



## Does cognitive behavioral therapy strengthen the effect of bariatric surgery for obesity? Design and methods of a randomized and controlled study<sup>☆</sup>

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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  $\geq 30$  kg/m<sup>2</sup>) 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  $\geq 40$  kg/m<sup>2</sup>) 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].

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

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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  $\geq 40$  kg/m<sup>2</sup>, or a BMI  $\geq 35$  kg/m<sup>2</sup> 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.

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