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Preventing Weight Gain

One-Year Results of a Randomized Lifestyle Intervention

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Background: Lifestyle interventions targeting prevention of weight gain may have better long-term success than when aimed at weight loss. Limited evidence exists about such an approach in the primary care setting.

Design: An RCT was conducted.

Setting/participants: Participants were 457 overweight or obese patients (BMI=25–40 kg/m^2, mean age 56 years, 52% women) with either hypertension or dyslipidemia, or both, from 11 general practice locations in the Netherlands.

Intervention: In the intervention group, four individual visits to a nurse practitioner (NP) and one feedback session by telephone were scheduled for lifestyle counseling with guidance of the NP using a standardized computerized software program. The control group received usual care from their general practitioner (GP).

Main outcome measures: Changes in body weight, waist circumference, blood pressure, and blood lipids after 1 year (dropout <10%). Data were collected in 2006 and 2007. Statistical analyses were conducted in 2007 and 2008.

Results: There were more weight losers and stabilizers in the NP group than in the general practitioner usual care (GP-UC) group (77% vs 65%; $p<0.05$). In men, mean weight losses were 2.3% for the NP group and 0.1% for the GP-UC group ($p<0.05$). Significant reductions occurred also in waist circumference but not in blood pressure, blood lipids, and fasting glucose. In women, mean weight losses were in both groups 1.6%. In the NP group, obese people lost more weight (−3.0%) than the non-obese (−1.3%; $p<0.05$).

Conclusions: Standardized computer-guided counseling by NPs may be an effective strategy to support weight-gain prevention and weight loss in primary care, in the current trial, particularly among men.

Trial registration: The study was registered with the Netherlands Trial Register (NTR), www.trialregister.nl, study no. TC 1365.

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Introduction

The prevalence of overweight and obesity is increasing in the Netherlands. The upward trend since 1980 is similar across genders, age groups, and degrees of urbanization.[1] Prevention of overweight is a public health priority because overweight and obesity are important risk factors for the development of coronary vascular diseases (partly independent of blood pressure and cholesterol levels[2]), type 2 diabetes, certain types of cancer, gastrointestinal diseases, and arthritis.[3]

According to (inter)national guidelines, persistent lifestyle changes are necessary for preventing and managing obesity.[4,5] Studies on lifestyle interventions have shown a decrease in the risk of type 2 diabetes[6–8] and hypertension.[9] Positive changes in lifestyle may improve health status even without losing weight.[10] There is no clear consensus on the most (cost) effective way to implement lifestyle interventions, but attention to both nutrition and physical activity, applying components from behavioral therapy, and continuity and intensity are important aspects.[11,12]

In the Netherlands, general practitioners (GPs) are often responsible for the treatment of hypertension and dyslipidemia, and according to their guidelines this

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treatment includes lifestyle advice. However, lack of time and knowledge to achieve behavioral changes and insufficient continuity of care impede this approach by GPs.[13] Specially trained nurse practitioners (NPs) are probably better equipped for lifestyle counseling than GPs and can avoid these barriers.[14]

Previous lifestyle interventions showed clinically relevant reductions in body weight after 1 year.[6] However, weight regain after initial success is a commonly acknowledged problem. Most of these studies were performed in obese populations. Further, many studies included small and mainly female samples and were hampered by large dropout rates. According to the WHO, additional high-quality trials are needed to widen our insight into the sustained effectiveness of lifestyle counseling on body weight.[3]

To investigate the long-term effects of lifestyle counseling by NPs, and its potential contribution in counteracting the rising trend of overweight and obesity, the Groningen Overweight and Lifestyle (GOAL) study was started in 2006. This RCT included more than 400 overweight or obese patients at relatively low risk for cardiovascular diseases. An early focus on preventing (progression of) overweight and comorbidities rather than on weight loss may be more successful in the long term. A 3-year follow-up for GOAL is foreseen.

The effects were evaluated after a 1-year follow-up of computer-guided lifestyle advice by NPs (intervention condition) in comparison to care as usual by GPs (control condition) on body weight and conventional risk markers. A secondary aim was to identify patient and study characteristics that are associated with weight loss.

