life. Stratified analyses showed an increase in waist circumference among men ( $\beta$  2.5 cm, 95% CI 0.5; 4.5) and obese intervention participants ( $\beta$  2.7 cm, 95% CI 0.6; 4.7) compared to control participants.

**Conclusion** The draft occupational health guideline was not more effective than usual care. Therefore, the guideline in its current form cannot be recommended for implementation.

**Trial Registration** ISRCTN/73545254 and NTR/1190.

## Introduction

Obesity and cardiovascular diseases (CVD) are two of the leading preventable causes of death worldwide (Mathers et al., 2009). In 2008, over 2.8 million deaths were due to overweight or obesity, and over 17 million deaths were caused by CVD (Alwan & et.al., 2011; Mendis et al., 2011). Both obesity and CVD are associated with an increased risk of morbidity, as well as with a reduced life expectancy (Guh et al., 2009). Moreover, obesity- and CVD-related health care use and medical costs have risen dramatically over the past years (Yach et al., 2006). As obesity and CVD prevalence and costs are expected to continue to rise (Low et al., 2009), efforts to prevent obesity and CVD are warranted.

Overweight, and in particular obesity, are directly related to CVD as an independent risk factor for CVD, but also indirectly related to CVD as an independent risk factor for biomedical risk factors such as atherosclerosis, high blood pressure, high blood cholesterol and type 2 diabetes (Poirier et al., 2006). To reduce the burden of disease, lifestyle interventions addressing shared modifiable risk factors such as physical activity and nutrition, have shown to be promising methods for prevention (Lee et al., 2003; Mente et al., 2009). For example, regular physical activity may reduce the risk of cardiovascular disease, including high blood pressure and diabetes (Stamler et al., 1999; Yusuf et al., 2004), as well as prevent weight gain (Verweij et al., 2011a; Weinstein & Sesso, 2006). Moreover, a diet low in saturated fat may reduce total cholesterol (Hooper et al., 2011), and a diet high in fruits and vegetables may reduce the risk of CVD (Health Council Netherlands, 2006), and decrease body weight (Alinia et al., 2009). A recent Cochrane review of interventions using counselling and education aimed at behaviour change however, showed no reduction in total or CHD mortality or clinical events in general populations (Ebrahim et al., 2011).

Improving physical activity and dietary behavior through lifestyle interventions is not only beneficial for health, but may also enhance quality of life, decrease health care costs and increase productivity by decreasing illness and absenteeism (Mendis et al., 2011). Few such interventions have been conducted by occupational physicians, while the occupational health care setting provides good opportunities to reach employees (Groeneveld et al., 2010b; Proper et al., 2005). In the Balance@Work project, the effectiveness of an occupational health practice guideline aimed at preventing weight gain among employees in the Netherlands is evaluated (Verweij et al., 2009). The intervention effects on physical activity and dietary behavior after 6 months follow-up are subject of another article. The aim of this study is to evaluate the effectiveness of the guideline during 18 months follow-up on body weight-related factors, CVD-risk factors and quality of life.

## Methods

The cluster randomized controlled trial was conducted between 2009 and 2011 as part of the Balance@Work project. Details of the study design have been published elsewhere (Verweij et al., 2009). The study protocol was approved by the Ethics Committee of the VU University Medical Center and all participants signed informed consent.

### **Study population**

OPs were recruited by the professional association of OPs, Netherlands Society of Occupational Medicine, via a direct mailing to their member registry (>2,100 OPs). OPs were asked to recruit one or more companies of medium or large size (>100 workers). OPs recruited employees via a health risk appraisal consisting of anthropometric measurements and a subsequent health advice. Employees were considered eligible to participate when they met the following criteria: 1) having unhealthy levels of daily physical activity or dietary behavior (i.e. not complying to public health physical activity or nutrition recommendations) (Haskell et al., 2007; Health Council of the Netherlands., 2006; Kemper HGC, 2000) and/or being overweight (i.e. waist circumference >80 cm for women and >94 cm for men); 2) being able to complete a questionnaire in Dutch at baseline; 3) not being on sick leave for more than 21 days; 4) not being pregnant or having a disease or condition that would make physical activity impossible.

