ORIGINAL CONTRIBUTIONS



A Pilot Study of an Acceptance-Based Behavioral Intervention for Weight Regain After Bariatric Surgery

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Abstract

Background Tens of thousands of bariatric surgery patients each year experience sub-optimal weight loss, significant regain, or both. Weight regain can contribute to a worsening of weight-related co-morbidities, and for some, leads to secondary surgical procedures. Poor weight outcomes have been associated with decreased compliance to the recommended postoperative diet. Decreased compliance may be partially due to a lack of psychological skills necessary to engage in healthy eating behaviors over the long term, especially as the effects of surgery (on appetite, hunger, and desire for food) decrease. Many behavioral interventions do not sufficiently address these challenges and often have limited effectiveness. The study aimed to evaluate the feasibility, acceptability, and preliminary effectiveness of a novel 10-week acceptance-based behavioral intervention to stop postoperative weight regain. Methods A sample of bariatric surgery patients (n=11) who regained at least 10 % of their maximum lost postoperative weight was recruited. All participants received the intervention, which emphasized psychological skills thought to be integral to successful weight control post-surgery.

Results The intervention was shown to be feasible and acceptable, with 72 % retention and high mean rating (4.25 out of 5.00) of program satisfaction among completers. Weight re-

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gain was stopped, and even reversed, with a mean total body weight loss of 3.58 ± 3.02 % throughout the 10-week intervention. There were also significant improvements in eating-related and acceptance-related variables.

Conclusions These findings provide initial support for the use of a psychological acceptance-based intervention for weight regain in bariatric surgery patients.

Keywords Postoperative weight regain · Behavioral intervention

Introduction/Purpose

Bariatric surgery is the most effective obesity treatment, typically resulting in substantial weight loss and improvement or resolution of co-morbidities [1]. However, weight regain is common and, in a substantial minority of patients, clinically significant weight regain can occur [2]. Nearly 9 % of gastric bypass patients and 25 % of gastric banding patients are considered treatment failures (i.e., <5 % loss of initial body weight) 10 years after surgery [3]. Weight outcomes are relatively homogenous within the first six postoperative months [4], though patterns of weight loss vary widely over the next several years with weight regain being common for a sizable percentage of individuals [4, 5]. Weight regain compromises the health benefits achieved after surgery. Increases in diabetes, hypertension, and hypertriglyceridemia have been demonstrated at long-term follow-up [3, 5]. In addition, patients who demonstrated a recurrence or worsening of weight-related co-morbidities regained an average of 37.7 % of their lost weight, whereas those who displayed improvement or remission of comorbidities regained an average of 15.4 % [6]. Targeting weight regain in this population is therefore crucial to maintain the significant health benefits achieved after surgery.



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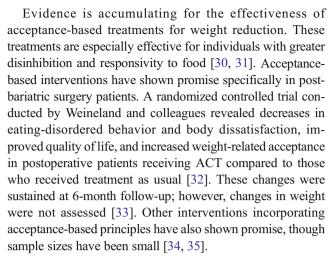
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Weight regain following bariatric surgery has been associated with decreased compliance with the restrictive postsurgical dietary recommendations [7]. Although bariatric surgery initially promotes changes in behavior via mechanical restriction and hormonal changes [8], psychological factors (e.g., responsivity to internal and external cues) that lead to overeating are not directly addressed by surgery. In addition, the ability and desire to consume greater amounts of food appears to return over time [9, 10]. Following the first postoperative year, patients tend to increase their daily calorie intake [3, 7], which has been associated with poorer weight outcomes [11].

In addition to gradual increases in daily calorie consumption, several eating behaviors that may be resistant to correction postoperatively can impact postoperative weight loss. Examples include grazing (i.e., eating small amounts of food frequently throughout the day) and the overconsumption of caloric liquids and soft foods [12–14]. Other maladaptive eating behaviors associated with poorer weight outcomes include binge eating, loss of control eating, and emotional eating [12, 13, 15–19]. Greater disinhibition and an inability to control urges to eat have been found to be predictive of postoperative weight regain [7, 20–22]. In a sub-set of patients, increases in hunger and food cravings have been shown to return in the long term [9, 10, 20, 23, 24].

