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Randomized Controlled Trial of Treatments for Loss-of-Control Eating Following Bariatric Surgery

Carlos M. Grilo, Ph.D.[1,2], **Valentina Ivezaj, Ph.D.**[1], **Andrew J Duffy, M.D.**[3], **Ralitza Gueorguieva, Ph.D.**[1,4]

[1]Yale School of Medicine, Department of Psychiatry, New Haven, CT, USA.

[2]Yale University, Department of Psychology, New Haven, CT, USA.

[3]Yale School of Medicine, Department of Surgery, New Haven, CT, USA.

[4]Yale School Public Health, Department of Biostatistics, New Haven, CT, USA.

Abstract

Background: Loss-of-control (LOC)-eating post-operatively is a consistent predictor of suboptimal longer-term bariatric surgery outcomes. This randomized controlled trial (RCT) examined the effectiveness of two guided-self-help treatments (cognitive-behavioral therapy [gshCBT] and behavioral weight-loss [gshBWL]) to a control (CON) for reducing LOC-eating and weight.

Methods: 140 patients with recurrent LOC-eating six months after bariatric surgery were randomly assigned (5:5:2 ratio) to one of three conditions: gshCBT (N=56), gshBWL (N=60), or CON (N=24). Three-month treatments were delivered by trained allied-health clinicians to increase generalizability to bariatric-surgery settings. Independent assessments were performed by doctoral research-clinicians using established interviews/measures; post-outcomes were obtained for 89% of patients.

Results: Mixed-models revealed significant improvements for LOC-eating frequency and weight-loss but no significant differences between treatments; race neither predicted (main-effect) nor moderated (interaction-effect) treatment outcomes. ITT categorical analyses of abstinence from LOC-eating (30% for gshCBT, 27% for gshBWL, 38% for CON) and proportion attaining

Correspondence should be addressed to Carlos M. Grilo, Ph.D., Yale School of Medicine, 300 George Street (9th floor, Psychiatry), New Haven, CT 06511. carlos.grilo@yale.edu.

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5% weight loss (20%, 22%, 17%) revealed no significant differences between treatments; non-White participants had higher proportion achieving LOC-eating abstinence but lower proportion attaining 5% weight-loss than White participants.

Conclusions: In this 12-week RCT following bariatric surgery, significant LOC-eating reductions and weight-loss did not differ significantly between treatments. Race was associated with post-treatment categorical outcomes.

Keywords

Obesity; bariatric surgery; binge eating; loss-of-control eating; behavior therapy

Introduction

Bariatric surgery, the most effective treatment for severe obesity, results in overall impressive weight-loss and improved medical comorbidities (1,2,3). Laparoscopic sleeve gastrectomy (LSG) and Roux-en-Y gastric-bypass (RYGB), the two most commonly performed procedures (4), result in roughly 50% excess weight loss; RYGB shows slight advantages in weight loss and medical improvements over LSG (which is surgically easier to perform and has fewer short-term surgically-related complications) and both are superior to adjustable gastric banding (5). Although bariatric surgery produces overall impressive outcomes, there is marked heterogeneity in weight-losses (6) and weight-regain after surgery is associated with reoccurrence of medical comorbidities (7). These findings are concerning and suggest bariatric surgery alone is often not enough, highlighting the need for research to identify predictors and methods to enhance outcomes.

Given concerns about variability and durability of outcomes achieved with bariatric surgery, emerging research has followed two main paths. Investigators have begun to test behavioral/psychological interventions delivered either prior to or following bariatric surgery for improving targets such as eating behaviors and functioning in the hopes of also enhancing weight losses (3). These interventions, mostly brief and low-intensity, evaluated in small trials have yielded some encouraging, albeit mixed, findings that weight-losses can be improved (3,8,9). One consistent finding is that optimal time to deliver adjunctive interventions appears to be early in the post-surgery period although more research is needed to inform the refinement of preliminary treatments (8).

Investigators have also attempted to identify predictors of poor outcomes which could inform “which patients” need adjunctive interventions and “what behaviors” to specifically target. Research examining a broad range of pre-surgical patient variables has failed to reliably identify any potentially modifiable predictors of weight-loss outcomes following bariatric surgery (3). In contrast, research has identified one reliable post-surgery predictor of subsequent outcomes – “loss of control” (LOC) eating” (10,11,12; see 3).

LOC while eating is one of two core components of “binge eating” criterion for binge-eating disorder (BED) in *Diagnostic and Statistical Manual of Mental Disorders–5th edition* [*DSM-5*](13). The second component of “binge eating” is that the episode involves an unusually large amount of food which, following bariatric surgery, is physically difficult.

However, eating smaller quantities of food while experiencing LOC remains possible following surgery. Emerging research with patients who have undergone bariatric surgery (14,15) along with considerable research with clinical/community samples across weight categories have documented that “loss of control” is the meaningful aspect of binge eating (regardless of quantity consumed) and is a strong predictor of eating-disorder psychopathology and psychological disturbance (16). Indeed, the salience of LOC eating for binge eating has been recognized officially in the recent version of *International Classification of Diseases* [*ICD-11*] (17). Research has found that LOC-eating following surgery (11), *not* binge-eating prior to surgery (18), is the most reliable modifiable predictor of poorer weight outcomes (12). Research is needed to identify treatments for LOC-eating following bariatric surgery.