### **Randomization, blinding and sample size**

Randomization to the intervention or control group was performed at the OP level. The randomization procedure was performed by an independent researcher using Random Allocation Software (version 1.0, Isfahan University of Medical Sciences, Iran). The intervention made blinding of participating OPs not possible. OPs were asked not to reveal their group to employees or assistants performing measurements. An a priori power calculation to detect a difference in waist circumference of 1.5 cm (SD 4.5) (Kwak et al., 2007) with 80% power and an alpha of 5%, determined that 175 employees per group were needed at follow-up. Taking a loss to follow-up of 20-40% into account and clustering of employees within OPs (intraclass correlation of 0.20), a total of 600 employees among 20 OPs were required at baseline (Verweij et al., 2009).

### **Control group**

OPs in the control group were asked to provide care as usual, which generally consisted of a health risk appraisal with anthropometric measurements and a subsequent health advice.

### **Intervention group**

OPs in the intervention group were additionally asked to provide guideline-based care. The development of the draft occupational health practice guideline has been described in detail elsewhere (Verweij et al., 2009). Briefly, the guideline consists of three sections: a) prevention at the environmental level (advice for the employer); b) prevention at the individual level (advice for the employee); and c) evaluation and maintenance.

For the first section, an environment scan was developed that provided an overview of environmental risk factors that could contribute to preventing weight gain (e.g. availability of bike sheds and shower facilities, pricing strategies in cafeteria). Based on this overview, environmental goals could be prioritized, and feasibility and barriers for implementation could be discussed with the employer, and with the workers' representative council at baseline and at 6-months follow-up.

For the second section, prevention at the individual level, a minimal intervention strategy was developed for OPs on how to promote employees' healthy lifestyle in five 20-30 minute counseling sessions during 6 months. For this purpose, OPs were trained during two days in applying behavioral change counseling, an adapted form of motivational interviewing suitable for brief consultations in healthcare settings (Verweij et al., 2009). In the first counseling session, after having discussed their risk profile and current health status, employees could choose which target behavior they would like to discuss (increasing physical activity, decreasing sedentary behavior, increasing fruit consumption, or reducing the energy intake derived from snacks). Next, ambivalence and motivation for change was assessed by discussing pros and cons of behavior change, and willingness, importance, and perceived confidence to change behavior. OPs then moved employees towards a decision balance and increased perceived behavioral control by asking employees to formulate a maximum of three implementation intentions. Last, employees set short- and long-term goals. In subsequent sessions, progress and barriers were discussed and short-term goals could be adjusted. No specific weight loss advice was provided, as the guideline aimed to prevent weight gain by improving employees' physical activity and healthy dietary behavior. Moreover, obese employees could be referred to the Dutch guideline for treatment of obesity (Quality Institute for Health Services Netherlands (Kwaliteitsinstituut voor de Gezondheidszorg CBO), 2008). To monitor their behavior, employees were provided with a toolkit containing a waist circumference measure tape, a pedometer, a diary, and leaflets on physical activity and nutrition from the Dutch Heart Foundations and the Netherlands Nutrition Centre.

Finally, the last section of the guideline considered the evaluation and maintenance of previous sections.

### **Outcome measures**

Outcome measures of this study were body weight-related outcomes (i.e. waist circumference (cm), body weight (kg), and BMI (kg/m<sup>2</sup>)), biomedical risk factors (i.e. systolic and diastolic blood pressure (in mmHG), total serum cholesterol (mmol/l)), and quality of life assessed at baseline and 6, 12 and 18 months follow-up. The physical measurements were performed by OPs or their assistants. Quality of life was assessed by questionnaire.

#### *Body weight-related outcomes*

Waist circumference was measured as midway between the lower rib margin and the iliac crest to the nearest 0.1 cm. Participants were measured in standing position without heavy outer garments and with emptied pockets, breathing out gently (Verweij et al., 2009). To standardize waist circumference measurement, OPs or assistants were provided with a Seca 201 waist circumference measuring tape (Seca, Hamburg, Germany). As blinding of OPs was not possible, control measurements were performed by independent researchers in a random sample of 141 employees during all measurements (8%). No differences were found between OP measured waist circumference and independent researcher measured waist circumference (-0.4 cm; SD=4.5; p=0.3), among and between intervention and control OPs.

Additionally, self-reported waist circumference was assessed from 1,010 employees during all follow-up measurements (80%) using a non-stretchable paper measuring tape (range 0-130 cm) and written measurement instructions. Compared to OPs, employees significantly under-reported their waist circumference by -1.4 cm (SD=3.9;  $p<0.01$ ). No difference was found between intervention or control participants. As employee measures tended to be less accurate, OP measured waist circumference remains the best of the two options.

