Improving Weight Loss Outcomes for Binge Eating Disorder

Study Protocol

NCT03712462

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RESEARCH STRATEGY

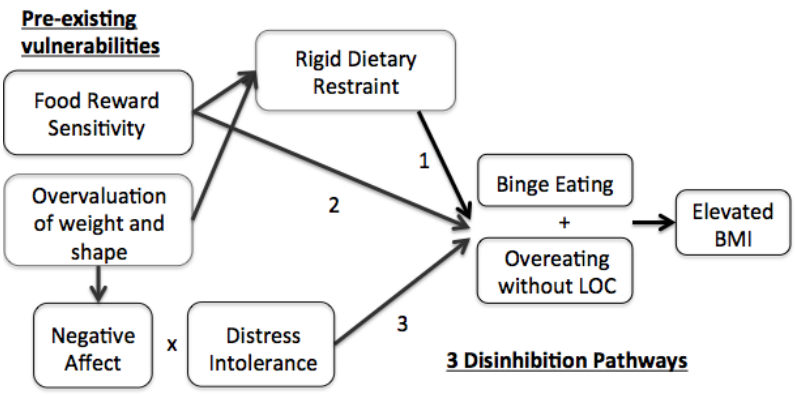
A. Significance

A1. Binge eating disorder (BED) is the most prevalent eating disorder and is associated with substantial psychiatric and medical comorbidity. BED affects more than six million Americans, with lifetime prevalence at 3% for women and 2% for men.[1] BED is characterized by frequent episodes of overeating accompanied by feelings of loss of control (i.e., binge eating episodes) without the use of compensatory behaviors (e.g., purging, excessive exercise).[2] Although obesity is not part of the diagnostic criteria for BED, more than 65% of individuals with BED are obese[3, 4], and more than a quarter of patients seeking treatment for obesity have BED.[5] Obese individuals with BED, versus those without, experience more severe obesity, greater eating disorder psychopathology (e.g., greater weight and shape concerns, higher body dissatisfaction), and lower self-esteem.[5-7] Obese individuals with BED are significantly more likely to suffer from health conditions such as dyslipidemia and impaired glucose levels compared to obese peers without BED[4], in addition to being at increased risk for health problems associated with obesity generally.[8, 9] Health complications due to obesity comprise a high proportion of the nation's healthcare budget[8], and the healthcare costs of individuals with BED are $18,152 higher than in obese peers without BED.[1] The prevalence of BED and the substantial burden of healthcare costs highlight the need for treatments that eliminate binge eating and produce weight loss.

A2. Obese patients with BED desire and would benefit from interventions that can improve binge eating and weight. Patients with BED frequently present to treatment seeking to both reduce binge eating and lose weight[10, 11] and there is growing consensus among practitioners that there is harm in failing to address obesity co-morbid with eating pathology.[12, 13] Although patients and practitioners recognize the value in treating both binge eating and obesity, there remains a lack of effective specialized interventions for obese individuals with BED. [14] Understanding why existing treatments for BED fail to adequately improve both binge eating and weight can inform the development of more effective treatments for obese patients with BED.

A3. Shared mechanisms contribute to binge eating episodes and overeating without loss of control for patients with BED. Individuals with BED show elevated risk for two types of eating behaviors that lead to weight gain: binge eating episodes and overeating episodes without loss of control. While calories consumed from binge eating episodes play a large role in the weight control difficulties observed in BED, individuals with BED also consume more calories than obese peers without BED outside of binge episodes.[15] When compared to obese individuals without BED, individuals with BED eat more when verbally instructed either to binge eat[16-20]or to eat normally[18, 20] and consume more calories over the course of a day.[21] These broader patterns of overeating appear to reflect a tendency for many internal factors (e.g., emotional states, cravings) and external factors (e.g., presence of palatable food) to trigger overeating episodes (with or without the loss of control that is the signature characteristic of binge eating) in patients with BED. Patients with BED appear to be particularly vulnerable to frequent episodes of disinhibited eating (i.e., the tendency, in those attempting to regulate their dietary intake, to overeat in response to internal and external cues).[22] Disinhibition is one of the few psychological variables known to predict poor weight outcomes[23, 24], suggesting that the greater vulnerability towards disinhibited eating in BED is an important target for treatment.

One factor that drives disinhibited eating in BED is high food reward sensitivity (i.e., a hyper-responsiveness of reward circuitry to food cues or intake).[15] Patients with BED demonstrate increased food reward sensitivity compared to obese peers without BED and have greater difficulty inhibiting intake of palatable foods.[15, 25-27] Patients with BED are often distressed by this elevated food reward sensitivity because of an overvaluation of weight and shape (e.g., a clinically elevated degree to which body weight or shape influences an individual's self-evaluation) and subsequent fears of weight gain.[28, 29] This fear of weight gain can encourage repeated attempts to control dietary intake. While efforts to restrain intake are not universally detrimental for patients with BED (as reviewed in greater detail below), rigid dietary restraint (e.g. strict adherence to dietary rules, avoidance of specific food groups) can increase vulnerability to both binge eating and overeating episodes.[30] Overvaluation of weight and shape and rigid dietary restraint consistently predict the onset and maintenance of binge eating behaviors.[31-37] A final factor that contributes to the development and maintenance of binge eating



and overeating episodes without loss of control in BED is elevated negative affect and distress intolerance (i.e., the perceived inability to tolerate negative emotional states).[38-42] For example, one recent study found that among patients with BED, days characterized by high or increasing negative affect were associated with a greater likelihood of either a binge episode or an overeating episode without loss of control occurring on that day.[43] Although binge eating often begins as an impulsive attempt to regulate negative emotion[39, 44-48], persistent binge eating can lead to a compulsive use of eating as a way to regulate emotions[45, 49] and reduce access to more adaptive coping strategies.[45, 50] Ultimately, eating becomes one of very few "tools in the tool-kit" for reducing distress.[50] As seen in the figure above, elevated food reward sensitivity, overvaluation of shape and weight, and negative affect and distress intolerance directly and indirectly (e.g., by increasing rigid dietary restraint) contribute to binge eating, overeating episodes without loss of control, and an elevated BMI in patients with BED. These widely accepted maintenance factors for BED reflect areas where treatments can intervene to reduce overeating episodes with and without loss of control. However, existing behavioral treatments for BED fail to adequately address these shared maintenance factors.

