

A Randomized Controlled Trial of Two Weight-Reducing Short-Term Group Treatment Programs for Obesity With an 18-Month Follow-Up

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We found in an earlier study that participants in a short-term treatment program for obesity showed a good weight reduction (10.4 kg) 18 months after treatment terminated. The program included elements from cognitive therapy (CT) and psycho-education. In the present study the efficacy of a slight modification of the same treatment program (cognitive treatment group) was compared with a behavioral program that included moderate-intensity physical activity and behavioral techniques (the control treatment group) in a randomized controlled trial. The primary effect variable was weight change 18 months after the end of therapy. Both treatment programs lasted for 10 weeks (2 hr/week), and thereafter the participants were weighed periodically over an 18-month period. The participants were obese women employed outside the home. Twelve of the participants did not receive treatment after randomization. Eleven of these participants had been randomized to the cognitive program, whereas the remaining participant was randomized to the control program. The mean age for those that began the 2 programs was 48.5 years, and the mean body mass index (BMI) was 36.6. For those who completed the treatment programs and participated in the 18-month follow-up, the baseline BMI was 34.7. One participant in the cognitive treatment group ($n = 16$) and 6 in the control program ($n = 26$) dropped out during treatment. Both per-protocol and intention-to-treat analyses were performed on the data. Fifteen participants (94%) completed the cognitive program. Of these, 13 (87%) participated at the 18-month follow-up. Their mean weight loss at treatment completion was 8.6 kg ($SD = 2.9$) and 18 months later 5.9 kg ($SD = 5.4$). Twenty participants (77%) completed the control program. Of these, 16 (80%) participated in the 18-month follow-up. Their mean weight loss at the end of treatment was 0.7 kg ($SD = 1.2$), and 18 months later they showed an increase in weight of 0.3 kg ($SD = 4.3$) as compared with baseline weight. The weight differences between the 2 program groups were highly significant ($p < .01-.001$) at all posttreatment weighings. In the intention-to-treat analysis, all participants who started the cognitive treatment ($n = 16$) or control program ($n = 26$) were included. The last observation carried forward was used for those who dropped out from therapy or from follow-up. Eighteen months after the end of therapy, the mean weight loss was 5.5 kg ($SD = 5.5$) in the cognitive group, whereas the control group evidenced a weight loss of 0.6 kg ($SD = 5.5$). The weight change differences between the 2 groups were highly significant at all follow-up weighings ($p < .001$). The low drop-out rate during the treatment period demonstrates that the participants found the 2 programs acceptable. The long-term efficacy of the cognitive treatment program seems to be satisfactory. With its group format and short treatment duration, the cognitive program is attractive from a cost-effective standpoint.

Key words: Body Mass Index, body weight, cognitive, obesity, occupational medicine, RCT, therapy, women

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Obesity has been classified as a worldwide epidemic by the World Health Organization (WHO; 1997). Because the most common treatment method—consultation about diet and exercise—has proved inadequate, behavior therapeutic methods are now being used with greater frequency in the treatment of obesity. Rather than analyzing underlying causes of inappropriate eating behavior (Liao, 2000), these methods focus on mapping eating behavior and learning of new habits. The treatment programs include biweekly meetings that may last for a relatively long time (up to 1 year; Wadden, et al., 1997; Williamson & Perrin, 1996). Weight reduction during the treatment period is common, but there is a strong tendency to regain the weight, with as much as 60% to 70% of the weight loss regained within the 1st year (Agras, Telch, Arnow, Eldredge, & Marnell, 1997; Liao; Waller, 1997). Strategies that are effective in bringing about weight loss during treatment may not be the same strategies when it comes to retaining this weight loss once treatment has terminated. Although individuals losing weight are taught to restrict their diets, they are not taught how to eat normal foods in normal portions (Foreyt & Goodrick, 1993; Williamson & Perrin). A possible reason for this is that the treatment effort, which lasts typically 15 to 25 months, is far too short (Wing, 1992). In the search for new models of obesity treatment, cognitive behavior therapy (CBT) is beginning to be used with increasing frequency, though it should be noted that even here follow-up results have been less than encouraging (Perri & Fuller, 1995).