Body weight and body height were measured with the participants standing without shoes and heavy outer garments. Participants were asked to push their heels softly to the wall, or the back of the stadiometer. BMI was calculated from measured height and weight as  $\text{kg}/\text{m}^2$ .

#### *CVD-risk factors*

Systolic and diastolic blood pressure (mmHG) were measured according to the standard Dutch protocol for blood pressure measurements (Quality Institute for Health Services Netherlands (Kwaliteitsinstituut voor de Gezondheidszorg CBO), 2006) on employees in a seated position, after several minutes of rest. During the first consult, both arms were measured twice. In follow-up consults, the arm with the higher pressure was used if there was a difference of  $>10$  mmHg between measurements. Otherwise, OPs were advised to measure the same arm (preferably the left arm) across the remaining measurements in order to standardise measurements (Clark et al., 2006). As blood pressure measurements were performed once by some OPs at follow-up, but performed twice by others, the first reading was used across all measurements (Kleefstra et al., 2007). Readings of participants whose arms were measured interchangeably across measurements were excluded from analyses ( $n=13$ ).

Total serum cholesterol (mmol/l) was assessed by the Reflotron or Accutrend finger capillary assay or by lab assessments. HDL and LDL cholesterol were measured among two intervention OPs ( $n=76$ ) and four control OPs ( $n=69$ ) at baseline. Therefore, these measurements were disregarded in this study.

#### *Quality of life*

We measured quality of life by the validated EQ-5D (Hoeymans et al., 2005). Five questions were asked on self-reported mobility, self-care, activities of daily living, pain, and anxiety. The three answer categories were dichotomized into 'no problems' versus 'some problems' and 'problems', to address the fact that relatively few problems exist in general populations. Health status today was assessed using a visual analogue scale (VAS) ranging from 0 (worst imaginable health state) to 100 (best imaginable health state). Two additional questions were asked on 'how would you rate your health in general ('not good' versus 'good') and 'compared to the last year my health today is...' ('worse' versus 'the same or better').

