Preventing weight gain by lifestyle intervention in a general practice setting - three-year results of a randomized controlled trial

ter Bogt, Nancy C. W.; Bemelmans, Wanda J. E.; Beltman, Frank W.; Broer, Jan; Smit, Andries J.; van der Meer, Klaas

Published in:
Archives of Internal Medicine

Publication date:
2011

Preventing Weight Gain by Lifestyle Intervention in a General Practice Setting

Three-Year Results of a Randomized Controlled Trial

Nancy C. W. ter Bogt, MSc; Wanda J. E. Bemelmans, PhD; Frank W. Beltman, MD, PhD; Jan Broer, MD, PhD; Andries J. Smit, MD, PhD; Klaas van der Meer, MD, PhD

Background: Weight regain after initial loss of weight is common, which indicates a need for lifestyle counseling aimed at preventing weight gain instead of weight loss. This study was conducted to determine whether structured lifestyle counseling by nurse practitioners (NPs) group compared with usual care by general practitioners (GP-UC) in overweight and obese patients can prevent (further) weight gain.

Methods: A randomized controlled trial in 11 general practice locations in the Netherlands of 457 patients (body mass index, 25-40 [calculated as weight in kilograms divided by height in meters squared]; mean age, 56 years; 52% female) with either hypertension or dyslipidemia or both. The NP group received lifestyle counseling with guidance of the NP using a standardized software program. The GP-UC group received usual care from their GP. Main outcome measures were changes in body weight, waist circumference, blood pressure, and fasting glucose and blood lipid levels after 3 years.

Results: In both groups, approximately 60% of the participants achieved weight maintenance after 3 years. There was no significant difference in mean (SD) weight change and change of waist circumference between the NP and GP-UC groups (weight change: NP group, –1.2% [5.8%], and GP-UC group, –0.6% [5.6%] [*P*=.37]; and change of waist circumference: NP group, –0.8 [7.1] cm, and GP-UC group, 0.4 [7.2] cm [*P*=.11]). A significant difference occurred for mean (SD) fasting glucose levels (NP group, –0.02 [0.49] mmol/L, and GP-UC group, 0.10 [0.53] mmol/L [*P*=.02]) (to convert to milligrams per deciliter, divide by 0.0555) but not for lipid levels and blood pressure.

Conclusions: Lifestyle counseling by NPs did not lead to significantly better prevention of weight gain compared with GPs. In the majority in both groups, lifestyle counseling succeeded in preventing (further) weight gain.

Trial Registration: trialregister.nl Identifier: NTR1365

Arch Intern Med. 2011;171(4):306-313

Author Affiliations: Departments of General Practice (Ms ter Bogt and Drs Beltman and van der Meer) and Internal Medicine (Dr Smit), University Medical Center Groningen, Centre for Prevention and Health Services Research, National Institute for Public Health and the Environment (Drs Bemelmans), and Municipal Public Health Service (Dr Broer), Groningen, the Netherlands.

THE RISING PREVALENCE OF overweight and obesity is a worldwide problem. An increased body mass index (BMI) is associated with higher mortality,[1] the development of coronary vascular disease (partly independent of blood pressure [BP] and cholesterol levels[2]), type 2 diabetes mellitus, certain types of cancer, gastrointestinal diseases, and arthritis.[3] The large impact of these diseases on shortening healthy lifespan and increasing health care costs stresses the need for strategies to tackle this problem.

See Invited Commentary at end of article

Studies show that lifestyle interventions (including a nutrition and physical activity component) are needed to maintain or lose weight.[4] Intensive lifestyle programs such as the Diabetes Prevention Program and the Diabetes Prevention Study showed weight losses of approximately 4 kg and 3 kg, respectively, after 3 years, accompanied by improvements in cardiovascular risk factor levels.[5,6] Because weight regain after weight loss in obese persons is a common problem, a more successful approach may be to prevent weight gain and focus on weight management in those with milder degrees of overweight. Small changes in lifestyle can improve health status even without losing weight[7,8] and might be easier to maintain in the long term.

The primary care setting is suitable for weight maintenance; previous studies have shown that lifestyle interventions in primary care can be effective, at least in the short term.[9-11] However, little is known about long-term effects (over several years) in this setting. Guidelines in the treatment of hypertension and dyslipidemia (often accompanied by overweight and obesity) for general practitioners (GPs) include lifestyle advice,[12] but in practice, compliance with the lifestyle component of these

guidelines seems limited.[13] Frequently reported barriers for lifestyle counseling by GPs include lack of time, lack of patient compliance, insufficient knowledge about the subject, and lack of evidence-based interventions.[14] A solution to some of these barriers may be to delegate lifestyle counseling to nurse practitioners (NPs).

The Groningen Overweight and Lifestyle (GOAL) study was conducted to compare the effects of structured lifestyle counseling by NPs with usual care by general practitioners (GP-UC) on preventing weight gain and improving health status in overweight and obese patients with either hypertension, dyslipidemia, or both.

Short-term, 1-year results of the GOAL study showed that mean weight losses in men were 2.3% in the NP group and 0.1% in the GP-UC group ($P<.05$), while no significant reductions were found in blood lipid levels, fasting glucose levels, and BP. In women, weight change in both groups was –1.6%. There were more individuals with weight loss (weight losers) and stable weight (stabilizers) in the NP group than in the GP-UC group (77% vs 65%) ($P<.05$).[15]

The present study reports on the long-term, 3-year results of lifestyle counseling by NPs compared with GP-UC in overweight and obese patients at relatively "low risk" for cardiovascular disease in preventing weight gain and improving health status. As a secondary objective, we investigated whether the aforementioned 1-year results were sustained after 3 years and if weight change differed within and between subgroups.

