



Does cognitive behavioral therapy strengthen the effect of bariatric surgery for obesity? Design and methods of a randomized and controlled study[☆]

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ABSTRACT

Background: (Extreme) obesity is a chronic harmful condition with high risk of medical comorbidities and negative social and emotional consequences. Bariatric surgery is an effective intervention for obesity, but approximately 20 to 30% of the patients experience adverse outcomes after surgery and there is a need for augmentation of current treatment strategies. This study examines the added value of pre-operative cognitive behavioral therapy (CBT) focused on modification of thoughts and behaviors in terms of eating behavior and physical exercise as well as preparation for surgery and postoperative life style. We hypothesize that pre-operative CBT will result in better weight loss maintenance, reduction of maladaptive eating behavior and better adherence to postoperative lifestyle on the long term as compared to bariatric surgery alone.

Methods: One hundred and twenty eight patients that are on a waiting list for bariatric surgery are randomly assigned to the control or treatment condition. Patients in the treatment condition receive 10 sessions of CBT before surgery aimed at modifying dysfunctional eating habits and behaviors and developing more rational weight and body-related beliefs in order to enable long term maintenance of a healthier lifestyle after surgery. Weight loss, eating behavior, eating disorders, depression, quality of life and psychological distress are assessed before and after treatment, as well as 1, 3, and 5 year following surgery.

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1. Introduction

Obesity (body mass index ≥ 30 kg/m²) is a major public health problem. Prevalence in the United States has been estimated at 35.1% in 2011–2012, and this has not changed significantly since 2003–2004 [41]. The prevalence of extreme obesity (body mass index ≥ 40 kg/m²) in the US has increased from 4.8% in 2003–2004 [42] to 6.4% in 2011–2012 [41]. Patients with the most severe forms of obesity have the highest risk of medical comorbidities [20], but also of psychiatric comorbidities [22,23,43,56]. The latter also holds for obese people seeking surgical weight loss treatment, who show psychological disturbances including depression, anxiety disorders as well as eating disorders [1,15].

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Over the last decades, bariatric surgery has been shown to be an effective treatment for extreme obesity [25,49]. However, approximately 20 to 30% of the patients experience adverse outcomes after surgery, including preliminary weight stabilization or weight regain over time [2, 11]. Apart from somatic and surgical-technical factors, surgical outcomes also appear to depend on active behavioral changes including the permanent adjustment of postoperative eating habits [7] and compliance with postsurgical diets [46]. A recent review of psychological predictors of surgical weight loss indicates that severe psychiatric psychopathology may be a negative predictor of postsurgical success [61]. Personality traits such as neuroticism, impulsiveness and low self-esteem appear to have an indirect effect on weight loss as they influence postsurgical adjustment [61]. Several studies indicate that binge eating, loss of control and emotional eating are associated with less weight loss and/or more weight regain after bariatric surgery [29,33,60].

Taking into account the substantial role of psychological factors in the maintenance of bariatric surgery outcomes, it has been recommended to

implement pre- or post-surgery psychological interventions as part of the treatment program [16,24]. Current guidelines regarding bariatric surgery are multidisciplinary and elaborate, although mainly focused on medical aspects [34]. Psychological interventions are not routinely offered, clinical practices vary and the role of psychological treatment is not well defined in the guidelines for extreme obesity and bariatric surgery yet [6]. In the Dutch guidelines for general obesity, cognitive behavioral therapy (CBT) is recommended as psychological treatment [48]. In general, CBT for obesity is designed to modify dysfunctional eating habits and behaviors, and to develop more rational weight and body-related beliefs in order to enable long-term maintenance of a healthier lifestyle [17].

Most but not all [9,10] randomized controlled trials (RCTs) studying the efficacy of CBT for obesity, show that CBT is more effective in reducing weight compared to a waiting list control group [31,51], physical exercise [58] and non-specific psycho-education [37]. Moreover, apart from weight loss, it has been shown that CBT for obesity improves mental and physical health-related quality of life [31,38], reduces emotional or external eating [37] and general psychopathology [58]. Although CBT as a stand-alone intervention may be insufficient for sustained weight loss for severe obese patients it is hypothesized that adding CBT to bariatric surgery can optimize results and reduce adverse outcomes [6].

