REGISTERED REPORT STAGE 1: STUDY DESIGN

The project COMPASS protocol: Optimizing mindfulness and acceptance-based behavioral treatment for binge-eating spectrum disorders

Adrienne S. Juarascio PhD[1,2] | Christina R. Felonis BA[1,2] [iD] |
Stephanie M. Manasse PhD[2] | Paakhi Srivastava PhD[2] | Laura Boyajian BS[2] |
Evan M. Forman PhD[1,2] | Fengqing Zhang PhD[1]

[1]Department of Psychology, Drexel University, Philadelphia, Pennsylvania

[2]Center for Weight, Eating, and Lifestyle Science, Drexel University, Philadelphia, Pennsylvania

Correspondence
Adrienne S. Juarascio, Department of Psychology, Drexel University, Stratton Hall, 3141 Chestnut Street, Philadelphia, PA 19104.
Email: asj32@drexel.edu

Abstract

Outcomes from cognitive behavioral therapy for binge-eating spectrum disorders are suboptimal, possibly due in part to deficits in self-regulation (i.e., the ability to control behavior in pursuit of long-term goals despite internal challenges). Mindfulness and acceptance-based treatments (MABTs) integrate behavioral treatment with psychological strategies designed to enhance self-regulation, yet little is known about how and for whom they are effective. The present study will utilize the multiphase optimization strategy to identify which of four MABT components (mindful awareness, distress tolerance, emotion modulation, values-based decision making) to include in a fully powered clinical trial. Participants ($n = 256$) will be randomized to 16 sessions in one of 16 conditions, each a different combination of MABT components being included or excluded from a base behavioral treatment. Our primary aim is to evaluate each component's independent efficacy on disordered eating symptoms. Our secondary aims are to confirm each component's target engagement (i.e., whether each component improves the targeted variable and outcomes), and test that each component's efficacy is moderated by baseline weaknesses in the same component (e.g., that participants with poor distress tolerance at baseline benefit most from the distress tolerance component). Our exploratory aim is to quantify the component interaction effects.

KEYWORDS
binge-eating disorder, bulimia nervosa, cognitive behavioral therapy, distress tolerance, emotion modulation, mindful awareness, mindfulness and acceptance-based treatment, multiphase optimization strategy, values-based decision making

1 | INTRODUCTION

Outcomes from cognitive behavioral therapy (CBT), the current most widely researched treatment approach for binge-eating spectrum disorders such as bulimia nervosa (BN) and binge-eating disorder (BED), are suboptimal with up to 70% of patients failing to achieve full

symptom remission by the end of treatment (Linardon, 2018; Peat et al., 2017). One potential reason for this is that CBT is highly behavioral in nature and requires patients to change behaviors maintaining binge eating (e.g., rigid dietary restriction outside of binge episodes, compensatory behaviors). For many patients, eliminating behavior such as restrictive eating or compensatory behaviors will temporarily

increase uncomfortable internal experiences (e.g., fear of weight gain, bloating and fullness) and this discomfort can prevent individuals from making the degree of behavior change needed. The ability to succeed in behavioral treatments like CBT thus likely requires an adequate capacity to control such behaviors despite temporary increases in discomfort as well as attentional, motivational, and cognitive challenges so as to align these behaviors with the pursuit of recovery and other long-term goals (i.e., self-regulation; Nielsen et al., 2018). Yet, relatively little time is spent in CBT teaching strategies that can enhance self-regulation. Consistently, while research shows that facets of self-regulation such as emotion dysregulation and inhibitory control can improve in CBT for binge-eating spectrum disorders (Wonderlich et al., 2014), these improvements are often minimal and deficits remain by the end of treatment (Barney, Murray, Manasse, Dochat, & Juarascio, 2019; Byrne, Fursland, Allen, & Watson, 2011; Peterson et al., 2017; Wilson, Fairburn, Agras, Walsh, & Kraemer, 2002). Given that many individuals who engage in recurrent binge-eating experience such deficits (Lavender et al., 2015; Leehr et al., 2015; Wu et al., 2013), it is unsurprising that worse self-regulation is being increasingly supported as predicting poor CBT outcomes (Accurso et al., 2016; Balodis et al., 2014).