METHODS

SUBJECTS

Participants were recruited (between June 2005 and February 2006) at 11 general practice locations in the northern part of the Netherlands. As previously described in detail,[15] after screening and selection, 457 participants (aged 40-70 years) were enrolled within a general practice setting. Eligible participants had a BMI between 25 and 40 (calculated as weight in kilograms divided by height in meters squared) and either hypertension and/or dyslipidemia. Hypertension was defined as a mean systolic BP of 140 mm Hg or higher and/or a diastolic BP of 90 mm Hg or higher (based on 2 measurements on at least 2 different visits) or current use of BP-lowering medication, and dyslipidemia was defined as a total serum cholesterol level higher than 5.5 mmol/L (to convert to milligrams per deciliter, divide by 0.0259) or a low high-density lipoprotein cholesterol level (HDL-C) level (male, <0.9 mmol/L; female, <1.1 mmol/L) or a total cholesterol/HDL-C ratio greater than 6 and/or current use of cholesterol level–lowering medication. Exclusion criteria were diabetes mellitus, hypothyroidism, pregnancy, liver or kidney disease, current treatment for malignant disease, severely shortened life expectancy, mental illness, and addiction to alcohol or drugs. The GOAL study was approved by the Medical Ethics Review Committee of the University Medical Center Groningen, Groningen, the Netherlands, and written informed consent was given by all participants.

MEASUREMENTS

At the GP locations, a trained research team (not blinded for study group) performed a structured medical examination that included measurements of body weight, length, waist circumference, and BP. Body weight was measured on a digital scale with subjects wearing light clothing and no shoes, height was measured using a wall-mounted measuring tape, and waist circumference was measured at the level midway between the lowest rib and the iliac crest. Blood pressure was measured twice, and mean values were used in the analysis. The presence of cardiovascular risk factors, medication use, and family history of disease and overweight/obesity were documented. Blood samples were collected in a general practice setting after an overnight fast to analyze fasting serum lipid and glucose levels (in the same central laboratory, LabNoord in Groningen, using conventional and certified laboratory assays). Several questionnaires were completed via the Internet (as part of the software program for the lifestyle intervention) or on paper (in case of no Internet access). They contained questions on general characteristics (eg, educational level and sex of the patient) and on several issues related to body weight (eg, history of dieting). The Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH) was used to determine physical activity.[16] Metabolic syndrome was defined according to criteria from the National Cholesterol Education Program's Adult Treatment Panel III[17] and Systematic Coronary Risk Evaluation (SCORE) scores to estimate 10-year risk of fatal cardiovascular disease were calculated as described by Conroy et al.[18] Baseline data were available for all participants, with the following exceptions: waist circumference (n=2), blood analyses (n=11), complete questionnaires (n=11), and items in questionnaire (range of missing items, 5%-11%). These missing baseline values are distributed equally among NP and GP-UC groups. The measurements were performed at baseline (between January and July 2006) after 1 and 3 years.

The number of visits in the NP and GP-UC groups was calculated via the registration system from the general practice locations. This means that both visits within the study protocol and other visits to the GP, NP, and practice assistant were included. Only visits with 1 or more components of lifestyle counseling were counted (eg, BP measurements and discussing results from blood analysis). Telephone calls and short visits were counted as 1 visit, and long visits were counted as 2 visits. The number of visits to a dietician during the study period was obtained from a separate questionnaire for the process evaluation of the study that was sent to the subjects after the 3-year measurements (50 participants did not respond to this questionnaire).

INTERVENTION

Patients were allocated by computer-generated random numbers to the NP (n=225) or GP-UC (n=232) groups. The lifestyle intervention consisted of 4 individual visits and 1 feedback session by telephone in the first year, in the next 2 years, 1 individual visit and 2 feedback sessions were planned each year. During these contact sessions the NP is guided by the standardized computerized software program (exclusive use for the NP group was guaranteed), which contains instructions on lifestyle counseling according to national and international guidelines[19,20] and allows data entry of the measurements. The NPs followed a specially developed training program (5 sessions of 4 hours each: 4 sessions before the intervention and 1 session after 1 year) and received an individual instruction about the software program before the start of the study. The program consisted of several elements of behavioral counseling such as individual goal setting, monitoring using food diaries and pedometers, and addressing barriers for lifestyle change. The primary aim of the intervention was to prevent weight gain and if patients were motivated to lose 5% to 10% of body weight. The intervention was previously described in detail.[15]

