Leisure-time activity is an important determinant of long-term weight maintenance after weight loss in the Sibutramine Trial on Obesity Reduction and Maintenance (STORM trial)[1–3]

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ABSTRACT

Background: The success rate of long-term maintenance of weight loss in obese patients is usually low. To improve the success rate, determinants of long-term weight maintenance must be identified.

Objective: The objective of the study was to identify determinants of long-term success in weight maintenance in obese subjects who completed the Sibutramine Trial on Obesity Reduction and Maintenance ($n = 261$), a multicenter European study of weight loss and weight maintenance in obesity that combines sibutramine treatment with dietary restriction and advice on exercise and behavior.

Design: We studied weight maintenance over 18 mo in subjects who had completed a 6-mo weight-loss phase. Factors included in the analysis were initial body weight, the percentage of initial body weight lost, dietary intake, various components of physical activity (measured with the Baecke questionnaire), the type of treatment (sibutramine or placebo), age, and sex.

Results: Multiple regression analysis identified treatment group (sibutramine or placebo), the percentage of the initial body weight that was lost during the 6-mo weight-loss phase, and the leisure-time physical activity index as significant determinants of weight maintenance. Together, these 3 factors explained 20% of the variation in weight maintenance ($P < 0.001$). Dietary factors, age, and sex were not significant predictors of weight-maintenance success in this study.

Conclusions: Weight-maintenance success after weight loss is positively influenced by sibutramine treatment during weight maintenance, by a greater initial weight loss, and by a higher leisure-time physical activity index, which reflects higher levels of activities such as walking and cycling and lower levels of television viewing. *Am J Clin Nutr* 2003;78:209–14.

INTRODUCTION

In most obese patients who are motivated to lose weight, significant weight loss can be achieved by using the current strategies for obesity treatment (1). However, long-term maintenance of this weight loss is difficult and often unsuccessful. Wing and Hill (2) recently reviewed studies of weight-loss maintenance. The success rate that can be derived from these studies depends on the definition of success in weight-loss maintenance and the duration of the follow-up period. A sustained loss of 5–15% of initial body weight is associated with significant health benefits, especially in persons with obesity-related comorbidities (3–5). If successful weight-loss maintenance is defined as an intentional weight loss of ≥10% of the initial body weight and maintenance of the new weight for ≥1 y, Wing and Hill estimated that at least 21% of overweight or obese persons may be regarded as successful. Ayyad and Andersen (6) reviewed more long-term (3–14 y; median: 5 y) success in weight maintenance and defined weight-maintenance success by 2 criteria: maintenance of the entire initial weight loss or maintenance of ≥9–11 kg of the initial weight loss. Overall, a median of 15% (range: 0–49%) of the patients met one of these criteria for success. Obviously, there is a clear need to improve the long-term success rate of weight-loss therapies. To further improve the success rate of long-term weight management after weight loss, it is necessary to elucidate the determinants of successful weight maintenance.

The Sibutramine Trial on Obesity Reduction and Maintenance (STORM trial) is a multicenter European study of weight loss and long-term weight maintenance in obese persons that combines sibutramine treatment with dietary restriction, exercise advice, and behavioral advice. The main results of the STORM trial were reported previously (7). The main outcome was that, of the subjects who completed the trial, 43% of those in the sibutramine-treated group maintained ≥80% of their original weight loss, whereas only 16% of those in the placebo-treated group did so over an 18-mo follow-up weight-maintenance period. However, there were large interindividual variations in weight maintenance within the sibutramine-treated and placebo-treated groups. The design of the STORM trial allows the study of a number of factors

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Received July 8, 2002.

Accepted for publication December 16, 2002.

related to treatment, dietary intake, and physical activity and of their association with long-term weight maintenance. In a recent analysis, Hansen et al (8) showed that 8–9% of the variation in weight loss from baseline to follow-up in the STORM trial could be explained by baseline body weight, treatment group (ie, sibutramine or placebo), and age. In the current analysis, we focused on weight maintenance during the 18 mo after the initial 6-mo weight-loss phase and included in the analysis additional factors, such as initial body weight (month 0); changes in body weight, dietary intake, and physical activity during the weight-loss phase (0–6 mo); type of treatment (sibutramine or placebo); and dietary intake and physical activity level (total activity and that associated with work, sports, or other leisure-time activities) during the weight-maintenance phase (6–24 mo).

SUBJECTS AND METHODS

The STORM trial comprises a 6-mo, open-label, run-in, weight-loss phase that is followed by an 18-mo, double-blind, randomized, placebo-controlled, weight-maintenance phase.