Methods

Recruitment and Assignment

Initially, 12 general practice locations (varying from one to seven GPs and one to three NPs per location) in the northern part of the Netherlands were willing to participate. Between June 2005 and February 2006, a total of 5738 patients (aged 40–70 years) were invited for a screening visit to check on the inclusion criteria for the GOAL study (chosen at random 200–250 patients for each GP). Almost 25% of the invited patients participated in the screening (n=1378). Presuming a BMI >25 kg/m^2 for 50% of the GP population,[1] the response rate was almost 50% (the invitational letter discouraged patients from coming if their BMI was <24 kg/m^2). Eligible patients had to have a BMI between 25 and 40 and either hypertension or dyslipidemia or both. Hypertension was defined as mean systolic blood pressure ≥140 mmHg and diastolic ≥90 mmHg (based on two measurements on at least two different visits) or current use of blood pressure–lowering medication, and dyslipidemia was defined as a total serum cholesterol >5.5 mmol/L or low HDL (men: <0.9; women: <1.1 mmol/L) or a ratio of total/HDL cholesterol >6 or current use of cholesterol-lowering medication.

Exclusion criteria were diabetes, hypothyroidism, pregnancy, liver or kidney disease, current treatment for malignancy, shortened life expectancy, mental illness, and addiction to alcohol or drugs. After the screening, eligible patients received additional information about the GOAL study (n=825) and 75% of them gave written informed consent (n=620). Between the screening and the start of the study, 26% of this group dropped out, because of withdrawal of one general practice location from the study (n=103); changes in the Dutch healthcare insurance system (n=14); and patient-related practical reasons (n=46), such as lack of time or moving to other areas (Figure 1). The GOAL study was approved on June 2005 by the Medical Ethics Review Committee of the University Medical Center Groningen.

Baseline Measurements

Between January and July 2006, baseline measurements took place, and patients were allocated using computer-generated random numbers to the NP (n=225) or general practitioner usual care (GP-UC) group (n=232; Figure 1). A structured physical exam by a trained research team was accomplished to measure body weight, length, waist circumference, and blood pressure. Body weight was measured on an electronic scale with subjects wearing light clothing and no shoes, height was measured using a wall-mounted measuring tape, and waist circumference was measured at a level midway between the lowest rib and the iliac crest. Blood pressure was measured

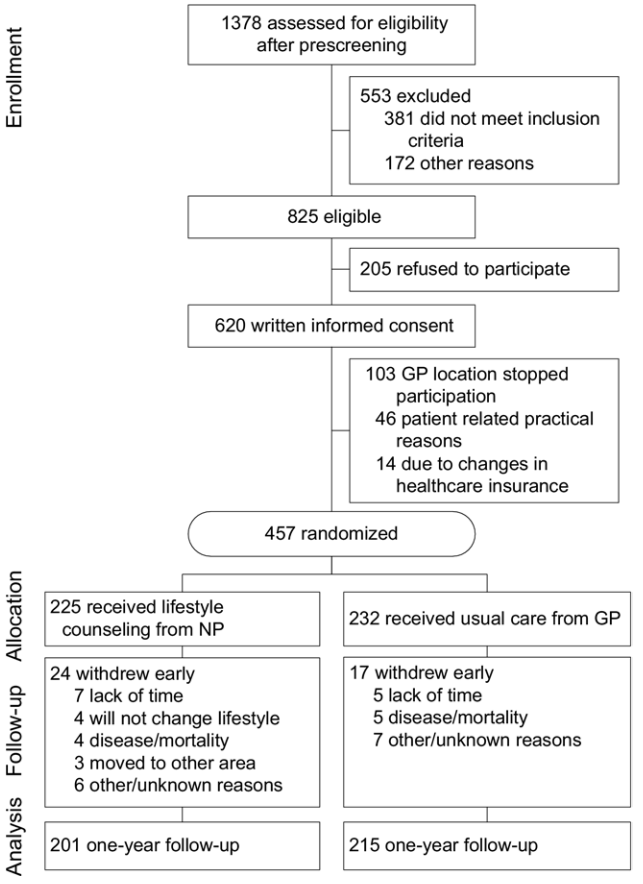

Figure 1. Flow of patients through the Groningen Overweight and Lifestyle study

twice and average values were used in analysis. The presence of cardiovascular risk factors, medication use, and family history of disease and overweight or obesity were documented. Blood samples were collected after an overnight fast to analyze fasting serum lipids and glucose (in the same central laboratory, using conventional and certified laboratory assays).