A4. Cognitive behavioral therapy effectively reduces binge eating, but fails to improve weight. The current gold-standard treatment for reducing binge eating in BED is Cognitive Behavioral Therapy (CBT)[51], which uses cognitive and behavioral techniques to regularize eating, reduce dietary restraint, and alter the cognitive manifestations of BED.[29] CBT for BED is superior to other treatments in eliminating binge eating, with up to 60% of patients achieving full remission from binge eating.[51] However, despite success in reducing binge eating, CBT fails to produce clinically significant weight loss in BED.[51-53]

CBT does not alter the calorie balance. Given that abstinence from binge eating is generally associated with modest weight loss[14, 41, 54, 55] the large reductions in binge episodes produced by CBT should presumably lead to weight loss, despite the fact that weight reduction is not an explicit goal. Weight loss in CBT, however, is typically minimal or non-existent[51-53] as calories previously consumed during binge episodes appear to be distributed over non-binge meals.[56, 57] The inability of CBT to reduce weight is likely due to CBT's emphasis on broadly reducing dietary restraint and a lack of attention to overeating episodes without loss of control.[29]

CBT incompletely addresses elevated food reward sensitivity, negative affect, distress intolerance, and overvaluation of weight and shape. CBT addresses elevated food reward sensitivity by encouraging patients to reduce access to "binge trigger" foods early in treatment and schedule alternative activities in between planned eating times to reduce urges to binge.[29] There are relatively few psychological skills provided for developing the ability to resist urges to eat palatable foods, which may explain why elevated food reward sensitivity predicts poor outcome in CBT.[58] Newer cognitive behavioral models of eating pathology posit that negative affect and mood intolerance can maintain eating pathology, and mood intolerance is targeted by a more complex version of CBT, Enhanced CBT (CBT-E).[29] However, mood intolerance is not a primary focus of standard CBT and even within CBT-E, mood intolerance is not addressed until later stages of treatment and is a relatively small treatment component. Negative affect and elevated emotional eating predict worse outcomes in CBT, further suggesting that CBT is not adequately addressing negative affect and distress intolerance.[59, 60] CBT targets overvaluation of shape and weight by addressing its "expressions," which are defined as behaviors that result from and maintain overvaluation of shape and weight.[17, 18] CBT also notes that increasing the importance of other life domains should indirectly reduce weight and shape concerns, but minimal session time is devoted to this objective. Existing data suggests that CBT produces only modest improvements in overvaluation of weight and shape[61] and baseline overvaluation of weight and shape continues to predict poorer treatment outcomes.[62]

A5. Behavioral weight loss interventions for BED are less effective than CBT at reducing binge eating and produce only modest weight loss. Behavioral weight loss (BWL; which uses behavioral techniques to reduce caloric intake and increase physical activity[63]) is the most effective behavioral treatment at producing weight loss in BED.[51] BWL also improves binge eating, although not as well or consistently as the improvements observed in CBT.[51] Although BWL is the most effective behavioral weight loss treatment to date for BED, weight loss remains, on average, modest. For example, Dr. Grilo found that BED patients in a BWL program showed only a 2.1 mean percent BMI loss at 12-month follow-up.[64] Most trials to date have found that patients with BED experience poorer weight outcomes than obese peers without BED, although a number of studies have not demonstrated this relation, particularly when using samples of self-assessed binge eaters or sub-threshold BED cases.[65, 66] These mixed findings may be related to methodological shortcomings (e.g., reliance on self-report questionnaires, inclusion of heterogeneous patients with sub-threshold levels of BED), and a lack of long-term follow-up data.[51, 64, 66] Despite the inconsistencies observed in individual trials, a recent meta-analysis conducted by our team comparing BED patients with matched obese peers without BED demonstrated a clear impact of BED on weight loss in BWL, with obese BED samples losing significantly less weight (M=6.95kg) compared to obese peers without BED (M=13.51). The long-term outcomes for BWL

treatments in BED are especially poor, as patients with BED tend to re-gain lost weight more quickly than obese peers without BED[67-69] and are more likely to drop out of treatment programs compared to obese peers without BED.[67-70] Weight gain is often exacerbated by continued, or re-emergent, binge eating.[64]

Most BWL programs have not tailored strategies to reduce caloric intake for BED patients. Though there exists considerable variability across BWL interventions, most BWL programs instruct patients to set low to moderate calorie goals and restrict intake of palatable high-calorie foods.[71, 72] While strict diets often improve binge eating in the short term (even among patients who are in the normative weight range[73, 74]) long-term adherence over time is 1) difficult to maintain and 2) could promote the reoccurrence of binge eating if dietary restraint is rigidly applied. A recent systematic review assessing the impact of very low calorie diets on binge eating[65] found that most interventions reduced binge eating during active treatment[75-83], but a re-occurrence in binge eating after treatment occurred in many (but not all) studies.[76, 77, 79, 84] BWL, if not tailored for BED, may encourage the use of unsustainable restrictive eating behaviors, reducing the efficacy of this approach.

BWL typically emphasizes reduced caloric intake as the primary method for altering the caloric balance, despite evidence that physical activity can reduce binge eating and encourage weight loss in BED. Because most weight loss in BWL is attributed to reductions in calorie intake rather than increases in physical activity[85, 86] BWL typically devotes more intervention time to maintaining changes in eating behavior rather than physical activity. However, the few available studies that have specifically evaluated physical activity interventions in BED have found that increases in physical activity can reduce binge eating[87, 88] and encourage weight loss[54, 55, 87-89], suggesting that a stronger emphasis on physical activity for BED may be warranted.[90-94]

Strategies to facilitate adherence to dietary and physical activity goals are limited. Facilitating long-term adherence to the prescribed dietary and physical activity goals remains a challenge for nearly all patients in BWL programs. BWL patients, on average, fall far short of maintaining prescribed calorie levels and physical activity goals, and lose far less weight than would be expected given these prescriptions.[91, 95] As noted above, patients with BED are prone to disinhibited eating, a strong predictor of poor adherence in BWL[10, 96]. For example, in a recent trial completed by our team, patients who reported one or more binge eating episodes in the three months prior to starting BWL experienced more dietary lapses during the first two weeks of treatment than obese peers without a binge eating history ($B=.39$, $SE = .19$, Wald $\chi 2 = 4.39$, $p = .04$). This result adds to a growing body of literature suggesting that patients with BED are especially vulnerable to lapses from treatment prescriptions in BWL and may benefit from novel treatment strategies to increase adherence.

BWL fails to adequately address elevated food reward sensitivity, negative affect, distress intolerance, and overvaluation of weight and shape. Most BWL programs encourage participants to use stimulus control techniques (e.g., strategies designed to reduce exposure to food cues) to limit access to high-calorie foods.[71, 72, 97] However, studies testing the use of stimulus control have found that commitment to maintaining these changes wanes over time.[98] Additionally, while it may be possible to change the home food environment, it is not possible for participants to completely remove themselves from the larger obesogenic environment, and therefore urges and cravings for highly palatable foods will still arise.[20-22] BWL devotes relatively little session time to urge management and elevated food reward sensitivity predicts poor outcome in BWL.[98-100] While BWL often includes a session or two on stress management or emotional eating, the amount of time devoted to negative affect is limited and distress intolerance is not addressed in standard BWL.[71, 72.] These absences reflect a significant limitation when treating those with BED, as negative affect and distress intolerance are strongly associated with both binge episodes[38-42] and overeating episodes without loss of control[101] in BED. Lastly, overvaluation of shape and weight is not addressed in BWL. Continued overvaluation of weight and shape may maintain a problematic emphasis on obtaining a weight or shape that is unlikely to be achieved in BWL. Patients with BED have reported that reaching their desired BMI would require a 36% reduction in weight, an expectation that far exceeds weight losses in BWL.[102] Even the BMI reduction patients with BED report as "disappointing" were 1.5 to 3 times greater than what could be expected in BWL. Although most obese patients want larger weight losses than are likely in BWL, the combined desire for substantial weight loss and overvaluation of weight and shape may reflect a particularly problematic combination. Once patients realize they are unlikely to achieve their desired weight, motivation to adhere to treatment prescriptions might decrease[103, 104,] which may explain, in part, why patients with BED are vulnerable to dropping out of BWL.[67-70]

A6. Integrating CBT and BWL does not improve outcomes in BED. Several researchers have attempted to improve weight loss outcomes for BED by integrating CBT and BWL or using a sequential treatment design (e.g., CBT followed by BWL or vice versa).[64, 82, 105, 106] While the appeal of this approach is clear, the results to date have consistently failed to show evidence of superior treatment outcomes. For example, a recent study by Dr. Grilo assessed whether sequential CBT and BWL treatment could produce greater weight loss than BWL alone and found no support for the sequential ordering of treatment.[64] These

results support the notion that the current iterations of both CBT and BWL (either alone or in conjunction) are unlikely to produce clinically meaningful weight outcomes for patients with BED.