So far only three studies have investigated the effectiveness of CBT in bariatric surgery patients, showing positive results in eating behavior and psychosocial functioning ([27]; post-operative CBT; [3]; pre-operative CBT; [6]; pre- and post-operative CBT). These studies focused mainly on the treatment of binge eating; not of obesity in general. The evidence should be considered preliminary given the small sample sizes in the studies of Leahey and Cassin (N = 7 and N = 8) and the lack of (active) control groups. However, these findings suggest that CBT is promising in the treatment of bariatric surgery.

This is the first randomized controlled trial (RCT) to study the effectiveness of CBT as an add-on prior to bariatric surgery in a large clinical sample of patients with extreme obesity, including long term follow-up measurements. This RCT aims to investigate whether preoperative CBT, aimed at modification of thoughts and behaviors in terms of eating and physical exercise, leads to better outcomes of bariatric surgery in terms of weight loss (maintenance), reduction of maladaptive eating behavior, eating disorders and depressive symptoms, improvement of quality of life and reduction of psychological distress.

2. Method

2.1. Design and power

This study is a cooperative effort between a research team from two sites of an outpatient mental health care center, PsyQ and two general hospitals, the Sint Franciscus Hospital and the Maasstad Hospital, in the city of Rotterdam, the Netherlands. They serve a large group of patients in the wider Rotterdam area. PsyQ Rotterdam is part of a nationwide network of PsyQ mental health treatment centers in the Netherlands. An RCT will be conducted, comparing 10 sessions of CBT with a no treatment control condition. Measurements will be carried out at five time points: pretreatment/pre-surgery, post-treatment/pre-surgery, and at one, three and five years after surgery. Ideally, the 5 year follow up will be used as primary outcome measure, although the 3-year follow up might be more realistic and feasible. The sample size to achieve a power of 0.80 ($\alpha = 0.05$) for detecting a medium difference ($f = .25$) is calculated at 64 per condition. In total 128 patients will be included in the study.

2.2. Participants

Patients will be recruited at the bariatric surgery department of the Sint Franciscus Hospital and the Maasstad Hospital.

Inclusion criteria are 1) a BMI ≥ 40 kg/m², or a BMI ≥ 35 kg/m² plus somatic comorbidity that meets the criteria for bariatric surgery, 2) on

the waiting list for gastric bypass surgery in either of the hospitals, and 3) age between 21 and 65 years.

Exclusion criteria are 1) current treatment by a dietician, psychiatrist or psychologist, 2) a diagnosis of schizophrenia, bipolar disorder, suicidality, substance addiction and 3) non-fluency in the Dutch language.

2.3. Procedure

Patients who are placed on the waiting list for gastric bypass surgery will be asked to participate in the study. Patients who are interested in participating will be sent a detailed briefing and informed consent document with a stamped return envelope. Two days later, these patients will be phoned and asked whether they want to participate or not. If yes, inclusion and exclusion criteria will be checked. Patients willing to participate will be requested to return the signed informed consent. Upon receipt, participants will be randomly assigned to one of the two conditions: CBT or control. This randomization will take place using an online generated randomization list. This list will be managed by an independent office manager of PsyQ to ensure allocation concealment. Participants who are assigned to the CBT condition will be scheduled for 10 individual sessions during 8 to 10 weeks.

The intervention will be carried out at the eating disorders and obesity units of two outpatient mental health treatment centers of PsyQ. The manual-driven treatment is based on the cognitive behavioral treatment of obesity [10,26,62]. The intervention will be delivered by psychologists and certified cognitive behavioral therapists, who are familiar with the application of CBT manuals in the treatment of patients with eating disorders and obesity. All seven therapists have been trained in the treatment program and have received the treatment manual. Additionally, each therapist has observed all sessions of a bariatric surgery patient treated by the first author (LP). During the course of the study two-monthly group supervision meetings led by the first and last author will take place. At these meetings all active cases and therapy notes will be reviewed against an intervention checklist that closely follows the content of the treatment manual, to ensure adherence to the manual and treatment quality.