A questionnaire, which was part of the software program for the lifestyle intervention, was completed via the Internet or on paper. It contained questions on general characteristics (e.g., education level, gender) and on several issues related to body weight (e.g., history of dieting). The Short Questionnaire to Assess Health-Enhancing Physical Activity was used to determine physical activity.[15] Metabolic syndrome was defined according to criteria from the National Cholesterol Education Program's Adult Treatment Panel III,[16] and Systematic Coronary Risk Evaluation (SCORE) scores to estimate 10-year risk of fatal cardiovascular disease were calculated as described by Conroy et al.[17] 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 were distributed equally between the NP and the GP-UC group.

Intervention

The NPs (contracted by the GPs) followed a specially developed training program (four sessions of 4 hours each) and received individual instruction about the software program. The lifestyle intervention consisted of four individual visits and one feedback session by telephone in the first year. During these contact sessions, the NP was guided by the standardized computerized software program that contained instructions on lifestyle counseling defined by international guidelines[4,5] and allowed data entry of the measurements.

Table 1 shows the content of the visits. A process evaluation was performed with a structured questionnaire after the first three visits to investigate feasibility of the software program in daily practice. All NPs had a positive or neutral attitude about this program and the individualized lifestyle goals for patients. A large majority (75%) favored future implementation with regular patients. Average duration of the visits was 35 minutes for the first and second visit (range 15–60 minutes) and 25 minutes for the third visit (range 15–40 minutes). The participants in the control group were offered one visit (approximately 10 minutes) with their GP to discuss results from the screening and thereafter received usual GP care. According to national guidelines, this is low-intensity or absent care (regarding focus on lifestyle) for a large majority.

Sample-Size Calculation

Power analysis revealed that each study arm should include 145 subjects to observe (with 80% power and a 5% significance level) an expected difference in weight loss of 2.8 kg (from −0.2 kg weight change in the GP-UC group to −3.0 kg weight change in the NP group).[6] Estimating a dropout rate of 15%, a minimum of 334 participants was needed to achieve 145 participants in each study arm. To allow for subgroup analyses (at least for gender), the aim was to include 667 patients.

Statistical Analyses

Differences in baseline characteristics and changes in main outcome measures after 1 year between the two study groups were evaluated with unpaired Student's t tests for continuous variables and chi-square analysis for categoric variables. A general linear model (GLM) was used to adjust for baseline values. Further, the GLM was used to examine the relationship between percentage weight loss after 1 year and patients' characteristics. Study group, gender, and each characteristic separately were entered in the model as fixed variables, and age, baseline BMI, and weight change between screening and baseline were entered as covariates. Thereafter, two models were analyzed: in the first one, significant variables from the GLM were used, and in the second model all variables were used. Multilevel analysis was used to examine the interaction between subjects and general practice location. Differences between relevant classes within study groups (number of visits to NPs and baseline weight class) were evaluated with Student's t tests for continuous variables and chi-square analysis for categoric variables. Subjects were categorized into the following

Table 1. Visits (including measurements) and contents of the lifestyle intervention for the Groningen Overweight and Lifestyle Study

Month	Visit	Contents	Group
0	BM	Baseline measurement	NP + GP-UC
1	VGP	At least one visit at the GP to discuss results from baseline measurements and if necessary start treatment and control visits according to the GPs guidelines	GP-UC
	V1	Information on healthy lifestyle, stimulating awareness of own lifestyle and body weight, extensive conversation on history of slimming and motivation to change lifestyle/lose weight and a first step in the development of the treatment plan	NP
2	V2	Feedback on lifestyle by critiquing food diary, physical activity (counting steps by pedometer received in V1) and baseline questionnaires; finish treatment plan (including individual goals)	NP
3	V3	Evaluate the attainability of the goals and if necessary change treatment plan and refer to dietician	NP
5	F1	Evaluate and support changes in lifestyle and, if necessary, change individual goals	NP
8	V4	Evaluate and support changes in lifestyle and, if necessary, change individual goals	NP
12	M1	Measurement after 1 year	NP + GP-UC

BM, baseline measurement; F1, feedback moment by telephone by nurse practitioner; GP-UC, general practitioner usual care (control group); NP, nurse practitioner (intervention group); VGP, visit with general practitioner; V1–V4, visit with nurse practitioner

Table 2. Baseline characteristics for NP group and GP-UC group, *n* (%) unless otherwise indicated