Several behavioral interventions targeting standard lifestyle modification skills have been developed with the objective of preventing or reversing postoperative weight regain (e.g., [25, 26]). However, a meta-analysis of these studies revealed minimal differences in percent excess weight loss between treatment and control conditions (i.e., 1.6 %) 6-12 months postintervention [27]. Although methodological factors may partially account for the lack of effectiveness of these behavioral treatments (e.g., interventions occurred too soon postoperatively, attrition), it is also likely that patients need more tailored psychological skills. Specifically, the above-outlined causes of dietary non-adherence should be targeted, including the return of internal experiences that make weight control difficult (e.g., hunger, food cravings) and subsequently lead to maladaptive eating behaviors (e.g., grazing, loss of control eating, eating in response to problematic internal and external

Acceptance-based behavioral treatments specifically target these psychological challenges postoperative patients face by providing them with skills to tolerate uncomfortable psychological experiences in the service of core long-term values [28]. This approach (largely based on acceptance and commitment therapy, i.e., ACT; [29]) directly addresses the causes of postoperative weight regain by fostering patients' abilities to make mindful decisions based on their weight control goals, in spite of the internal states that make doing so difficult. For example, patients are taught skills that allow them to gain psychological distance from thoughts and emotions, allowing them to act independently of these internal experiences.



The purpose of the current study was to conduct a preliminary evaluation of a newly developed acceptance-based behavioral intervention, specifically assessing its feasibility, acceptability, and preliminary effectiveness. We hypothesized that following the intervention, participants would display significant weight loss and improvements in self-reported eating behavior and acceptance-related variables.

Materials and Methods

Participants

Participants were recruited through a survey sent to 716 patients who received bariatric surgery at a large urban teaching hospital in Philadelphia, PA, between September 2008 and December 2010 [9]. This survey collected information on patients' preferences for postoperative behavioral interventions. At the end of the survey, patients had the option of indicating interest in participating in a study of an intervention. Potential participants were screened by phone and then at an in-person assessment to determine eligibility. Inclusion criteria were the ability to give consent, ability to speak, write, and understand English, aged 21-70 years old, regained at least 10 % of lost weight from minimum postoperative weight lasting for at least 3 months prior to enrollment, and stable on medication affecting weight for at least 3 months. Potential participants were excluded if they were enrolled in another weight loss program, were pregnant or planned to become pregnant within 6 months of the study enrollment, had a serious medical condition that could affect weight or disallowed them from engaging in prescribed behavior changes, and reported severe psychiatric symptoms that interfered with the ability to benefit from the intervention.

Procedures

An open trial design was used, given the preliminary nature of the research. Therefore, all participants received the



intervention. Participants were assessed prior to the start of treatment, mid-treatment, and post-treatment. Participants were compensated \$10 for completing the mid-treatment assessment and \$20 for completing the post-treatment assessment.

The intervention consisted of 10, 75-min weekly group sessions conducted by trained doctoral students in clinical psychology. Groups were implemented in two waves, and changes to the treatment manual were made in an iterative fashion.

Intervention

Results of the previously described survey indicated that postoperative patients experience a number of challenges after the initial weight loss phase, including the ability to consume larger amounts of food and increased hunger and food cravings [9]. Based on these data, combined with the literature reviewed above, a treatment manual was developed. The manuals for acceptance-based behavioral treatments for obesity previously developed by our research group were modified for the bariatric surgery population [30, 36]. In addition to the inclusion of topics specific to surgery patients (e.g., adherence to the postoperative diet), other topics from the previous manuals were framed in the context of the post-surgery experience.

The program focused on fostering key psychological skills to enhance participants' ability to adhere to the restrictive postoperative diet. Specifically, the intervention focused on acceptance-based strategies including acceptance of internal experiences, willingness, defusion (i.e., psychological distancing), clarification and commitment to core values, and linking values to in-the-moment decision-making [29, 36]. A focus was placed on willingness to experience distressing thoughts, feelings, and sensations, especially as they pertain to the deteriorating effects of surgery, in order to live a life in accordance with one's key long-term values (e.g., living a healthy lifestyle). The intervention also included standard behavioral techniques for weight loss including self-monitoring, stimulus control, and psychoeducation. The psychologicalacceptance-based skills were described as a means to facilitate engaging in these behaviors that are crucial for long-term weight control. See Table 1 for a list of intervention components by session. Prior to each session, each participant was weighed to track his or her progress and to increase motivation. Each session also began with a brief check-in from each group member to review progress towards the goals established in the prior session.

