Cognitive-behavioral treatment reduces attrition in treatment-resistant obese women: results from a 6-month nested case-control study

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Abstract **OBJECTIVE:** The aim of this nested case-control study was to compare the effectiveness of cognitive-behavioral treatment (CBT) for treatment-resistant obese (body mass index [BMI] \geq 30 kg/m²) women compared with standard dietary treatment. The main outcome measures were attrition and weight loss success. METHODS: We designed a 6-month case-control study, nested within a cohort of adult (age \geq 18 years) treatment-resistant (history of at least two previous diet attempts) obese women. Cases were 20 women who were offered CBT sessions. Controls (n=39) were randomly selected from the source population and matched to cases in terms of baseline age, BMI, and number of previous diet attempts. **RESULTS:** Compared with controls, cases were significantly more likely to complete the 6-month program in both age-adjusted (odds ratio [OR]=2.94, 95% confidence interval [CI]=1.05-8.97) and multivariate-adjusted (OR=2.77, 95% CI=1.02-8.34) analyses. In contrast, cases were not more likely to achieve weight loss success in age-adjusted (OR=1.32, 95% CI=0.86-1.67) and multivariateadjusted (OR=1.21, 95% CI=0.91-1.44) analyses. **CONCLUSIONS:** Compared with a standard dietary treatment, CBT was significantly more effective in reducing attrition in treatment-resistant obese women,

without differences in terms of weight loss success.

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Abbreviations:

CBT	- Cognitive-Behavioral Treatment
BMI	- Body Mass Index
SCL-90-R	- Symptoms Checklist-90-R
BDI	- Beck Depression Inventory
BES	- Binge Eating Scale

INTRODUCTION

With the prevalence of obesity reaching epidemic proportions worldwide, there is an urgent need to explore ways in which to stem its burden on our society (Wang et al. 2011). In general, dietary guidelines are appropriate targets at a population level for achieving nutritional balance and protecting health across a broad range of risk factors in the long-term (Jebb 2005). However, they are not directed towards tackling obesity in themselves and they do not provide guidance for the achievement or maintenance of weight loss (Ryan & Jensen 2013). Although achieving and sustaining appropriate body weight is vital to maintaining good physical and psychosocial effects in obese subjects, overcoming barriers to successful obesity treatment is a difficult endeavor (Lagerros & Rossner 2013). Notably, most obese subjects have an extensive history of diet attempts with negligible long-term success (Ayyad &Andersen 2000; Curioni & Lourenço 2005). In general, treatment-resistant obesity may refer either to premature termination of treatment without achieving meaningful weight loss goals (treatment attrition) (Moroschko et al. 2011) or to the propensity to regain weight after initial weight loss (Brantley et al. 2014; Dulloo & Montani 2015). A consistent set of predictors for treatment resistance has not yet been identified (Moroschko et al. 2011). A higher body fat percentage, greater anger-hostility, early dieting attempts, and the lack of achievement of early weight loss are independent predictors of dropout from obesity treatment (Colombo et al. 2014; Dalle Grave et al. 2005a; Hadžiabdić et al. 2015; Michelini et al. 2014). Attrition has been also associated with dropout in previous weight-reducing programs (Dalle Grave et al. 2005a; Teixeira et al. 2004), the presence of binge eating (Ho et al. 1995; De Zwaan 2001), emotional disorders (Yass-Reed et al. 1993), and full-time employment (Inelmen et al. 2005). Furthermore, unrealistic weight loss expectations have been implicated in the onset of attrition (Dalle Grave et al. 2005a; Dalle Grave et al. 2005b; Teixeira et al. 2004), Treatment adherence is paramount to positive and long-lasting results (Dalle Grave et al. 2005b). Although the study of physical and psychological predictors of drop-out is clinically relevant as it can serve as a basis for program improvement (Petroni et al. 2007), no standard approach to the management of attrition to obesity treatment currently exists. A potential option in the field is psychological treatment (Masheb et al. 2011) (Buscemi et al. 2013). Previous studies have shown that cognitive-behavioral treatment (CBT), the most widely available structured complementary psychotherapy for obesity, is effective for identifying and tackling the cognitions and behaviors that maintain obesity while heightening the motivation for change (Corbalan et al. 2009; Sbrocco et al. 1999). CBT has been investigated in the treatment of obesity with and without psychological comorbidities (Cooper et al. 2010; Van Dorsten & Lindley 2011; Masheb et al. 2011; Annesi & Tennant 2012; Vanderlinden et al. 2012; Wisotsky & Swencionis 2003). However, previous studies have not included a comparison group of patients who were treated with standard dietary treatment, indicating that the comparative effectiveness of CBT versus standard care has not been adequately assessed. Scarce access to psychological treatment in obesity has meant that, in clinical practice, CBT is often reserved for individuals who have not adequately responded to standard treatment. Under the hypothesis that CBT could be associated with a higher likelihood of success as compared with standard dietary treatment, our academic obesity outpatient unit offers to patients with a previous history of two or more treatment failures the possibility to undergo a 6-month CBT program instead of usual care. The aim of this nested case-control study was to examine the effectiveness of CBT for subjects with treatment-resistant obesity compared with standard dietary treatment. The main outcome measures included both treatment attrition and weight loss success. We specifically focused on treatment-resistant who have failed trials of traditional weight loss methods because they pose special challenges in terms of clinical management.