Subjects

Initially, 605 obese subjects aged 17–65 y with a body mass index (in kg/m^2) of 30–45 were recruited for the study. After the 6-mo run-in phase, 467 subjects were randomly assigned in a ratio of 3 to 1 to receive sibutramine (10–20 mg/d, depending on maintenance of weight loss) or placebo during an 18-mo weight-maintenance phase. Of the initial 605 subjects, 261 completed the study—204 who received sibutramine and 57 who received placebo during the weight-maintenance phase. Ethical approval for the study was obtained from each of the participating institutions.

Design

During the 6-mo run-in phase, all subjects were treated with sibutramine (10 mg/d) in combination with a prescribed 600-kcal deficit diet with < 30% of energy from fat and 15% of energy from protein. Advice to increase physical activity was given (9, 10). In addition, information on behavioral modification was provided. A dietitian saw the subjects every 2 wk. Subjects who lost > 5% of their initial weight during the 6-mo run-in phase were randomly assigned for the weight-maintenance phase.

During the 18-mo weight-maintenance phase, subjects were given dietary advice to maintain weight and were seen every 4 wk by a dietitian, who encouraged them to remain physically active. Body weight, dietary intake, and physical activity were determined at baseline. These measurements were repeated at 6, 12, 18 (except physical activity), and 24 mo. In addition, both the dietitian and the subject estimated dietary compliance on a 5-point scale (1 = full, 5 = none) at the end of the follow-up period (24 mo).

Methods

Dietary intake was assessed from 4-d (including one weekend day) food diaries completed by the subjects. National food tables and programs were used to calculate energy and nutrient intakes. Physical activity levels were obtained from the Baecke questionnaire (11), which was completed by the subjects. This validated and reproducible questionnaire quantifies various components of physical activity (work, sports, other leisure-time activities, and total activity). Each component is expressed as an index. The work index is derived from the subject's main occupation; the frequency of sitting, standing, walking, lifting heavy loads, and sweating during work; tiredness after work; and the subject's estimation of the physical demands of his or her job in comparison with those of the subject's age peers. The sports index is derived from the 2 most frequently played sports with an estimation of their intensity and the number of hours per week and of months per year these 2 sports are played by the subject, an estimation of the level of physical activity compared with that of the subject's age peers, the frequency of sweating during leisure time, and the frequency of playing sports. The leisure-time physical activity index is based on the frequency of television viewing, walking, and cycling and on the time spent walking or cycling for transportation.

TABLE 1
Characteristics of subjects in the total sample and in the 2 treatment groups[1]

	Sibutramine group (n = 204)	Placebo group (n = 57)	Total sample (n = 261)
Sex			
Female [n (%)]	168 (82.3)	46 (80.7)	214 (82.0)
Male [n (%)]	36 (17.7)	11 (19.3)	47 (18.0)
Age (y)	41.4 ± 9.7[2]	41.3 ± 10.0	41.4 ± 9.8
BMI (kg/m^2)			
Month 0	36.6 ± 4.2	37.1 ± 3.8	36.8 ± 4.2
Month 6	32.0 ± 4.0	32.7 ± 3.7	32.2 ± 3.9

[1] There were no significant differences between the 2 groups.
[2] $\bar{x}$ ± SD.

Data analysis

Results were analyzed only in those subjects who completed the study (n = 261) and are reported as means (± SDs). Weight maintenance was calculated as the percentage of the body-weight loss during the weight-loss phase (months 0–6) that was maintained during the weight-maintenance phase (months 6–24). Changes in body weight, macronutrient intake, and physical activity during the weight-loss phase were calculated (Δ0–6 mo). During the weight-maintenance phase, dietary intakes and physical activity scores were averaged over the period of 12–24 mo. The values at 6 mo were not included in the mean for the weight-maintenance phase because they were collected at the end of the weight-loss phase. However, including the values at 6 mo did not change the results significantly.

Changes in the variables during the weight-maintenance period were analyzed by repeated-measures analysis of variance and post hoc paired t test with Bonferroni correction for multiple comparisons. Simple regression analysis with percentage of weight (loss) maintained as the independent variable was performed. Multivariate stepwise regression analysis was applied to ascertain which factors contributed independently to weight maintenance. Factors were included in the regression model if their contribution was significant at $P < 0.05$.