Characteristic	NP group (*n*=225)	GP-UC group (*n*=232)
General (years), M (SD)		
Age	55.3 (7.7)	56.9 (7.8)
Men	113 (50.2)	107 (46.1)
Low education	71/212 (33.5)	67/217 (30.9)
Relationship	177/213 (83.1)	188/226 (85.5)
Physical exam and blood analysis		
BMI (kg/m^2) M (SD)	29.5 (3.1)	29.6 (3.6)
BMI ≥30 kg/m^2 (cm), M (SD)	79 (35.1)	85 (36.6)
Waist circumference for men (cm), M (SD)	104 (7.8)	105 (9.5)
Waist circumference for women (cm), M (SD)	97 (9.8)	97 (11.8)
Total cholesterol (mmol/L), M (SD)	5.66 (1.0)	5.56 (1.0)
HDL cholesterol (mmol/L), M (SD)	1.44 (0.4)	1.43 (0.4)
LDL cholesterol (mmol/L), M (SD)	3.50 (0.9)	3.43 (0.9)
Fasting glucose (mmol/L), M (SD)	5.20 (0.5)	5.25 (0.7)
Systolic blood pressure (mmHg), M (SD)	146 (18.5)	145 (15.5)
Diastolic blood pressure (mmHg), M (SD)	87 (9.6)	86 (8.2)
Hypertension	137 (60.9)	145 (62.5)
Using medication for hypertension[a]	61/136 (44.9)	74/144 (51.4)
Dyslipidemia	83 (36.9)	96 (41.4)
Using medication for dyslipidemia[b]	31/83 (37.3)	43/96 (44.8)
SCORE score, M (SD)	3.55 (4.0)	3.29 (3.0)
SCORE score <5	175/219 (79.9)	182/226 (80.5)
Metabolic syndrome	98/224 (43.8)	102/232 (44.0)
Lifestyle		
Current smokers	46/224 (20.5)	42/232 (18.1)
>3 attempts to lose weight during the past 5 years	33/207 (15.9)	55/213 (25.8*)
≥30 minutes of moderate-intensity physical activity 5 days/week	123/216 (56.9)	150/220 (68.2*)

[a]Percentage of participants with hypertension
[b]Percentage of participants with dyslipidemia
*Chi-squared NP vs GP-UC group $p<0.05$
GP-UC, general practitioner usual care; HDL, high-density lipoprotein; LDL, low-density lipoprotein; mmol/L, millimoles per liter; NP, nurse practitioner; SCORE, Systematic Coronary Risk Evaluation

classes according to percentage of weight change after 1 year: 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 (gained >1%). Differences in main outcome variables among these four categories were tested with ANOVA and a post hoc Bonferroni test.

The analyses followed the intention-to-treat principle. Results are primarily presented with exclusion of dropouts and missing values, adjusting for baseline values. All analyses were also performed using baseline observation carried forward for dropouts. This did not alter the results except for the percentage of stabilizers and weight losers, which (naturally) was higher when copying baseline values (79.1% vs 67.2% in the NP and GP-UC group, respectively, after 1 year).

All analyses were performed in 2007 and 2008 using SPSS/PC statistical program version 14.0 for Windows. A *p*-value <0.05 was considered significant.

Results

Baseline Measurements

Table 2 shows that there were no differences in the two study groups at baseline except for higher percentages having sufficient physical activity and a history of >3 previous attempts to lose weight in the past 5 years in the GP-UC group compared with those in the NP group. When stratified for gender, women in the GP-UC group were older (aged 57 vs 55 years); had hypertension more often (66% vs 54%); and were sufficiently physically active more often (75% vs 58%) ($p<0.05$ for all); in men there were no significant differences in baseline values between the NP and the GP-UC group.

Follow-Up Measurement and Dropout During the First Year

One year later, the baseline measurements were repeated with a total of 416 people (91%). There were no differences between these subjects and the dropouts ($n=41$; 9%) for age, educational level, blood pressure, and serum lipids. Dropouts had a higher mean value of fasting glucose, higher prevalence of hypertension, and lower prevalence of dyslipidemia ($p<0.05$; data not shown). Figure 1 presents reasons for dropout.

Changes in main outcome measures for the NP and GP-UC groups after 1 year. After 1 year there were more (successful) weight losers and stabilizers in the NP group than in the GP-UC group (77% vs 65%) ($p<0.05$). Mean weight change was −1.9% (SD 4.9) in the NP group and −0.9% (SD 5.0) in the GP-UC group ($p<0.05$). Mean waist circumference decreased by 2.4 cm (SD 7.1) in the NP group and by 1.2 cm (SD 5.9) in the GP-UC group ($p=0.07$). No significant differences occurred for changes in serum lipids or blood pressure.