A7. Tailored dietary and physical activity recommendations for patients with BED may improve weight loss outcomes. One of the key challenges for improving treatment outcomes in BED is the need to achieve a calorie deficit sufficient to produce meaningful weight loss without substantially increasing hunger, cravings, and perceived deprivation, all of which could increase urges to binge or overeat. Compared to obese peers without BED, individuals with BED are more likely to report hunger and cravings when dieting, and demonstrate greater food intake in response to hunger and cravings in laboratory tests.[41, 107-109] Similarly, patients with BED experience greater hedonic hunger (i.e., hunger that occurs in the absence of an energy deficit and is largely driven by the palatability of food) than obese peers without BED[110, 111] and greater feelings of deprivation when restricting intake of highly palatable foods, even in the absence of caloric restriction.[112, 113] This predisposition to hunger, cravings, and perceived deprivation in patients with BED suggests a need to tailor dietary prescriptions. A small body of evidence suggests that modified dietary recommendations can improve weight outcomes in BED compared to the traditional recommendations of BWL.[105, 114, 115] For example, a reduced energy density diet lowers caloric intake among BED patients in laboratory studies without increasing self-reported hunger[115] and changes in the energy density of food intake have been related to weight loss in previous trials.[105, 114] To date, direct investigation of tailored strategies to reduce hunger, cravings, and perceived deprivation in patients with BED remains limited but worthy of study.

As described above, incorporating physical activity into treatment for BED both reduces binge episodes[87, 88] and encourages weight loss.[54, 55, 87-89] For example, one study found that for patients with BED, CBT plus nutritional counseling alone was less effective at producing weight loss than CBT plus nutritional counseling and physical activity.[88] Only participants in the physical activity condition experienced reductions in drive for thinness, suggesting that physical activity may also target overvaluation of weight and shape. Physical activity is known to reduce depressive symptoms in patients with BED, and reduces the impact of anxiety sensitivity (e.g., fear of anxiety and related sensations, conceptually related to distress intolerance) on binge eating pathology, perhaps because physical activity functions as a coping strategy and reduces reliance on binge eating as a way to reduce emotional distress.[116] A recent systematic review of physical activity for BED concludes that adding exercise to behavioral treatments for BED can facilitate reduced binge eating and weight loss both directly (e.g., by burning calories) and indirectly (e.g., by improving depression, reducing reliance on binge eating to reduce emotional distress).[117] Despite the many known benefits of physical activity, existing treatments either do not include any physical activity (CBT) or target physical activity as only a secondary goal of treatment given evidence that reducing caloric intake is more important for producing initial weight loss (BWL).[72, 118] Greater session time devoted to physical activity and a focus on physical activity as a primary method for directly and indirectly reducing binge eating and facilitating weight loss appears warranted.

A8. Acceptance-based psychological strategies may be able to improve negative affect, distress intolerance, and overvaluation of weight and shape and support long-term adherence to BWL prescriptions despite elevated food reward sensitivity. Acceptance-Based Behavioral Treatments (ABBTs, a group of novel "third-generation" behavior therapies including Dialectical Behavior Therapy[119] and Acceptance and Commitment Therapy (ACT)[120]) teach patients a set of psychological strategies that we believe can reduce binge eating and overeating without loss of control in patients with BED. The goal of ABBT is not to reduce the frequency of aversive experiences (e.g., hunger, cravings, fatigue); rather, the aim is to foster willingness to experience aversive internal experiences while simultaneously engaging in behaviors consistent with long-term goals and values (e.g., choosing to exercise even while feeling fatigued, adhering to a meal plan while having urges to eat more palatable foods). Patients are taught a number of psychological strategies (reviewed in detail in the *ABBT Condition* section below) designed to disrupt key maintenance factors in BED (e.g. experiential acceptance as an alternative to distress intolerance, values clarification to identify alternative valued life domains and reduce overvaluation of weight and shape). The conceptual fit between ABBTs and binge eating is well noted in existing literature and has led to the development of a number of acceptance-based treatment approaches designed to reduce binge eating including but not limited to Mindfulness-based Eating Awareness Training[121, 122], Mindfulness-based Stress Reduction[123, 124], DBT[125-127], and ACT.[128, 129] Recent systematic reviews and meta-analyses indicate that ABBTs can produce medium to large reductions in binge episodes[123, 130] and support the promise of these interventions for reducing binge eating behavior in BED.

While this early work is promising, no ABBT developed to date has focused on using acceptance-based strategies to increase adherence to BWL prescriptions in BED. A small number of the ABBT for BED trials described above examined weight loss as a secondary outcome (n=7), but results were typically subpar, likely because adherence to a prescribed weight loss diet was not a key goal of treatment.[125, 127, 131-135] We believe that

ABBTs focus on learning to tolerate uncomfortable internal states in the service of goal-directed behaviors is uniquely well-suited to improving adherence to BWL prescriptions. Recent work by our study team (reviewed in detail below) provides early support for the ability of ABBT to increase adherence to BWL prescriptions in obese individuals without BED.[136, 137] As described above, patients with BED are especially vulnerable to lapses from treatment prescriptions in BWL, suggesting that psychological strategies designed to increase adherence may be particularly beneficial. Although ABBTs have shown promise at reducing binge eating symptoms in BED and facilitating weight loss in obese adults without BED, an ABBT designed to directly target both binge eating and weight loss in patients with BED has yet to be evaluted.

A7. Current study. We propose to (a) compare the efficacy of an ABBT that targets both binge eating and weight loss in patients with BED to a Standard Behavioral Weight Loss Treatment (SBT), (b) evaluate the extent to which ABBT and SBT target shared maintenance factors for binge eating and overeating episodes, and (c) assess whether treatment efficacy is moderated by baseline values of constructs targeted in ABBT.

B. Innovation

B1. Our study will be the first to evaluate an ABBT for BED designed to 1) address maintenance factors that give rise to both binge eating episodes and overeating episodes without loss of control and 2) increase adherence to BWL prescriptions. Existing ABBTs for BED have focused almost exclusively on reducing binge eating episodes. Our team conducted a review of treatment protocols of ABBTs for BED and found that session content dedicated to the use of acceptance-based strategies to augment adherence to BWL prescriptions or reduce overeating episodes without loss of control is minimal or non-existent in treatments that have been evaluated to date. For example, in a recent trial of Mindfulness-Based Eating Awareness Training[131], weight loss was evaluated as a secondary outcome and recommended calorie goals were provided. However, the authors state that "calorie levels specifically encouraged participants not to target weight loss, but rather to maintain current weight while addressing eating difficulties" and weight management was only briefly mentioned in two out of twelve sessions. Unsurprisingly, only 28% experienced >5 lb weight loss over approximately five months of treatment, a percentage that was nearly identical to the control condition. Similar patterns were observed for all existing ABBT for BED protocols published to date, indicating that the ability of ABBT to improve weight loss outcomes in BED has not been adequately tested.