RESULTS

The 261 subjects (214 women, 47 men) included in this analysis had a mean age of 41.4 ± 9.8 y and a mean body mass index of 36.8 ± 4.2 at the start of the study. After randomization, there was no difference in sex distribution, age, or body mass index between the treatment groups (**Table 1**).

Body-weight loss after the 6-mo run-in phase was 12.4 ± 4.6% (range: 5.0–29.5%), and it did not differ significantly between the groups that subsequently were randomly assigned to placebo

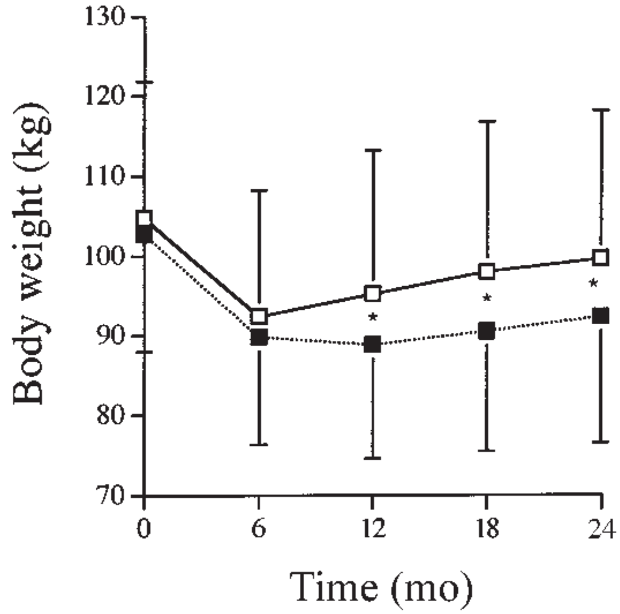

FIGURE 1. Mean (±SD) body weight in sibutramine-treated (■; $n = 204$) and placebo-treated (□; $n = 57$) groups in the weight-loss phase (month 0–month 6) and in the weight-maintenance phase (month 6–month 24). Repeated-measures ANOVA: main effect of time, $P < 0.001$; main effect of treatment, $P = 0.022$; time × treatment interaction, $P < 0.001$. *Significant difference between groups, $P < 0.01$ (post hoc ANOVA, adjusted according to Bonferroni).

or sibutramine treatment (11.9 ± 3.9% and 12.6 ± 4.8%, respectively; $P = 0.31$) (**Figure 1**). During the follow-up phase, there was a significant increase in body weight (repeated-measures analysis of variance, $P < 0.0001$), which differed between the placebo- and sibutramine-treated subjects (time × treatment interaction, $P < 0.0001$). Body weight remained significantly lower in the sibutramine-treated group than in the placebo-treated group. Body weight in both groups at the end of follow-up (month 24) was significantly ($P < 0.001$) lower than that at baseline (month 0) (post hoc analysis of variance with Bonferroni correction) (Figure 1).

The mean values of the studied variables at the various time points are shown in **Table 2**. Body weight, energy intake, and relative fat intake decreased during the 6-mo weight-loss phase. During follow-up, these variables gradually increased, but, at month 24, they were still significantly lower than at baseline. The total and sports activity indexes and the relative protein and carbohydrate intakes increased during the weight-loss phase, gradually decreased during the follow-up, but were still significantly higher at month 24 than at baseline. The leisure-time physical activity index also increased during the weight-loss phase, and this increase was maintained during follow-up. The work activity index did not change during the 24-mo study period (Table 2). At baseline, the sports and leisure-time physical activity indexes were correlated ($r = 0.254$, $P < 0.001$), but neither the leisure-time and work activity indexes nor the sports and work activity indexes were significantly correlated.

The simple correlation coefficients of various variables with weight maintenance are shown in **Table 3**. Statistically significant correlations were found for the initial body-weight loss [Δbody weight (0–6 mo)]; for the total, sports, and leisure-time physical activity indexes during follow-up; and for fat intake as a percentage of energy during follow-up. Multivariate stepwise regression analysis with these variables and treatment group as the independent variables and weight maintenance as the dependent variable identified the following independent predictors of weight maintenance: treatment group (sibutramine or placebo), the percentage of the initial body weight lost, and leisure-time physical activity index. The regression equation was as follows:

$$\text{Percentage of weight loss maintained} = 71.293 - 39.10 \times \text{treatment group (1, sibutramine; 2, placebo)} + 3.162 \times \Delta\text{body weight (0–6 mo) (\%)} + 16.578 \times \text{leisure-time physical activity index (12–24 mo)} \quad (1)$$