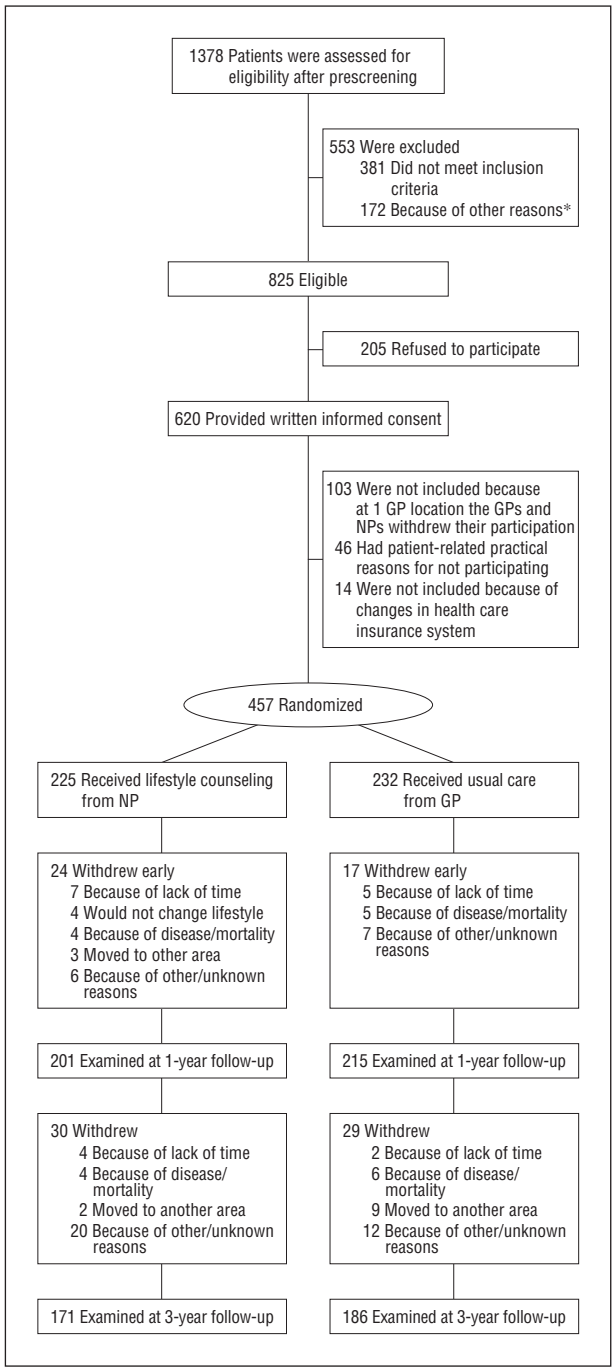

Figure. Flow of patients through the Groningen Overweight and Lifestyle (GOAL) study. GP indicates general practitioner; and NP, nurse practitioner. *For example, not showing up at follow-up measurements during the screening without providing a reason or not willing to participate in further measurements like blood analyses.

The control group visited the GP after each measurement to discuss the results, and thereafter they received usual care according to GP guidelines.[12]

SAMPLE-SIZE CALCULATION

The sample-size calculation was previously described in detail.[15] On the basis of previous investigations, a difference in weight loss of 2.8 kg after 1 year could be expected, resulting in the aim to include at least 145 participants in each study arm. The follow-up period in the next 2 years was meant to investigate the percentage of weight maintenance.

STATISTICAL ANALYSES

Differences in baseline characteristics and changes in main outcome measures after 1 and 3 years between the 2 study groups were evaluated with unpaired *t* tests for continuous variables and χ^2 tests for categorical variables. General linear model (GLM) analysis was performed to adjust for baseline values in continuous variables. For lipid levels and BP, adjustments were made for changes in cholesterol- and BP-lowering medications, respectively. Logistic regression, with adjustments for baseline fasting glucose level, was used to examine the relation between study group and the prevalence of an impaired fasting glucose level (which is defined as a fasting glucose level >6.0 mmol/L [to convert to milligrams per deciliter, divide by 0.0555]).

Furthermore, GLM analysis was used to examine the percentage of weight loss after 1 and 3 years in subgroups of patients. Study group, sex, and each characteristic subgroup were separately entered in the model as fixed variables and age, baseline BMI, and weight change between screening and baseline as covariates. We also used GLM analysis to investigate interaction between patients' sex and study group. Regainers were defined as subjects who lost 5% of body weight or more after 1 year and returned to baseline body weight after 3 years (≥0%). Subjects were categorized into the following classes according to percentage of weight change after 1 and 3 years: successful weight losers (lost ≥5%), weight losers (weight loss from 1% to 5%), stabilizers (between >1% weight loss and 1% weight gain) and weight gainers (gain >1%). Differences in main outcome variables between these categories were tested with analysis of variance and post hoc Bonferroni test.

Results are presented with exclusion of dropouts and missing values and were adjusted for baseline values. Thereafter, all analyses were also performed following the intention-to-treat principle by BOCF (baseline observation carried forward) for dropouts. Usually, BOCF indicates that there is no weight change, so in our study this would mean that dropouts were characterized as successful because they did not gain 1% or more of their body weight. But this might be an overestimation of the percentages of the participants who achieved weight maintenance. Therefore we also performed analyses in which all dropouts were considered as not successful, which is probably an underestimation of the success rate. Percentages of participants who achieved weight maintenance are presented as a range of both methods.

All analyses were performed in 2009 using SPSS/PC statistical program version 16.0 for Windows (SPSS Inc, Chicago, Illinois). $P < .05$ was considered statistically significant.

RESULTS

The dropout percentage was 24% for the NP and 20% for the GP-UC group (not significant, $P = .28$) (**Figure**). Participants who dropped out had a higher diastolic BP (89 vs 86 mm Hg; $P = .003$) and more often had a BMI of 30 or greater (reasons of dropout did not significantly differ between participants with a BMI above or under 30); there were no differences in other characteristics between dropouts and participants who attended the follow-up measurement after 3 years. **Table 1** gives the baseline characteristics for both groups. Participants in the GP-UC group more often had greater than 3 recent dieting attempts than in the NP group and more fre-

Table 1. Baseline Characteristics for the NP and GP-UC Groups

Characteristic	NP Group (n=225)	GP-UC Group (n=232)
General		
Age, mean (SD), y	55.3 (7.7)	56.9 (7.8)
Men, No. (%)	113 (50.2)	107 (46.1)
Low education, No./total (%)[a]	71/212 (33.5)	67/217 (30.9)
Relationship, No./total (%)[b]	177/213 (83.1)	188/226 (85.5)
Physical examination and blood analysis		
Body weight, mean (SD), kg	88.2 (12.1)	87.8 (14.0)
BMI, mean (SD)	29.5 (3.1)	29.6 (3.6)
BMI ≥30, No. (%)	79 (35.1)	85 (36.6)
Waist circumference for men, mean (SD), cm	104 (7.8)	105 (9.5)
Waist circumference for women, mean (SD), cm	97 (9.8)	97 (11.8)
Total cholesterol, mean (SD), mmol/L	5.66 (1.0)	5.56 (1.0)
HDL-C, mean (SD), mmol/L	1.44 (0.4)	1.43 (0.4)
LDL-C, mean (SD), mmol/L	3.50 (0.9)	3.43 (0.9)
Fasting glucose, mean (SD), mmol/L	5.20 (0.5)	5.25 (0.7)
Impaired fasting glucose, No./total (%)[c]	14/219 (6)	20/226 (9)
Systolic BP, mean (SD), mm Hg	146 (18.5)	145 (15.5)
Diastolic BP, mean (SD), mm Hg	87 (9.6)	86 (8.2)
Hypertension, No. (%)	137 (60.9)	145 (62.5)
Using medication for hypertension, No./total (%)[d]	61/136 (44.9)	74/144 (51.4)
Dyslipidemia, No. (%)	83 (36.9)	96 (41.4)
Using medication for dyslipidemia, No./total (%)[e]	31/83 (37.3)	43/96 (44.8)
SCORE score, mean (SD)	3.55 (4.0)	3.29 (3.0)
SCORE score <5, No./total (%)	175/219 (79.9)	182/226 (80.5)
Metabolic syndrome, No./total (%)	98/224 (43.8)	102/232 (44.0)
Lifestyle		
Current smokers, No./total (%)	46/224 (20.5)	42/232 (18.1)
>3 Attempts to lose weight during last 5 y, No./total (%)	33/207 (15.9)	55/213 (25.8[f])
≥30 Minutes of moderate-intensity physical activity, 5 d/wk, No./total (%)	123/216 (56.9)	150/220 (68.2[f])