This study was a randomized controlled trial (RCT) to evaluate effective treatments from the BED/obesity fields adapted for patients following bariatric surgery who are experiencing LOC-eating. In non-bariatric samples, certain psychological treatments, such as cognitive-behavioral therapy (CBT), are effective for binge-eating and produce significant durable improvements (19,20). Research has supported “scalable” guided self-help CBT (gshCBT) for binge eating (21,22). Preliminary findings suggest that brief-CBT delivered six months following bariatric surgery shows promise for reducing problematic eating (23). Although CBT treatments improve eating behaviors, they consistently fail to produce substantial weight-loss in patients with obesity (22,24). In contrast, RCTs have demonstrated that certain behavioral treatments (lifestyle behavioral weight loss (BWL)) and pharmacological methods, produce substantial reductions in binge eating but offer a potential advantage over CBT for weight-loss (22,24,25).

This RCT was designed to specifically test the effectiveness of two guided-self-help treatments (gshCBT and gshBWL) for improving LOC- eating, weight, and associated features following bariatric surgery. Because experimental conditions should demonstrate superiority over usual/standard care (26), a control (CON) condition with standard care was chosen to provide additional context. The study used allied-health clinicians to deliver treatments; this was intended as a methodologic match to the CON condition and to enhance generalizability to bariatric surgery settings which have allied-health clinicians in such roles. This strategy was supported by research suggesting that such scalable guided-self-help interventions can be delivered by generalist clinicians (27) and are cost-effective (28). Finally, the study aimed to examine whether race predicts/moderates or is associated with treatment outcomes given research findings given research findings that, relative to White patients, Black patients experience lower weight-loss following bariatric surgery (31) and treatments for BED despite being more likely to stop binge eating in analyses of data aggregated across RCTs (32).

Methods

Participants

Participants were 140 consecutively randomized patients recruited September 2014 to December 2017 interested in treatment for eating/weight concerns approximately six months following laparoscopic RYGB or SG. Participants were recruited from a single bariatric

center-of-excellence at an academic medical center using flyers/mailings soliciting postoperative patients with eating concerns interested in a behavioral treatment study. Inclusion criteria included age 18–65 and regular LOC-eating (≥once weekly) during past 28 days (feeling unable to stop/control an eating episode at least once weekly regardless of quantity). Exclusion criteria, minimal to enhance generalizability, included medications known to effectively influence eating/weight, substance dependence, or severe psychiatric illness requiring acute care determined by clinical/diagnostic interviews during intake. Assessments were conducted independently from bariatric center. This study received Yale Institutional Review Board approval; participants provided written informed consent.

Participants had a mean age of 45.6 (SD=10.9) years, were predominately female (*n*=119, 85.0%), and diverse in ethnicity (n=15 (10.7%) identified as Hispanic/Latino/a) and race [(*n*=79 (56.4%) White, *n*=44 (31.4%) Black, *n*=11 (7.9%) "Other", *n*=3 (2.1%) Bi/Multiracial, *n*=2 (1.4%) American-Indian/Alaska-Native, and *n*=1 (0.7%) Native-Hawaiian/Other Pacific-Islander]. Table 1 shows categorization of White/Non-White used in statistical models. Of the 140 participants, 123 (87.9%) had LSG, 17 (12.1%) had RYGB. At study enrollment, mean time since surgery was 6.4 (*SD*=1.5; range 4–10) months, and percent weight-loss was 20.3 (*SD*=7.9).

Diagnostic and Repeated Outcomes Measures

Trained and monitored doctoral research-clinicians (blinded to treatment; see below) administered the *Eating Disorder Examination-Bariatric-Surgery-Version* (EDE-BSV) (33,34) interview at baseline and post-treatment (end-of-treatment without time lapse). EDE-BSV, a semi-structured investigator-based interview, assessed frequency of LOC-eating and eating-disorder psychopathology (reflected in Global Score). EDE-BSV, the modified version of the EDE interview which has good psychometric properties in studies of obesity and BED(35,36), was adapted specifically for bariatric research, including the Longitudinal Assessment Bariatric Surgery (LABS) study(12,33,34). In the present study, interrater reliability, assessed with N=20 cases, was excellent for both LOC-eating frequency (ICC=0.90) and Global Score (ICC=0.95).

Weight/Height Variables.—Measured height and measured weight (baseline, monthly, post-treatment) obtained using a high-capacity digital scale were used to calculate BMI and %TWL *during* treatment ([(Session 1 Weight)−(Post Weight)]/[(Session 1 Weight)]*100). Per bariatric-surgery guidelines (37), percent weight-loss *at time of enrollment* was computed: ([(Preoperative Weight)−(Postoperative Weight)]/[(Preoperative Weight)]*100).

Self-report measures were completed at baseline, monthly during treatment, and post-treatment. *Beck Depression Inventory (BDI-II)*(38) is a psychometrically-sound measure of depressive symptom levels. *Godin Leisure Time Exercise Questionnaire* (GLTEQ)(39) assesses mild, moderate, and vigorous physical activity, has good test-retest reliability, and has been validated against objective measurements(40). *Medical Outcomes Study Short-Form Health Survey* (SF-36)(41), assesses health-related quality-of-life, includes two summary scores for physical (SF-PCS) and mental (SF-MCS) health, and has good validity

and reliability(42). Scores are transformed and computed as *t*-scores with mean of 50 and standard deviation of 10.

Treatment Conditions

Treatments were delivered over 12 weeks by trained (by C.M.G. and V.I.) allied-health clinicians (e.g., masters'-level nurses with various specialties including mental/behavioral health and nutrition, APRNs, graduate students in clinical psychology or public health in behavioral/social science) who were monitored (weekly supervision focused on quality and fidelity of sessions including review of audiotapes) throughout the study to maintain adherence to manualized treatment protocols described below. Using "generalist" allied-health clinicians to deliver the scalable guided-self-help treatments, per previous research(22,27), served as a methodologic match to the CON control condition and increases generalizability to bariatric surgery settings. The CON condition comprised standard care available at the Yale bariatric center-of-excellence including support groups and nutrition education following national guidelines(29,30) delivered by allied-health professionals. Although all participants had access to the bariatric center's standard care, participants assigned to the CON condition were specifically encouraged to continue working with the bariatric center's clinicians and resources by the study research-clinicians assigned to them for baseline and monthly assessments, which was intended as a partial "control-for-attention." Experimental treatments (gshCBT, gshBWL) were closely matched to each other in number of sessions and time, session structure and in-between session tasks, and self-care materials.