ABBT for weight loss, developed by Dr. Forman and colleagues, has been called an advancement in behavioral treatment by experts in the field after a recent RCT of this approach produced one of the largest initial weight losses in the behavioral treatment literature absent the use of an aggressive diet or weight loss medication.[138] At present, five large clinical trials have compared a treatment program that uses acceptance-based techniques to facilitate weight loss, with three of the five trials showing superior results for the acceptance-based condition compared to SBT.[136, 137, 139-141] Post-hoc analyses have indicated that patients with features often elevated in BED (e.g. high disinhibition, elevated food reward sensitivity, food-specific impulsivity; see *Preliminary Studies* section below for more details) experience the most added benefit from ABBT. However, all of these trials have excluded patients with full-threshold BED. Our study will be the first to test an ABBT with an explicit focus on 1) altering shared mechanisms that give rise to both binge eating and overeating without loss of control *and* 2) increasing adherence to BWL prescriptions in patients with BED.

B2. Very few studies to date have altered standard behavioral treatment prescriptions to address the unique needs of patients with BED. Our treatment will modify standard behavioral treatment recommendations to achieve a calorie deficit while minimizing hunger, cravings, and perceived deprivation that could increase urges to binge or overeat. These methods (described in greater detail in the *ABBT Condition* section) include providing guidance on the types of foods patients can eat to enhance satiety, eliminating rigid dietary rules (e.g., avoiding specific food groups, not eating after set times), incorporating portion-controlled, palatable foods (e.g., desserts, salty snack foods) to avoid feelings of deprivation, and promoting high levels of moderate-to-vigorous physical activity as a primary method for altering the calorie balance. While other studies have attempted to modify BWL for patients with BED, existing work has focused largely on the incorporation of CBT strategies into BWL treatments.[64, 82, 105, 106] Our study will be one of the first to alter standard behavioral treatment prescriptions to increase suitability for a BED population.

B3. Assessing mechanisms of action is treatment outcome studies for BED remains rare. To date, very few treatment outcome trials for eating disorders assess mechanisms of action.[142] Recent NIH initiatives call for an increased emphasis on evaluating the impact of treatment on identified clinical targets to better inform treatment development.[143, 144] The proposed study will test whether ABBT works through the hypothesized pathways and alters shared maintenance factors for binge eating and overeating in patients with BED. A primary goal is to assess whether patients who receive ABBT demonstrate (a) larger increases in

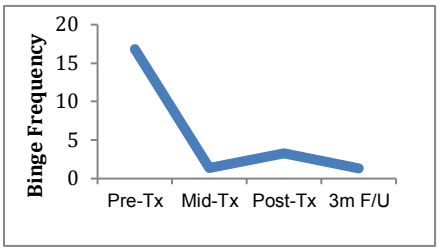
flexible (but not rigid) dietary restraint, (b) greater adherence to caloric and physical activity goals, (c) larger improvements in negative affect and distress intolerance, and (d) greater reductions in overvaluation of weight and shape compared to patients in SBT, and whether changes in these targets are associated with outcomes.

B4. Few studies of BED have assessed baseline moderators of weight loss. Although a growing number of studies have assessed baseline predictors of treatment outcome for binge eating, data on predictors of weight loss in BED is limited.[145] If we can *a priori* identify specific individuals who may need a specialized intervention such as ABBT, we can appropriately refer patients to the correct type of care. Alternatively, if we identify individuals who can achieve clinically significant weight loss in SBT, an easily disseminable and relatively low-cost treatment, we can reduce the need for specialty treatments. Food reward sensitivity, overvaluation of weight and shape, negative affect, and distress intolerance have all been proposed as markers of a more severe subset of BED patients who may not respond as well to current interventions.[146-148] Assessing baseline moderators of treatment outcome will provide meaningful data to personalize treatment selection.

C. Approach

C1. Preliminary studies. Promising results from several of our team's studies demonstrate that 1) this team has the expertise and resources necessary to conduct the proposed research (e.g., recruit and retain BED participants, deliver SBT and ABBT), and 2) the hypotheses to be tested in this study are likely to be supported.

CARE Project I. Drs. Juarascio and Forman recently completed an open-trial pilot study of ABBT for BED.[128] Weight loss was not an aim of this ABBT and the trial included patients who were normal weight in addition to patients who were overweight or obese. Participants (n=19) reported high acceptability of the treatment and retention rates were high at 89.4%. Generalized linear multilevel modeling revealed large and significant improvements in global eating pathology and binge frequency. Increases in distress tolerance predicted decreases in binge eating across several measures (rs = .35-.54).



CARE Project II. Dr. Juarascio recently completed a ten-session ABBT weight loss program with a small number of overweight and obese BED patients (n=5) who previously completed CARE Project I. Patients reported high acceptability of the program and lost 2.7% body weight by week 10. Although results are preliminary, past research has demonstrated that early weight loss predicts subsequent success in BWL.[149-151]

REACT Project. Drs. Juarascio and Forman previously assessed ABBT in a sub-sample of obese patients (n= 20, Mean BMI: 39.44) with eating pathology in a larger treatment study.[152] The full study examined whether the addition of ABBT groups to treatment as usual in a residential treatment facility for eating disorders would improve treatment outcomes.[153] Results revealed that obese patients in the ABBT condition trended towards larger reductions in shape/weight concern and global eating pathology by discharge, with effect sizes in the moderate range (partial eta squared of .29 to .38). Patients in the ABBT condition also lost more weight (ABBT: 2.31 kg, TAU: 1.30 kg), despite the fact that weight loss was not explicitly a goal of this version of ABBT.

Mind Your Health I. A previous NIH-funded project (Dr. Forman, PI) assigned participants (n=128) to 30 sessions of ABBT or SBT for weight loss.[154] Attendance at ABBT groups was excellent (M = 81.7% of 30 sessions) and higher than in SBT (M=73.9%) indicating that the acceptability of ABBT is high. When administered by clinicians with obesity treatment experience, percent weight loss was significantly higher in ABBT than SBT at post-treatment (13.2% vs. 7.5%; p = .01) and 6-month follow-up (11.0% vs. 4.8%; p = .01). Although BED patients were excluded, higher levels of depression, disinhibition and responsivity to food (characteristics typically elevated in BED) moderated the main effect of treatment. For example, among individuals with depression at baseline, 40-week weight losses were 18.2% for ABBT and 5.5% for SBT.

