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## A pilot randomized controlled trial of telephone-based cognitive behavioural therapy for preoperative bariatric surgery patients



Stephanie E. Cassin <sup>a, b, \*</sup>, Sanjeev Sockalingam <sup>b, c</sup>, Chau Du <sup>c</sup>, Susan Wnuk <sup>b, c</sup>, Raed Hawa <sup>b, c</sup>, Sagar V. Parikh <sup>b, d</sup>

- <sup>a</sup> Department of Psychology, Ryerson University, Toronto, Canada
- <sup>b</sup> Department of Psychiatry, University of Toronto, Toronto, Canada
- <sup>c</sup> Bariatric Surgery Program, Toronto Western Hospital, Toronto, Canada
- <sup>d</sup> Department of Psychiatry, University of Michigan, Ann Arbor, USA

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#### ABSTRACT

*Background:* Psychosocial interventions can improve eating behaviours and psychosocial functioning in bariatric surgery candidates. However, those that involve face-to-face sessions are problematic for individuals with severe obesity due to mobility issues and practical barriers.

*Objective*: To examine the efficacy of a pre-operative telephone-based cognitive behavioural therapy (Tele-CBT) intervention versus standard pre-operative care for improving eating psychopathology and psychosocial functioning.

*Methods:* Preoperative bariatric surgery patients (N = 47) were randomly assigned to receive standard preoperative care (n = 24) or 6 sessions of Tele-CBT (n = 23).

Results: Retention was 74.5% at post-intervention. Intent-to-treat analyses indicated that the Tele-CBT group reported significant improvements on the Binge Eating Scale (BES), t (22) = 2.81, p = .01, Emotional Eating Scale (EES), t (22) = 3.44, p = .002, and Patient Health Questionnaire-9 (PHQ-9), t (22) = 2.71, p = .01, whereas the standard care control group actually reported significant increases on the EES, t (23) = 4.86, p < .001, PHQ-9, t (23) = 2.75, p = .01, and General Anxiety Disorder-7 (GAD-7), t (23) = 2.93, p = .008 over the same time period.

*Conclusions:* Tele-CBT holds promise as a brief intervention for improving eating psychopathology and depression in bariatric surgery candidates.

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Major clinical guidelines recommend bariatric surgery for individuals with extreme obesity, defined as a body mass index  $(BMI = kg/m^2)$  exceeding 40 kg/m², and for individuals with a BMI exceeding 35 kg/m² if there are significant obesity-related comorbidities (Mechanick et al., 2013; National Institute for Health and Clinical Excellence, 2006). Bariatric surgery restricts the amount of food an individual is able to consume at one time and can be conceptualized as a forced behavioural modification program. Gastric bypass bariatric surgery is very effective in reducing weight

E-mail address: stephanie.cassin@psych.ryerson.ca (S.E. Cassin).

in the short-term, with maximum weight change typically occurring in the first year post-surgery; however, weight change trajectories are highly variable (Courcoulas et al., 2013). Approximately 50% of patients experience some weight regain by 2 years post-surgery (Magro et al., 2008). In 24% of patients, the extent of weight regain is considerable relative to their overall weight loss at 3 years post-surgery (Courcoulas et al., 2013).

One potential explanation for the variability in post-operative outcomes is that surgery alone does not directly address the psychological factors that contribute to the development and maintenance of obesity, including counterproductive cognitions (e.g., self-defeating or self-sabotaging thoughts) and negative emotions (e.g., depression, anxiety, anger) that lead to maladaptive eating behaviours. High rates of psychiatric comorbidity have been documented in bariatric surgery candidates including mood, anxiety, and eating disorders (Muhlhans, Horbach, & De Zwaan, 2009). Although the impact of pre-operative psychiatric disorders and

Abbreviations: BES, Binge Eating Scale; EES, Emotional Eating Scale; GAD-7, Generalized Anxiety Disorder 7-item scale; PHQ-9, Patient Health Questionnaire 9-item scale; SF-36, Short-Form 36 Health Survey; Tele-CBT, Telephone-based cognitive behavioural therapy.

 $<sup>\</sup>ast$  Corresponding author. Department of Psychology, Ryerson University, Toronto, Canada.

various forms of disordered eating on post-operative weight loss is currently inconclusive (Livhits et al., 2012), post-operative binge eating, loss of control eating, uncontrolled eating/grazing, and depression have been shown to negatively impact weight loss outcomes, and adherence to dietary guidelines has been shown to positively impact weight loss outcomes (Meany, Conceicao, & Mitchell, 2014; Sheets et al., 2015).

In light of these issues, adjunctive psychosocial interventions are increasingly being recommended in the clinical management of bariatric patients (Beck, Johannsen, Stoving, Mehlsen, & Zachariae, 2012; Kalarchian & Marcus, 2015; Meany et al., 2014; Sheets et al., 2015). However, psychosocial interventions are not yet routinely offered in most bariatric surgery programs, in part because no "best practices" have been established. A search of the empirical literature suggests that the most common forms of psychosocial interventions include multi-component behavioural lifestyle interventions and cognitive behavioural therapy (CBT) interventions. Behavioural lifestyle interventions typically include components such as dietary advice, physical activity, food monitoring, and stimulus control. CBT interventions include many behavioural interventions, but also incorporate cognitive strategies (e.g., identifying, challenging, and altering counterproductive thoughts).