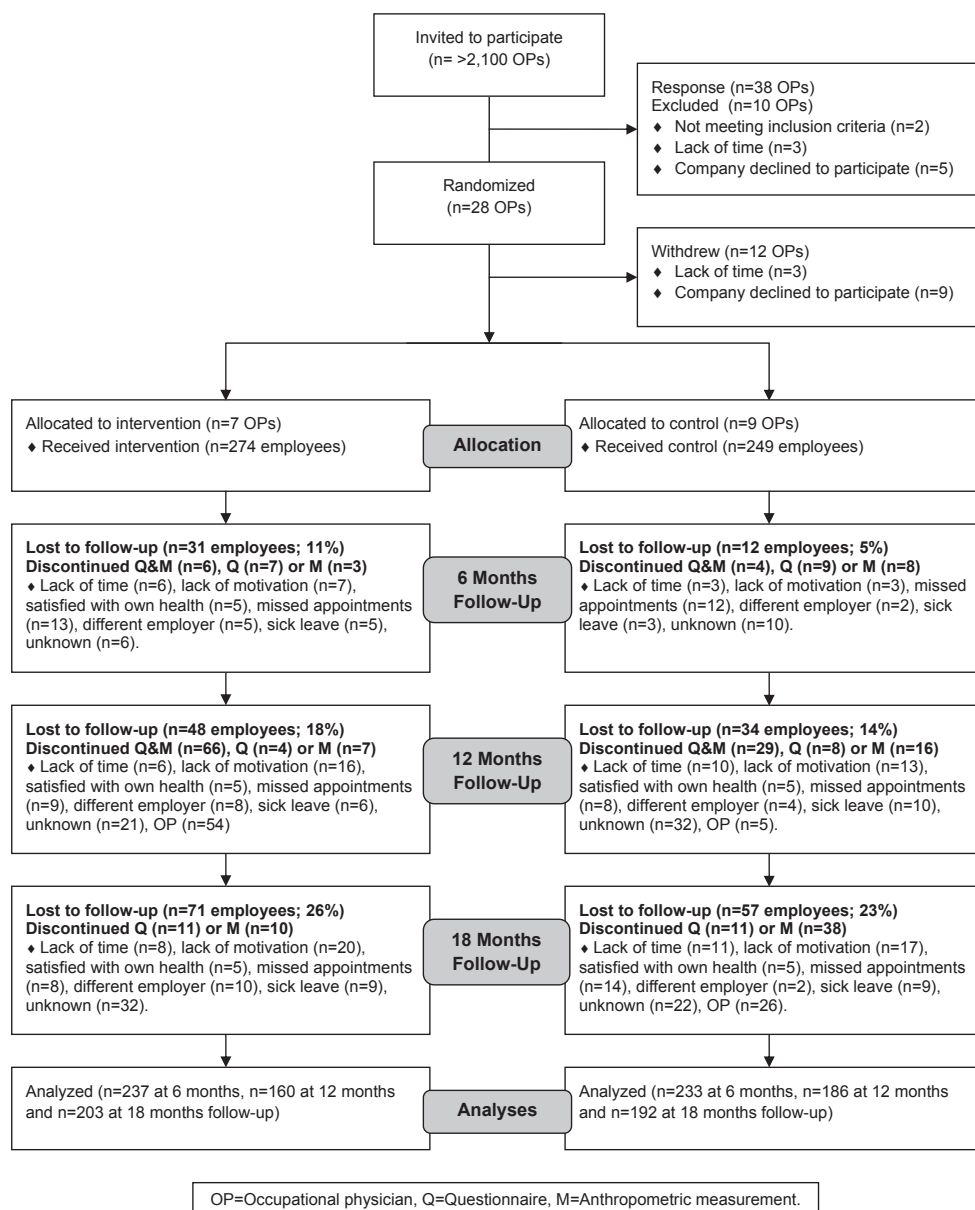
### Statistical analyses

Baseline differences between the intervention and control group were checked using *t*-tests for continuous variables and chi-square tests for categorical variables. To evaluate the intervention effects, multilevel analyses were performed for all outcome variables in order to adjust for the possible dependency of observations (Twisk, 2006). Three levels were identified: 1) time (four occasions), 2) employees, and 3) OPs. For each outcome variable, two analyses were performed. A crude analysis was performed to determine the differences between the intervention and control group at 6, 12 and 18 months follow-up, adjusted for the corresponding baseline outcome variable. Next, an adjusted analysis was performed to account for potential confounders (gender, age, irregular work hours). Confounding was assigned when >10% change occurred in the regression coefficient. Effect modification was considered for age, gender, BMI and the 10-year risk of fatal cardiovascular disease measured at baseline. A *p*-value<0.10 of the interaction term was used to indicate effect modification. The 10-year risk of fatal cardiovascular disease was estimated using the European Systematic COronary Risk Evaluation instrument (SCORE), using gender, age, smoking status, total cholesterol and systolic blood pressure (Conroy et al., 2003). Age was extrapolated to 60 years to address the problem of a high relative but low absolute risk in younger persons (Lakerveld et al., 2008). The continuous SCORE variable was dichotomized at a minimum risk of 10% for CVD, to assess the risk status of our population. *P*-values <0.05 were considered to be significant. All analyses were performed using PASW software (version 18.0) and MLwiN (version 2.18).

## Results

### Participants

After recruitment, 38 OPs expressed an interest to participate. 28 OPs were eligible and were randomized to either the intervention or control group. The Balance@Work project started with seven intervention OPs and nine control OPs because twelve OPs withdrew after randomization (Figure 1). No significant differences were found between OPs who completed the study and OPs who withdrew between randomization and baseline on demographic, behavior-related or job-related characteristics of their worker population. Moreover, intervention OPs did not differ significantly from control OPs at baseline. During the 6-month intervention period, none of the OPs were lost-to-follow-up. After 6 months, three OPs were lost to follow-up due to ending of their contracts and a reorganisation, as a result of which the Balance@Work team took over the follow-up measurements. Moreover, six OPs perceived difficulties in collecting data during the follow-up measurements due to pregnancy, sick leave, resistance of an employer, switching jobs, time constraints and one OP passed away. Therefore, several follow-up measurements were discontinued (Figure 1).



**Figure 1.** Flow chart of participants during the phases of the Balance@Work study, conducted in the Netherlands between 2009 and 2011.