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; GP-UC, usual care by a general practitioner; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NP, nurse practitioner; SCORE, Systematic Coronary Risk Evaluation.

Conventional unit conversion factors: To convert cholesterol and glucose to milligrams per deciliter, divide by 0.0259 and 0.0555, respectively.

[a] Percentage of participants with a lower professional education or less.

[b] Percentage of participants who were married or living together with a partner.

[c] Fasting glucose level higher than 6 mmol/L.

[d] Percentage of participants with hypertension.

[e] Percentage of participants with dyslipidemia.

[f] NP vs GP-UC group $P<.05$ (χ^2 test).

quently fulfilled the norm on physical activity ($P<.05$ for both).

CHANGES IN MAIN OUTCOME MEASURES AFTER 3 YEARS

After 3 years, no differences in mean (SD) weight change were present between the NP and GP-UC groups (NP, –1.2% [5.8%]; GP-UC: –0.6% [5.6%]; $P=.37$). Approximately 60% of the participants in both groups were weight losers or stabilizers after 3 years (**Table 2**).

In the NP group, a positive effect was found on mean (SD) fasting glucose level at the 3-year follow-up compared with the GP-UC group (–0.02 [0.49]) mmol/L vs 0.10 (0.53) mmol/L; $P=.02$). After 3 years the prevalence of impaired fasting glucose level was 6% (n=10) in the NP group vs 12% (n=21) in the GP-UC group ($P=.17$) (Table 2). In persons with a BMI of 30 or greater, the prevalence was lower in the NP than in the GP-UC group (7% [n=4] vs 22% [n=14]) but was not significant after adjustment for baseline values ($P=.14$) (data not shown). No significant differences between the NP and GP-UC groups occurred for serum lipid levels and BP at the 3-year follow-up (Table 2).

CHANGES IN MAIN OUTCOME MEASURES AFTER 3 YEARS COMPARED WITH 1 YEAR

Contrary to the results after 3 years, the percentage of mean (SD) weight loss after 1 year differed between the NP and GP-UC groups (NP group, –2.2% [7.0%]; GP-UC group, –0.7% [4.6%]; $P=.002$), and there were more weight losers and stabilizers after 1 year in the NP group than in the GP-UC group (80% vs 64%; $P=.001$) (**Table 3**). The percentage of regainers in the NP group was comparable to the GP-UC group (14% and 16%, respectively) (Table 2).

WEIGHT LOSS AFTER 3 YEARS BETWEEN AND WITHIN SUBGROUPS

There were no differences in weight change after 3 years between the NP and GP-UC groups in subgroups of patients' characteristics at baseline (Table 3). Interaction

Table 2. Changes[a] in Main Outcome Measures at 1- and 3-Year Follow-up in the NP and GP-UC Groups

	1-y Follow-up					3-y Follow-up				
Main Outcome Measure	No.	NP Group	No.	GP-UC Group	*P* Value	No.	NP Group	No.	GP-UC Group	*P* Value
Body weight, mean (SD), kg	171	−2.0 (4.3)	186	−0.6 (4.0)	.002	171	−1.1 (5.3)	186	−0.5 (5.0)	.34
Body weight, mean (SD), % change	171	−2.2 (4.6)	186	−0.7 (4.6)	.002	171	−1.2 (5.8)	186	−0.6 (5.6)	.37
BMI, mean (SD)	171	−0.7 (1.4)	186	−0.2 (1.4)	.002	171	−0.4 (1.8)	186	−0.2 (1.7)	.31
Waist circumference, mean (SD), cm	169	−2.6 (7.0)	186	−1.1 (5.8)	.03	169	−0.8 (7.1)	182	0.4 (7.2)	.11
Total cholesterol, mean (SD), mmol/L	164	−0.10 (0.75)	181	−0.06 (0.71)	.50	164	0.07 (0.92)	178	−0.05 (0.93)	.15
HDL-C, mean (SD), mmol/L	164	−0.08 (0.22)	181	−0.09 (0.22)	.61	164	−0.17 (0.26)	178	−0.17 (0.25)	.75
LDL-C, mean (SD), mmol/L	162	0.04 (0.68)	179	0.05 (0.65)	.63	160	0.20 (0.81)	176	0.05 (0.86)	.09
Fasting glucose, mean (SD), mmol/L	163	−0.08 (0.48)	181	−0.06 (0.45)	.46	162	−0.02 (0.49)	176	0.10 (0.53)	.02[b]
Impaired fasting glucose, No. (%)[c]	163	8 (5)	181	13 (7)	.70	162	10 (6)	176	21 (12)	.17
Systolic BP, mean (SD), mm Hg	171	−7.0 (18.6)	186	−3.3 (15.3)	.03	171	−5.9 (17.3)	186	−3.8 (14.5)	.38
Diastolic BP, mean (SD), mm Hg	171	−1.5 (10.2)	186	−0.3 (8.1)	.20	171	−2.0 (10.8)	186	−1.1 (9.3)	.41
Weight losers/stabilizers, No. (%)[d]	171	136 (80)	186	119 (64)	.001	171	106 (62)	186	118 (63)	.78
Regainers, No. (%)[e]						37[f]	5 (14)	31[f]	5 (16)	.76

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; GP-UC, usual care by a general practitioner; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NP, nurse practitioner.