2.4. Conditions and treatment

Both the intervention and control condition will follow the standard preoperative preparation procedure of the hospital. This procedure consists of a mandatory group meeting in which information about the surgical procedure and medical aspects before and after surgery is provided by the surgeon or nurse practitioner and a mandatory group or individual consultation by dietician. Patients also receive a detailed information booklet on the surgery.

Patients in the *control condition* will receive this regular preoperative preparation procedure only, no psychological interventions will take place. In addition to the regular preparation procedure for surgery, the *treatment condition* will consist of a treatment protocol based on cognitive behavioral therapy of 10 individual sessions of 45 min. The intervention pertains to awareness of psychological factors underlying eating behaviors such as emotional eating and loss of control over eating, the development and internalization of new eating and activity behavior and coping with emotions, as well as to cognitive restructuring. Homework assignments are part of the treatment (see Table 1 for a detailed overview).

2.5. Assessments

Outcome measures include weight loss as the primary outcome measure and eating behavior, eating disorders, depression, quality of life and overall psychological health as secondary measures. The secondary measurements will be collected with online questionnaires, for which participants will be invited by e-mail.

Table 1
Overview of the intervention.

Session	Description of topics and techniques ^a	Homework
1. Information and motivation	Treatment rationale – obesity as behavioral problem Weight course Cost–benefit analysis of overeating/underactivity and lifestyle change, obstructive factors	Reading information about obesity Composing or complementing cost–benefit analysis
2. Motivation and nutritional management	Fate or guilt – contributing and influencable factors in development of obesity Nutritional management – anamnesis and normalization eating pattern Self-monitoring – eating diary Favorable circumstances development eating pattern	Composing list influencable factors Composing list benefits and motivation lifestyle change Eating diary
3. Nutritional and activity management I	Advise daily physical activity History of physical activity, obstructive factors Self-monitoring – physical activity diary Week goal eating	Composing list physical activities Eating diary Physical activity diary Week goal
4. Nutritional and activity management II	Week goal eating and activity	Eating diary Physical activity diary Week goals
5. Cognitive restructuring I: introduction	Relation eating related thoughts and eating behavior breaking vicious circle by constructive thoughts Types of eating behavior (restraint, emotional, external) Psycho-education – maladaptive thinking leads to affect and behavior Relation various cues and eating Problem solving – alternative coping strategies (e.g. asking for support, taking a rest) Week goal eating and activity	Reading information cognitive therapy Registering situations in which the problem behavior did not occur Eating diary – also thoughts and feelings Physical activity diary Week goals
6. Cognitive restructuring II: behavioral analysis	Analysis of eating situation with ABC model ^b Analysis of underactivity situation with ABC model ^b Week goals eating and activity	Analysis of recent situation of undesirable eating behavior and of underactivity Eating and physical activity diary Week goals Registration difficult and success moments
7. Cognitive restructuring III: constructive thoughts	Obstructive thoughts in difficult moments – replacing by constructive thoughts Increasing credibility of constructive thoughts Week goals eating and activity	Registration difficult and success moments Practicing constructive thoughts Eating and physical activity diary
8. Self-control	Stimulus control – diminishing probability of undesirable eating behavior by organization of environment (e.g. eating of small plate) Stimulus-response intervention – applying alternative behaviors for urge to eat (e.g. taking a walk) Response consequences – linking undesirable behavior (overeating) to negative consequence (e.g. cleaning) Week goals eating and activity	Composing list with self-control measures Performing one self-control measure Registration difficult and success moments Eating diary and physical activity diary Week goals
9. Self-control, mindfulness, relapse prevention plan	Mindful eating Behavioral exercise: mindfully eating a raisin Relapse prevention: future difficult moments, behavioral alternatives and constructive thoughts Week goals eating and activity	Completing relapse prevention plan Practicing mindful eating Practicing self-control measures Eating and physical activity diary Week goals
10. Relapse prevention and future prospectives	Details of relapse prevention plan Expectations of and preparation for (period after) surgery Evaluation of treatment	

^a Every session starts with a discussion of homework.

^b A (activating event), B (beliefs/thoughts), C (consequences; actions, emotions).