OPs recruited 524 participants between March 2009 and March 2010. All employees met the inclusion criteria. One underweight subject was excluded from analyses because of having a weight gain goal. The baseline characteristics of the two study groups are described in Table 1. Intervention employees were significantly different from control employees on



age and irregular work hours at baseline. Intervention subjects were younger (46 versus 48 years) and worked less irregular work hours (19% versus 29%). After 18 months, 71 intervention employees (26%) and 57 control employees (23%) were lost-to-follow-up. These subjects were significantly younger, more often female, and had a lower income than study completers, but this did not differ significantly between the intervention or control group.

**Table 1.** Baseline characteristics of the study population by treatment group.

	Intervention n = 274	Control n = 249	All n = 523
Gender (% male)	62	65	63
Age, mean (SD)	46 (8)	48 (9)	47 (8) *
Education (% College/University)	55	51	53
Nationality (% Dutch)	89	92	91
Income, mean € per month (SD)	2118 (676)	2214 (781)	2162 (727)
Married/cohabitating (%)	81	85	83
Smoking (% yes)	15	15	15
Body Mass Index (BMI, %)	33	27	30
Normal weight (18.5≤BMI<25)	40	45	42
Overweight (25≤BMI<30)	27	29	28
Obese (BMI≥30)			
Chronic disease (% yes)	40	38	39
Medication use (% yes)	32	31	32
10-year risk of fatal CVD (% yes)	7	8	8
Type of worker (%)	15	17	16
Blue collar	70	73	72
White collar	15	10	13
Client contact			
Irregular work hours (%)	19	29	24 *

\*Significant difference  $p < 0.05$ .

## Intervention effects

### *Body weight-related outcomes*

Table 2 presents the values for waist circumference, body weight and BMI for baseline and 6, 12 and 18 months follow-up per study group, as well as the results of the multilevel linear regression analyses. In general, no statistically significant intervention effects were found for waist circumference, body weight and BMI. Contrary to what could be expected based on the group means, the multilevel analyses at 12-months follow-up showed a significant increase in waist circumference among the intervention group ( $\beta$  2.7 cm, 95% CI 0.8; 4.6). This difference disappeared in the longitudinal analyses using all follow-up measurements. Moreover, gender and BMI modified the intervention effect on waist circumference. Waist circumference increased among men and women in the intervention group compared to the control group ( $\beta$  2.5 cm, 95% CI 0.5; 4.5; and  $\beta$  0.4 cm, 95% CI -1.4; 2.0, respectively).

These differences were significant among men. Also, waist circumference increased among normal weight, overweight and obese participants in the intervention group compared to controls ( $\beta$  0.1 cm, 95% CI -1.9; 2.1;  $\beta$  0.6 cm, 95% CI -1.1; 2.4, and  $\beta$  2.7 cm, 95% CI 0.6; 4.7, respectively). These differences were significant among obese intervention participants compared to obese control participants.

**Table 2.** Intervention effects at 6, 12, and 18 months, and after 18 months on body weight-related measures and risk factors for cardiovascular diseases.