MATERIALS AND METHODS

Source population and participants

We designed a 6-month case-control study, nested within a cohort of adult (age ≥ 18 years) treatmentresistant (history of at least two previous diet attempts) obese (body mass index [BMI] \geq 30 kg/m²) women. The source population consisted of subjects were consecutively referred for weight loss to the Human Nutrition Research Center, University of Pavia (Italy) between January and June 2011. Because the large majority of subjects referred to our center are women, only female subjects were deemed eligible. All of the subjects in the source population aimed at achieving a clinically meaningful weight loss (i.e., $\geq 5\%$) within 6 months. Exclusion criteria included pregnancy, major physical illnesses, and a history of psychiatric disorders (i.e., psychosis, mental retardation, major depression, bipolar disorder, personality disorders). Subjects who were being treated with psychotropic drugs or psychotherapy were also excluded. This study was conducted according to the tenets of the Declaration of Helsinki and the local Institutional Review Board gave ethics approval. Written informed consent was obtained from all participants.

Study design

Women who met the definition of treatment-resistant obesity were contacted by a researcher for inclusion in the study. A total of 20 consecutive obese women treated with CBT served as cases. Controls were randomly selected from the source population and matched to cases in terms of baseline age, BMI, and number of previous diet attempts. A case:control ratio of 1:2 was planned to ensure an adequate sample size. The control group consisted of a sample of 39 age- and BMI-matched women who received standard dietary treatment. All of the participants underwent an initial baseline assessment that included collection of clinical, dietary, and psychological parameters. The Symptoms Checklist-90-R (SCL-90-R), a self-report checklist inquiring about symptoms during the preceding week, was used as a measure of general psychopathology (Derogatis *et al.* 1973). Depressive symptoms and eating behaviors were determined using the Beck Depression Inventory (BDI) (Beck *et al.* 1961) and the Binge Eating Scale (BES) (Gormally *et al.* 1982), respectively. Only patients without missing data were eligible for inclusion.