Within the past two decades, mindfulness and acceptance-based treatments (MABTs) have emerged as an alternative behavioral treatment approach for a variety of psychological disorders (Haynos, Forman, Butryn, & Lillis, 2016; Kahl, Winter, & Schweiger, 2012; Öst, 2008). MABTs such as mindfulness-based eating awareness training (MB-EAT), acceptance and commitment therapy (ACT), and dialectical behavior therapy (DBT) integrate behavioral treatment with psychological strategies such as mindful awareness, distress tolerance, emotion modulation, and values-based decision making, all of which are hypothesized to enhance self-regulation and facilitate behavior change (Baumeister, Heatherton, & Tice, 1994; Forman & Butryn, 2015; Shapiro, Carlson, Astin, & Freedman, 2006; Zimmerman, 2000). MABTs have proven effective for a wide range of problems including mood disorders (Van Aalderen et al., 2012), anxiety disorders (Bluett, Homan, Morrison, Levin, & Twohig, 2014; Evans et al., 2008; Roemer & Orsillo, 2007; Strauss, Cavanagh, Oliver, & Pettman, 2014; Vøllestad, Sivertsen, & Nielsen, 2011), chronic pain (Cederberg, Cernvall, Dahl, von Essen, & Ljungman, 2016; Chiesa & Serretti, 2011; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011), smoking (Brewer et al., 2011; Bricker, Wyszynski, Comstock, & Heffner, 2013; Gifford et al., 2011; Rogojanski, Vettese, & Antony, 2011; Singh et al., 2013), and obesity (Butryn, Forman, Hoffman, Shaw, & Juarascio, 2011; Forman, Butryn, Manasse, Crosby, et al., 2016a; Forman, Butryn, Manasse, Crosby, et al., 2016b; Lillis et al., 2016; Wadden & Berkowitz, 2016), with overall rates of efficacy comparable to traditional CBTs.

Given the promise of MABTs, an increasing number of researchers are evaluating treatment approaches that combine traditional behavioral treatment recommendations with mindfulness and acceptance-based skills in an effort to improve outcomes for individuals with binge eating. Though research is nascent and results variable, preliminary evidence suggests such treatments are efficacious (Godfrey, Gallo, & Afari, 2015; Katterman, Kleinman, Hood, Nackers, & Corsica, 2014; Linardon, Fairburn, Fitzsimmons-Craft, Wilfley, & Brennan, 2017). In addition to the growing research interest, MABTs have quickly become one of the most frequently used treatments in clinical practice for individuals with binge eating (Linardon et al., 2017). The conceptual fit, preliminary efficacy, and widespread clinical use of MABTs for binge-eating spectrum disorders support the need for additional research on these approaches.

MABTs are commonly delivered as "kitchen-sink" treatment packages, which complicates our understanding of how and for whom they are effective. Specifically, the considerable variability in which MABT components are included in different treatment packages and the degree of emphasis on each component limits our ability to identify which components are most impactful. While mediation analyses allow us to identify which components contribute to improvements in outcomes, very few studies have conducted such analyses in MABTs for individuals with binge eating (Barney et al., 2019). Simple analyses of pre-post changes in MABT constructs are more common (and results have largely been consistent with hypothesized mechanisms), however, inadequate study design (e.g., lack of mid-treatment assessments), inconsistent measurement tools, and lack of adequate comparison conditions (e.g., whether changes in MABT constructs also occur in CBT) limit our understanding of how and for whom existing MABTs are most effective.