	Intervention		Control		B (95% CI)
	n	mean (SD)	n	mean (SD)	
<i>Waist circumference (cm)</i>					
Baseline *	274	94.5 (13.1)	248	98.0 (13.5)	
6 months	233	94.0 (12.6)	222	97.3 (12.1)	0.4 (-1.4; 2.2)
12 months	151	95.1 (13.0)	175	97.2 (12.5)	2.7 (0.8; 4.6)**
18 months	193	93.3 (12.7)	154	96.8 (12.2)	1.1 (-0.8; 3.0)
overall change					<b>1.2 (-0.6; 2.9)</b>
<i>Body weight (kg) ††</i>					
Baseline	274	86.0 (16.8)	248	87.5 (17.0)	
6 months	233	84.9 (16.1)	223	87.1 (16.1)	-0.1 (-1.5; 1.3)
12 months	148	83.0 (15.6)	174	87.1 (16.4)	0.3 (-1.1; 1.7)
18 months	190	84.6 (16.0)	153	86.7 (15.8)	0.9 (-0.5; 2.3)
overall change					<b>0.3 (-1.0; 1.6)</b>
<i>Body mass index (kg/m<sup>2</sup>) ††</i>					
Baseline	274	27.6 (5.0)	248	28.0 (4.9)	
6 months	233	27.3 (4.7)	223	27.8 (4.5)	0 (-0.4; 0.4)
12 months	148	27.0 (4.7)	173	27.6 (4.6)	0.1 (-0.3; 0.5)
18 months	190	27.0 (4.6)	152	27.4 (4.4)	0.3 (-0.1; 0.7)
overall change					<b>0.1 (-0.3; 0.5)</b>
<i>Systolic blood pressure (mmHG) †</i>					
Baseline *	273	133.2 (17.5)	248	138.0 (20.3)	
6 months	227	132.6 (19.3)	217	134.1 (15.5)	1.3 (-2.8; 5.5)
12 months	146	127.3 (15.7)	168	133.2 (15.7)	1.4 (-3.0; 5.8)
18 months	186	134.2 (18.0)	134	135.5 (16.4)	2.0 (-2.4; 6.4)
overall change					<b>1.7 (-2.4; 5.8)</b>
<i>Diastolic blood pressure (mmHG) †</i>					
Baseline *	273	83.6 (10.4)	248	85.6 (10.8)	
6 months	227	83.4 (10.1)	217	83.5 (9.6)	1.1 (-0.4; 2.6)
12 months	146	80.6 (9.2)	168	83.9 (9.7)	-1.2 (-3.0; 0.5)
18 months	186	83.1 (9.7)	134	85.3 (9.8)	0 (-1.8; 1.8)
overall change					<b>0.3 (-1.0; 0.6)</b>
<i>Cholesterol (mmol/l)</i>					
Baseline *	221	5.0 (0.9)	239	5.3 (1.0)	
6 months	178	4.9 (0.9)	221	5.1 (0.9)	-0.1 (-0.3; 0.1)
12 months	121	5.0 (0.9)	163	5.2 (0.9)	0.1 (-0.2; 0.3)
18 months	156	5.2 (0.9)	144	5.3 (1.0)	0.1 (-0.1; 0.3)
overall change					<b>0 (-0.2; 0.2)</b>

\*Significant difference ( $p < 0.05$ ) between the intervention and control group at baseline.

\*\* Significant difference between groups at follow-up, corrected for baseline values and clustering of repeated measurements within workers, and of workers within OPs.

Model corrected for age (†), or for age and irregular work hours (††).

**Table 3.** Intervention effects at 6, 12, and 18 months on quality of life indicators.

	Intervention		Control		OR (95% CI)
	n	%	n	%	
<i>Mobility §</i>					
Baseline	274	11	247	13	
6 months	230	9	223	13	0.6 (0.3; 1.3)
12 months	156	11	181	13	0.9 (0.4; 2.1)
18 months	191	13	181	9	1.7 (0.7; 3.7)
overall change					<b>0.9 (0.6; 1.5)</b>
<i>Self-care §</i>					
Baseline	274	1	247	2	
6 months	229	0	229	0	0.9 (0.1; 16)
12 months	156	2	181	1	3.8 (0.4; 39)
18 months	191	3	181	1	5.3 (0.6; 47)
overall change					<b>3.2 (0.8; 14.0)</b>
<i>Activities of daily living §</i>					
Baseline	274	25	247	22	
6 months	230	18	223	17	1.0 (0.5; 2.2)
12 months	156	19	181	24	0.7 (0.3; 1.4)
18 months	191	14	181	17	0.7 (0.3; 1.6)
overall change					<b>0.8 (0.4; 1.3)</b>
<i>Pain § †</i>					
Baseline	274	43	247	36	
6 months	230	38	223	32	1.4 (0.8; 2.7)
12 months	156	33	181	39	0.8 (0.4; 1.5)
18 months	191	34	181	32	1.0 (0.5; 2.0)
overall change					<b>1.1 (0.7; 1.7)</b>
<i>Anxiety §</i>					
Baseline	274	16	247	14	
6 months	230	15	223	11	1.6 (0.8; 3.0)
12 months	156	11	181	16	0.6 (0.3; 1.3)
18 months	191	8	181	13	0.6 (0.3; 1.2)
overall change					<b>0.9 (0.6; 1.4)</b>
<i>Health in general §§ ††</i>					
Baseline	274	87	248	87	
6 months	230	90	223	90	0.9 (0.4; 1.9)
12 months	156	90	181	87	1.2 (0.5; 2.8)
18 months	191	89	181	90	0.9 (0.4; 2.0)
overall change					<b>1.0 (0.6; 1.6)</b>
<i>Health today ¶ ††</i>					
Baseline	274	16	248	20	
6 months	230	16	223	18	0.9 (0.4; 1.9)
12 months	156	15	181	22	0.9 (0.4; 2.1)
18 months	191	16	181	21	1.1 (0.5; 2.4)
overall change					<b>1.0 (0.5; 1.7)</b>
	n	mean (SD)	n	mean (SD)	B (95% CI)‡
<i>Health today (VAS) ¶¶ †</i>					
Baseline *	273	72 (15)	247	75 (13)	
6 months	230	75 (14)	224	77 (12)	0.4 (-1.8; 2.7)
12 months	155	74 (15)	181	77 (13)	-0.4 (-3.1; 2.2)
18 months	190	77 (13)	180	76 (14)	3.0 (0.5; 5.5)**
overall change					<b>1.0 (-0.8; 2.8)</b>