Cognitive-behavioral therapy

In this nested case-control study, cases received twentyfour 50-min individual sessions of CBT provided by a psychologist and a registered dietician with the sessions being weekly for the first four weeks and every two weeks thereafter. Current CBT for obesity includes the following strategies: nutrition education, selfmonitoring, physical activity, cognitive restructuring, behavioral chaining, behavioral strategies and relapse prevention (Shapiro & Bulik 2011). As far as nutrition education is concerned, patients are educated about healthy and balanced nutrition, portion control, and setting of regular eating times throughout the day (e.g., three meals and two planned snacks). Self-monitoring of food intake enables patients to become aware of their current eating patterns (e.g., type and amount of food), helps them learn about the nutritional value of foods, assist in planning meals, and support healthy food choices. CBT for obesity recommends that patients gradually increases both lifestyle and structured exercise as well as decrease their sedentary time spent in front of a computer or television. Cognitive techniques helps individuals identify negative and unhealthy thoughts related to food, eating and weight, and develop more rational beliefs. Following general CBT, individuals learn to identify their automatic thoughts, challenge them, consider alternative views, determine the effect of the automatic thought on other thoughts, feelings, and behaviors, and identify typical thinking errors. CBT helps individuals identify triggers to their eating behavior. Triggers may be anything that leads to unhealthy eating, including negative thoughts, certain moods, and different situations (e.g., social gatherings, interpersonal conflict, and food advertisements). The subjects also learn about the positive and negative consequences of their eating behaviors. Aside from challenging thoughts, CBT incorporates behavioral strategies to help resist unhealthy eating patterns. In addition to stimulus control strategies, CBT helps individuals strengthen cues for desired behaviors and avoid eating in response to various triggers. Because weight regain occurs frequently, prevention of relapses is clinically paramount. Subjects are instructed to identify and properly react to high-risk situations. Review cards are created to remind positive self-statements, coping responses, alternative behaviors and phone numbers of support people.

Standard dietary therapy

Controls underwent a standard medically-supervised dietary weight loss program with the goal of losing 5-10% of their initial body weight (Colombo et al. 2014). To determine the level of caloric restriction, 500-800 kcal were subtracted from baseline resting energy expenditure multiplied by a physical activity factor of 1.4, corresponding to a sedentary state (Institute of Medicine 2005). Macronutrient diet composition was prescribed as follows: 55%, 30%, and 15% of energy intake, respectively from carbohydrates, lipids, and, proteins. The prescribed caloric intake ranged between 1100 and 1800 kcal/day. The patients were required to visit our center on a monthly basis for follow-up visits, which were conducted by a physician specialized in clinical nutrition. During the visits, we checked patient body weight and body composition and, when necessary, delt with obstacles hindering weight loss and physical activity. Moreover, possible changes to the dietary plan were discussed with the dietician.

Outcomes

Attrition and weight loss served as the main outcome measures. Attrition was defined as failing to complete the 6-month program (Colombo *et al.* 2014). Weight change was also computed in two ways, i.e., 1) absolute change in weight between baseline and 6 months and 2) percent change from baseline weight. Weight loss success was defined as a reduction of \geq 5% from initial weight at 6 months (Fabricatore *et al.* 2009).

Statistical analysis

The statistical power was calculated with the StatMate software, version 2.0 (GraphPad, San Diego, CA, USA). Based on the observed attrition rate in the control group (38%), our sample size had an 80% power to detect an odds ratio (OR) of 2.15 for completing the 6-month program between patients who underwent CBT and those who received standard dietary treatment with a significance level (α) of 0.05. Hence, the power calculation suggests that our sample would have been sufficient to detect moderate (OR of 1.65-2.65) differences in attrition rates between cases and controls. Baseline characteristics are given as mean ± standard deviation or counts and percentages, as appropriate. The chi-square test was used for categorical data. Unpaired Student's t-tests were used to compare the general characteristics between cases and controls at baseline. One-sample paired Student's t-tests were performed for within-group comparisons between baseline and post-treatment values. Multiple logistic regression analyses were performed to determine the associations between attrition and weight loss and the baseline characteristics of the study participants. In line with previous studies (Savan *et al.* 2014; London *et al.* 2013), all baseline variables showing assocations with the study outcomes at a p<0.1 level in simple logistic regression analysis were included in the multivariate model. Multivariate-adjusted ORs are presented with 95% confidence intervals (CIs). Data analysis was per-

Tab. 1. General baseline characteristics of cases (n = 20) and controls (n = 39).