Changes in body weight stratified for patient characteristics. Table 3 shows changes in body weight after 1 year stratified for patient characteristics. In the NP group, average weight loss was −2.3% for men and −1.6% for women, whereas in the GP-UC group, women lost more weight than men (−1.6% vs −0.1%; $p<0.05$). In the NP group, obese participants (BMI≥ 30 kg/m^2) and participants who visited the NP at least three times lost more body weight than participants with a lower baseline BMI (−3.0% vs −1.3%, respec-

tively) and those with zero to three visits (−2.3% vs −0.4%; $p<0.05$).

Characteristics associated with weight loss. Two GLMs were composed; the first model ($p<0.001$, $R^2=0.08$) showed that weight loss is associated with study group ($p=0.03$); study group X gender ($p=0.03$); BMI at baseline ($p=0.03$); and weight change between screening and baseline ($p<0.001$); and not with gender and age. In the second model ($p<0.001$, $R^2=0.12$), all variables from Table 3 were added to the first model, but this did not alter the results except for weight change between screening and baseline ($p=0.06$). Multilevel analyses were performed, but the variance resulting from general practice location was very low and not significant (intraclass correlation=0.02).

Table 3. Percentage change in body weight at 1-year follow-up stratified for patients' characteristics for both study groups

	NP group		GP-UC group	
	n	% change in body weight (95% CI)[a]	*n*	% change in body weight (95% CI)[a]
Total (uncorrected)	201	−1.9 (−2.6, −1.2)	215	−0.9 (−1.5, −0.2)*
Total (adjusted)[a]	200	−1.9 (−2.5, −1.2)	214	−0.9 (−1.5, −0.2)*
Gender				
Men	97	−2.3 (−3.2, −1.3)	100	−0.1 (−1.1, 0.8)
Women	103	−1.6 (−2.5, −0.6)	114	−1.6 (−2.5, −0.7)**
Age (years)				
<60	141	−2.2 (−3.0, −1.4)	127	−0.9 (−1.7, −0.0)
≥60	59	−1.2 (−2.4, 0.0)	87	−0.8 (−1.8, 0.3)
Education				
Low	64	−2.5 (−3.7, −1.3)	64	−1.2 (−2.4, 0.0)
Other	126	−1.7 (−2.5, −0.8)	136	−0.6 (−1.5, 0.2)
BMI (kg/m^2)				
<30	128	−1.3 (−2.1, −0.5)	136	−0.7 (−1.5, 0.1)
≥30	72	−3.0 (−4.1, −1.9)**	78	−1.1 (−2.2, 0.0)
Attempts to lose weight during the past 5 years				
Never	80	−2.4 (−3.5, −1.3)	75	−1.1 (−2.3, 0.1)
1–3	73	−2.2 (−3.3, −1.1)	70	−0.4 (−1.6, 0.8)
>3	32	0.1 (−1.6, 1.9)	52	−1.0 (−2.4, 0.4)
Visits to NP				
0–3	42	−0.4 (−1.9, 1.0)		—
>3	158	−2.3 (−3.0, −1.6)**		—
Treatment recommended[b]				
Yes	188	−2.1 (−2.7, −1.4)	198	−0.7 (−1.4, −0.1)
No	12	0.3 (−2.5, 3.1)	16	−2.2 (−4.7, 0.3)

[a]Changes are calculated as the value at 1-year follow-up minus the value at baseline and adjusted for gender, age, BMI at baseline, and weight change between screening and baseline (for one man in the intervention group and one man in the control group, screening data were missing).
[b]Treatment on overweight and obesity indicated according to (inter)national guidelines (motivation of patient not taken into account)
*$p<0.05$ NP vs GP-UC group
**$p<0.05$ within NP or GP-UC group
GP-UC, general practitioner usual care; NP, nurse practitioner

Changes in main outcome variables separately for gender. The GLM showed that gender is an effect modifier, and Table 3 shows that weight loss differed according to number of NP visits and baseline weight class (obesity versus [moderate] overweight). Table 4 therefore presents changes in main outcome variables after 1 year for the NP and GP-UC groups, separately for men and women. For women, no significant differences were found between the NP and GP-UC groups although the percentage of weight losers and stabilizers tended to be higher in the NP group (73% vs 64%, respectively; $p=0.17$). For men, changes in body weight (in kilogram and percentage) and waist circumference were significantly more favorable in the NP group compared with those in the GP-UC group. The percentage of weight losers and stabilizers was higher in the NP group than in the GP-UC group (81% vs 65%, respectively; $p<0.05$). Subgroup analyses were also performed within the NP group (also separately for men and women) for at least three visits versus less than three visits and for obese versus non-obese participants. For women, no significant differences were found. For men, changes in body weight (in kilogram and percentage) and waist circumference were significantly more favorable in obese men in the NP group compared with those in men with a BMI <30 kg/m^2 in the NP group. Obese men in the NP group had a greater reduction in systolic blood pressure (−14 mmHg) than did obese men in the GP-UC group (−5 mmHg; $p<0.05$), in addition to lower body weight (in kilogram and percentage) and smaller waist circumference ($p<0.05$; data not shown).