The partial correlation coefficients were −0.302, 0.294, and 0.219, respectively. Together these 3 determinants explained 20% of the variation in weight maintenance between subjects ($P < 0.001$). The respective contributions were 9% for treatment, 8% for initial body-weight loss, and 3% for leisure-time physical activity index. However, these numbers do not necessarily indicate that leisure-time physical activity is less influential than the other 2 factors. When sex was included as an independent variable in

TABLE 2
Variables studied in the total sample at various time points during the study[1]

Variable	Time points during study					P^2 (month 0–month 24)
	Month 0	Month 6	Month 12	Month 18	Month 24	
Total activity index	7.58 ± 1.25	8.37 ± 1.35[3]	8.31 ± 1.31[3]		8.23 ± 1.30[3,4]	<0.0001
Work activity index	2.72 ± 0.69	2.73 ± 0.69	2.72 ± 0.67		2.72 ± 0.65	0.984
Sports activity index	2.12 ± 0.59	2.53 ± 0.68[3]	2.48 ± 0.65[3]		2.44 ± 0.69[3,4]	<0.0001
Leisure-time activity index	2.73 ± 0.72	3.10 ± 0.66[3]	3.11 ± 0.66[3]		3.07 ± 0.65[3]	<0.0001
Energy intake (kcal/24 h)	2183 ± 651	1556 ± 392[3]	1620 ± 460[3,4]	1640 ± 439[3,5]	1662 ± 452[3,5]	<0.0001
Carbohydrate intake (% of energy)	45.3 ± 7.1	50.7 ± 6.5[3]	50.7 ± 6.9[3]	49.1 ± 6.7[3,5]	50.0 ± 7.5[3]	<0.0001
Fat intake (% of energy)	35.2 ± 6.3	27.0 ± 6.5[3]	27.3 ± 6.8[3]	29.1 ± 7.0[3,6]	29.1 ± 6.7[3,6]	<0.0001
Protein intake (% of energy)	16.0 ± 3.6	19.7 ± 3.3[3]	19.2 ± 3.4[3]	18.6 ± 3.3[3,6]	18.0 ± 3.2[3,6]	<0.0001

[1] $\bar{x}$ ± SD; $n = 261$. No significant interactions between time and treatment group were found for these variables.
[2] Repeated-measures ANOVA.
[3] Significantly different from month 0, $P < 0.001$ (Bonferroni correction for multiple comparisons).
[4–6] Significantly different from month 6 (Bonferroni correction for multiple comparisons): [4] $P < 0.05$, [5] $P < 0.01$, [6] $P < 0.001$.

TABLE 3
Results of simple regression analysis for the total sample with weight maintenance (% of initial weight loss) as the independent variable[1]

	r	P
Age (y)	0.020	0.753
Body weight, 0 mo (kg)	0.038	0.546
ΔBody weight, 0–6 mo (%)	0.289	<0.0001
ΔTotal physical activity index, 0–6 mo	0.055	0.381
ΔWork activity index, 0–6 mo	0.036	0.569
ΔSports activity index, 0–6 mo	0.090	0.148
ΔLeisure-time physical activity index, 0–6 mo	0.033	0.596
ΔFat intake, 0–6 mo (% of energy)	0.005	0.944
Total physical activity index, 12–24 mo	0.167	0.007
Work activity index, 12–24 mo	0.027	0.668
Sports activity index, 12–24 mo	0.150	0.016
Leisure-time physical activity index, 12–24 mo	0.195	0.002
Fat intake, 12–24 mo (% of energy)	0.125	0.049
Carbohydrate intake, 12–24 mo (% of energy)	0.051	0.421
Protein intake, 12–24 mo (% of energy)	0.089	0.162

[1] n = 261. Δ, change.

the stepwise regression analysis, it did not enter the final prediction equation.

Differences in weight maintenance between placebo- and sibutramine-treated subjects with below- or above-average initial weight loss and leisure-time physical activity index during follow-up are shown in **Figure 2**. Weight maintenance was almost 100% in the sibutramine-treated subjects with above-average initial body-weight loss (≥12.5%) and leisure-time physical activity index (≥3.1) during follow-up. Almost all body weight lost was regained in the placebo-treated subjects with below-average initial body-weight loss and below-average leisure-time physical activity index during follow-up.