Mind Your Health II. A nearly completed NIH-funded project (Dr. Forman, PI) assessed the long-term efficacy of ABBT versus SBT for overweight and obese adults. Participants (n=190) were randomly assigned to 25 sessions of ABBT or SBT. At post-treatment, ABBT yielded statistically and clinically significant greater percent weight loss (M= 13.3%) compared to SBT (M= 9.8%) and the superiority of ABBT was maintained at one-year follow-up.[137] Post-treatment retention rates (82.6% at 12 months) exceeded our target. Similar to Mind Your Health I, patients with BED were excluded from the study; however, patients with high food-specific impulsivity (which is elevated in BED[155]) performed better in ABBT.[156]

Project ENACT. Another NIH-funded project from our team (Dr. Forman, Co-I) randomized 283 overweight and obese participants to receive 26 sessions of group-based SBT (with or without a focus on changing the home environment) or ABBT. As in the previous trials, patients with full-threshold BED were excluded from

treatment. However, patients with sub-clinical binge eating (defined as no more than three binge episodes in the three months before treatment) were included and preliminary results indicate greater weight loss in the ABBT condition (M=11.58%) than the SBT (M=9.71%) conditions for this subgroup.

C2. Study design. Participants will be randomly assigned to SBT or ABBT. Treatment will be delivered in 75-minute, small (12-15 participants), closed-group sessions. Groups will be held weekly in months 1-3, biweekly in months 4-6, and monthly in months 7-12, for a total of 25 sessions. Assessments will occur at months 0 (baseline), 1 (midpoint 1), 3 (midpoint 2) 6 (midpoint 3), 12 (post-treatment), and 24 (1-year follow-up).

C3. Alternative designs considered. While we considered a shorter treatment duration (to reduce burden and increase disseminability), we ultimately chose a 25-session treatment for three reasons. First, 25 sessions over 1 year is about the modal length and the recommended intensity for gold standard weight loss treatment. Second, this length is consistent with the increasingly-supported chronic care model of obesity.[157] Third, clinical trial experts have recommended that, for initial tests of efficacy, treatments should be evaluated at full potency to reduce the likelihood that failure occurs because of sub-optimal dosage.[158] If ABBT improves weight loss outcomes for BED, methods for reducing the intensity (e.g. optimization and refinement of session content) and increasing the scalability (e.g. use of alternative delivery methods and/or non-experts clinicians, both of which have been successfully completed with ABBTs for other disorders[159]) can be explored in future studies. We also considered including a second follow-up assessment, but determined that given the time needed to recruit and treat 130 participants with BED, a longer follow-up period would not be feasible.

TIMELINE	Year 1				Year 2				Year 3				Year 4				Year 5				*R= recruitment*
Manual refinement	X	X																			
Therapist training		X																			
Wave 1		R	A1	A2	A3		A4				A5										*A = assessment (A1, A2, A3, A4, A5 = months 0, 3, 6, 12, 24, respectively).*
Wave 2			R	A1	A2	A3		A4				A5									
Wave 3					R	A1	A2	A3		A4				A5							
Wave 4						R	A1	A2	A3		A4				A5						
Wave 5								R	A1	A2	A3		A4				A5				
Wave 6									R	A1	A2	A3		A4				A5			
Data analysis																			X	X	
Manuscript preparation																			X	X	*Intervention period shaded.*
Planning future studies, e.g, optimization																			X	X	

C4. Participants. 130 participants will be recruited who meet the following inclusion criteria: DSM-5 diagnosis of BED, BMI 27-45 kg/m2; age 18-70 years; and ability to engage in PA (i.e., can walk 2 blocks without rest). Exclusion criteria are as follows: medical condition (e.g., acute coronary syndrome, type I diabetes) or psychiatric condition (e.g., active substance abuse, severe depression) that may pose a risk to the participant during intervention, cause a change in weight, or limit ability to comply with the recommendations of the program; pregnant or planning to become pregnant in the next 2 years; planned move out of the Philadelphia area in the next 2 years; recently began a course of or changed the dosage of medication that can cause significant change in weight; history of bariatric surgery; and weight loss of > 5% in the past 6 months.

C5. Recruitment, enrollment, and randomization. Recruitment will be conducted in six waves. Drs. Juarascio, Forman, and Grilo have established a variety of referral sources (including college counseling centers, private practitioners, and medical practices) for their ongoing grants recruiting patients with BED, bulimia nervosa, and obesity. We will also advertise in newspapers and radio stations. We will specially design advertisements (e.g., featuring images of men/ethnic minorities) and select media (e.g., that have high male/ethnic minority readership/listenership) to maximize participation of men and ethnic minorities. In Dr. Grilo's most recent RCT (DK49587), similar recruitment methods yielded N=191 randomized BED patients (which exceeded target of N=175) and yielded 35% men and 24% minority enrollment. We considered making special effort to recruit participants high in proposed moderators to ensure adequate power for Secondary Aim 2, but based on available literature[112, 127, 160, 161] and our own pilot data[162] we believe we will recruit a sample with sufficient variability in proposed moderators using existing methods. Drs. Juarascio, Forman, and Grilo will have monthly videoconference meetings to discuss any concerns related to recruitment, enrollment, or retention and will meet in-person during twice yearly during national conferences to review study progress.

Participants will be screened by phone to assess preliminary eligibility. Phone screens will use questions from the Mini International Neuropsychiatric Interview (MINI)[163] to assess psychiatric comorbidity and will be conducted by trained graduate students, similar to procedures used successfully in our other NIH-funded trials. Those who appear eligible will attend an orientation session where they will receive detailed information about the study. At a subsequent clinic visit, eligibility will be verified, informed consent obtained, and the baseline assessment completed. The enrollment process will provide participants with an adequate opportunity

to determine whether the assessment burden and demands of the program are acceptable; this is expected to reduce attrition. After the baseline assessment, participants will be randomized to condition in blocks of 6, stratifying by BMI category (<30, 30-40, and >40), sex, race/ethnicity, and frequency of binge episodes.

C6. Therapy conditions. We decided to use SBT as our control condition given that weight loss is our primary outcome. We considered including CBT as an alternative control condition, but ultimately decided that CBT would be a sub-par control because this treatment does not directly encourage weight loss and consistently produces minimal to no weight loss for patients with BED.

C6a. Standard Behavior Therapy (SBT) condition. SBT will be adapted from state-of-the art SBT manuals our team has used for previous weight loss studies, which were themselves adapted from Look AHEAD and the Diabetes Prevention Program protocols.[71, 72] Components of SBT include nutrition and physical activity education, self-monitoring of calorie intake, physical activity, and weight; stimulus control techniques; identifying triggers for overeating; setting individualized realistic goals for calorie intake, physical activity, and associated behaviors; using problem solving skills as a way of overcoming obstacles to behavior change; developing social support; and relapse prevention techniques. Patients will be given calorie goals based on weight, in accordance with standard balanced deficit diet guidelines[164] (e.g., patients weighing 250-299 lbs. will be prescribed 1500 kcal/day). Patients will be instructed to gradually increase their physical activity until they reach at least 250 minutes per week of moderate activity, as consistent with American College of Sports Medicine[165] and American Journal of Clinical Nutrition recommendations, and emerging data suggesting this higher level of PA is most associated with successful weight loss maintenance.[166-168]

C6b. Acceptance-Based Behavioral Treatment (ABBT) Condition. The ABBT manuals will be based on the manuals developed by Dr. Juarascio for the CARE I and CARE II Projects and the manuals developed by Dr. Forman for MYH1 and MYH2. ABBT is a behavioral treatment approach, and as such, uses some of the same behavioral techniques used in CBT and SBT, particularly during Phase 1. As described in greater detail below, many of the standard behavioral techniques and recommendations were modified to better suit the unique needs of patients with BED or facilitate weight loss. Because acceptance-based techniques are designed to work in conjunction with behavioral treatment recommendations, we first introduce patients to modified behavioral strategies drawn from CBT and SBT during Phase 1 and subsequently introduce acceptance-based techniques to improve adherence and address key maintenance factors for BED during Phase 2.