Associations between outcome measures and weight changes. Except for HDL cholesterol and fasting glucose, the outcome variables differed among the four categories of weight change, with successful weight losers achieving the most favorable and weight gainers the least favorable results on outcome variables (Table 5).

Discussion

Lifestyle counseling using a prestructured software program in a primary care setting succeeded in a weight reduction of 3% in obese people and weight

Table 4. Changes[a] in main outcome measures at 1-year follow-up, M (SD) unless otherwise indicated

	Women		Men	
	GP-UC group (n=114)	NP group (n=103)	GP-UC group (n=101)	NP group (n=98)
Body weight (kg)	−1.4 (4.9)	−1.5 (4.1)	−0.0 (3.9)	−2.1 (4.8)*
Body weight (% change)	−1.6 (5.6)	−1.7 (4.9)	−0.1 (4.0)	−2.1 (4.8)*
Waist circumference (cm)	−1.5 (6.8)	−2.0 (7.8)	−0.9 (4.5)	−2.8 (6.2)*
Total cholesterol (mmol/L)	−0.06 (0.8)	0.02 (0.8)	0.03 (0.7)	−0.18 (0.6)
HDL cholesterol (mmol/L)	−0.12 (0.2)	−0.11 (0.2)	−0.05 (0.2)	−0.06 (0.2)
LDL cholesterol (mmol/L)	0.02 (0.7)	0.15 (0.7)	0.12 (0.6)	−0.04 (0.6)
Fasting glucose (mmol/L)	−0.11 (0.5)	−0.08 (0.6)	−0.05 (0.8)	−0.03 (0.6)
Systolic blood pressure (mmHg)	−2.2 (16.5)	−5.3 (20.1)	−5.3 (12.7)	−8.5 (16.8)
Diastolic blood pressure (mmHg)	0.2 (8.4)	−0.3 (9.6)	−1.3 (7.8)	−2.6 (11.2)
SCORE score	0.46 (1.3)	0.10 (1.7)	−0.07 (1.3)	−0.23 (2.8)
Weight losers and stabilizers,[b] n (%)	73 (64.0)	75 (72.8)	66 (65.3)	79 (80.6)*

[a]Changes are calculated as the value at 1-year follow-up minus the value at baseline.
[b]Percentage of subjects who gained less than 1% body weight between baseline and 1-year measurement
*p<0.05 men in NP vs men in GP-UC group after adjustment for baseline values
GP-UC, general practitioner usual care; HDL, high-density lipoprotein; LDL, low-density lipoprotein; mmol/L, millimoles per liter; NP, nurse practitioner; SCORE, Systematic Coronary Risk Evaluation

maintenance in people with moderate overweight, which is precisely according to the guidelines.[4,5] The results were more favorable in men, with significant effects on waist circumference, than in women, where no differences were found between the NP and the GP-UC groups.

Previous research showed that clinically relevant weight loss of 5% can be achieved after 1 year, but that intensive programs are necessary.[6] Because of the (relatively) low intensity of the lifestyle counseling strategy, this intervention was expected to prevent weight gain or establish marginal weight loss only. In line with this expectation, for GOAL, a study group was selected with low cardiovascular risk (mean SCORE score 3.4), to aim primarily at prevention of weight gain and related comorbidities in a "healthy population." Nonetheless, despite this overall aim and a BMI >25 kg/m^2 as a cutoff for inclusion, in the NP group 94% had an indication for losing weight according to (inter)national guidelines on obesity (n=188).[4,5] In this percentage, the patient's motivation to lose weight was not taken into account. The NPs discussed motivational aspects in the first visit (NP group only), and during this visit about 75% of the participants expressed a motivation for losing weight.