Even if large well-designed randomized controlled trials (RCTs) with formal mediation analyses were conducted, it may still be difficult to understand the relative contribution of MABT components on outcomes. For example, a lack of a mediation effect could represent a true absence of a relationship between variables, or measurement error (e.g., due to demand biases or limited psychological insight; Paulhus & Vazire, 2007), or poor assessment timing (i.e., measuring proposed mediators or outcomes too early or too late; Gelfand & DeRubeis, 2015). Moreover, for most comprehensive treatment packages, it is impossible to know whether change in a mediator was caused by any one component. For example, increases in self-reported mindful awareness cannot be ascribed to the mindful awareness component specifically because another component (e.g., distress tolerance) or no component (e.g., self-monitoring thoughts and feelings that occurred while eating) could have been responsible. Accordingly, mediation analyses do not accommodate determining whether MABT components interact with each other synergistically to produce meaningful results. In sum, definitive conclusions about the independent and interactive efficacy of MABT components cannot be drawn from the existing body of research and it is questionable if they could be optimally drawn even from well-designed RCTs.

A highly acclaimed and increasingly recognized alternative to traditional RCTs is the Multiphase Optimization Strategy (MOST), that is, a comprehensive, engineering-inspired framework for optimizing and evaluating multicomponent behavioral interventions (Collins et al., 2011; Collins, Murphy, Nair, & Strecher, 2005; Dziak & Nahum-Shani, 2016; Manasse, Clark, Juarascio, & Forman, 2019; Penn State Methodology Center, 2016). MOST emphasizes first identifying the most promising treatment components for inclusion in

multicomponent interventions before evaluating the interventions via fully powered RCTs. Conventional RCTs often evaluate full treatment packages that may contain inert components, thereby leading to inefficient treatment development and evaluation. In contrast, MOST argues that optimization and refinement should occur *prior* to obtaining extensive evidence for the superiority of any one particular treatment package to avoid testing a treatment that may contain ineffective components or inadequate emphasis on others.

MOSTs occur in three phases: (a) Preparation, during which identifying treatment components to test occurs (via the development and/or parsing of a theoretical model); (b) Optimization, during which treatment components are empirically evaluated through an efficient randomized trial (e.g., a factorial design where all possible component combinations are tested to evaluate main and interaction effects) so that their efficacy can determine inclusion or exclusion from an optimized treatment package; and (c) Evaluation, during which the optimized intervention (with only efficacious components) is tested against the current standard (typically via a traditional RCT). Consistent with Phase I, we derived four MABT components from a review of existing treatment manuals and manuscripts: (a) Mindful Awareness (i.e., what one does while practicing mindfulness, for example, paying attention to the present moment; Baer, 2015), (b) Distress Tolerance (i.e., the ability and/or willingness to endure aversive internal experiences without engaging in cognitive or behavioral strategies to change, reduce, or avoid the distressing internal experience; M. Linehan, 1993), (c) Emotion Modulation (i.e., the ability to effectively modulate emotional experiences, including managing the duration and intensity of emotions; Gratz & Tull, 2010), and (d) Values-Based Decision Making (i.e., the ability to engage in behaviors consistent with non-ED values), each of which has been hypothesized to enhance self-regulation (Baumeister et al., 1994; Forman & Butryn, 2015; Shapiro et al., 2006; Zimmerman, 2000) and improve outcomes for EDs. Evaluation of these four MABT components through a factorial design (i.e., Phase II) will allow us to determine their independent and interacting efficacies, assess each component's impact on its hypothesized clinical target, and identify subsets of individuals most or least responsive to each component.