Conventional unit conversion factors: To convert cholesterol and glucose to milligrams per deciliter, divide by 0.0259 and 0.0555, respectively.

[a] Changes are calculated as the value at 1- or 3-year follow-up minus the value at baseline, and adjusted for baseline values (for lipids and blood pressure, for changes in cholesterol- and BP-lowering medications, respectively).

[b] Adjustments for differences between the NP and the GP-UC groups on baseline characteristics (physical activity and number of recent attempts to lose weight) did not alter this result.

[c] Fasting glucose level higher than 6 mmol/L, *P* values: logistic regression adjusted for baseline values.

[d] Percentage of subjects who gained less than 1% of body weight between baseline and 1- or 3-year measurement.

[e] Percentage of subjects who lost 5% of body weight or more after 1 year and returned to baseline body weight after 3 years (≥0%).

[f] Number of subjects who lost 5% of body weight or more after 1 year.

between sex and study group was absent. Within the NP group, participants with 3 or fewer attempts to lose weight during the last 5 years lost more weight after 3 years than participants with 4 or more attempts ($P<.05$). These participants gained 1.4% (95% confidence interval, −0.9 to 3.7) of their baseline weight after 3 years.

CHANGES IN MAIN OUTCOME VARIABLES AFTER 3 YEARS STRATIFIED BY WEIGHT LOSS CATEGORIES

Successful weight losers achieved the most favorable results and weight gainers the least favorable results after 3 years on physiological outcome variables except for systolic BP (**Table 4**). After 3 years, stabilizers and weight gainers (n=192) achieved significantly better results for mean (SD) fasting glucose level (0.10 [0.50] mmol/L) than regainers (0.57 [0.60] mmol/L) ($P=.008$) but not for lipid levels and BP (data not shown).

INTENTION-TO-TREAT ANALYSIS

Intention-to-treat analysis did not substantially alter the results after 3 years. For example, mean (SD) weight loss after 3 years in the NP group was −0.8% (5.0%) and −0.5% (5.0%) in the GP-UC group ($P=.45$). Change in mean (SD) low-density lipoprotein cholesterol (LDL-C) level did not differ between the NP and GP-UC groups (NP group, 0.15 [0.71] mmol/L; GP-UC group, 0.04 [0.77] mmol/L; $P=.11$). Change in mean (SD) fasting glucose level after 3 years differed significantly between the NP and GP-UC groups (−0.01 [0.43] mmol/L vs 0.08 [0.47] mmol/L, respectively; $P=.03$). The percentages of participants who achieved weight maintenance varied from 47% to 71% in the NP group and from 51% to 71% in the GP-UC group (depending on whether dropouts are considered successful or not).

COMMENT

The design of our study was different from several other published weight intervention studies because we focused on weight maintenance in persons with a relatively low mean BMI (almost 30) and because we had a considerably longer follow-up than in most other studies, within a "realistic" primary care setting. The relevance of prolonged follow-up is reflected by the differences between the 1-year and the somewhat disappointing 3-year results on weight maintenance. After 1 year, 80% of the participants in the NP group indeed achieved weight maintenance vs 64% in the GP-UC group. However, after 3 years, differences between both groups had disappeared: with 60% success in weight maintenance of the participants in both groups. Changes in fasting glucose levels differed in favor of the NP group, especially among obese persons the prevalence of an impaired fasting glucose level differed considerably after 3 years (7% vs 22%), but owing to lack of power in this subgroup analysis, this result was not significant when adjusted for baseline values ($P=.14$).

In comparison with other studies with prolonged follow-up, Jeffery and French[21] described a weight gain of approximately 1.5 kg after 3 years for treatment and control groups, but they used a low-intensity intervention mostly conducted by mail. Another randomized controlled trial with a longer follow-up of 54 months was reported by Simkin-Silverman et al,[22] but this was done

Table 3. Percentage Change in Body Weight at 1- and 3-Year Follow-up, Stratified by Subgroups of Patients' Characteristics for Both Study Groups