In non-indicated and nonmotivated patients, the NP lifestyle counseling was explicitly aimed at weight stabilization, and no personal weight loss target was discussed or evaluated. Those with a medical indication for weight loss lost more weight after 1 year than the non-indicated, but this difference was not significant (Table 3). This absence of difference may be due to the fact that GOAL is an RCT and all patients gave informed consent and thereby commitment to the study. During the intervention, the average number of NP visits was almost equal among patients with counseling focused on weight loss (n=4.5) versus prevention of weight increase (n=4.1). In actual practice, the impact of patient's motivation and targeting by NPs will probably be larger.

The GOAL study is a well designed RCT and its strengths are the large study population (allowing

Table 5. Changes[a] in main outcome variables at 1-year follow-up across treatment groups, M (SD)

	Successful weight losers (n=79)	Weight losers (n=125)	Stabilizers (n=89)	Weight gainers (n=123)	p-values[b]
Body weight (kg)	−8.1 (3.9)	−2.4 (1.0)*	0.1 (0.4)*	3.3 (2.3)*	<0.001
Body weight (% change)	−8.9 (3.7)	−2.7 (1.1)*	0.1 (0.5)*	3.8 (2.4)*	<0.001
Waist circumference (cm)	−7.9 (7.1)	−2.4 (5.3)*	−0.6 (4.3)*	1.9 (5.5)*	<0.001
Total cholesterol (mmol/L)	−0.41 (0.9)	−0.02 (0.6)*	0.00 (0.7)*	0.12 (0.7)*	<0.001
HDL cholesterol (mmol/L)	−0.05 (0.2)	−0.07 (0.2)	−0.09 (0.2)	−0.11 (0.2)	0.06
LDL cholesterol (mmol/L)	−0.26 (0.8)	0.11 (0.5)*	0.10 (0.6)*	−0.20 (0.6)*	<0.001
Fasting glucose (mmol/L)	−0.19 (0.4)	−0.08 (0.5)	−0.08 (0.9)	0.03 (0.6)	0.02
Systolic blood pressure (mmHg)	−11.1 (20.2)	−8.5 (15.0)	−1.7 (13.0)*	−0.6 (16.9)*	<.001
Diastolic blood pressure (mmHg)	−3.6 (10.1)	−2.1 (8.4)	0.2 (9.2)	1.1 (9.3)*	<.001

[a]Changes are calculated as the value at 1-year follow-up assessment minus the value at baseline.
[b]p-value for linear trend
*p<0.01 ANOVA with post hoc Bonferroni test with successful weight losers as the reference category
HDL, high-density lipoprotein; LDL, low-density lipoprotein; mmol/L, millimoles per liter

subgroup analyses) and the low dropout rate after 1 year (9%). The process evaluation, using a structured questionnaire, showed that most NPs favored future implementation. Some limitations of the GOAL study need to be discussed. There were some baseline differences between the NP and GP-UC groups (physical activity and attempts to lose weight), but in stratified analyses these characteristics were not related to weight change after 1 year. Second, regression to the mean may be involved owing to the fact that both the GP-UC and the NP group patients gained on average 1.0 kg between screening and baseline measurements (a period of 3–12 months). Weight gain during the pre-study period was significantly inversely related with weight change during the first year. However, when also evaluated from the screening on, this intervention succeeds in preventing weight gain. Regression to the mean also cannot account for the gender difference: The effect of study group was seen in men only (the difference of 2.1 kg is in line with the 2.8 kg as estimated in the power analysis; because of a smaller SD this difference was significant even with fewer than 145 male participants). In general, women might have more knowledge and experience regarding weight maintenance (e.g., dieting is more common in women,[18] and more men than women underestimate their body weight[18,19]), and a low-intensity intervention may have limited additional impact in experienced patients.

Third, randomization was done at the patient level, allowing contamination of research conditions within the same GP practice. For GOAL, this risk is considered quite small because there were on average (only) 40 participants per general practice location (with one to seven GPs per location). On the other hand, NPs were allied to GPs and were allowed to discuss the patients' treatment with the GP. However, GPs did not follow the special training and could not use the software program (no license, no data available from participants). Seventeen participants from the GP-UC group were referred to the NP group following usual procedures in the practice (the GPs and NPs did not know that the patients belonged to the control group of the GOAL study). These 17 people did not receive the same lifestyle counseling as the NP group because the software program could be used for participants in the NP group only. Elimination of these 17 people did not alter the results.