Phase 1 (Sessions 1-8): The first eight sessions of ABBT will use behavioral strategies from both CBT and SBT to 1) reduce binge eating episodes and 2) alter the calorie balance.

CBT techniques. We chose to focus on reducing binge episodes during Phase 1 based on data suggesting that early reductions in binge eating impact weight loss outcomes.[14, 169-171] Sessions 1-3 will provide psychoeducation on the maintenance factors for binge eating episodes, introduce patients to self-monitoring, and start the regular eating interventions, which is a key driver of early reductions in binge eating in CBT.[142, 172] Patients with BED who consume more frequent meals weigh less, suggesting regular eating might indirectly assist in weight loss.[173, 174] Regular eating produces a rapid reduction in binge eating episodes and rapid response to treatment is highly predictive of successful treatment outcomes, further supporting a strong focus on reducing binge eating episodes early in treatment.[175-178] Unlike the regular eating interventions typically implemented in CBT, our regular eating intervention will incorporate personalized caloric goal ranges for each meal and snack designed to reduce caloric intake. As described above, regular eating interventions are typically weight neutral, likely because calories previously consumed during binge episodes are distributed over non-binge meals.[56, 57] We believe that providing explicit calorie goals for each eating episode during the implementation of regular eating can help prevent re-distribution.

SBT techniques. During Phase 1, patients will be taught many of the same behavioral strategies described in the SBT section above to assist in meeting their calorie goals (e.g., self-monitoring of calorie intake; stimulus control techniques; problem solving skills). While many techniques will be similar to SBT, some modifications will be made to address the unique needs of patients with BED. For example, patients will receive education about the ways rigid dietary restraint can trigger binge episodes (e.g., severe caloric restriction, hedonic restriction, avoiding specific food groups, going long periods of time without eating), and will learn how to reduce caloric intake in ways that will minimize hunger and cravings. The table to the right provides examples of these strategies. One core difference will be that patients in ABBT will be encouraged to incorporate portion controlled palatable foods regularly to avoid feelings of deprivation that could trigger binge eating. While avoiding highly palatable foods can be a successful strategy for many obese patients, hedonic deprivation may be less sustainable for patients with BED and could encourage future binge eating or overeating episodes.

The exercise progression in ABBT will be the same as in SBT, with specific session content dedicated to psychoeducation about the benefits of physical activity for BED in Session 8. The ABBT treatment will also

provide psychoeducation relevant to patients with BED (e.g., session content on avoiding compensatory and compulsive exercise). We chose to begin the exercise progression in Phase 1 because 1) this will allow patients who are currently sedentary time to safely build up to the recommended exercise progression, and 2) research indicates that exercise can indirectly reduce binge eating episodes by improving depression, self-efficacy, and body image as well as reducing the degree to which binge eating episodes are used to regulate emotions.[117] We considered using a more intensive exercise progression for ABBT, but decided that given the low long-term adherence rates observed in SBT[90-94], the feasibility of meeting even higher activity goals would be limited.

Phase 2 (sessions 9-19): Phase 2 will focus on the use of acceptance-based strategies to improve adherence to dietary and physical activity goals and address shared maintenance factors for binge eating and overeating episodes. Below we will review how acceptance-based techniques will be incorporated in Phase 2.

Values clarity/commitment enhancement. Consistent with principles of ACT[120] and intrinsic motivation theory[179], ABBT will emphasize that participants must choose goals that emanate from freely-chosen, personal life values (e.g., living a long and healthy life; being a present, active mother). A structured process for the identification of such life values will be followed and the connections between these values and eating and physical activity behaviors will be emphasized. Participants will be taught that commitment to difficult behavioral goals is only likely to be maintained when one connects psychologically with life values important enough and meaningful enough to make such effort and sacrifice worthwhile. Commitment will be presented as a critical component of maintaining changes to the personal food and physical activity environment. Values clarity interventions will also be used to alter overvaluation of weight and shape. An underlying assumption about values is that they are finite; that is, there is a limit to what can be encapsulated in an individual's value base. Thus, the overvaluation of weight and shape that occurs in BED necessitates that there is less "room" for other valued domains.[128] By helping patients pursue committed actions towards personal values, ABBT may be able to foster awareness of the values-inconsistent nature of binge eating and overeating episodes, reduce overvaluation of weight and shape, and improve motivation for adherence to program goals.

Distress tolerance. ABBT will help participants recognize that, 1) eating-related distress (e.g. urges to binge, hunger, cravings) is bound to occur in today's obesogenic environment, particularly given the elevated food reward sensitivity common in BED and 2) attempts to avoid these internal experiences are often ineffectual or even counterproductive. Participants will learn to tolerate aversive states related to eating (e.g., cravings) and physical activity (e.g., boredom, discomfort) while continuing to engage in the desired behaviors through in-session experiential activities and at-home practice. For example, in one session, participants will hold themselves in the "plank" (an unsupported sitting) position and practice tolerating the bodily discomfort that is generated by this exercise. *Willingness* (simultaneously engaging in a valued action while accepting the discomfort it generates) will be framed as more adaptive than distress *in*tolerance (i.e., eating foods or ceasing/avoiding activity to avoid being uncomfortable). Experiential exercises will allow participants to practice distancing themselves from thoughts and feelings in a way that enhances willingness to experience them, thereby reducing the necessity of acting (e.g., ending a walk early, eating a chocolate bar) to alter the experience. Unlike SBT, ABBT assumes that attempts to distract from or modify thoughts and feelings are rarely productive; rather, long-term adherence to health behaviors depends on the ability to tolerate unpleasant internal experiences. Distress tolerance will also be used to address elevated negative affect that contributes to binge eating and overeating episodes. Reductions in binge eating have been mediated by changes in distress tolerance, supporting its importance as a treatment target in BED.[180] Patients will be taught how to tolerate negative affect without using food as a way to distract from or numb out uncomfortable experiences.

Phase 3 (sessions 20-25): The final phase will have a strong focus on achieving weight loss maintenance by enhancing long-term adherence to dietary and physical activity recommendations. Acceptance-based strategies such as values clarity and committed action will be used to address reductions in motivation. Patients will also be taught how to address a reoccurrence of binge eating if this behavior emerges at any point during their weight loss efforts (e.g., re-establish self-monitoring, reduce dietary restriction, reincorporate regular eating).