Guided-Self-Help Cognitive-Behavioral Therapy—Guided-Self-Help Cognitive-Behavioral Therapy (gshCBT) followed manualized protocols(21) used in RCTs for BED adapted for use for patients following bariatric surgery. gshCBT, delivered via 6 individual sessions (25–30 minutes) over 12 weeks, was keyed to a self-care manual along with standard bariatric nutrition education provided to participants. gshCBT follows six steps to assess and modify maladaptive eating-related behaviors and cognitions (e.g., shape/weight concerns) hypothesized to maintain the disordered eating. Clinicians "guide" the gshCBT by addressing patients' questions about the CBT approach, helping with difficulties around following behavioral steps and cognitive-restructuring exercises, and reinforcing importance of self-monitoring, record keeping, and goal-setting.

Guided-Self-Help Behavioral Weight Loss—Guided-Self-Help Behavioral Weight Loss (gshBWL) followed manualized protocols used previously for BED(21) based initially on the LEARN (lifestyle, exercise, attitudes, relationships, and nutrition) program and adapted for use for patients following bariatric surgery. gshBWL, delivered via 6 individual sessions (25–30 minutes) over 12 weeks, was keyed to a self-care manual along with standard bariatric nutrition education provided to participants. gshBWL focuses on making gradual and modest lifestyle changes during the challenging post-operative period, including re-establishing acceptable eating and nutrition patterns given the restrictions of surgery, gradually increasing physical activity, and problem-solving social/interpersonal contexts to sustain changes.

Treatment Randomization and Blind Assessment Protocols

Randomization followed an allocation ratio of 5:5:2 to the three treatments (gshCBT, gshBWL, and CON, respectively). Randomization with unequal proportions to treatments was used to attempt to increase efficiency/power by reducing numbers of participants to certain treatments such as controls; this strategy, demonstrated for instances of three treatments(43), was used previously in RCT for BED(21). Restricted randomization procedure using randomly permutated blocks of 12 was used to approximate the allocation ratio across treatments. The randomization schedule, created by the biostatistician, was kept blind from research-clinicians and participants until starting treatment. Study-coordinator assigned participants to treatment conditions in the order they were enrolled by research-clinicians after completing all assessments and meeting eligibility. Independent assessors performing outcome evaluations were blind to specific treatments and participants were reminded not to disclose which treatments they received.

Statistical Analyses

Sample size was based on power calculations for primary aim hypothesis of greater LOC reductions and abstinence rates for the gshCBT and greater weight-loss for the gshBWL over the CON condition based on relevant data from (non-bariatric) RCTs for BED/obesity cited above, considering clinically-meaningful effect sizes, and performing sensitivity analyses for different outcomes. A target sample of N=120 (which was exceeded with N=140) allocated in a 5:5:2 ratio yielded >80% power to detect meaningful effect sizes (f=0.32, d=0.64) for main outcomes at two-sided alpha level of 0.05.

Analyses designed to compare treatments were “intent-to-treat” (ITT) and were performed for all randomized patients. Baseline characteristics (demographic and clinical variables) for the treatment groups were compared using chi-square analyses for categorical variables and ANOVAs for continuous measures.

The two primary treatment outcome variables were LOC-eating and weight-loss, each considered using complementary (categorical and continuous) approaches. LOC-eating was analyzed continuously (pre- to post-treatment) as frequency and categorically (end-point) as proportion achieving abstinence. Weight-loss was analyzed continuously (percent weight loss from baseline) and categorically (end-point) as proportion attaining 5% weight loss. Abstinence from LOC eating was defined as zero episodes during the past 28 days (regardless of size/quantity assessed by the EDE-BSV). For the categorical analyses, in instances of treatment dropouts or missing data, pre-treatment baseline data were carried forward (i.e., failure imputed). Secondary treatment outcomes were eating-disorder psychopathology (EDE-BSV global score), depression (BDI-II total), physical activity (GLTEQ total score), and functioning (SF36 Mental and Physical Scale total scores) tested continuously.

For analyses of continuous measures, ITT approach was followed with all available data (baseline, month 1, month 2, and posttreatment) used in mixed models analyses without imputation. Mixed effects models allow for different numbers of observations per subject, use all available data on each subject, and are unaffected by randomly missing data. They

also provide flexibility in modeling the correlation structure of the data. In each model, we included fixed effects of time, treatment condition, treatment-by-time interaction, race, and all possible interactions. In the mixed models, treatment-by-time interaction is the primary test for the effectiveness of the treatments on outcome variables. In the mixed models, race was included in the analyses as a main effect ("predictor") and as an interaction effect with treatment ("moderator"). Examining race as a predictor/moderator (a priori analysis) seemed indicated given findings in the obesity literature regarding racial differences in outcomes; for example, recent studies reported findings that, relative to White patients, Black patients have less weight-loss following bariatric surgery (31) and following treatments for BED (32) despite being more likely to stop binge eating in aggregated RCT data (32). Type of surgery (LSG, RYGB) main effects were also added to the models run on the entire data set (N=140). We also performed sensitivity analyses restricted only to the sample of individuals with LSG (N=123); no differences in results were observed and therefore they are not reported. Variables not conforming to normality were transformed prior to analysis. In each model the best-fitting variance-covariance structure was selected based on the Schwartz' Bayesian Criterion (BIC). Significant main/interaction effects were explained by tests of simple effects or pairwise comparisons.