1.1 | Current study

In a clinical trial funded by the National Institute of Mental Health (R01MH122392, registered at clinicaltrials.gov, approved by Drexel University's Institutional Review Board), we will use the MOST approach (including a full $2 \times 2 \times 2 \times 2$ factorial design) and assign 256 individuals with BN or BED to one of 16 treatment conditions representing each permutation of the MABT components described above being included or excluded from the base treatment (BT). The BT will include only the key behavioral treatment components of CBT to avoid overlap between CBT cognitive or emotional ingredients and MABT component skills. Our primary aim is to evaluate the independent efficacy of mindful awareness, distress tolerance, emotion modulation, and values-based decision making on disordered eating symptoms (at post-treatment and 6- and 12-month follow-ups) over and above the key behavioral treatment components of CBT. Our secondary aims are to (a) test target engagement of each MABT component, that is, confirm that each component impacts the variable which it targets and that improvements in these are associated with improvements in outcomes, and (b) test the hypotheses that the efficacy of each component is moderated by related baseline weaknesses (e.g., individuals with worse distress tolerance at baseline are most likely to benefit from conditions that include the distress tolerance component). Our exploratory aim is to quantify the component interaction effects, which may be synergistic (because components complement each other), fully additive (because each component adds its total independent contribution), or partially additive (because components overlap and/or there is diminishing return). The current study will allow us to identify which commonly used MABT components are most effective for enhancing self-regulation and reducing ED symptoms, and set the stage for MOST Phase III in which a MABT package containing only effective components will be compared to a full CBT package.

2 | METHOD

2.1 | Study design

To accomplish the factorial design, we will randomize 256 participants to one of the 16 treatment conditions described above. Since the factorial design pools conditions to examine each main and interaction effect, all analyses will be fully powered and compare one set of 128 participants (those receiving the component) to another set of 128 participants (those not receiving the component). For all conditions, treatment will be delivered in 16 weekly individual outpatient therapy sessions over a period of approximately 4 months. As per Table 1, each component "On" (i.e., included in the condition) will add 10 min of weekly session time dedicated specifically to introducing, teaching, and reviewing component skills and strategies (for a total of 160 dedicated treatment minutes per component, evenly spread over 16 sessions). Thus, the simplest treatment (i.e., BT) will use 45-min weekly sessions and the most complex treatment with all four MABT components "On" will use 85-min weekly sessions. In this way, the amount of time devoted to core behavioral skills will be held constant at 12 total treatment hours (e.g., on average, 45 min per session for 16 sessions). Additionally, by using this approach, the amount of session time devoted specifically to introducing, teaching, and reviewing each MABT component (160 min, or slightly over 2.5 hr) will be consistent across cells for which that component is "On," thus allowing the factorial design to collapse across cells without concerns about inequal amounts of time devoted to each component in different conditions. Of note, as the MABT components are designed to facilitate behavior change, clinicians will also be encouraged to integrate behavioral and MABT components. For example, in the BT + distress tolerance condition, although 160 min are formally allotted to introducing new skills and strategies specific to distress tolerance, clinicians will

TABLE 1 The 16 conditions of a full (2 × 2 × 2 × 2) factorial design

| Cell # | Treatment condition | Treatment components | | | | Session length |
		Mindful awareness	Distress tolerance	Emotion modulation	Values decision making	
1	BT (behavioral treatment) only	Off	Off	Off	Off	45 min
2	BT + M (mindful awareness)	**On**	Off	Off	Off	55 min
3	BT + DT (distress tolerance)	Off	**On**	Off	Off	55 min
4	BT + EM (emotion modulation)	Off	Off	**On**	Off	55 min
5	BT + V (values decision making)	Off	Off	Off	**On**	55 min
6	BT + M + DT	**On**	**On**	Off	Off	65 min
7	BT + M + EM	**On**	Off	**On**	Off	65 min
8	BT + M + V	**On**	Off	Off	**On**	65 min
9	BT + DT + EM	Off	**On**	**On**	Off	65 min
10	BT + DT + V	Off	**On**	Off	**On**	65 min
11	BT + EM + V	Off	Off	**On**	**On**	65 min
12	BT + M + DT + EM	**On**	**On**	**On**	Off	75 min
13	BT + M + DT + V	**On**	**On**	Off	**On**	75 min
14	BT + M + EM + V	**On**	Off	**On**	**On**	75 min
15	BT + DT + EM + V	Off	**On**	**On**	**On**	75 min
16	BT + M + DT + EM + V	**On**	**On**	**On**	**On**	85 min

also be encouraged to suggest using distress tolerance skills when relevant to facilitate compliance with BT recommendations (e.g., using willingness to adhere to a regular eating schedule). Manuals will include suggested integrations to help ensure that integrating behavioral and MABT components occurs at similar frequency across components.