2.5.1. Weight loss

The calibrated weighing scales of the departments of bariatric surgery of Maasstad Ziekenhuis and Sint Franciscus Gasthuis will be used. Weight loss will be operationalized in terms of BMI reduction and percentage excess weight loss (%EWL), which is the standard in bariatric surgery nomenclature [40]. The percentage EWL calculation will be derived from the formula: percentage of excess weight loss = (weight loss / excess weight) × 100, where excess weight = total preoperative weight – ideal weight. The ideal weight is defined as the weight to achieve a BMI of 25. Weight will be expressed in kilograms and height in meters.

2.5.2. Eating behavior

To assess eating behavior, the Dutch Eating Behavior Questionnaire will be used (DEBQ; [54]). Four subscales are distinguished, including eating in response to clearly labeled emotions (9 items, e.g. “Do you have a desire to eat when you are irritated?”), eating in response to diffuse emotions (4 items, e.g. “Do you have a desire to eat when you have nothing to do?”), external eating (10 items, e.g. “If food smells and looks

good, do you eat more than usual?”), and restrained eating (10 items, e.g. “Do you try to eat less at mealtimes than you would like to eat?”). The 33 items can be answered on a 5-point scale ranging from 1 ‘never’ to 5 ‘very often.’

The DEBQ has high internal consistency and factorial validity [55,57]. The predictive validity of the external eating subscale has been questioned by Jansen et al. [21]. However, in a study that used a semi naturalistic setting, predictive validity was shown for extreme external eating scores [53].

2.5.3. Eating disorders

Eating disorder symptomatology and cognitions regarding relevant aspects such as weight, shape and eating will be measured by the Eating Disorder Examination Questionnaire (EDE-Q; [18], Dutch translation by [39]). Twenty-two of the twenty-eight items assess the core attitudinal aspects of ED symptomatology over the last 28 days. The remaining 6 items relate to frequencies of eating disorder behaviors such as binge eating and do not contribute to the subscales scores. The 22 items comprise 4 subscales, namely dietary restraint (5 items, e.g. “On how many of the last 28 days... Have you tried to eat as little as possible?”), eating

concerns (5 items, e.g. “On how many of the last 28 days... Have you had a definite fear of losing control over eating?”), weight concerns (7 items, e.g. “On how many of the last 28 days... Have you had a strong desire to lose weight?”), and shape concerns (5 items, e.g. “On how many of the last 28 days... Did your shape influence the way you think about yourself?”). These items are answered on a 7-point Likert scale ranging from 0 ‘not one day’ to 6 ‘every day’. The score of each subscale is provided by the sum and average of the subscale items. The global score is calculated by summing and averaging those subscale scores. The EDE-Q has demonstrated acceptable to excellent internal consistency and test-retest reliability [4,30]. The validity of the EDE-Q has not been well established, however, two studies have shown accurate discriminate validity [35,36].

2.5.4. Depressive symptoms

Depressive symptomatology will be measured by the Quick Inventory of Depressive Symptomatology-Self Rating (QIDS-SR; [45]), a self-report questionnaire for depression based on the DSM-IV criteria. The QIDS-SR contains 16 items, which are related to the 9 symptom domains of the DSM-IV major depressive disorder criteria: sleep disturbance (4 items), psychomotor disturbance (2 items), appetite/weight disturbance (4 items), depressed mood (1 item), decreased interest (1 item), decreased energy (1 item), worthlessness/guilt (1 item), concentration/decision making (1 item), and suicidal ideation (1 item). These items are answered on a 4-point Likert scale ranging in severity from 0 to 3. Responses apply to experiences over the last 7 days (e.g. “Feeling sad: 0. I do not feel sad; 1. I feel sad half the time; 2. I feel sad more than half the time; 3. I feel sad nearly all of the time”). The sum of the scores on each of the 9 symptom domains determines the total score, which ranges from 0–27. The QIDS-SR has high internal consistency and high concurrent validity [45].