For analyses of categorical outcomes (end-point post-treatment analyses of LOC-eating abstinence and attaining 5% weight loss) chi-square tests were performed overall, and separately by race.

Results

Randomization and Participant Characteristics

Figure 1 shows the flow of participants throughout the study. Of the 140 randomized patients, N=56 received gshCBT, N=60 received gshBWL, and N=24 received CON. Treatment groups did not differ significantly in sex, race/ethnicity, education, history of *DSM-5*-defined BED diagnosis, type of bariatric surgery procedure (LSG, RYGB), time since surgery, or percent total weight loss at time of enrollment; only age differed significantly (p=.02; η_p^2=.056), with gshCBT being older than gshBWL (Table 1). Treatment groups did not differ significantly on pretreatment levels of *any* outcome variables (Table 2): primary outcomes (LOC-eating (F(2,140)=0.46,p=.63) and weight (F(2,140)=0.36,p=.70)) and secondary outcomes (EDE Global (F(2,140)=0.45,p=.64), BDI-II (F(2,140)=1.04,p=.36), GLTEQ (F(2,140)=0.12,p=.90), SF36 (F(2,140)=1.27,p=.29)).

As Figure 1 shows, treatment completion rates, defined as at least five of six treatment sessions for active treatment groups (gshBWL and gshCBT) and attendance at three monthly assessment sessions for CON group) did not differ significantly (gshCBT (78.6%), gshBWL (81.7%), and CON (70.8%) ($\chi^2(2)=1.20$, p=.55)) nor did post-treatment assessment completion rates (gshCBT (89.3%), gshBWL (88.3%), and CON (87.5%) ($\chi^2(2)=0.10$, p=.97)). Post-treatment assessment completion rates did not differ significantly by race overall: 88.7% (N=55/62) for non-white and 84.0% (N=63/75) for white participants (chi-square (df=1)=0.63, p=0.43) or by group: CON: 90.0% (n=9/10) for non-white and 75.0% (n=9/12) for white participants (Fisher's Exact Test p-value =0.59); gshBWL group: 88.0% (n=22/25) for non-white and 85.7% (n=30/35) for white participants (Fisher's Exact Test

p=1.00); gshCBT: 88.9% (n=24/27) for non-white and 85.7% (n=24/28) for white participants (Fisher's Exact Test *p*=1.00). Thus, end-point categorical analyses are unlikely to be confounded by missing data.

LOC-Eating Outcomes

Mixed models analyses of LOC-eating frequency (Table 2), which was log-transformed, revealed overall significant reductions from baseline to post-treatment across conditions (F(3,312)=10.96, *p*<.0001) but no significant differences between treatments (F(2,148)=0.15,*p*=0.86) nor significant treatment-by-time interactions (F(3,312)=0.52, *p*=0.79). No significant effects were observed for surgery type or for racial group (p-values > 0.10).

Figure 2 summarizes findings for LOC-eating abstinence at post-treatment across the treatment conditions (gshCBT (30.4%), gshBWL (26.7%), and CON (37.5%)) which did not differ significantly ($\chi^2(2)=0.96$, *p*=.62;phi=.08). Overall, abstinence rates differed significantly by race (White (17.3%) versus Non-White (43.6%) participants ($\chi^2(1)=11.28$, *p*=.001;phi=.29). Figure 2 also summarizes LOC-eating abstinence rates by race across the three treatment conditions. For gshCBT (N=55), abstinence rates for White (17.9%) and non-White (44.4%) participants differed significantly ($\chi^2(1)=4.55$, *p*=.03;phi=.29). For gshBWL (N=60), abstinence rates for White (14.3%) and non-White (44.0%) participants differed significantly ($\chi^2(1)=6.58$,*p*=.01;phi=.33). For CON (N=22), abstinence rates for White (25.0%) and non-White (40.0%) participants did not differ significantly (Fisher's Exact Test *p*=.65; phi=.16).

Weight-Loss Outcomes

Table 2 summarizes findings for percent weight-loss across treatment conditions (and shows BMI values for descriptive context). Mixed models analyses of percent weight-loss (log-transformed) revealed overall significant reductions from baseline to posttreatment (F(3, 113)=11.89, *p*<.0001) but no significant differences between treatments (F(2, 130)=0.55, *p*=0.58) nor significant treatment-by-time interactions (F(5,133)=0.43, *p*=0.86). No significant effects were observed for surgery type or for racial group (all p>.08).

Figure 3 shows rates of attaining 5% weight-loss at post-treatment across the three treatment conditions: gshCBT (19.6%), gshBWL (21.7%), and CON (16.7%); these rates did not differ significantly ($\chi^2(2)=0.28$, *p*=.87;phi=.04). Overall rates of attaining 5% weight-loss differed significantly by race (White (26.7%) versus Non-White (11.3%) participants ($\chi^2(1)=5.07$, *p*=.02;phi=.19). Figure 3 also shows rates of attaining 5% weight-loss at post-treatment by race across the treatment conditions. For gshBWL, rates of 5% weight-loss attainment for White (31.4%) and non-White (8.0%) participants differed significantly ($\chi^2(1)=4.72$, *p*=.03;phi=.28). In contrast, rates of 5% weight-loss attainment with gshCBT did not differ for White (25.0%) and non-White (11.1%) participants (Fisher's Exact Test *p*=.30;phi=.18) nor did the rates differ by race in the CON condition (White (16.7%) versus non-White (20.0%); Fisher's Exact Test *p*=1.00;phi=.04).