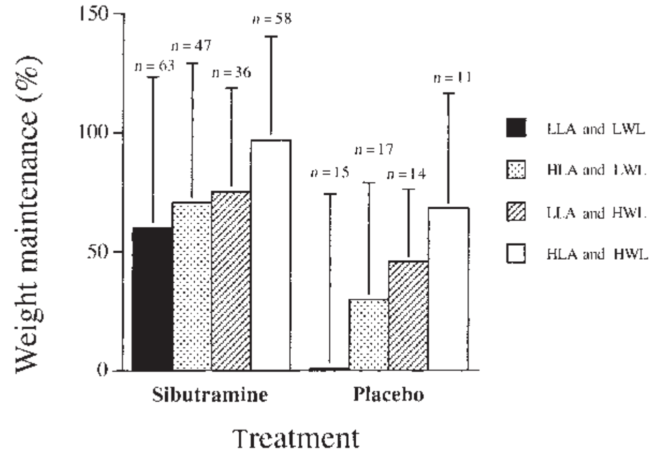

FIGURE 2. Mean (±SD) weight maintenance (%) in sibutramine- and placebo-treated groups with a below-average (L) or above-average (H) leisure-time activity (LLA and HLA, respectively) index during follow-up (month 12–month 24) and L or H weight loss (LWL and HWL, respectively) during the initial weight-loss phase (month 0–month 6). Main effects: treatment, $P < 0.001$; initial body-weight loss, $P = 0.0002$; leisure-time physical activity index, $P = 0.011$. None of the interaction terms were significant: 3-way interaction of leisure-time physical activity index, initial body-weight loss, and treatment, $P = 0.59$; two-way interaction for treatment and leisure-time physical activity index, $P = 0.55$; interaction for treatment and initial body-weight loss, $P = 0.20$; and interaction for leisure-time physical activity index and initial body-weight loss, $P = 0.88$.

DISCUSSION

The multicenter European STORM trial is a large randomized trial of weight maintenance after weight loss (7). Weight loss was induced by a combination of energy restriction, exercise and behavioral advice, and treatment with sibutramine. During the 18-mo weight-maintenance phase, subjects were randomly assigned to placebo or sibutramine treatment, and they continued to receive dietary and exercise advice. Because of its size, the STORM trial offers an excellent opportunity for study of the factors that determine success in weight maintenance.

Many factors may be involved in successful weight maintenance, as recently reviewed by Wing and Hill (2). They suggest that differences in behavior are stronger predictors of weight regain than are differences in physiology or metabolism. Three behaviors were identified in successful weight maintainers: high levels of physical activity, low dietary fat and high dietary carbohydrate intakes, and regular self-monitoring of weight. Others have identified factors related to eating behavior as important predictors of weight maintenance (12–14). For the present study, we mainly focused on factors related to dietary intake and (components of) physical activity. In addition, the roles of sibutramine treatment, body weight and body-weight changes, age, and sex were studied. The results of the study indicate that success in weight maintenance was related to sibutramine treatment, the initial body-weight loss, and the level of leisure-time physical activity. Twenty percent of the variation in weight maintenance in the subject population could be explained by these 3 factors.

The better weight maintenance in the sibutramine-treated group than in the placebo-treated group was reported previously from the STORM trial (7) and other long-term trials on the effectiveness of sibutramine in weight maintenance (15, 16). Long-term treatment with another antiobesity drug (orlistat) after weight loss also was shown to improve weight maintenance (17, 18).

The percentage of the initial body weight that was lost was an important predictor of successful weight maintenance in this trial. Anderson et al (19) and Fogelholm et al (20) also identified a greater weight loss during a very-low-calorie-diet period as a predictor of better weight maintenance during follow-up (3 y and 10 mo, respectively). A positive correlation between weight maintenance and initial weight loss is likely to reflect better compliance with the treatment, in both the weight-loss and weight-maintenance phases, in the more successful weight maintainers. This is supported by the significant ($P < 0.0001$) negative correlations between ratings of dietary compliance by the subject and the dietitian and the weight maintenance at the end of the follow-up period (month 24) ($r = -0.347$ and -0.475, respectively).

Many studies identified physical activity as an important determinant of weight maintenance after weight loss (2, 21, 22), although a review by Fogelholm and Kukkonen-Harjula (13) showed that one-half of the reviewed randomized interventions with a prospective follow-up of ≥1 y were unable to show better weight maintenance in subjects assigned to an exercise intervention than in the control group. They suggested that a relatively large increase in the energy expenditure of physical activity is needed to improve weight maintenance, but that most interventions either do not prescribe this amount of expenditure (6.3–8.4 MJ/wk) or are affected by low adherence to the prescribed exercise program (13).