Characteristic	No. of Participants	NP Group % Change in Body Weight (95% CI)[a]		GP-UC Group % Change in Body Weight (95% CI)[a]		
		1-y Follow-up	3-y Follow-up	No.	1-y Follow-up	3-y Follow-up
Total, uncorrected	171	−2.2 (−2.9 to −1.5)[b]	−1.2 (−2.0 to −0.3)	186	−0.7 (−1.3 to −0.0)	−0.6 (−1.4 to 0.2)
Total, adjusted[a]	170	−2.2 (−2.9 to −1.5)[b]	−1.2 (−2.1 to −0.4)	185	−0.7 (−1.4 to −0.0)	−0.5 (−1.3 to 0.3)
Sex						
Men	84	−2.3 (−3.2 to −1.3)[b]	−1.4 (−2.6 to −0.1)	82	−0.1 (−1.1 to 0.9)	−0.2 (−1.4 to 0.9)
Women	86	−2.1 (−3.2 to −1.2)	−0.9 (−2.2 to 0.3)	103	−1.1 (−2.0 to −0.3)	−0.9 (−1.9 to 0.2)
Age, y						
<60	117	−2.6 (−3.5 to −1.8)[b]	−0.8 (−1.9 to 0.2)	110	−0.5 (−1.4 to 0.4)	0.0 (−1.1 to 1.1)
≥60	53	−1.4 (−2.6 to −0.1)	−1.8 (−3.4 to −0.3)	75	−0.8 (−1.9 to 0.3)	−1.4 (−2.7 to −0.1)
Education						
Low	56	−3.0 (−4.3 to −1.7)	−1.2 (−2.8 to 0.3)	56	−1.2 (−2.4 to 0.1)	−0.4 (−1.9 to 1.1)
Other	106	−1.9 (−2.8 to −1.0)[b]	−1.1 (−2.3 to −0.0)	119	−0.3 (−1.1 to 0.5)	−0.7 (−1.7 to 0.3)
BMI						
<30	113	−1.7 (−2.5 to −0.8)[c]	−0.7 (−1.7 to 0.4)	121	−0.6 (−1.4 to 0.3)	−0.3 (−1.3 to 0.7)
≥30	57	−3.3 (−4.5 to −2.1)[b]	−2.1 (−3.6 to −0.6)	64	−0.8 (−2.0 to 0.4)	−1.1 (−2.6 to 0.3)
Attempts to lose weight during last 5 y						
≤3 times	131	−2.6 (−3.4 to −1.8)[b,c]	−1.5 (−2.5 to −0.5)[c]	125	−0.4 (−1.3 to 0.4)	−0.5 (−1.5 to 0.5)
>3 times	26	−0.0 (−1.9 to 1.8)	1.4 (−0.9 to 3.7)	47	−1.1 (−2.5 to 0.3)	−0.7 (−2.5 to 1.0)
Treatment recommended[d]						
Yes	159	−2.4 (−3.1 to −1.7)[b]	−1.2 (−2.1 to −0.3)	171	−0.6 (−1.3 to 0.1)	−0.5 (−1.3 to 0.3)
No	11	0.1 (−2.7 to 3.0)	0.2 (−3.3 to 3.7)	14	−1.3 (−3.8 to 1.2)	−1.3 (−4.2 to 1.7)
No. of visits[e]						
≤Mean	108[f]	−2.3 (−3.2 to −1.4)	−1.6 (−2.7 to −0.5)	126[f]	−0.5 (−1.3 to 0.3)	−0.4 (−1.4 to 0.6)
>Mean	62[f]	−2.1 (−3.3 to −0.9)	−0.5 (−1.8 to 0.9)	58[f]	−0.9 (−2.2 to 0.3)	−1.0 (−2.4 to 0.5)
Visiting a dietician						
No	116		−1.6 (−2.7 to −0.6)	152		−1.8 (−1.6 to 0.1)
Yes	20		−0.1 (−2.5 to 2.8)	17		−0.4 (−3.1 to 2.3)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CI, confidence interval; GP-UC, usual care by a general practitioner; NP, nurse practitioner.

[a] Changes are calculated as the value at 1- or 3-year follow-up minus the value at baseline and adjusted for sex, age, BMI at baseline, and weight change between screening and baseline (for 1 man in the intervention group and 1 man in the control group, screening data were missing).

[b] $P<.05$, NP vs GP-UC group.

[c] $P<.05$ within NP or GP-UC group.

[d] Treatment for overweight/obesity was indicated according to national and international guidelines[19,20] (motivation of patient not taken into account).

[e] Separately for the NP group (mean after 1 year, 10 visits; mean after 3 years, 18 visits) and the GP-UC group (mean after 1 year, 2 visits; mean after 3 years, 4 visits).

[f] After 3 years, NP group (≤mean, n=100; >mean, n=70) and GP-UC group (≤ mean, n=123; >mean, n=61).

Table 4. Changes[a] in Main Outcome Variables at 3-Year Follow-up Across Treatment Groups, Stratified for 4 Categories of Weight Change

Main Outcome Measure	Successful Weight Losers (n=71)	Weight Losers (n=84)	Stabilizers (n=69)	Weight Gainers (n=133)	*P* Value[b]
Body weight, mean (SD), kg	−8.4 (4.5)	−2.3 (1.0)[c]	−0.1 (0.4)[c]	3.8 (2.6)[c]	<.001
Body weight, mean (SD), % change	−9.3 (4.2)	−2.7 (1.0)[c]	−0.1 (0.5)[c]	4.4 (2.9)[c]	<.001
Waist circumference, mean (SD), cm	−7.0 (8.1)	−1.2 (6.2)[c]	0.4 (4.9)[c]	3.7 (5.0)[c]	<.001
Total cholesterol, mean (SD), mmol/L	−0.23 (0.94)	0.02 (0.93)	0.05 (0.78)	0.11 (0.95)[d]	.009
HDL-C, mean (SD), mmol/L	−0.11 (0.27)	−0.17 (0.30)	−0.13 (0.23)	−0.22 (0.22)[d]	.02
LDL-C, mean (SD), mmol/L	−0.14 (0.92)	0.16 (0.85)	0.16 (0.62)	0.22 (0.87)[d]	.008
Fasting glucose, mean (SD), mmol/L	−0.11 (0.54)	−0.03 (0.46)	0.13 (0.52)[d]	0.12 (0.52)[d]	.001
Systolic BP, mean (SD), mm Hg	−7.3 (17.2)	−3.3 (16.5)	−7.9 (13.6)	−2.9 (15.6)	.25
Diastolic BP, mean (SD), mm Hg	−4.7 (10.0)	−1.2 (10.1)	−2.5 (7.9)	0.5 (10.6)[c]	.002

Abbreviations: ANOVA, analysis of variance; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

Conventional unit conversion factors: To convert cholesterol and glucose to milligrams per deciliter, divide by 0.0259 and 0.0555, respectively.

[a] Changes are calculated as the value at 3-year follow-up minus the value at baseline.

[b] *P* value for linear trend.

[c] $P<.01$, ANOVA with post hoc Bonferroni test with "successful weight losers" as reference category.

[d] $P<.05$, ANOVA with post hoc Bonferroni test with "successful weight losers" as reference category.

in postmenopausal women with normal weight and cardiovascular risk and showed that weight maintenance is possible with a lifestyle intervention. It is notable that we found a small difference in the fasting glucose level, while in the Diabetes Prevention Study, differences between intervention and control groups were absent for fasting glucose levels, although significant differences in weight change did occur.[6] Other studies have shown that changes in lifestyle without losing weight can improve health status.[7,8]

Most of the participants in both groups achieved weight maintenance. Several factors may be responsible for the long-term lack of difference that we expected between the NP and GP-UC groups. Patients in the GP-UC group may be more adherent to advice given by the GP because of the study circumstances. In line with the ethical committee demands, all patients were fully informed about the study purpose, and hence they knew beforehand that body weight was assessed as well as adherence to lifestyle advice. This in itself may, through some kind of Hawthorne effect, lead to modified behavior so that all patients were more adherent than they might have been under other circumstances, and this may have diluted any differences between the groups. Moreover, both groups in this trial comprised volunteers and were thus a selection of motivated patients.