MABT component content will be drawn from existing manuals developed by Drs. Juarascio (K23MH105680, R01DK117072) and Forman (R01DK119658) for other grant-funded projects evaluating MABT approaches. These manuals themselves drew content from approaches such as MB-EAT (Kristeller, Wolever, & Sheets, 2013), ACT (S. C. Hayes, Strosahl, & Wilson, 2012), and DBT (M. M. Linehan, 1987). Clinicians will receive intensive training in all components and how they are assembled in each condition. Weekly clinical supervision will be provided throughout treatment by licensed psychologists. Therapy sessions will be video recorded and monitored for the proportion of time spent on each component, as well as treatment competence, fidelity, and contamination for 25% of sessions. Assessments will occur at baseline, mid-treatment (after session 8), post-treatment (after session 16), and at 6- and 12-month follow-ups.

2.2 | Participants

Adults aged 18–70 who report at least 12 objective or subjective binge episodes (i.e., eating either an unambiguously large amount of food or an amount deemed large only by the patient combined with a sense of loss of control over eating; Fairburn et al., 2008) in the past 3 months and who otherwise meet *DSM-5* criteria for an ED

(e.g., BED, BN, Anorexia binge/purge subtype, Other Specific Feeding or Eating Disorder) will be recruited from the community. Participants will be screened by phone to assess preliminary eligibility and psychiatric comorbidity using the Mini International Neuropsychiatric Interview (Sheehan et al., 2015). Potentially eligible participants will then provide informed consent and complete the Eating Disorder Examination (EDE; Cooper & Fairburn, 1987) to determine study eligibility. EDE assessors are trained until reaching acceptable reliability (i.e., >.80) on scoring and 100% agreement on ED diagnosis. Individuals will be excluded if they have a body mass index (BMI) < 16, are already receiving ED treatment, require immediate treatment for medical complications resulting from ED symptoms, or are experiencing other severe psychopathology that would limit their ability to comply with the current study's demands (e.g., severe depression with suicidal intent, active psychotic disorder).

2.3 | Base behavioral treatment

The behavioral skills from Fairburn's 2008 CBT manual (Fairburn et al., 2008) form the BT. We retained (a) self-monitoring of food intake and ED symptoms, (b) weekly in-session weigh-ins, (c) regular eating (i.e., scheduling eating episodes at regular intervals throughout the day), (d) reducing dietary restraint (i.e., eating both a sufficient amount of food at each meal or snack to prevent acute hunger and eating a sufficient range of food, including foods the patient may fear eating, to reduce feelings of deprivation), (e) urge management skills such as scheduling alternative activities during high risk times, (f) binge analysis and proactive problem solving, and (g) reducing body

checking and avoidance behaviors. We removed cognitive or emotional ingredients of CBT that might overlap with skills included in the components being tested (e.g., specific mood management strategies, recommendations to build in valued life activities outside of the ED).

3 | MEASURES

3.1 | Primary outcome measures

The EDE is a widely utilized, semi-structured interview for assessing ED symptoms. We will use *frequency of objective and subjective binge episodes in the last 28 days* and *EDE global scores* as the primary outcomes. *Remission status* will also be evaluated at each assessment following the baseline assessment, defined as the absence of any binge episodes or compensatory behaviors in the 28 days prior to the assessment point and an EDE global score within 1 standard deviation of the community norm (<1.74; Fairburn et al., 2009). We will also assess *BMI* to ensure weight remains in a healthy range (or reaches a healthy range for individuals who are underweight at the start of treatment) and *compensatory behaviors in the last 28 days* as secondary outcome variables.