C7. Intervention cultural sensitivity. The research team will recruit participants from the Philadelphia metropolitan area, which is 38% non-white based on the most recent census data.[181] All interventions will be culturally sensitive by, for example, discussing barriers to behavior change unique to each participant's social context (e.g., neighborhood safety as a barrier to exercise), and emphasizing health benefits and general wellbeing as the motivation for weight loss and exercise.[182-184]

C8. Clinician training, supervision, competence and fidelity. Group leaders will be clinicians with a graduate degree in psychology or a related field and previous experience conducting both BWL and CBT. Research indicates that previous experience with an acceptance-based approach is not necessary for effective treatment delivery and that brief training is sufficient.[153, 185-193] Clinicians will complete a 10-hour initial

training and attend weekly supervision provided by Dr. Manasse. Consistent with our previous clinical trials of ABBT for obesity, clinicians will be balanced across conditions. Data from our MYH II and ENACT trials have demonstrated that contamination across conditions is extremely low based on codings of audio-recorded sessions (MYH II: 0.12/10, ENACT: 0.23/10; 0= perfectly avoided contamination and 10= substantial contamination occurred). All treatment sessions will be audio-recorded, and 25% will be rated for competence and fidelity. Feedback on competence and fidelity will be shared after each rated session and shortcomings will be addressed immediately. An intervention allegiance survey also will be administered to all clinicians.

C9. Assessments and Measures. Assessments will occur at the start of treatment (baseline), 1 month (midpoint 1), 3 months (midpoint 2), 6 months (midpoint 3), 12 months (post-treatment), and 24 months (1-year follow up). All outcome and process measures described below will be completed at each assessment. Acceptability will be assessed at post-treatment. All assessments will be completed onsite in Drexel University's Department of Psychology. Efforts will be made to schedule midpoint assessments directly after or directly before a treatment session to reduce participant travel burden (e.g. month 3 assessment will occur between sessions 12 and 13, with effort made to schedule participants right after session 12 or right before session 13 if possible). All assessments will be conducted by blind raters (graduate students who will be highly trained and closely supervised by Dr. Manasse). Blind raters will receive training on standard procedures for collecting anthropometric data and administering all process measures described below. Raters will be required to pass a "mock" assessment with Dr. Manasse and reach 100% agreement on eating disorder diagnosis and acceptable reliability (>.80) on EDE scoring before they will be cleared to conduct assessments.

Feasibility and Acceptability. Assessment of feasibility will include number of patients screened per month, % of eligible patients enrolled, treatment attrition (% of patients that prematurely terminate treatment), study retention (% of patients that complete all assessments), treatment adherence, and treatment fidelity. Acceptability will be assessed using the Feedback Questionnaire and Credibility/Expectancy Questionnaire[194] to gauge participant's attitudes and feelings toward the treatment.

Outcomes. The primary outcome measure for the study will be change in **weight**. Weight will be measured in street clothes without shoes using a standardized Secca® scale accurate to 0.1 kg. **Eating pathology** will be a secondary outcome measure and will be measured by The Eating Disorder Examination (EDE), a widely utilized, semi-structured interview for eating disorder symptoms.[195] Participant's EDE global scores and objective binge frequency will be the primary outcome measures for eating disorder pathology.

Process Measures. The study will assess whether patients who receive ABBT show greater improvements in 1) flexible restraint (and less rigid dieting behaviors), 2) adherence to caloric and physical activity goals, 3) negative affect, 4) distress tolerance, and 5) overvaluation of weight and shape compared to patients who receive SBT. Measurement tools were selected on the basis of assessing clinical targets using multiple assessment approaches. We will assess **flexible restraint and disinhibited eating** with the Eating Inventory (Three Factor Eating Questionnaire)[196], a commonly used measure of dietary restraint. Three specific subscales within this measure will be of particular focus: *Rigid Control of Eating Behaviors, Flexible Control of Eating Behaviors, and Disinhibition*.[197] **Dietary intake** will be measured by 72 hours of recalled intake using the Automated Self-administered 24-hour Dietary Recall (ASA24), a National Cancer Institute-designed free software tool that enables self-administered, but interactive, 24-hour dietary recalls.[198] ASA24 is based on the well-validated Automated Multiple Pass Method which is as or more accurate than nutritionist-administered 24-hour food recall when using doubly-labeled water as the criterion.[199]

We will define **physical activity (PA)** in kcal/wk of energy expended through MVPA[200] with ActiGraph GT3X tri-axial, solid state accelerometers. Accelerometers, particularly models made by Actigraph, have been found to be valid and reliable means of measuring PA.[201, 202] The tri-axial models can measure movements in multiple planes and assess activity intensity providing more accurate estimates of energy expenditure than do less sophisticated methods such as pedometers or self-report questionnaires.[203-205] The data collection interval will be set at one minute with a minimum of 12 hours constituting a valid day. We will also use a 7-day Physical Activity Recall[200] measure to gather further information about duration and intensity of bouts of swimming, biking, and strength training. Estimates of PA will be calculated with and without imputation from these self-report data. For assessment purposes, accelerometers will be distributed just prior to each assessment point, either through mail or at group meetings, and returned at each assessment visit. For 7 consecutive days at each assessment point, participants will wear accelerometers for all waking hours.

A Negative Mood Induction (NMI) task will be used to assess **negative affect** and **distress intolerance** during and after an acute stressor. Following completion of all study measures participants will undergo an autobiographical recall task, a commonly used negative mood induction.[206-208] Mood will be assessed using the Short Positive and Negative Affect Scale (PANAS)[209] before and after the mood induction and after a ten-minute waiting period following the mood induction. Heart rate (a physiological measure of emotional state)

will be monitored throughout the induction and post-induction period using the Polar E600 heart rate monitor. Several prior studies have utilized mood inductions to assess ability to regulate and tolerate negative emotions in response to a stressor.[210-213] Distress intolerance will also be measured using the Difficulties in Emotion Regulation Scale (DERS).[214] The DERS assesses awareness and understanding of emotions, ability to tolerate emotional arousal, and effective action in the presence of intense emotions. We will also use two behavioral measures of distress intolerance. The computerized Mirror-Tracing Persistence Task[215, 216] measures the amount of time a participant is willing to engage in a frustrating task (tracing a dot on a computer screen that moves in the opposite direction as one moves the computer mouse). The cold pressor test measures the length of time a participant is willing to leave her hand in water kept at 3° C through the use of a circulating water bath system (Lauda RM6) For safety reasons, participants are not allowed to exceed 300 sec of exposure to the cold water.[217] Both of the aforementioned behavioral tasks have proven valid measures of distress tolerance in health behavior areas, particularly smoking cessation.[216, 218-223] Lastly, depressive symptoms will be assessed using the Beck Depression Inventory-II, a 21-item measure assessing levels of depressive symptomology.[224] This self-report scale is widely used and has proven reliable across a variety of demographic groups and in both clinical and nonclinical populations.

Overvaluation of shape and weight will be assessed using the following two questions pulled from the Eating Disorder Examination: "Over the past four weeks, has your shape influenced how you feel about (judge, think, evaluate) yourself as a person?" and "Over the past 4 weeks has your weight influenced how you feel about (judge, think, evaluate) yourself as a person?". This method of defining and assessing overvaluation of weight/shape has been used in several past studies with BED patients.[32, 225] Measures used to assess values clarity will be the Valued Living Questionnaire II[226], a commonly used quantitative measure of values, and the Values Clarity Measure, which is an open-ended, qualitative assessment where responses are recorded and coded. The Values Clarity Measure has been proven reliable and valid as a mediator of outcome in a lifestyle modification pilot study conducted by this research team.[227] **Reward sensitivity** will be assessed with the Power of Food Scale, a self-report questionnaire that has been shown to reliably and validly measure thoughts and feelings about highly palatable foods when not physically hungry.[27, 228, 229]

C10. Statistical Analyses

Descriptive statistics will be generated for all variables. Data summaries will be produced for the combined sample and separately by treatment arm. Continuous variables will be summarized using mean/median as measures of location and SD/inter-quartile range as measures of dispersion; normalizing transformations will be used if there is evidence of skewness/kurtosis. Categorical variables will be presented as proportions.