Secondary Outcomes: Eating-Disorder Psychopathology, Depression, Physical Activity, and Social Functioning Measures

Table 2 shows descriptive analyses for secondary (continuous) outcomes of eating-disorder psychopathology (EDE global score), depression (BDI-II), physical activity (GLTEQ), and social functioning (SF-36 composite scales). Mixed models revealed significant main effects for time in EDE global ($F(1,117)=24.49$, $p<.0001$), BDI ($F(3, 112)=8.86$, $p<.0001$), and SF-36 Mental Functioning Scale ($F(2, 132)=3.27$, $p=0.04$) scores; main effects for time were not significant for either GLTEQ or SF-36 Mental Functioning scores. Mixed models revealed no significant differences between treatments nor any significant treatment-by-time interactions on any of these secondary outcomes (all p-values >0.05). No significant effects were observed for race on any of these outcomes, except for a borderline significant main effect on EDE Global ($F(1,129)=3.82$, $p=0.05$) with White participants having greater ED psychopathology scores.

Discussion

The objective was to evaluate effective treatments from the BED and obesity fields adapted for use for patients who have undergone bariatric surgery and are experiencing recurrent LOC-eating postoperatively. This 12-week RCT compared the effectiveness of two guided-self-help treatments (gshCBT and gshBWL) and a control (CON) condition comprising standard care from the bariatric center. Overall, significant reductions in LOC-eating frequency and weight-losses were observed that not differ significantly across the treatments. Rates of abstinence from LOC-eating were 30% (for gshCBT), 27% (for gshBWL), and 38% (for CON) and the proportion of patients achieving 5% weight loss were 20%, 22%, and 17%, respectively; these categorical post-treatment findings also did not differ across treatments. Mixed analyses also revealed significant reductions (changes pre- to post-treatment) in dimensional secondary outcomes (levels of eating-disorder psychopathology, depression, and mental functioning) that did not differ significantly across treatments. Although mixed models of treatment changes in continuous variables revealed that race neither predicted nor moderated treatment outcomes, analyses of treatment endpoints for categorical variables revealed non-White participants had higher proportion attaining abstinence from LOC-eating but lower proportion achieving 5% weight loss than White participants.

This is the first RCT post-bariatric surgery specifically targeting LOC-eating. These acute results suggest reducing LOC-eating post-surgery does not appear to lead to meaningful improvements in weight loss. Comparisons to the literatures is offered descriptively for context but needs to be viewed cautiously given differences across studies in methodologies, comparison groups, therapists, patient groups and clinical settings. One small pilot study(23) with 16 patients of a similar low-intensity CBT also delivered 6 months post-bariatric surgery reported statistically significant reductions in binge-eating-related symptoms (not specifically LOC-eating), weight, and depression but did not have any control group. Reviews(3,8,9) have concluded that some small RCTs of behavioral/psychosocial interventions post-bariatric surgery have reported statistically significant results although weight losses, like those in our RCT, tend to be modest and mixed across trials. More

broadly, our gshCBT abstinence rates for LOC-eating are comparable to binge-eating abstinence rates reported by Peterson(44) though lower than those we reported for patients with BED who had not undergone bariatric surgery(21); overall, these rates fall within the range across RCTs for gshCBT(19,20) for BED. The observed gshBWL outcomes for LOC are favorable to those reported for gshBWL for BED(21) but inferior to those for traditional BWL for BED(21,22,24). Finally, while some research has found scalable versions of CBT can be effectively delivered by "generalist" clinicians(26), other research in generalist medical settings has not(45).

Collectively, these findings suggest that longer and more intensive interventions may be needed to provide greater benefit to patients with recurrent LOC-eating following bariatric surgery. As a parallel, inspection across RCTs at our center for BED suggests that intensive CBT and BWL treatments(24,25) outperform scalable guided-self-help versions(21). In this postoperative group, the statistically significant weight loss (a function of time, not specific treatments) was not clinically meaningful. Importantly, the amount of post-surgical weight-loss at 6–9 months (time of RCT enrollment) was only 20.3%; this is dampened relative to what is typically reported (5,6); moreover, early postoperative weight loss predicts maximal weight-loss (6). Thus, it appears that this subgroup with recurrent LOC-eating postoperatively derives less benefit from bariatric surgery and perhaps requires more intensive adjunctive specialist treatments. Future research should investigate the utility of pharmacological treatments and employ stepped care approaches to assist non-responders to initial treatments(25).

Race was associated with different end-point outcomes reflecting clinically-meaningful categories. Specifically, non-White participants had higher proportion attaining LOC-eating abstinence (43.6% vs 17.3%) but lower proportion achieving 5% weight loss (11.3% versus 26.7%) than White participants. These findings are consistent with previous studies that Black patients have lower weight losses with bariatric surgery(31) and with treatments for BED(32) despite being more likely to achieve abstinence from binge eating(32). Although analyses did not reveal moderation effects for race, White patients had lower LOC-eating abstinence rates than non-White patients if receiving either gshCBT or gshBWL (17.9% or 14.3% versus 44.4% or 44.0%, respectively). The racial difference was less salient in the CON condition; although in the same direction (25% versus 40.0%) it was not significant perhaps reflecting less statistical power as fewer participants were allocated to CON. In terms of attaining 5% weight loss, White patients were significantly more likely than non-White patients to exceed 5% weight loss if receiving gshBWL (31.4% versus 8.0%) but the trends in the same direction for gshCBT and CON treatments did not achieve statistical significance.