The relationship between psychological factors and obesity is still rather obscure. In recent decades depression in obese persons has commonly been regarded as a consequence of being excessively fat (Perri, Nezy, & Viegner, 1992; Roberts, Delger, Strawbridge, & Kaplan, 2003; Stunkard & Wadden, 1992; Wadden & Stunkard, 1987). Other findings indicate that depression could be a cause of obesity (Noppa & Hällström, 1981). Foreyt and Goodrick (1994) and Kayman, Bruvold, and Stern (1990) viewed stress as one of the primary predictors of relapse and overeating, which implies that teaching patients methods for reducing stress and tension may be critical (Foreyt & Walker, 1998).

Cognitive behavioral approaches offer patients the opportunity to identify behavioral and thinking patterns that relate to their particular weight problems (Liao, 2000). CBT and cognitive therapy (CT) have the potential of being useful in the treatment of obesity because they provide the means to influence cognitions associated with behavior change (and dieting in particular), relapse, repeated treatment failures, and so on.

To reach the growing number of overweight men and women, an attempt has been made to develop cognitively oriented overweight programs that can be used with occupational groups (Paulsen, Lutz, McReynolds, & Kohrs, 1976). The desire for a manual

consisting of knowledge on self-confidence training and dealing with stress, as well as how psychological technicians can train obese persons has been evinced (Liao, 2000). In a recent randomized study of obesity, Stahre and Hällström (2005) found substantial weight reduction up to 18 months posttreatment with a new, short-term, 10-week cognitive group treatment program that was based on just such a treatment manual (Stahre, 2002). In that study 105 obese patients from the waiting list for nonsurgical treatment of the Obesity Unit at Karolinska University Hospital at Huddinge in Stockholm, Sweden, participated. Of these 105 patients, 62 took part in the treatment program and 43 served as waiting-list controls. For the 34 patients who participated in the study 18 months after treatment was terminated, the mean weight loss was 10.4 kg ($SD = 10.8$). The waiting-list control group experienced a mean weight gain of 2.3 kg ($SD = 7.0$) over the same period. The weight difference between the treatment and control groups at the 18-month follow-up was highly significant ($p < .001$).

The main objective of this article is to describe the method and evaluate the long-term efficacy (weight reduction 18 months after treatment) of a slight modification of the same cognitive treatment program as used in Stahre and Hällström (2005) in a randomized controlled study. In the present study a control group received another active treatment for the same length of time (10 weeks) as the cognitive treatment group. Another objective is to show to what extent the two programs delivered program-specific knowledge to the participants.

Method

Participants

After a health survey directed to child care providers (preschool teachers, children's nurses, cooks, family child care providers, cleaning personnel, and directors of child care centers in the Huddinge community in Stockholm, Sweden), 97 obese women (i.e., those having a body mass index [BMI] ≥ 30 kg/m²) were identified. These 97 women were asked to participate in a health program within the occupational health services. All participants received oral and written information about dieting and exercise and the favorable health outcomes of weight reduction.

Two years later those who were still employed ($n = 94$) and still had a BMI of 30 kg/m² or higher were asked to participate in a randomized controlled trial involving two weight-reducing programs. Of the 94 eligible women, 54 voluntarily agreed to participate in this study. No exclusion criteria were imposed. All 54 participants had previously taken part in numerous group or individual weight-loss programs. The majority of the women characterized themselves as perpetual dieters. Twenty-seven women were randomized to the

cognitive treatment group and 27 to a weight-reducing program resembling those often in use at occupational health care centers in Sweden. The participants in the latter group served as controls.

All participants received both oral and written information about the study. The study was approved by the Ethics Committee of Karolinska Institutet (Karolinska University Hospital at Huddinge).

Procedure

Each of the two weight-reducing programs was divided into two treatment subgroups. The participants in the two programs were allocated at the same time so that the programs started simultaneously.

Sociodemographic data and smoking habits were extracted from the occupational health care center files. All participants were weighed immediately after the termination of the 10-week treatment programs and again at 6, 12, and 18 months after the end of treatment. Weight change at 18 months posttreatment was predefined as the primary outcome variable. The participants in the two programs were weighed and measured regarding height on the same occasions. Weighing of the participants was done using a calibrated scale with light clothing and without shoes. Two persons checked the measurements of the participants' weight. No booster treatment was given once the programs were terminated.