Until now, most lifestyle interventions have investigated strategies to lose weight, but the first priority should be to prevent further weight gain.[12,20] A previous low-cost intervention[21] and public health messages[22] did not succeed in reducing weight gain with age. A recent study that compared three strategies for achieving weight maintenance after initial weight loss showed that monthly, brief personal contact provided modest benefit.[23] In the GOAL study, lifestyle changes are small (consistent with modest weight loss), which probably makes it easier not to relapse to former patterns.

Preventing overweight is a public health issue with a high priority in many countries. The wider context of this study was a media climate in the Netherlands that focused much attention on overweight and a healthy lifestyle, and countrywide campaigns were run in the same period. This may explain why even the control group was quite successful (65% weight losers and stabilizers). It is an important result that even against this background of other public health initiatives, lifestyle counseling in the primary healthcare setting is indeed of additional value. This is in line with WHO statements that acknowledge the primary healthcare setting as key for overweight prevention.[3] Booth et al.[24] showed that GPs gave healthy lifestyle advice to obese patients rather than to those with a BMI between 23 and 30 kg/m^2, although this latter group might gain more health benefits from prevention. Hence, increased awareness among GPs and measurement of BMI is necessary to ensure adequate referral to NPs. The 3-year results of GOAL, together with cost-effectiveness analyses, will determine if this method of lifestyle advice succeeds in sustained weight reduction or stabilization in primary care.

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References

1. Gast G-CM, 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. Int J Obes 2006;31:515–20.
2. Bogers RP, Bemelmans WJ, Hoogenveen RT, et al. 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;167:1720–8.
3. WHO. The challenge of obesity in the WHO European Region and the strategies for response. Branca F, Nikogosian H, Lobstein T, eds. Copenhagen: WHO Regional Office for Europe, 2007.
4. Zelissen PM, Mathus-Vliegen EM. Treatment of overweight and obesity in adults: proposal for a guideline. Ned Tijdschr Geneeskd 2004;148:2060–6.
5. NIH. The practical guide: identification, evaluation and treatment of overweight and obesity in adults. NIH Publication Number 00-4084. Bethesda MD: NIH.
6. McTigue KM, Harris R, Hemphill B, et al. Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2003;139:933–49.
7. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002;346:393–403.

8. Lindstrom J, Ilanne-Parikka P, Peltonen M, et al. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. Lancet 2006;368:1673–9.
9. Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. JAMA 2003;289:2083–93.
10. Powell KE, Pratt M. Physical activity and health. Br Med J 1996;313:126–7.
11. Pi-Sunyer X. A clinical view of the obesity problem. Science 2003;299: 859–60.
12. Serdula MK, Khan LK, Dietz WH. Weight loss counseling revisited. JAMA 2003;289:1747–50.
13. Hiddink GJ, Hautvast JGAJ, van Woerkum CMJ, Fieren CJ, van 't Hof MA. Driving forces for and barriers to nutrition guidance practices of Dutch primary care physicians. J Nutr Educ 1997;29:36–41.
14. Lyons F. Weight management in primary care: the Counterweight Project. J Fam Health Care 2005;15:77–9.
15. 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;56:1163–9.
16. 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.
17. Conroy RM, Pyorala K, Fitzgerald AP, et al. Estimation of ten-year risk of fatal cardiovascular disease in Europe: the SCORE project. Eur Heart J 2003;24:987–1003.
18. Blokstra A, Burns CM, Seidell JC. Perception of weight status and dieting behaviour in Dutch men and women. Int J Obes Relat Metab Disord 1999;23:7–17.
19. Steenhuis IH, Bos AE, Mayer B. (Mis)interpretation of body weight in adult women and men. J Hum Nutr Diet 2006;19:219–28.
20. Hill JO, Thompson H, Wyatt H. Weight maintenance: what's missing? J Am Diet Assoc 2005;105:S63–S66.
21. Jeffery RW, French SA. Preventing weight gain in adults: the Pound of Prevention Study. Am J Public Health 1999;89:747–51.
22. Williams L, Germov J, Young A. Preventing weight gain: a population cohort study of the nature and effectiveness of mid-age women's weight control practices. Int J Obes (Lond) 2007;31:978–86.
23. Svetkey LP, Stevens VJ, Brantley PJ, et al. Comparison of strategies for sustaining weight loss: the weight loss maintenance randomized controlled trial. JAMA 2008;299:1139–48.
24. Booth AO, Nowson CA, Huang N, Lombard C, Singleton KL. Evaluation of a brief pilot nutrition and exercise intervention for the prevention of weight gain in general practice patients. Public Health Nutr 2006;9: 1055–61.