Most of the empirical studies conducted to date have examined the impact of post-operative psychosocial interventions on outcomes such as diet, physical activity, disordered eating, psychosocial functioning, and weight loss (for reviews, see Beck et al., 2012; Kalarchian & Marcus, 2015; Rudolph & Hilbert, 2013). In comparison, fewer studies have examined the effectiveness of preoperative psychosocial interventions; however, preliminary evidence suggests that bariatric candidates may benefit from acquiring coping skills prior to surgery in order to help them prepare for surgery and adjust following surgery. Uncontrolled studies suggest that pre-operative CBT is feasible and potentially useful in helping bariatric surgery candidates improve their eating behaviours (Ashton, Drerup, Windover, & Heinberg, 2009) and lose more weight following surgery (Ashton, Heinberg, Windover, & Merrell, 2011). A prospective observational study that followed 30 patients for two years found that those who had received 12 sessions of preoperative CBT were far more likely to have lost over 50% of their excess weight following surgery (94% vs. 12%) (Abiles et al., 2013). A recent randomized controlled trial (RCT) reported that a 6 session pre-operative CBT intervention was efficacious in increasing objectively measured physical activity (Bond et al., 2015), and another RCT reported that a 10 session CBT intervention was efficacious in improving eating behaviours, depression, and anxiety during the pre-operative period relative to standard care, but did not confer additional benefits beyond surgery at the 1 year followup (Gade, Friborg, Rosenvinge, Småstuen, & Hjelmesæth, 2015).

Previous research interventions have employed almost exclusively face-to-face treatments, although some studies have incorporated the use of telephone sessions (Gade et al., 2015; Kalarchian et al., 2012). Travelling for appointments poses practical barriers (e.g., missing work, childcare issues), and is even more difficult for bariatric patients due to mobility challenges secondary to obesity (King et al., 2012). Few patients live in close proximity to bariatric surgery programs, and travel distance is inversely associated with attendance at appointments (Lara et al., 2005), further reinforcing the need for psychosocial treatment modalities that can overcome this barrier. Telephone-based CBT (Tele-CBT) has previously been utilized in medical populations by adapting standard CBT manuals (Mohr et al., 2000); however, no published studies have examined the efficacy of Tele-CBT in a bariatric surgery population.

Our team developed a CBT manual for bariatric surgery patients adapted to delivery by telephone (Cassin et al., 2013). The objective

of the current pilot RCT was to compare the efficacy of a preoperative Tele-CBT intervention (Tele-CBT) to standard preoperative bariatric care (Control) in improving eating psychopathology (primary outcome) and psychosocial functioning (secondary outcome). Specifically, it was hypothesized that the Tele-CBT group would report significant improvements in eating psychopathology, depression, anxiety, and quality of life immediately following the intervention, and that their scores would improve to a greater extent than the standard care control group.

#### 1. Methods

#### 1.1. Participants

Participants (N=72) were adult bariatric surgery candidates recruited from a Canadian Bariatric Surgery Program. Exclusion criteria included current ineligibility for bariatric surgery, lack of computer access, or having significant language barriers, poorly controlled psychiatric illness or severe medical illness that would render Tele-CBT very difficult. Given the absence of clear preoperative psychological predictors of bariatric surgery outcome (Livhits et al., 2012), participation was not limited to bariatric candidates with clinically significant eating psychopathology (e.g., binge eating) or general psychopathology (e.g., depression, anxiety). The intervention focused on the development of adaptive coping skills that are thought to be helpful for all patients in adhering to dietary guidelines (see description of Tele-CBT protocol below).

#### 1.2. Design

Ethical approval for the study was obtained from the Institutional Research Ethics Board, and the trial was registered at clinicaltrials.gov (NCT01508585). Patients were informed about the study by a dietician, social worker, or research coordinator during the pre-surgical assessment process. The pre-surgical assessment process includes a psychodiagnostic assessment conducted by a psychologist or psychiatrist (see Sockalingam et al. (2013) for more information about the presurgical assessment process and exclusion criteria for surgery). Patients who were determined to be eligible for surgery and who were interested in learning more about the study provided their contact information. After completing informed consent and a phone screen to determine eligibility, participants were e-mailed a link to the online questionnaire packet administered through Survey Monkey TM. Participants were randomly assigned using a computer generated random sequence to either the Tele-CBT group or Control group at an allocation ratio of 1:1, and a research coordinator notified them of their group assignment upon completion of the questionnaire packet. Participants assigned to the Tele-CBT group were scheduled their first session approximately one week after completing their baseline questionnaire packet. On average, the first Tele-CBT session occurred 4.7 months prior to bariatric surgery. Those in the control condition received standard bariatric care. The time interval between the pre- and post-measures was 7 weeks.

#### 1.3. Telephone-based cognitive behavioural therapy

The six Tele-CBT sessions were each approximately 55-min in duration and scheduled weekly at a time convenient for the participants. Two Master-level psychometrists experienced in the assessment and treatment of bariatric surgery patients conducted the sessions. They received training on the Tele-CBT protocol and worked under the supervision of two doctoral level registered clinical psychologists (SC and SW).

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