Primary Aim (Efficacy of ABBT). Analyses will be conducted via linear mixed effects models for longitudinal data, which increase power by fully exploiting the strong correlation in treatment outcomes of interests (i.e., primarily, percent weight loss and secondarily, percent binge frequency reduction) across time. Patterned covariance matrices as implemented in SAS/STAT PROC MIXED V9.2 will be used to evaluate between group differences for percent weight loss and percent binge reduction across the study as a whole, and at each assessment post-baseline.[225] Separate variance components will be used to capture therapist and participant-within-therapist variation. The within-subject covariance matrix will be assumed common across study arms, with an exponential variance function to deal with heteroscedasticity and a continuous-time AR(1) correlation matrix to accommodate residual autocorrelation over the unequal–size time intervals between follow-ups. Outcomes at all six time points will be estimated jointly for maximum statistical efficiency in the presence of intermittent missingness and loss to follow-up. The model will include random effects for subject and time (with higher-order effects if needed to capture nonlinear change), and fixed effects for treatment arm, time by treatment interaction, demographic information, and baseline values of weight, dietary intake and physical activity. Time-specific covariate-adjusted contrasts will be used to compare outcome between groups.

Secondary Aim 1 (Between-Subjects Mediation). We will examine the extent to which variables of interest (i.e., dietary restraint, adherence to caloric and physical activity goals, negative affect and distress tolerance, overvaluation of shape/weight, and values clarity) will mediate differences in weight loss and reduction in binge eating between treatments. Specifically, we will determine whether temporally-precedent changes in each mediator from baseline to 1 month and baseline to 3 months mediate subsequent differences in weight loss at 6, 12 and 24 months respectively. We will use the mediation model outlined by Preacher and Hayes and Mplus version 6.12 to estimate the total and specific indirect effects of each hypothesized mediator individually.[230, 231] This approach expands on Baron and Kenny's methods by providing additional guidelines and techniques that allow for the most robust and accurate interpretation of these mediating effects.[232, 233] Confidence intervals for the indirect effects will be generated using the bias-corrected (BC) bootstrapping approach.[234]

Secondary Aim 2 (Between-Subjects Moderation). Reward sensitivity, overvaluation of shape/weight, negative affect, and distress tolerance will be added to the model described in Aim 1, and allowed to interact with time and treatment arm, to determine whether these variables moderate the effect of treatment. Statistically significant interactions will be interpreted by plotting simple regression lines for each variable.[235]

Missing data. Our likelihood-based estimation methods remain unbiased when missingness is related to previously-observed outcomes as well as model covariates.[236] If loss to follow-up is related to the missing outcome itself (an assumption that by its very nature cannot be tested empirically), we will use sensitivity analyses based on multiple imputation models[237] to explore how robust our findings are with respect to a range of assumptions regarding missing data. We feel that these approaches are superior to alternatives (such as including only subjects with complete data or assigning a pre-specified score to the missing data) because these methods typically generate tests that are less powerful than the tests used assuming random censoring. We have experience with each of these approaches for handling non-ignorable non-response, and will analyze the data using several of these methods, which incorporate varying assumptions about the missing observations. To determine the extent to which the pattern of missing data might influence our findings, two approaches will be used. Compliance rates will be calculated for each participant. Participants with markedly low compliance rates (e.g., attendance at fewer than 3 assessments) will be considered for exclusion from analyses. Secondly, pattern mixture models[169, 172, 174, 175] based on a random regression model (RRM)[238, 239] will be used to examine the impact of missing data patterns on all variables. Subjects will be divided into groups based on their missing data pattern following the guidelines provided by Hedeker & Gibbons.[240] The influence of missing data patterns on key variables will then be evaluated using RRM by comparing groups. If missing data patterns are found to be associated with key variables, this variable will be used as a covariate in subsequent analyses.

C11. Power Analyses

Primary Aim (Efficacy of ABBT). The study's data will consist of repeated assessments over time within randomized individuals within each treatment condition. Therefore, power calculations are dependent on both an expected difference between treatment arms as well as the clustering of the data (repeated observations within an individual with up to six repeated measures per participant within one of the two treatment conditions), resulting in a multilevel model structure. Using the method described by Raudenbush[252-254] and implemented with the software Optimal Design, power calculations were made for this multilevel model structure. No results are available which directly compare the effect of ABBT and SBT on weight loss in BED patients. However, effect size can be predicted by deriving effect sizes from trials with elements similar to the proposed study, e.g., percent weight loss comparison between ABBT and SBT from the Mind Your Health II study (effect size at 12 months d=0.39) and percent weight loss and binge reduction comparison of CBT vs. SBT (d=0.625; 30% difference in binge reduction rates).[64] Based on previous studies, we aim to detect a clinically meaningful difference for both weight and binge eating frequency (3.5% weight loss between groups (d=0.46) and a difference in 4 binge eating episodes over the 4-week time period). Baseline covariates that can account for variability in the trial outcomes were taken into consideration in the power analysis. Given these assumptions, a sample size of 104 (52 for each group) is required for 80% power with the significant level of 0.05 and five assessment points, assuming the ratio of the variability of level-1 coefficient to the variability of level-1 residual is one. While allowing for up to 20% attrition, the proposed sample size of 130 is adequately powered to examine a clinically meaningful difference between treatment conditions for both percent weight loss and frequency of binge episodes. We believe this power estimate to be conservative given: 1) attrition estimates are greater than the team has achieved in similar weight control studies; and 2) missing values will be imputed using multiple imputation to maximize the number of the observations used to estimate models.

Secondary Aim 1 (Between-Subjects Mediation). Tests of mediation will utilize bias-corrected bootstrapping which demonstrates the best balance of statistical power and type I error.[255-257] Fritz and MacKinnon[255] documented sample size requirements to guarantee 80% power at a significance level of 0.05 for regression-based mediation models. Under the assumption of small to medium effect sizes for intervention with the mediator and for the mediator on outcome controlled for intervention, a sample size of 130 (58 per group) is required to achieve 80% power.[241, 244, 255] Given a sample size of 130 and the pattern of weight loss and attrition described above, we will be sufficiently powered to evaluate our hypothesized effects.

Secondary Aim 2 (Between-Subjects Moderation). In the linear mixed models used for the primary hypotheses, we will add as covariates both the main effects of our proposed moderators and their interactions with intervention assignment. Given N=130 and the pattern of weight loss, binge reduction, and attrition described above, we will have 80% power to detect moderation if the standardized coefficient for the treatment x moderator interaction is ≥ 0.3 (accounts for at least 8% of the variance) in a model in which the total variance accounted for is ≥ 20%.

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