To study to what extent the two programs delivered specific knowledge, we asked all participants to respond to 20 questions or statements about cognition, eating, and obesity, with 10 questions in each program covering central aspects of the knowledge each program sought to convey. The response format was mini-essays. The researchers responsible for each program formulated the questions, which were then sent to all participants 1 month after treatment terminated. The participants were instructed to give the correct response only to those questions that corresponded to the information content in their own treatment program. The test was anonymous and corrected blindly for group affiliation. A correct answer was worth 2 points, and an incorrect answer or no response were worth 0 points. A total score (maximum score = 40) was calculated for each participant.

Sample of statements and questions. The statements related to the cognitive program included the following:

- Formulate relationships between thoughts, feelings, and behaviors.
- Give a negative pattern of thought.
- Give one of your earlier schema that is connected with your old eating behaviors.

Questions relating to the control program included the following:

- How many times per week should a person exercise to improve his or her condition?
- According to the plate model, how large a proportion of a plate should consist of meat or fish?
- Which kind of symbols or markings are there on lean and fiber-rich alternative products in the stores?

Treatment Programs

Each program consisted of 20 hours divided into 10 lessons, with each lesson given once a week (i.e., the programs extended over a 10-week period).

The Cognitive Group Treatment Program

The purpose of the cognitive program was to inform the participants about probable causes of their dysfunctional eating behavior, as well as provide them with information that could be useful in changing and controlling such eating behavior. Special attention was given to deficiencies in self-control, low self-esteem, and experiences of stress. Participants were assigned homework at the end of each intervention session. The only difference between this treatment program and that which was adopted in our earlier study (Stahre & Hällström, 2005) was that the participants in that study prepared and ate food together at the end of each lesson.

The intervention was done by a social worker with special competence in CT (same person as in our previous study). She strictly followed a manual designed specifically for such an intervention (Stahre, 2002). The embedded nutrition program was a traditional weight-reduction program with 1,200 to 1,300 kcal/day (Stahre; Stahre & Hällström, 2005). The program included elements from cognitive psychotherapy and psychoeducation.

Each lesson was structured and arranged into four blocks: A, B, C, and D.

Block A: Questionnaire manual. A special questionnaire manual, which consisted of questions about situations that, in different ways, influenced the participants' eating behavior during the week, was included in the program. These questions, administered to the participants in the beginning of each lesson, had a central role in the treatment of weight problems.

Block B: Previous lesson's homework. The lesson concerned group discussion and participant analysis of the previous lesson's homework.

Block C: Theme of the lectures. Each lesson contained its own theme that supplied information

from the field of cognitive psychology by first providing facts and then by encouraging discussions among the participants. Each theme consisted of both theory and concrete examples that illustrated the theory. The various themes were cumulative in the sense that each lesson furnished new information to the earlier themes. The content of all the themes was related to eating behavior.

The lesson themes included the following, among others:

- How assumptions develop and how basic rules of life can be formed that have meaning regarding the way one conducts oneself in private life, in work, and especially in eating behavior.
- Self-image, self-confidence, and eating behavior.
- Associations between thinking, feelings, and eating behavior (the cognitive triangle).
- Functional and dysfunctional thought patterns.
- Control and helplessness.
- Positive and negative stress. Stress is a subjective experience and as such can be altered.
- The importance of being able to draw one's own boundaries and its significance for eating behavior.

Block D: New homework. The aim of the homework was that patients should examine and apply the content of each lecture's theme in relation to their daily life activities, especially regarding their eating behavior.

The Control Group Treatment Program

The control program aimed to achieve behavioral changes in the realm of dieting, stress management, and physical training. The program was performed by the municipality's occupational doctor, occupational nurse, occupational physiotherapist, and external people representing diverse areas of expertise. The program consisted of lectures, group discussions, and practical demonstrations so that the participants received both theoretical information and a practical understanding of the issues.

Lesson themes included the following:

- Women's health and lifestyle.
- How weight reduction can be attained.
- Information on dieting.
- Principles of dieting.
- Practical exercises and information about food.
- Applied knowledge about food; practical training.
- Computers as an aid in eating well and achieving nutritional goals; applied training.
- The importance of being cognizant of one's body.

- Relaxation techniques and how to deal with stress.
- The importance of physical training.
- Strength training; instruction and practical exercises.

Statistical Methods

Student's *t*-test statistic was used to test weight change differences between group means. The Mann-Whitney *U* test was applied in the analysis of the obesity knowledge test. Differences in proportions between groups were analyzed with the chi-square test. Statistically significant differences were assumed when $p < 0.05$ (two-tailed test).