\*Significant difference ( $p < 0.05$ ) between the intervention and control group at baseline.

\*\* Significant difference between groups at follow-up, corrected for baseline values and clustering of repeated measurements within workers, and of workers within OPs.

Model corrected for age (†), for irregular work hours (††), or for age, gender and irregular work hours (‡).

§ Dichotomous; 0=no problems, 1=problems.

§§ Dichotomous; 0=not good, 1= good.

¶ Dichotomous; compared to last year; 0=worse, 1=the same or better.

¶¶ Visual analogue scale; 0=worst imaginable health state, 100=best imaginable health state.

### *CVD-risk factors*

No significant intervention effects were found on systolic and diastolic blood pressure. Also, no effects were found on total serum cholesterol (Table 2). Although all values slightly decreased in both groups at 6 months follow-up, all values regained at 12 and 18 months follow-up.

### *Quality of life*

The intervention did not result in significant effects on quality of life indicators (Table 3). A significant increase among the intervention group was found on health status (assessed by VAS-scale) at 18 months follow-up ( $\beta$  3.0, 95% CI 0.5; 5.5), but this difference disappeared in the longitudinal analyses using all follow-up measurements.

## **Discussion**

The aim of this study was to evaluate the effectiveness of a draft occupational health guideline aimed at preventing weight gain among employees in the Netherlands. No significant effects were found on body weight-related outcomes, CVD-risk factors or quality of life. Stratified analyses showed an increase in waist circumference among men and obese intervention participants.

The results of this study on body weight-related outcomes contrasts two meta-analyses of workplace physical activity and nutrition interventions, that found moderate evidence for a net decrease in body weight of -1.3 kg and -1.2 kg, and in BMI of -0.5 kg/m<sup>2</sup> and -0.3 kg/m<sup>2</sup>, respectively (Anderson et al., 2009; Verweij et al., 2011a). Contrary to our study, the majority of the studies in the meta-analyses aimed to reduce CVD-risk or improve physical fitness, via programs that often included exercise schemes, and that were generally more intensive than ours. A more intensive intervention might thus be needed produce better effects. However, the programs used in many of the trials far exceed what may be feasible in routine clinical practice (Ebrahim et al., 2011; Verweij et al., 2011a).

The significant increase in waist circumference among the intervention group at 12-months follow-up may be the result of non-random missing data, that occurred due to time constraints at one intervention company. Although it has previously been shown that multilevel analyses is very flexible with handling missing data (Twisk, 2006), our results suggest the multilevel analyses was influenced by non-random missings at the 12-months measurement. Future research should examine this finding. As for our results, additional sensitivity analyses showed no important difference in effects (data not shown).

Remarkably however, obese and male intervention participants increased in waist circumference. A possible explanation may be that the guideline was not suitable for obese employees. Attendance rates among obese participants were significantly lower compared to normal or overweight participants (data not shown). Moreover, others have shown that more intensive interventions may be necessary for obese workers, including guided dieting and physical activity, psychological interventions, and when necessary medication or surgery (Quality Institute for Health Services Netherlands (Kwaliteitsinstituut voor de Gezondheidszorg CBO), 2008). Obese employees may therefore best be referred to the

Dutch guideline for treatment of obesity (Quality Institute for Health Services Netherlands (Kwaliteitsinstituut voor de Gezondheidszorg CBO), 2008). The increase in waist circumference among male intervention participants was not influenced by attendance rates, but based on additional interviews we found that dissatisfied participants under one intervention OP significantly gained in waist circumference and body weight (data not shown).