Measures

Anthropometric Data

A calibrated Seca scale was used to measure participants' weights at each assessment point. Participants were instructed

to remove their shoes and any extra layers of clothing that they felt comfortable removing to increase accuracy. Week 9 weights were carried forward for two participants for medical reasons affecting their measured weight at post-treatment (i.e., one due to inability to remove heavy boots following surgery; one due to a reported acute medical condition that caused fluid retention). A stadiometer was used to measure participants' height at the baseline assessment, which was used to calculate body mass index (BMI).

Treatment Acceptability

A treatment acceptability questionnaire was adapted by the investigators from previous measures used for this purpose. A 5-point Likert scale was used (1=not at all, 3=somewhat, 5=very) to evaluate how helpful participants found the treatment, their satisfaction with treatment, and how likely they would be to recommend the treatment to a friend.

Eating Behavior Variables

The Emotional Eating Scale (EES) assesses the relationship between overeating and negative emotions, classified into three subscales (anger/frustration, anxiety, and depression) [37]. This measure has been found to have good construct validity and adequate test-retest reliability [37] and has been previously used with post-bariatric surgery patients [34].

The Food Cravings Questionnaire-Trait (FCQ-T) is a 39item measure that assesses a range of common characteristics of food cravings [38]. This questionnaire has a good test-retest reliability and excellent internal consistency [38].

The Eating Inventory contains 51 items and is comprised of multiple subscales including restraint, disinhibition, and reactivity to internal and external cues [39]. Disinhibition scores have been shown to decrease with weight loss treatment [40], including bariatric surgery [7], while cognitive restraint has been shown to increase postoperatively [7].

The Eating Disorder Examination Questionnaire (EDE-Q) was used to measure symptoms of binge eating. As described by White and colleagues (2010) [19], because many bariatric surgery patients cannot physically consume large amounts of food in one sitting, both subjective and objective binge eating episodes as assessed by the EDE-Q were included. Good concurrent validity with the EDE interview has been established for the EDE-Q [41].

Grazing behavior over the past 2 weeks was assessed by a questionnaire created by the researchers due to the lack of validated measures for this eating behavior. The definition of grazing used was the consumption of small amounts of food continuously over an extended period of time, eating more than the participants consider best for them [12].



Table 1	Intervention
compone	ents

Session	Behavioral components	Acceptance-based components			
Program overview		Limitations of experiential control			
	 Self-monitoring food intake 				
2	Energy balance	 Acceptance as the alternative to control 			
	 Keeping track of calories 	• Introduction to willingness			
	 Self-monitoring weight 				
	 Postoperative nutrition information 				
3	 Physical activity guidelines 	 Review of acceptance and willingness 			
		 Willingness skills continued 			
		Values clarification			
4	• Challenges of the obesogenic environment	 Incorporating values into behavior 			
	• Portion control	Behavioral flexibility			
5	Protein intake after surgery	• The problem with mindless eating			
		Mindful decision-making			
6	Handling holidays, weekends, and vacations	• Defusion (i.e., cognitive distancing)			
7	 Slowing down rate of eating 	• Strategies to help defuse and increase willingness			
	Decreasing grazing				
8	 Decreasing fat intake 	Defusion review			
		Urge surfing			
9	 Preparing for the end of group 	 Review of major concepts 			
	Distinction between lapse and relapse	• Responding to decreased motivation in the long term			
10	Congratulations	Continued commitment			
		• Final review of concepts			

Acceptance-Related Variables

The Philadelphia Mindfulness Scale (PHLMS) assesses present moment awareness and acceptance, the two main components of mindfulness [42]. This self-report measure has good internal consistency and adequate concurrent validity.

The Drexel Defusion Scale (DDS) is a self-report measure assessing the extent of the ability to defuse (i.e., attain psychological distance) from different internal experiences. This measure has good internal consistency [43].

The Food-Related Acceptance and Action Questionnaire (FAAQ) is used to assess the acceptance of the internal experiences associated with food. Acceptable reliability and validity have been established for this measure [44].

The Physical Activity Acceptance Questionnaire (PAAQ) is a 10-item measure that assesses self-reported acceptance of psychological and physical discomfort associated with engaging in physical activity. This questionnaire has good internal reliability and concurrent validity [45].