2.5.5. Quality of life

Quality of life will be measured by the World Health Organization Quality of Life (WHOQoL-BREF; [19]), a self-report questionnaire developed by the WHO. The WHOQoL-BREF instrument comprises 26 items, which measure four broad domains: physical health (7 items, e.g. “How satisfied are you with your ability to perform your daily living activities?”), psychological health (6 items, e.g. “How satisfied are you with yourself?”), social relationships (3 items, e.g. “How satisfied are you with your personal relationships?”), and environment (8 items, e.g. “How satisfied are you with the condition of your living place?”). Two remaining items assess the overall quality of life and general health. Answers are made on a 5-point Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied). The mean score of items within the domain will be used to calculate the domain score. Scores will be scaled in a positive direction, e.g. higher scores are related to a higher quality of life. WHOQOL-BREF domain scores demonstrated good discriminant validity, content validity, internal consistency and test-retest reliability [50].

2.5.6. Psychological distress

To assess the level of psychological distress and psychiatric disorders, the Brief Symptom Inventory will be used (BSI; [12]). This is a short version of the Symptom Checklist-90-R (SCL-90-R; [14]), which measures the same dimensions of psychopathological symptoms; somatization (7 items, e.g. “Faintness or dizziness”), obsession-compulsion (6 items, e.g. “Having to check and double-check what you do”), interpersonal sensitivity (4 items, e.g. “Feeling inferior to others”), depression (10 items, e.g. “Feeling no interest in things”), anxiety (6 items, e.g. “Feeling tense or keyed up”), hostility (5 items, e.g. “Having urges to break or smash things”), phobic anxiety (5 items, e.g. “Feeling uneasy in crowds, such as shopping or at a movie”), paranoid ideation (5 items, e.g. “Others not giving you proper credit for your achievements”), and psychoticism (5 items, e.g. “The idea that something is wrong with your mind”). The BSI has 53 items which are ranked on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely).

These rankings reflect the intensity of distress during the past 7 days. In addition to the 9 symptom dimensions, 3 global indices assess general psychological distress. The Global Severity Index (GSI) is an indicator of the overall level of distress, as calculated by the average of the 53 items. The Positive Symptom Total (PST) is the number of endorsed items. The Positive Symptom Distress Index (PSDI) is a measure of the severity of symptoms adjusted by the number of endorsed symptoms. The GSI is used to reflect the level of psychological distress. Psychometric properties are adequate [5], as the instrument has good internal reliability showing an average rating above .7 for the scales and a range for test-retest reliability of .68 to .91 [12]. Convergent validity has been consistently substantiated in the literature [13,44].

2.6. Statistical analysis

Multilevel analyses will be performed to analyze the outcome measures over time. The outcome measures weight, eating behavior, eating disorder, mood disorder, quality of life, psychological well-being are all of interval or ratio level of measurement, therefore linear mixed models with a random intercept [52] are used. It will be examined whether models with random slopes have a better fit than those without random slopes. The difference between these models follows a chi-square distribution with degrees of freedom as the difference in number of estimated parameters. Improved fit will be examined by means of a likelihood ratio test. Predictors include condition (control vs. treatment) and time (pretreatment, post-treatment and one year follow up). This time factor will be modeled on ordinal measurement level. The baseline measurement is used as a predictor. The interaction between condition and time will be included in the models. The analyses will be carried out according to the intention-to-treat strategy. Missing values will be imputed using multiple imputations.

3. Discussion

This is the first randomized controlled trial to study the effectiveness of CBT as an add-on prior to bariatric surgery in a large clinical sample of patients with extreme obesity, including long term follow-up measurements. In many review studies the need of such a pre- or postoperative intervention is stressed (e.g. [47]). We hope to find that preoperative psychological treatment, specifically CBT focused on changing maladaptive eating behaviors and stimulating physical activity, contributes to optimizing weight loss results as well as psychological functioning and adjustment after bariatric surgery. The preoperative nature of the therapy could be a positive factor, since many patients are less compliant with follow-up after surgery [59]. Developing skills to cope with stress or new situations takes time; an early preparation may enhance the possibility of fully adapting to a new life style in the postoperative period. Fortunately, CBT for obesity appears to have long-term effects, beyond the end of treatment [58]. Moreover, dysfunctional eating behavior or even eating disorders may also develop after surgery [8,32]. Our follow-up measurements may reveal whether preoperative CBT effectively prevents those behaviors or psychopathology in the postoperative period. Future randomized controlled trials are needed to investigate the relative effectiveness of preoperative vs. postoperative psychological treatment.

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