We note potential strengths and weaknesses. Strengths include randomized controlled comparison of two scalable treatments and control condition (standard-of-care at bariatric center-of-excellence), doctoral research-clinicians performing blinded independent assessments, and rigorous assessment methods for primary outcomes. Self-report for secondary outcomes (e.g., physical activity) represents a limitation and future studies such consider objective measures. Relatively small sample size, particularly for the CON, represents a potential limitation in terms of statistical power to detect small differences. RCT

designs with CON group receiving standard-care tend to have lower effect-sizes than efficacy trials with wait-list controls; although CON did not differ in assessment/completion rates from other treatments, lack of data on frequency/types of standard-care obtained is a limitation. For example, it is not known whether the CON participants attended support/nutrition groups more than is typical (perhaps due to study encouragement) and this might potentially have contributed to limiting the differences with the treatment groups. Findings may not generalize to different centers, to groups differing in sociodemographic characteristics, or to different treatment delivery methods (which range from pure self-help to intensive versions delivered by "specialists"). Our findings pertain only to acute outcomes following 12 weeks of treatment, and longer-term analyses are needed to address questions regarding durability, maintenance, and longer-term effects, as well as whether reducing LOC-eating enhances longer-term weight outcomes.

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Study Importance Questions

What is already known about this subject?

- Postoperative loss-of-control (LOC) eating predicts poorer bariatric surgery outcomes.
- Optimal time for adjunctive psychosocial interventions is following bariatric surgery, but research has yet to test treatments specifically for LOC eating after bariatric surgery.

What are the new findings in your manuscript?

- Reductions in LOC-eating and weight-loss were statistically significant over time, but the three treatments did not differ significantly from each other.
- LOC-eating abstinence rates following treatments were 30% for gshCBT, 27% for gshBWL, and 38% for the control condition.

How might your results change the direction of research or the focus of clinical practice?

- LOC eating following bariatric surgery is challenging to treat and may require intensive specialist treatments.
- Future research should investigate more intensive forms of psychological, behavioral, and pharmacological treatments to reduce LOC eating.

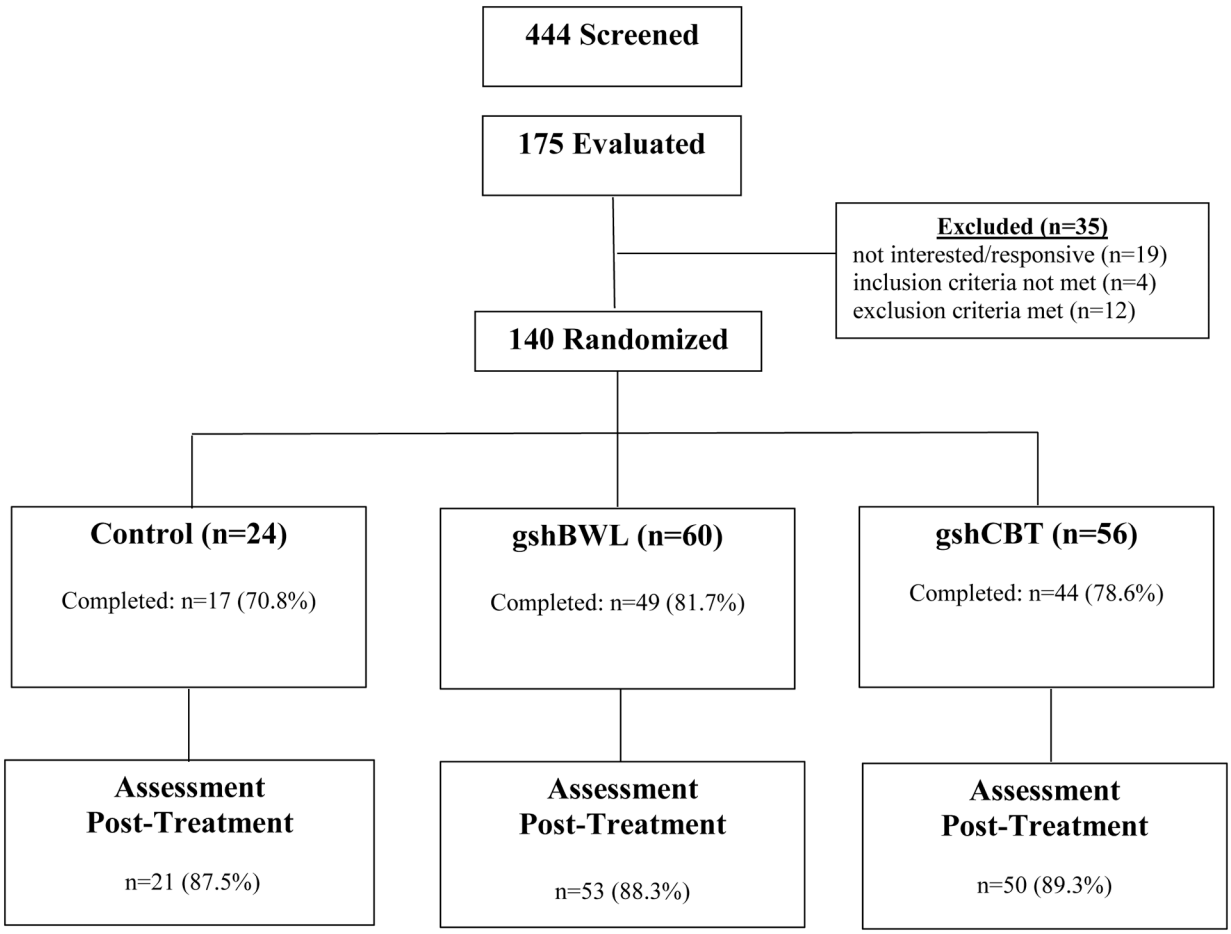

Figure 1.
Flow of participants throughout study.