Results

Twenty-seven participants were randomized to the cognitive program. Three withdrawals before start of therapy were due to change of employment. One person was excluded after she missed attending the first therapy session. Seven participants dropped out before therapy started: 3 because their job situation hindered them from attending, 3 because they had lost their motivation, and 1 because her doctor had advised her not to participate because of medical reasons. The baseline mean weight of these women was 100.3 kg ($SD = 14.8$) as compared to 95.1 kg ($SD = 11.5$) for rest of the sample that accomplished the cognitive program and completed the 18-month follow-up. Taking into account those who withdrew or dropped out before treatment, the number of participants in the cognitive program was 16 (divided into two subgroups of 5 and 11, respectively), whereas in the control program the number of participants was 26 (divided into two subgroups of 12 and 14, respectively). Of the 16 women who started the cognitive program, only 1 did not complete the 10-week treatment. For those 26 women who began the control program, 20 (77%) completed the 10-week treatment. Of the 6 women who discontinued, 4 did so because of their work, 1 because she was on sick leave, and 1 for unknown reasons.

The mean age of the participants in the cognitive treatment group was 50.1 years ($SD = 7.8$, range = 36–61), and in the control group, 47.0 years ($SD = 8.2$, range = 24–61; $p = .25$). Additional demographic data are presented in Table 1. No statistically significant differences were observed on any of the demographic variables between the cognitive treatment group and the control group.

Per-Protocol Analysis

Figure 1 displays the mean weight changes ($\pm SE$) from the start of the two treatment programs, at the end

Table 1. Demographic Characteristics of the Two Treatment Groups

	Cognitive Group ^a		Control Group ^b		<i>p</i>
	<i>n</i>	%	<i>n</i>	%	
Education					.14
Primary school only	2	13	3	12	
Vocational training	10	63	9	35	
Secondary school	3	19	4	15	
Higher education	1	6	9	35	
Born in Sweden	11	69	20	77	.72
Smoking					
Smoking: Yes	1	6	9	35	.06
Quit more than one year ago	7	44	13	50	.76
Never smoked	8	50	4	15	.03

^a*n* = 16. ^b*n* = 26.

of the treatment programs, and at the 6-, 12-, and 18-month follow-ups for those participants who successfully completed both the treatment program and follow-up. Thirteen (87%) of the women who completed the cognitive program and 16 (80%) of the women who completed the control program participated in the follow-up 18 months after treatment terminated.

Mean weight at baseline for those who participated in the 18-month follow-up was 95.1 kg (*SD* = 11.5; BMI = 35.5) in the cognitive group and 91.5 kg (*SD* = 14.1; BMI = 34.1) in the control group. This difference is not statistically significant (*p* = .46). Mean weight immediately after the end of treatment was 86.5 kg (*SD* = 10.4) in the cognitive group and 90.8 kg (*SD* = 14.5) in the control group.

The mean weight loss immediately after therapy was 8.6 kg (*SD* = 2.9) in the cognitive group and 0.7 kg (*SD* = 1.2) in the control group. Mean weight 18 months after the treatment ended was 89.2 kg (*SD* =

12.7; BMI = 33.3) for the cognitive group and 91.8 kg (*SD* = 14.0; BMI = 34.2) for the control group. The mean weight loss 18 months after the end of therapy in the cognitive group was 5.9 kg (*SD* = 5.4), whereas weight gain in the control group was 0.3 kg (*SD* = 4.3). The weight change differences between the cognitive and control groups were significant (*p* < .01–.001) at all follow-up weighings (Figure 1). Effect size for the cognitive program at 18 months was 1.1.

In the cognitive group, the mean BMI decreased from 35.5 to 33.3 kg between baseline and 18 months after the end of treatment. Because the two cognitive subgroups had different sizes, they were analyzed separately: At the 18-month follow-up, the BMI decrease was 2.1 kg/m² in one subgroup (*n* = 5) and 2.2 in the other (*n* = 11). During the same period, the mean BMI increased from 34.1 to 34.2 in the control group.

Table 2 shows the distribution of weight change in the cognitive and control groups based on measurements taken before treatment intervention and at the 18-month follow-up. In the cognitive group, only one patient weighed more (.1 kg) at this follow-up as compared to before therapy. Among the controls, the corresponding proportion was 10 of 16 (63%).