The results of our study also identify physical activity as a factor contributing to successful weight maintenance. The leisure-time physical activity index, rather than the sports activity or total activity indexes, predicted weight maintenance success. Physical activity was determined with the use of the Baecke questionnaire (11). The validity and reliability of this questionnaire were studied in various populations (although not specifically in the obese) by using various methods (23–26).

The scores for total activity and its various components found in this cohort compare well with those found in other European populations (11, 25), except for the lower sports activity index in our study (2.1 compared with 2.4–2.8), which is probably due to the greater obesity of our population. At baseline, all subjects in this study were given exercise advice that was based on an aerobic exercise program, with walking, cycling, and jogging as the exercise modalities (9, 10). Reported physical activity increased during the course of the study, which was reflected in increases in both the sports and leisure-time physical activity indexes. The total activity index increased correspondingly. However, the level of leisure-time activity was the best single physical activity predictor of success in weight maintenance. Including the sum of the leisure-time physical and sports activity indexes in the regression analysis did not increase the amount of explained variance in weight maintenance. The leisure-time physical activity index is based on time spent walking, cycling, and watching television. It is possible that the leisure-time physical activity index is a better discriminator for a sedentary or more active lifestyle than is the sports activity index. This would be in line with data from Westerterp (27) suggesting that daily energy expenditure can be more readily increased by exchanging sedentary activity for moderate activity than for vigorous activity.

Data on dietary intake were collected by means of 4-d food diaries. Baseline intakes of fat, carbohydrate, and protein (35%, 45%, and 16% of energy, respectively) were similar to those in another large multicenter European trial, the Carbohydrate Ratio Management in European National diets (CARMEN) study (36%, 44%, and 15% of energy, respectively) (28). During the course of the study, reported dietary intake changed as expected with the dietary advice given during the study: energy intake decreased by 500–600 kcal from baseline, fat intake decreased by 6–8% of energy and was on average < 30% of energy, and the reduction in relative fat intake was compensated for by an increase in relative carbohydrate intake. Macronutrient composition of the diet during the weight-maintenance phase did not significantly contribute to success in weight maintenance. This result for fat intake contrasts with the results of other studies (14, 29). It is unlikely that this result was due to a limited variation in dietary fat intake in response to the dietary advice given during the study, because reported fat intake during the weight-maintenance phase still ranged from 14% to 44% of energy. The validity of self-reported dietary intakes is generally low, even if the reports are collected by experienced dietitians, as in the STORM trial. In obese subjects, discrepancies of 20–50% between reported energy intakes and measured energy expenditures have been described (30). Discrepancies may be due to underreporting, undereating, or both (31, 32). In addition, underreporting has been shown to be selectively preferential for fat intake (31). It is therefore likely that the reported energy and macronutrient intake values in our study underestimate actual intakes. More important, the amounts of underreporting and undereating show large interindividual variations (32). Although the changes in dietary intakes measured during the course of the study (decreased energy and fat intakes and increased carbohydrate intake) probably reflect real changes, it is doubtful whether the methods used in this study to determine dietary intake were sufficiently robust to rank individuals by proportions of fat intake.

In conclusion, we showed that successful weight maintenance after weight loss (achieved by lifestyle modification and sibutramine treatment) is positively influenced by continued sibutramine treatment during weight maintenance, a greater initial weight loss, and a higher leisure-time physical activity index. The leisure-time physical activity index, derived from the Baecke questionnaire, includes activities such as walking and cycling but does not include sports activities. Time spent watching television has a negative effect on the leisure-time physical activity index. These results suggest that promoting a less sedentary lifestyle with an increase in time spent on activities such as walking and cycling may be more effective for weight management than is promoting an increase in sports activities. Sibutramine treatment, initial weight loss, and the level of leisure-time physical activity explain < 20% of the variation in weight maintenance between persons, which indicates that other factors such as those related to eating behavior and metabolic susceptibility to weight gain, which were not addressed in this study, also play an important role.

We thank all members of the STORM Study Group and Eileen Butler and Michael Goulder from Knoll Pharmaceuticals for their contributions to the STORM trial.

All authors were involved in the design of the study and either participated in or supervised the data collection in their centers. MAvB analyzed the data for the study and wrote the manuscript; all of the other authors reviewed the draft and contributed comments for the final manuscript. MAvB, NF, and AVA are members of various advisory boards of Abbott, the current manufacturer of sibutramine. None of the authors had a personal or financial conflict of interest with regard to the company sponsoring this study.

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