	Cases	Controls	p-value
Age (years)	42.2±10.4	42.4±14.0	0.964
Weight (kg)	96.2±16.2	93.4±12.6	0.460
Height (cm)	162.8±7.0	162.1±5.7	0.693
Body mass index (kg/m ²)	36.1±4.4	35.6±5.1	0.696
Body fat skinfold (% weight)	41.7±3.0	41.8±3.4	0.886
Waist circumference (cm)	111.4±10.8	106.5±11.5	0.122
Highest weight in adult age (kg)	99.1±16.7	101.6±23.2	0.200
Lowest weight in adult age (kg)	67.7±13.0	65.5±13.4	0.910
Age at first dieting attempt (years)	29.9±11.7	24.0±9.7	0.054
Number of dieting attempts	2.8±0.7	3.1±0.9	0.109

Data are given as means ± standard deviations.

Tab. 2. General psychometric characteristics of cases (n = 20) and controls (n = 39).

SCL-90	Cases	Controls	<i>p</i> -value
Somatization	1.03±0.73	1.04±0.59	0.960
Obsessivity-compulsivity	1.21±0.74	0.88±0.57	0.077
Interpersonal sensitivity	1.20±0.69	0.84±0.72	0.072
Depression	1.46±0.78	1.08±0.70	0.072
Anxiety	1.03±0.80	0.83±0.59	0.302
Anger-hostility	0.63±0.53	0.79±0.69	0.388
Phobic anxiety	0.41±0.57	0.30±0.41	0.421
Paranoid ideation	0.90±0.74	0.76±0.70	0.487
Psychoticism	0.63±0.53	0.44±0.49	0.176
GSI	1.04±0.58	0.79±0.47	0.090
BES	19.82±8.41	13.59±8.91	0.013
BDI	16.41±7.66	11.26±6.19	0.008

SCL-90: Symptom Checklist-90; GSI: Global Severity Index; BES: Binge Eating Scale; BDI: Beck Depression Inventory. Data are given as means ± standard deviations. formed using the Statistical Package for Social Sciences software, version 17.0 (SPSS, Chicago, IL). A two-tailed *p*-value <0.05 was considered statistically significant.

RESULTS

Table 1 shows the general baseline characteristics of cases and controls. The two groups did not differ significantly in terms of age, anthropometric parameters, highest and lowest weight, number of previous dieting attempts (ranging from 2 to 7), and age at first dieting attempt

The baseline psychometric characteristics of the study participants are reported in Table 2. Compared with controls, cases had significantly higher BDI and BES scores at baseline.

Attrition

Thirteen cases (65%) and 15 controls (38%) completed the weight loss treatment (p=0.05). The most common reasons for dropout included inadequate motivation, personal or family reasons, or lack of achievement of a satisfactory weight loss. Overall, cases were significantly more likely to complete the 6-month program, compared with controls, in age-adjusted (OR=2.94, 95% CI=1.05–8.97) and multivariate-adjusted (OR=2.77, 95% CI=1.02–8.34) analyses.

Weight loss

Weight losses did not differ significantly at 6 months in the study groups: 8.4 ± 3.5 kg and 7.8 ± 3.2 kg for cases and controls, respectively (p=0.67). Similarly, the mean percent weight change from baseline did not differ significantly in the two groups ($9.2\pm3.7\%$ in cases and $8.0\pm3.4\%$ in controls, respectively, p=0.42). Cases were not more likely to achieve weight loss success, compared with controls, in age-adjusted (OR=1.32, 95% CI=0.86–1.67) and multivariate-adjusted (OR=1.21, 95% CI=0.91–1.44) analyses.