The attention on health (and body weight) during the measurements in combination with abundant country-wide campaigns for a healthy lifestyle held during the course of the study may, besides the visits to the GP, also have been responsible for lifestyle changes in the control group. In comparison with the Dutch population, where an average increase in BMI of 0.05 per year (between 1981 and 2004) was described by Gast et al,[23] we found a decrease of –0.4 in the NP group and –0.2 in the GP-UC group. Thus, we can consider that the majority in the NP and GP-UC groups succeeded in preventing (further) weight gain.

Besides the limitations like baseline differences between NP and GP-UC groups and randomization at a patient level instead of at a practice level, as previously described in detail,[15] another limitation of the GOAL study needs to be discussed. The visits to the NP after the first year occurred at a low frequency and may not be sufficient to sustain weight loss. Overall, in both groups, achieving weight maintenance was not influenced by the mean number of visits (Table 3). In the Diabetes Prevention Study, 4 face-to-face visits each year were scheduled after the first year to achieve sustained weight loss after 3 years.[6] Bogers et al[24] also described that higher intervention costs (indicative for the intensity of an intervention) are associated with greater weight loss. Although this association with weight loss was determined after 1 year, it is plausible that it will also apply for long-term weight loss.

In intention-to-treat analysis regarding weight change, we chose a conservative way to deal with the dropouts by carrying the baseline observation forward. This means that we assumed that dropouts during the intervention lost no weight or regained all the weight that might be lost in the first year of the intervention and thereby possibly underestimated the weight loss of the dropouts in both groups.

The strengths of our study are the large study population with an equal amount of male and female participants, a relatively low dropout after 3 years, the prolonged follow-up, and the use of an intervention that is feasible in a primary care setting. The software program can easily be used at other locations, and the intervention is not time intensive and expensive. More research is planned to evaluate the process of the GOAL intervention, which is useful for further implementation.

Analyses in subgroups showed that within the NP group participants with 3 or fewer recent attempts to lose weight had a lower weight after 3 years compared with participants with more than 3 attempts. The latter participants' mean weight gain was 1.4% (95% confidence interval, –0.9% to 3.7%). This means that our intervention is not suitable for experienced dieters.

Regainers achieved unfavorable results on fasting glucose levels compared with stabilizers and weight gainers, which is in line with other negative health effects of weight cycling that were described.[25-27] No clear results have been reported on the relation between repeated weight losses and mortality and the underlying mechanisms.[28-31]

We can conclude that preventing weight gain by NPs did not lead to significantly better results than by GPs. More follow-up sessions in the NP group may lead to a higher percentage of maintenance of the weight that was lost after 1 year.

Accepted for Publication: July 20, 2010.
Correspondence: Nancy C. W. ter Bogt, MSc, Sector F: Department of General Practice, University Medical Center Groningen, A. Deusinglaan 1, 9713 AV Groningen, the Netherlands (n.c.w.ter.bogt@med.umcg.nl).
Author Contributions: Dr van der Meer had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Bemelmans, Beltman, Broer, Smit, and van der Meer. *Acquisition of data:* ter Bogt, Beltman, and Broer. *Analysis and interpretation of data:* ter Bogt, Bemelmans, Beltman, Smit, and van der Meer. *Drafting of the manuscript:* ter Bogt and Smit. *Critical revision of the manuscript for important intellectual content:* Bemelmans, Beltman, Broer, Smit, and van der Meer. *Obtained funding:* Bemelmans, Beltman, and Broer. *Administrative, technical, and material support:* ter Bogt, Beltman, and Broer. *Study supervision:* Bemelmans, Beltman, Smit, and van der Meer.
Financial Disclosure: None reported.
Funding/Support: The GOAL study was financially supported by the Netherlands Organization for Health Research and Development (Zon-Mw, project No. 6200.0016) and Foundation Fund "De Gavere."
Role of the Sponsors: The funders had no role in the design and conduct of the study; collection, management, analyses, and interpretation of the data; and preparation, review, or approval of the manuscript.
Additional Contributions: We are grateful to the participating general practices and their patients for their enthusiasm and cooperation. Thanks to all the students of the research team for performing measurements and data collection. We also thank the members of the

Hypertension Service Groningen for generating the GOAL-study. Neither received compensation.