Intention-to-Treat Analysis

All participants who started the cognitive (*n* = 16) or control (*n* = 26) programs were included here. The last observation carried forward was used for those who dropped out from therapy or from follow-up. Mean baseline weight was 94.4 kg (*SD* = 10.9) in the cognitive group, and 93.3 kg (*SD* = 14.0) in the control group; *p* = .80.

The mean weight loss immediately after therapy was 7.7 kg (*SD* = 3.8) in the cognitive group and 1.4 kg (*SD* = 1.6) in the control group. At the 18-month fol-

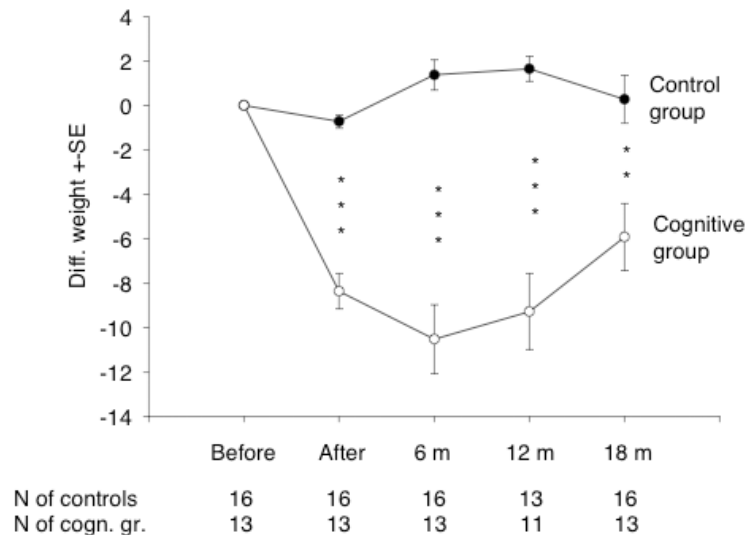


Figure 1. Mean weight change (± *SE*) in participants who completed the therapy program and all follow-up weighings (at 6, 12, and 18 months). Note. ***p* < .01. ****p* < .001.

Table 2. Distribution of Weight Change in the Cognitive and Control Groups From Measurements Taken Before Treatment Intervention and at the 18-Month Follow-Up

Weight change	Cognitive Group ^a		Control Group ^b	
	<i>n</i>	%	<i>n</i>	%
Gain	1	8	10	63
Loss less than 5%	6	46	4	25
Loss 5% or more but less than 10%	3	23	2	13
Loss 10% or more	3	23	—	—
Total	13	100	16	100

^a*n* = 13. ^b*n* = 16.

Table 3. The Results of the Obesity Knowledge Questions and Statements

	Cognitive Group ^a	Control Group ^b	<i>p</i>
	<i>Mdn</i>	<i>Mdn</i>	
Knowledge relevant to cognitive program	17.5	4.0	< .001
Knowledge relevant to control program	16.0	18.0	.025

Note. Numbers represent median scores out of a possible maximum score of 40.

^a*n* = 14. ^b*n* = 13.

low-up, the mean weight loss was 5.5 kg (*SD* = 5.5) in the cognitive group, and 0.6 kg (*SD* = 5.5) in the control group. The weight change difference between groups were highly significant ($p < .001$) at all follow-up weighings. Effect size at 18 months was 1.0 for the cognitive program.

Knowledge Examination

Whereas the questions relevant to the control program dealt with diet, exercise, and strategies to change behavior, questions and statements relevant to the cognitive program were specific to a CT approach.

The cognitive group scored much higher than did the control group on knowledge relevant to cognitive treatment of obesity ($p < .001$) but somewhat lower on knowledge of nutrition and physical activity (Table 3).

Thus, the results from the obesity knowledge questions and statements indicate that the two treatment programs convey different types of information

Discussion

In this randomized study we compared a manualized (Stahre, 2002) short-term cognitive group treatment program with a control group program. The

controls received active treatment to the same extent as the participants in the cognitive program. We consider the 18-month follow-up as relatively long. The drop-out rate during the treatment period was low, particularly in the cognitive treatment group. Furthermore, the follow-up period showed a low drop-out rate, regardless of treatment programs. The small sample size and the fact that only women served as participants, however, are two methodological limitations of the study. Another limitation concerns the high drop-out rate that occurred before treatment started in one of the subgroups randomized to the cognitive program. Consequently, this subgroup became small, which could have impacted on degree of individual focus. Moreover, there could have been a selection bias in this subgroup that could have affected the outcome. However, there was no substantial difference between the two cognitive subgroups regarding outcome at 18 months. Thus, the high proportion of participants who dropped out between randomization and treatment start in one of the cognitive subgroups had no obvious influence on the results.