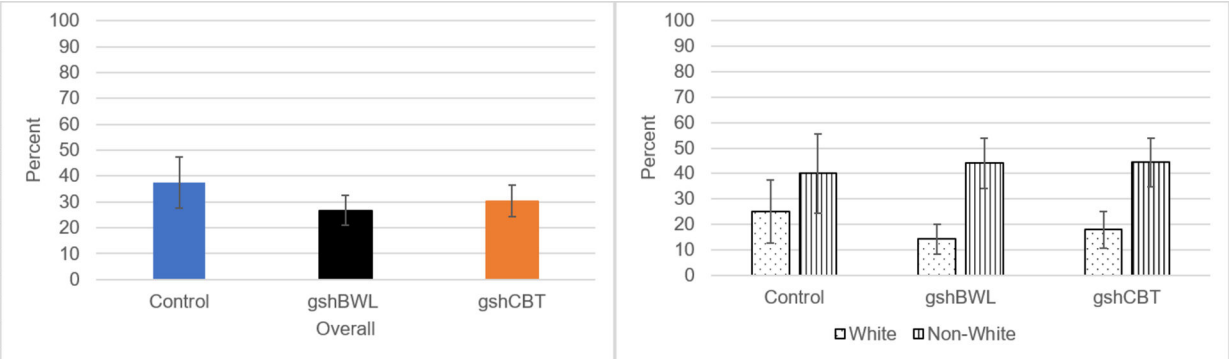

Figure 2.

Percentage of LOC Eating Abstinence Overall and by Race Across Treatment Groups

Note: Left Panel summarizes LOC-eating abstinence rates across treatments which did not differ significantly ($\chi^2(2)=0.96$, $p=.62$). Right Panel shows LOC-eating abstinence rates were significantly lower for White than non-White participants in gshCBT ($\chi^2(1)=4.55$, $p=.03$) and gshBWL ($\chi^2(1)=6.58$, $p=.01$) but not in CON (Fisher's Exact Test $p=.65$).

For context, descriptive data (Mean (SD)) for LOC-eating frequency for pre-treatment, post-treatment, and change, respectively for CON (17.1 (14.6), 6.4 (9.1), −10.6 (11.9) for White participants and 19.9 (21.0), 2.3 (2.6), −17.1 (SD 20.2) for non-White participants), for gshBWL (20.1 (19.6), 6.7 (8.8), −11.5 (19.3) for White participants and 27.9 (47.1), 6.9 (11.2), −21.5 (45.7) for non-White participants), and for gshCBT (25.0 (24.0), 9.2 (14.4), −14.8 (23.0) for White participants and 19.8 (22.6), 3.9 (8.0), −17.4 (20.5) for non-White participants).

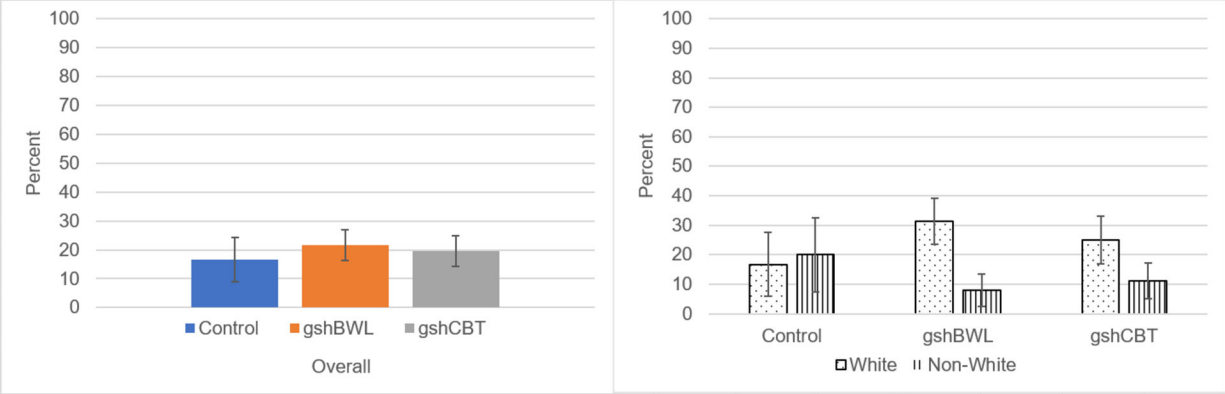

Figure 3.

5% Weight Loss Overall and by Race Across Treatment Groups

Note: Left Panel summarizes proportion achieving 5% weight loss across treatments which did not differ significantly ($\chi^2(2)=0.28$, $p=.87$). Right Panel shows LOC-eating abstinence rates were significantly higher for White than non-White participants in gshBWL ($\chi^2(1)=4.72$, $p=.03$) but did not differ significantly in either CON (Fisher's Exact Test $p=1.00$) or gshCBT (Fisher's Exact Test $p=.30$).

For context, descriptive data (Mean (SD)) for weight for pre-treatment, post-treatment, and change, respectively for CON (211.7 (57.6), 201.8 (66.9), −3.2 (6.9) for White participants and 224.4 (59.1), 226.2 (67.4), −2.7 (10.4) for non-White participants), for gshBWL (228.1 (51.8), 213.7 (45.4), −6.5 (8.2) for White participants and 228.9 (48.9), 224.2 (51.4), −2.4 (7.4) for non-White participants), and for gshCBT (222.7 (54.1), 223.4 (61.6), +3.3 (8.0) for White participants and 221.8 (48.5), 223 (51.2), +2.2 (5.3) for non-White participants).