REFERENCES

1. Whitlock G, Lewington S, Sherliker P, et al; Prospective Studies Collaboration. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. *Lancet*. 2009;373(9669):1083-1096.
2. Bogers RP, Bemelmans WJ, Hoogenveen RT, et al; the BMI-CHD Collaboration Investigators. Association of overweight with increased risk of coronary heart disease partly independent of blood pressure and cholesterol levels: a meta-analysis of 21 cohort studies including more than 300 000 persons. *Arch Intern Med*. 2007;167(16):1720-1728.
3. Branca F, Nikogosian H, Lobstein T. *The Challenge of Obesity in the WHO European Region and the Strategies for Response*. Copenhagen, Denmark: WHO Regional Office for Europe; 2007.
4. Wu T, Gao X, Chen M, van Dam RM. Long-term effectiveness of diet-plus-exercise interventions vs. diet-only interventions for weight loss: a meta-analysis. *Obes Rev*. 2009;10(3):313-323.
5. Knowler WC, Barrett-Connor E, Fowler SE, et al; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med*. 2002;346(6):393-403.
6. Lindström J, Louheranta A, Mannelin M, et al; Finnish Diabetes Prevention Study Group. The Finnish Diabetes Prevention Study (DPS): lifestyle intervention and 3-year results on diet and physical activity. *Diabetes Care*. 2003;26(12):3230-3236.
7. Laaksonen DE, Lindström J, Lakka TA, et al. Physical activity in the prevention of type 2 diabetes: the Finnish diabetes prevention study. *Diabetes*. 2005;54 (1):158-165.
8. Powell KE, Pratt M. Physical activity and health. *BMJ*. 1996;313(7050):126-127.
9. Davis Martin P, Rhode PC, Dutton GR, Redmann SM, Ryan DH, Brantley PJ. A primary care weight management intervention for low-income African-American women. *Obesity (Silver Spring)*. 2006;14(8):1412-1420.
10. Nanchahal K, Townsend J, Letley L, Haslam D, Wellings K, Haines A. Weight-management interventions in primary care: a pilot randomised controlled trial. *Br J Gen Pract*. 2009;59(562):e157-e166.
11. Team CP; Counterweight Project Team. Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement. *Br J Gen Pract*. 2008;58(553):548-554.
12. Dutch Institute for Healthcare Improvement CBO and Dutch College of General Practitioners. *Dutch Guideline Cardiovascular Risk Management*. Utrecht, the Netherlands: Dutch Institute for Healthcare Improvement CBO; 2006.
13. Milder IEJ, Blokstra A, de Groot J, van Dulmen S, Bemelmans WJE. Lifestyle counseling in hypertension-related visits—analysis of video-taped general practice visits. *BMC Fam Pract*. 2008;9:58.
14. Hiddink GJ, Hautvast JG, Van Woerkum CM, Fieren CJ, Van't Hof MA. Driving forces for and barriers to nutrition guidance practices of Dutch primary care physicians. *J Nutr Educ*. 1997;29(1):36-41.
15. ter Bogt NC, Bemelmans WJ, Beltman FW, Broer J, Smit AJ, van der Meer K. Preventing weight gain: one-year results of a randomized lifestyle intervention. *Am J Prev Med*. 2009;37(4):270-277.
16. Wendel-Vos GC, Schuit AJ, Saris WH, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. *J Clin Epidemiol*. 2003;56(12):1163-1169.
17. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. 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(19):2486-2497.
18. Conroy RM, Pyörälä K, Fitzgerald AP, et al; SCORE project group. Estimation of ten-year risk of fatal cardiovascular disease in Europe: the SCORE project. *Eur Heart J*. 2003;24(11):987-1003.
19. National Institutes of Health, National Heart, Lung, and Blood Institute, North American Association for the Study of Obesity. *The Practical Guide: Identification, Evaluation and Treatment of Overweight and Obesity in Adults*. Bethesda, MD: National Institutes of Health; 2000. Publication 00-4084.
20. Zelissen PM, Mathus-Vliegen EM. Treatment of overweight and obesity in adults: proposal for a guideline. *Ned Tijdschr Geneeskd*. 2004;148(42):2060-2066.
21. Jeffery RW, French SA. Preventing weight gain in adults: the pound of prevention study. *Am J Public Health*. 1999;89(5):747-751.
22. Simkin-Silverman LR, Wing RR, Boraz MA, Kuller LH. Lifestyle intervention can prevent weight gain during menopause: results from a 5-year randomized clinical trial. *Ann Behav Med*. 2003;26(3):212-220.
23. Gast GCM, Frenken FJM, van Leest LATM, Wendel-Vos GCW, Bemelmans WJE. Intra-national variation in trends in overweight and leisure time physical activities in the Netherlands since 1980: stratification according to sex, age and urbanisation degree [published correction appears in *Int J Obes (Lond)*. 2007;31(3):566]. *Int J Obes (Lond)*. 2007;31(3):515-520.
24. Bogers R, Barte J, Schipper C, et al. Relationship between costs of lifestyle interventions and weight loss in overweight adults. *Obes Rev*. 2010;11(1):51-61.
25. Hamm P, Shekelle RB, Stamler J. Large fluctuations in body weight during young adulthood and twenty-five-year risk of coronary death in men. *Am J Epidemiol*. 1989;129(2):312-318.
26. Lissner L, Odell PM, D'Agostino RB, et al. Variability of body weight and health outcomes in the Framingham population. *N Engl J Med*. 1991;324(26):1839-1844.
27. Olson MB, Kelsey SF, Bittner V, et al; Women's Ischemia Syndrome Evaluation Study Group. Weight cycling and high-density lipoprotein cholesterol in women: evidence of an adverse effect: a report from the NHLBI-sponsored WISE study. *J Am Coll Cardiol*. 2000;36(5):1565-1571.
28. Brownell KD, Rodin J. Medical, metabolic, and psychological effects of weight cycling. *Arch Intern Med*. 1994;154(12):1325-1330.
29. Field AE, Malspeis S, Willett WC. Weight cycling and mortality among middle-aged or older women. *Arch Intern Med*. 2009;169(9):881-886.
30. Jeffery RW. Does weight cycling present a health risk? *Am J Clin Nutr*. 1996;63 (3)(suppl):452S-455S.
31. Rzehak P, Meisinger C, Woelke G, Brasche S, Strube G, Heinrich J. Weight change, weight cycling and mortality in the ERFORT Male Cohort Study. *Eur J Epidemiol*. 2007;22(10):665-673.

INVITED COMMENTARY

Is Primary Care Practice Equipped to Deal With Obesity?

Obesity is associated with a long list of serious medical complications that impair health, reduce quality of life, and shorten lifespan.[1] These complications can be improved or completely resolved by weight loss. Therefore, obesity is a legitimate medical concern that should involve the implementation of therapeutic weight loss by primary practice physicians. However, an evaluation of a large primary care database in the United States found that only 20% of obese patients were given a diagnosis of obesity, and only 40% of those patients were given an obesity management plan.[2] These data suggest that general medical practices are not addressing the issue of weight management in obese patients.

In this issue, ter Bogt and colleagues report the results of a randomized controlled trial that evaluated the effect of lifestyle counseling, provided by trained NPs within a primary care setting, on long-term weight