All participants with a complete 18-month follow-up in the cognitive program except one (94%) demonstrated a lasting weight loss 18 months after treatment had terminated. In the control program the majority of the participants with a complete 18-month follow-up evidenced a weight gain between baseline and 18 months after treatment had terminated.

It has been shown that a 5% to 10% loss of body weight produces beneficial change in health risk factors (Goldstein, 1992; Kanders & Blackburn, 1992; Tremblay, et al., 1999; Wing & Jeffery, 1995). A report from the U.K. Royal College of Physicians (1998) similarly defines *successful weight loss* as a loss of more than 5% of initial weight. In the present study 46% of those participating in the cognitive program 18 months after treatment ended showed a weight reduction of 5% or more in comparison with only 13% in the control program. Thus, the long-term result of the cognitive program can be described as *successful* in about half of the cases. Effect size for the cognitive program at the 18-month follow-up was 1.1 in the per-protocol analysis and was reduced to 1.0 in the intention-to-treat analysis. Such a difference is expected, and considering that no booster treatment had been carried out after treatment was completed, the results of the cognitive treatment program must be interpreted as satisfactory.

The results of this study confirm the main result of our earlier finding, namely that the cognitive program was efficacious in maintaining long-term weight loss (Stahre & Hällström, 2005). The current findings also support the earlier study's results that the cognitive program's method is accepted by most of its participants and that the method produces quick weight loss that lasts at least 1 year after the program has terminated. Good efficacy was also observed at the

18-month follow-up, though a slight weight gain between 12 and 18 months indicates that a booster treatment would likely be of value 1 year after treatment is completed. The trend to weight increase that occurs during the follow-up period is common to all treatment methods for obesity and is confirmed in our study.

Because of its group format and relatively short treatment duration, the cognitive method is highly cost effective. Other behaviorally directed treatments for weight reduction have a treatment period that is often 5 to 10 times longer (Melin, Karlström, Lappalainen, Mohsen, & Vessby, 2003; Wadden & Bell, 1990; Wing, 1992) in that obesity is considered a chronic illness whose treatment result is presumed to be related to the length of the treatment period (Wadden & Bell; Wing).

The results of the obesity knowledge test show that the cognitive program gave the participants certain knowledge that the control program did not provide. However, the information that the control program conveyed was largely the same kind of information available to the participants in the cognitive program. Because every member of both groups had previously taken part in weight-loss programs and because media are replete with information about weight-reduction methods, it seems probable that before the respective interventions, both groups (treatment and control) had this information already in their repertoire. The new information of the cognitive program and its fostering of new attitudes to eating, self-control, self-esteem, stress, and so on, as well as its application of cognitive strategies likely contributed to the participants' satisfactory weight reduction. Because the obesity knowledge test was anonymous, it was possible to demonstrate such a relation at the group level but not at the individual level.

The mean weight reduction in the cognitive treatment group at 18 months after end of therapy (5.3 kg) was more modest in this study in comparison with our earlier study in which the mean weight reduction was 10.4 kg (Stahre & Hällström, 2005). A major reason for this difference might be that the earlier study had a larger number of participants with a BMI over 35, whereas only a small number of participants in the current study had a BMI over 35. Effect sizes were similar in these two studies: 1.0 in the earlier study and 1.0 to 1.1 in the present study. Another difference that could account for the somewhat different findings between the two studies is that the participants of the present study were nonpatients who were in an occupational health program, whereas in our earlier study the participants were waiting-list patients from an obesity clinic. In the present study we asked the participants to take part in the study, whereas in the earlier study the participants themselves took the initiative to take part in a treatment program. Consequently, it is reasonable to assume that the participants in the earlier study were

more motivated to cooperate in the treatment program. In contrast to our former study, the participants in the present study did not prepare nor eat any food at the interventions. It seems unlikely, however, that this social event should have influenced the long-term results of the earlier study in any apparent way.

Conclusions

The low drop-out rate during treatment demonstrates that the participants accepted the two programs (cognitive and control) used in this study. The long-term efficacy of the cognitive program seems to be satisfactory. With its group format and short treatment duration, the cognitive program is a cost-effective approach to treating obesity.

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