The overall lack of effectiveness of the guideline may also be due to several other factors. First, the guideline may have been poorly implemented, limiting the ability to detect effects. Although attention for both environmental and individual influences was incorporated in the current draft guideline (Shain & Kramer, 2004), process data indicated that the environmental component and counseling were not performed to the full extent by intervention OPs (Verweij et al., 2011b). Moreover, co-intervention was applied by one control OP, and control employees received four health risk appraisal with feedback for evaluation purposes as well, which in itself may have motivated control participants to change their behavior (Hawthorne effect (Landsberger, 1958)). These findings suggest that the contrast between the intervention and control group may have been too small. The question remains if the guideline could be effective in case of optimal implementation. Secondary analyses among intervention participants at 6 months follow-up suggested greater results can be achieved on waist circumference and body weight among those with higher attendance (5 versus <5 counseling sessions) and satisfaction scores (8 versus <8 on a scale 1-10) (Verweij et al., 2011b). These differences however, were not sustained at 18 months follow-up.

Second, the evaluation of the guideline among a general workforce may have provided little room for improvement in the outcome measures. Two systematic reviews recently described that interventions using counselling and education aimed at behaviour change may not reduce CVD morbidity or mortality in general populations (Ebrahim et al., 2011; Groeneveld et al., 2010a; Robroek et al., 2011). Comparable programs among high-risk populations indeed found better results, such as modest reductions in blood pressure, cholesterol and weight, possibly because high risk participants are more likely to achieve measurable changes in behavior (Groeneveld et al., 2010a; Groeneveld et al., 2010b; van Wier et al., 2011). The high risk approach however, does not solve the origin of the problem (Rose, 1985). It may be worthwhile to evaluate an adapted form of the guideline among high risk groups, such as populations at risk for CVD, hypertension, or diabetes. To achieve a meaningful degree of prevention and protection at the workplace, ultimately a combination of primary, secondary and tertiary interventions may be needed (Rose, 1985).

A final point that should be considered is the quality of the measurement instruments. Despite the use of standardized protocols, the fact that our study was performed in daily practice made it impossible to standardise blood pressure and cholesterol measurements. This is important for evaluative research, as variations in blood pressure and cholesterol measurements may lead to different results (Kleefstra et al., 2007; Tolonen et al., 2005). Nevertheless, we do not feel that these variations affected our study greatly considering our lack of results. As for measuring quality of life, the generic EQ-5D may not have been appropriate in our population due to ceiling effects (EuroQol Group, 2004). The EQ-5D is a standardized health-related quality of life questionnaire developed to provide a simple,

generic measure of health for clinical and economic appraisal (Hoeymans et al., 2005). Among populations with a high GDP (gross domestic product) per capita, such as the Netherlands, however high mean VAS ratings are found (EuroQol Group, 2004). Moreover, few problems are often report on the quality of life domains by general populations (Hoeymans et al., 2005). Thus, the assessment of quality of life for evaluation purposes may have limited value in intervention studies using general populations, such as ours.

Strengths of this study include the practice-based nature of the guideline and the minimized risk of contamination due to randomization at the OP level. There were some limitations as well. Due to randomization at the OP level, intervention and control employees were significantly different at baseline with respect to age and irregular work hours. We attempted to dissolve this selection bias by controlling for these variables in all analyses. Moreover, 24% of the employees were lost-to-follow up after 18 months. Although high drop-out rates are a common problem among this type of research (Groeneveld et al., 2010b; Robroek et al., 2011) the internal validity of our results may be lower as those lost to follow-up were younger, females, and had a lower income than study completers. Also, only a small group of all OPs in the Netherlands (2%) participated in our study, implying generalizability of our results may be low. Finally, many OPs perceived difficulties collecting data for the follow-up measurements, indicating supporting structures for OPs, such as a linkage group, may be necessary for long-term performance of the guideline (Verweij et al., 2011b).

### **Conclusion**

The draft occupational health guideline was not effective in preventing weight gain, reducing CVD-risk factors, or improving quality of life during 18 months follow-up among the intervention group compared to the control group. Therefore, the guideline in its current form cannot be recommended for implementation. It may be worthwhile to evaluate an adapted, more intensive, form of the guideline among high risk groups. Also, more attention could be paid to maximizing attendance and satisfaction rates, as this may favourably affect results. Finally, future research should determine feasible ways to effectively prevent weight gain via occupational health services among general populations at the worksite.

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