Predictors of attrition and weight loss

After adjustment for potential confounders in multivariate analysis, the main independent predictor of attrition in cases was the age at first dieting attempt (beta=-9.02, t=-5.04, p<0.05), whereas SCL-90 angerhostility subscale independently predicted attrition among controls (beta=7.86, t=5.40, p<0.05). We did not find any independent significant predictor of weight loss success in both study groups.

DISCUSSION

Despite extensive knowledge on weight reduction techniques, weight loss programs continue to be plagued with high attrition rates and limited success (Moroschko *et al.* 2011). The main finding of this nested-case control study is that, compared with a standard dietary treatment, CBT was significantly more effective in reducing attrition in treatment-resistant obese women, without differences in terms of weight loss success. As ancillary findings, we have shown that the main independent predictor of attrition in subjects who underwent CBT was the age at first dieting attempt, whereas the SCL-90 anger-hostility subscale independently predicted attrition among subjects who underwent a standard dietary treatment.

To our knowledge, this is the first report demonstrating that CBT is superior to standard dietary treatment for reducing attrition in treatment-resistant obese women. Several studies have shown that subjects attempting to lose weight will experience greater difficulty if they are not motivated toward weight loss or feel that they are unable to be successful in following their weight loss plan (Moroschko et al. 2011; Cooper et al. 2010; Dalle Grave et al. 2004). In this context, CBT which is a treatment based on the principles of classical and operant conditioning - may help prevent drop-out when obese subjects are unable to meet certain weight loss goals or begin having difficulty following their healthy eating plan (Sbrocco et al. 1999; Vanderlinden et al. 2012). CBT for obesity involves multiple components such as keeping a food diary, activity records, slower eating, nutritional education, identification of eating cues, teaching problem solving, and cognitive restructuring skills to patients (Cooper et al. 2010; Dalle Grave et al. 2004). These techniques help the patient modify his or her food environment in order to decrease access to additional calories. Our finding that subjects who underwent CBT showed lower attrition rates in treatment-resistant obese women is promising. This discovery may allow researchers and clinicians to encourage CBT in obese women with a history of at least two previous diet attempts (as opposed to concentrating only on dietary measures) in order to prevent patients from becoming discouraged and abandoning their efforts.

Knowledge of the variables that lead to attrition is another important factor that may assist program developers in identifying patients who may struggle with their weight loss. Moreover, it can also aid in helping to remedy issues that contribute to attrition before or during the weight loss program. In our study, the age at first dieting attempt was an independent predictor of attrition in obese women who underwent CBT, whereas SCL-90 anger-hostility subscale independently predicted attrition among those treated with standard dietary treatment. These findings are in accordance with those previously reported in our outpatient academic setting (Colombo et al. 2014). The association between age at first diet attempt and attrition in cases who underwent CBT suggests that early and unsuccessful diet-related experiences may have a negative impact on the likelihood of keeping subjects engaged in subsequent weight reduction programs. These findings indicate the significant impact of previous negative experiences with dieting attempts on attrition from

future weight loss programs (regardless of CBT use). On the other hand, the reduction in anger and hostility in resistant patients undergoing standard dietary treatment may ultimately increase their chance of success in losing weight.

The findings of our study should be interpreted within the context of some limitations. First, the singlecenter nature of our study may have introduced some selection bias and differences in baselines characteristics. Notably, the data were collected in consecutively enrolled participants in a real-life academic setting. Because of the relatively small number of subjects enrolled, the findings need to be confirmed in larger prospectively designed studies. Second, our study was conducted on a limited number of Italian treatmentresistant obese women; therefore, our results might not apply to different settings and need further validation before firm conclusions can be made. Finally, we did not evaluate long-term outcomes in relation to attrition and weight loss.

The results of the present study were encouraging toward the use of CBT in treatment-resistant obese women for reducing drop-out rates. Compared with a standard dietary treatment, CBT was significantly more effective in reducing attrition in treatmentresistant obese women, without differences in terms of weight loss success. A more extended follow-up of this approach is required to further evaluate its efficacy.

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