Table 1.

Demographic and Clinical Characteristics of 140 Randomized Patients Overall and Separately for Treatment Groups

	Overall N=140		Control n=24		gshBWL n=60		gshCBT n=56		Test Statistic	*p*-value
	M	***SD***	***M***	***SD***	***M***	***SD***	***M***	***SD***	**F**	
Age	45.6	10.9	45.3	7.2	43.0	10.9	48.6	11.7	4.03	0.020
Months since surgery	6.4	1.5	6.5	1.7	6.4	1.5	6.3	1.4	0.13	0.731
Weight loss at enrollment (%)	20.3	7.9	20.9	8.0	20.8	8.4	19.5	7.4	0.54	0.586
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**Chi-Square**	***p*-value**
Gender (Female)	119	85	21	87.5	48	80.0	50	89.3	2.10	0.350
Race[1]									0.64	0.727
White	75	54.7	12	54.5	35	58.3	28	50.9		
Non-White	62	45.3	10	45.5	25	41.7	27	49.1		
Hispanic	15	10.7	3	12.5	5	8.3	7	12.5		
Education									5.60	0.061
At least college degree	56	40.0	14	58.3	25	41.7	17	30.4		
Some college	55	39.3	6	25.0	23	38.3	26	46.4		
High school	25	17.9	4	16.7	10	16.6	11	19.7		
Less than high school degree	4	2.8	0	0.0	2	3.4	2	3.6		
Binge-Eating Disorder (lifetime, pre-surgical)	65	46.4	10	41.7	29	48.3	26	46.4	0.31	0.858
Surgery										
Bypass	17	12.1	3	12.5	8	13.3	6	10.7	0.19	0.910
Sleeve	123	87.9	21	87.5	52	86.7	50	89.3		

Note: *N=140.* BWL = behavioral weight loss (guided self-help); CBT = cognitive behavioral therapy (guided self-help).

Test statistic = chi-square for categorical variables and ANOVAs for dimensional variables. *M*= Mean; *SD* = standard deviation.

BED = binge-eating disorder.

[1]denotes that chi-square was performed for two collapsed categories given low frequencies of some variables (i.e., white versus non-white [excluded *n*=1 Native Hawaiian or Other Pacific Islander and *n*=2 American Indian or Alaska Native] and college graduate versus less than college degree).

Table 2.

Clinical Variables Across Treatment Groups Pre- and Post-Treatment Following Bariatric Surgery

	Control n=24			gshBWL n=60			gshCBT n=56		
	N	***M***	***SD***	***N***	***M***	***SD***	***N***	***M***	***SD***
EDE LOC eating									
Pre-Treatment	24	17.0	16.9	60	23.4	33.7	56	22.1	23.2
Post-Treatment	20	4.0	6.6	52	6.8	9.8	49	6.4	11.7
Change	20	−13.2	15.7	52	−15.8	33.1	49	−15.9	21.4
Weight									
Pre-Treatment	24	218.5	55.7	60	228.4	50.2	56	223.0	50.8
Post-Treatment	20	215.7	64.0	52	218.1	47.8	48	223.4	55.5
Change	20	−2.6	8.3	52	−4.7	8.1	48	−3.4	7.8
BMI									
Pre-Treatment	24	36.5	7.8	60	36.8	6.1	56	36.9	6.6
Post-Treatment	20	35.8	9.2	52	35.5	6.2	48	36.8	7.2
Change	20	−0.4	1.4	52	−0.8	1.3	48	−0.6	1.3
%TWL during treatment									
Pre-Treatment	--	--	--	--	--	--	--	--	--
Post-Treatment	20	−1.6	4.2	52	−2.1	3.8	48	−1.7	3.5
EDE Global Score									
Pre-Treatment	24	1.9	1.0	60	2.1	0.8	56	2.1	1.0
Post-Treatment	20	1.7	1.0	52	1.6	1.0	49	1.6	1.0
Change	20	−0.4	0.8	52	−0.5	0.9	49	−0.5	0.8
BDI-II									
Pre-Treatment	24	9.6	8.2	60	10.9	9.4	56	12.8	10.6
Post-Treatment	21	7.4	8.2	53	7.6	8.6	50	9.9	11.2
Change	21	−2.7	5.6	53	−2.9	8.9		−2.8	8.9
GLTEQ									
Pre-Treatment	24	35.4	22.2	60	35.4	22.2	56	32.6	26.4
Post-Treatment	21	52.7	53.1	53	52.7	53.1	50	41.9	48.2
Change	21	16.6	55.0	53	8.5	41.4	50	10.6	42.3
SF36-MFS									
Pre-Treatment	24	76.8	17.4	60	74.9	16.2	56	68.5	20.1
Post-Treatment	21	82.5	16.0	53	74.0	18.1	49	68.9	23.2
Change	21	7.2	14.1	53	−1.1	16.3	49	0.9	17.5
SF36-PFS									
Pre-Treatment	24	78.5	26.1	60	80.8	24.4	56	73.0	29.2
Post-Treatment	21	80.2	26.3	53	84.8	18.9	49	71.0	29.6
Change	21	4.8	11.0	53	2.5	17.1	49	−0.4	21.8

Note: *N=140*. Data reported are raw data. BWL = behavioral weight loss (guided self-help); CBT = cognitive behavioral therapy (guided self-help). *M* = mean; *SD* = standard deviation. EDE = eating disorder examination interview; BDI-II = beck depression inventory-II; GLTEQ = godin leisure-time exercise questionnaire; SF36-MFS = medical outcomes study short form health survey-mental health functioning; SF36-PFS = medical outcomes study short form health survey-physical health functioning.