Statistical Analysis

All variables are reported as mean ± standard deviation or frequency and percentages. Acceptability and outcome data were

reported for treatment completers. *T* tests were used to assess changes in weight and secondary variables (eating behaviors and acceptance-related constructs) pre- to post-treatment.

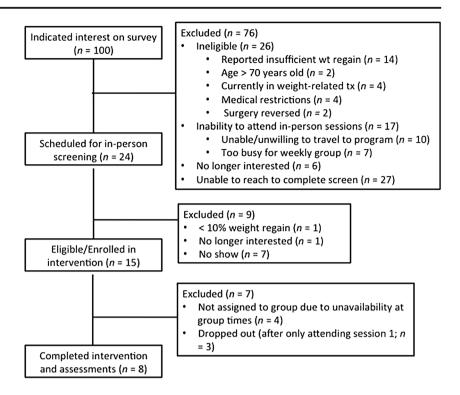
Results

Recruitment and Enrollment

At the time of recruitment, 100 survey responders requested that the research team provide them with more information about this program. Of those, 73 could be reached directly to complete a telephone screening. Twenty-six of these participants were ineligible, while 23 decided that they were no longer interested (e.g., due to travel time to group meetings, scheduling issues). The remaining 24 were scheduled for an in-person screening (7 of those did not attend), yielding 15 eligible participants, and 11 who enrolled and attended the first session (4 participants were unavailable during the scheduled group time). Three enrolled participants attended only the first session of groups and subsequently withdrew from the study. Therefore, acceptability and outcome data were collected on 8 total participants. See CONSORT diagram (Fig. 1) for details on screening and enrollment.



Fig. 1 CONSORT diagram



Participant Characteristics

Participant demographic data are outlined in Table 2. Of note, the sample was primarily White, female, and nearly 4 years post-surgery. The majority of participants underwent Rouxen-Y gastric bypass. Prior to beginning the intervention, participants reported a mean weight gain of 35.9 ± 21.1 % of their maximum postoperative weight loss.

Feasibility and Acceptability

Mean ratings of treatment acceptability were high (i.e., $4.00/5.00\pm0.93$ for helpfulness of acceptance-based strategies, 4.25 ± 0.89 for overall satisfaction, and 4.75 ± 0.71 for confidence in recommending).

Three participants withdrew from the study after the first session (two participants cited personal reasons and the third indicated that he did not feel that he needed assistance losing weight). All of the remaining eight participants attended at least seven sessions of the intervention, including the last session.

Preliminary Effectiveness

All participants lost weight over the 10 weeks. Collectively, participants experienced a statistically significant weight loss (M=3.33 kg, SD=2.71, t(7)=3.27, p=0.01); percent total body weight loss ranged from 0.37 to 8.18 % (M=3.58 %, SD=3.02 %). Weight trajectories since surgery are shown in Fig. 2, and percent weight losses for each participant are displayed in Fig. 3.

Process Variables

Change in process variables are displayed in Table 3. Significant and generally medium-to-large improvements in eating-related variables were observed from pre- to post-treatment. In addition to the changes in scores on these validated measures, changes were also observed in items from our grazing questionnaire. Specifically, the percentage of participants who endorsed problematic grazing decreased from 37.5 % at baseline to 12.5 % at post-treatment ($\chi^2(1) = 0.69$, p = .41, $\phi = -.29$). Specific items from the EDE-Q revealed no difference in the number of participants who endorsed binge eating symptoms from baseline to post-treatment; however, mean number of overeating episodes and episodes of loss of control eating (over the past 28 days) decreased (though differences did not reach statistical significance), i.e., 2.25 vs. 1.13 (t(7) = 0.97, p = 0.36, Cohen's d = 0.49) and 1.88 vs. 1.38 episodes (t(7)=0.35, p=0.74, Cohen's d=0.19), respectively. Changes in psychological acceptance-related variables from pre- to post-treatment were large and in the expected direction, including in mindfulness, defusion (i.e., psychological distancing), and physical activity acceptance. Changes in foodrelated acceptance scores were particularly large.

Discussion

This pilot study provides preliminary support for an acceptance-based behavioral intervention for postoperative



Table 2	Participant demos	ranhice
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	Mean \pm SD or % of sample		
Age (year)	53.36 ± 8.72		
Completers	55.87 ± 7.90		
Dropouts	46.67 ± 8.33		
Time since surgery (year)	3.61 ± 0.54		
Completers	3.62 ± 0.49		
Dropouts	3.58 ± 0.79		
Women (%)	63.6 %		
Completers	87.5 %		
Dropouts	0 %		
White (%)	81.8 %		
Completers	75.0 %		
Dropouts	100 %		
African American (%)	18.2 %		
Completers	25.0 %		
Dropouts	0 %		
Non-Hispanic (%)	100.0 %		
Married or living with partner (%)	63.6 %		
Completers	62.5 %		
Dropouts	66.7 %		
Employed full-time (%)	54.5 %		
Completers	50.0 %		
Dropouts	66.7 %		
Previous psychological treatment (%)	27.3 %		
Completers	25.0 %		
Dropouts	33.3 %		
Gastric bypass (%)	72.7 %		
Completers	62.5 %		
Dropouts	100 %		
Gastric sleeve (%)	9.1 %		
Completers	12.5 %		
Dropouts	0 %		
Gastric banding (%)	18.2 %		
Completers	25.0 %		
Dropouts	0 %		

weight regain. In patients who had regained at least 10 % of their maximum lost postoperative weight, the intervention was feasible and acceptable, with 72 % retention (100 % retention in those who attended more than one session) and high mean rating (4.25 out of 5.00) of satisfaction with the program. Weight regain in all participants stopped and, on average, participants lost 3.58 % of their pre-treatment weight. There were also significant improvements in acceptance-related and eating-related variables.

Ratings of treatment acceptability in our sample were comparable to those of acceptance-based treatments for obesity in a non-surgery population [30]. In addition, weight losses were similar to those seen in Kalarchian and colleagues' [26]

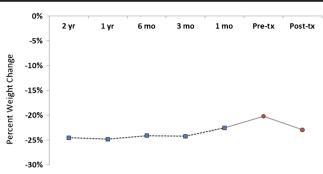


Fig. 2 Mean percent weight change since surgery from 2 years pretreatment to post-treatment. ■ Self-reported ● Measured at assessments

postoperative standard behavioral intervention in patients with <50 % excess weight loss. Our results appear to be particularly promising, given that weight losses were achieved in 3 months, rather than 6 months. These data provide initial support that providing psychological skills that directly target the challenges patients face after the initial weight loss phase is beneficial. Results also provide support for intervening after patients have demonstrated a weight regain trajectory. Previous research has shown limited effects on behavioral interventions preoperatively or immediately after surgery (e.g., [25, 26, 46]). However, controlled trials are necessary to better understand the optimal timing of intervention to enhance weight outcomes. Stopping weight regain in this population is essential, given that weight-related co-morbidities that have remitted as a result of surgery often return as weight is regained [6]. Enhancing health benefits from the surgery is particularly significant in this population, as 95 % of patients have at least one weight-related co-morbidity prior to surgery [47]. Given the preliminary nature of this study, we did not assess changes in co-morbidities; however, this will be an important next step in future research.

As predicted, significant changes in eating-related variables were also observed, including large effects on disinhibition and internal responsivity to food cues. These factors appear to be particularly important to target, as those individuals who present for bariatric surgery tend to report greater

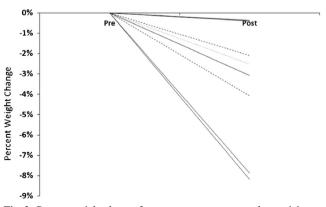


Fig. 3 Percent weight change from pre- to post-treatment by participant.

— Roux-en-Y gastric bypass. — Gastric sleeve. Gastric banding



Table 3 Process variables: change between baseline and post-treatment (paired *t* test)

	Baseline		Post-treatment		Paired t test $(df=7)$		
	M	SD	\overline{M}	SD	t	p	d
EI disinhibition	9.25	3.15	6.88	3.44	2.10	0.07	0.72
EI cognitive restraint	12.50	4.24	15.25	3.92	-2.43	0.05	0.67
EI internal	4.00	2.00	2.50	1.69	2.51	0.04	0.81
EI external	3.38	1.60	2.75	1.83	1.49	0.18	0.37
EES anger	22.38	10.20	20.63	6.74	0.51	0.63	0.20
EES depression	14.63	4.37	13.13	3.48	1.12	0.30	0.38
EES anxiety	22.13	8.24	19.13	5.69	1.51	0.18	0.42
FCQT	127.50	46.69	104.75	30.90	2.52	0.04	0.57
PHLMS	66.64	11.81	74.00	5.04	-2.53	0.04	0.81
DDS	39.13	8.32	44.13	4.79	-1.40	0.21	0.74
FAAQ	36.13	11.05	56.50	7.98	-3.70	0.01	2.11
PAAQ	54.75	20.69	68.88	12.44	-2.16	0.07	0.83

EI Eating Inventory, EES Emotional Eating Scale, FCQT Food Cravings Questionnaire-Trait, PHLMS Philadelphia Mindfulness Scale, DDS Drexel Defusion Scale, FAAQ Food-Related Acceptance and Action Questionnaire, PAAQ Physical Activity Acceptance Questionnaire

disinhibition and responsivity compared to individuals who seek lifestyle modification for weight loss [48]. Decreased inhibition has also been shown to be associated with better postoperative weight outcomes [20]. The intervention appeared to be successful in improving maladaptive eating behaviors, including moderate effects on emotional eating, grazing, and binge eating behaviors. These behaviors have been shown to be predictive of postoperative weight status [12, 15]. Improvements in food cravings were also demonstrated, which have been shown in other acceptance-based interventions [49, 50]. As the main focus of this intervention was improving eating behavior, changes in physical activity were not assessed.

The current study adds to the growing support for acceptance-based interventions for weight loss. The specialized psychological skills targeted here are believed to help foster the engagement in the rigorous behavioral changes required for long-term weight control after bariatric surgery. Improvements in acceptance-related variables were demonstrated, including increased mindfulness and increased foodrelated and physical activity-related acceptance, providing some support that participants utilized the strategies delivered. Food-related acceptance was a mediator of weight change in those with high levels of emotional eating in our RCT evaluating an acceptance-based intervention for obesity in a nonsurgical population [30]. Unfortunately, the small sample size of the current study did not allow for mediation analyses. Given the preliminary nature of this study, we cannot conclude that the addition of specialized psychological strategies to standard behavioral techniques in the intervention were responsible (or necessary) for the observed weight outcomes. It is possible that the behavioral strategies or even simply group attendance were sufficient to produce weight losses. Future research (e.g., with active control conditions and formal mediation analyses) is necessary to assess the independent effects of the acceptance-based treatment components in this population. In addition, it is unclear how effective this intervention would be at controlling weight over the long term.

The study had several other limitations. The sample size was small, compromising the generalizability of our results. Further, the sample may not necessarily have been representative of bariatric surgery patients as a whole, but rather those with the level of commitment, concern, and motivation to attend weekly group sessions. Additionally, we did not assess participants' engagement in support groups during the intervention. Although support group attendance has been shown to be associated with improved weight outcomes, e.g., [51], it is not clear that support groups have a causal effect on weight, as studies in this area have not been controlled. Difficulties with recruitment and retention also were noteworthy. Only 22 % of patients contacted by survey responded and of those individuals expressing initial interest in the intervention only 15 % were enrolled, with 20 % of potential participants excluded due to geographical and scheduling constraints. In addition, three participants dropped out of the study following the first session. Difficulties with recruitment and attrition appear to be consistent across similar studies in this area [25, 26]. Given the demonstrated challenges with postoperative retention of bariatric patients, whether in the context of a research study or clinical program, translating this intervention to a remotely delivered treatment (e.g., via e-learning or videoconferencing platforms) may be particularly useful.



Conclusions

Our findings suggest that acceptance-based behavioral interventions may be promising for bariatric surgery patients experiencing postoperative weight regain. Given the increased popularity of bariatric surgery, it will be important to improve and refine current treatments targeting weight regain. Standard behavioral interventions may be beneficial; however, given the unique challenges faced by these patients (i.e., return of internal experiences that make weight control particularly difficult), they likely need additional strategies. Overall, this pilot study is a meaningful first step in this line of research, indicating feasibility, acceptability, and preliminary effectiveness of this newly developed treatment.

Compliance with Ethical Standards

Conflict of Interest D. B. Sarwer is a consultant for BAROnova, EnteroMedics, and Kythera and received consulting fees from these organizations during the time of the study. The remaining authors have no commercial associations that might be a conflict of interest in relation to this article.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Institutional Review Boards of the University of Pennsylvania and Drexel University.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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