3.2 | Target engagement, moderator, and interaction effect variables

3.2.1 | Mindful awareness

Mindful awareness will be assessed using three self-report scales: (a) the Five Facet Mindfulness Questionnaire, which assesses five factors representing elements of mindfulness (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2016); (b) the Reliance on Hunger and Satiety Cues subscale of the Intuitive Eating Scale, which measures the tendency to follow physical hunger and satiety cues when making eating-related decisions (Tylka & Kroon Van Diest, 2013); and (c) the Toronto Alexithymia Scale, which assesses difficulty identifying and describing emotions and the tendency to focus attention externally (Bagby, Parker, & Taylor, 1994).

3.2.2 | Distress tolerance

Distress tolerance will be assessed using the Nonjudging of Inner Experience subscale of the self-report Five Facet Mindfulness Questionnaire (Baer et al., 2016). Behaviorally, distress tolerance will be assessed using the Eating Disorder Affect Tolerance Scale, which measures the inability and/or unwillingness to endure negative emotional experiences pertaining to ED symptoms and beliefs about the self (Manasse, 2017).

3.2.3 | Emotion modulation

Emotion modulation will be assessed using three self-report scales: (a) the eating for physical rather than emotional reasons subscale of the Intuitive Eating Scale (Tylka & Kroon Van Diest, 2013); (b) the short form of the Affect Lability Scale, which assesses change across various modalities of affective functioning (Oliver & Simons, 2004); and (c) the DBT Ways of Coping Checklist, which assesses use of adaptive coping skills in difficult situations (Neacsiu, Rizvi, Vitaliano, Lynch, & Linehan, 2010).

3.2.4 | Values-based decision making

Values-based decision making will be assessed using three self-report scales: (a) the Engaged Living Questionnaire, which assesses the process of engaged and valued living (Trompetter et al., 2013); (b) the Quality of Life Inventory, which assesses an individual's attached importance to and current satisfaction with each of 16 life domains (Frisch, 1994); and (c) the beliefs about Appearance Scale, which assesses dysfunctional attitudes regarding appearance hypothesized to be unique to EDs (Spangler & Stice, 2001).

3.3 | Statistical analyses

Across all analyses, we will examine patterns of missing data. Both likelihood-based estimation methods and multiple imputation models will be used to handle missing data (Yuan, 2010). Power calculations revealed that a sample size of 256 is adequate for the analyses described below while allowing for up to 15% attrition. Baseline characteristics will be compared between the MABT components and their combinations using ANOVA (or non-parametric Kruskal Wallis test, as appropriate) for continuous variables and a chi-square test for categorical variables. Key baseline variables that differ by condition will be considered for use as covariates in the analyses described below.

3.3.1 | Primary aim: Evaluating component independent efficacy

To evaluate the effect of each MABT component on primary outcomes, we will model the pattern of change in binge frequency and EDE global scores separately over time using multilevel models (Raudenbush & Bryk, 2002). The cross-level interaction between time and the MABT component (e.g., Mindful awareness) will be used to determine the effect of the MABT component on the pattern of change in the primary outcomes.

3.3.2 | Secondary aim 1: Assessing component target engagement

To test whether each MABT component impacts the variable it targets, we will conduct mediation analysis to determine whether temporally-precedent changes in the MABT component mediate

differences in the primary outcomes between the two conditions for which the corresponding MABT component is turned "On" and "Off" (Andrew F. Hayes & Preacher, 2014; Kristopher & Andrew, 2004). In particular, we will examine improvement in each MABT component from baseline to mid-treatment assessment predicting post-treatment outcomes and improvement at post-treatment predicting 6-month and 12-month follow-ups.

3.3.3 | Secondary aim 2: Testing moderators

Potential moderators will be added to the multilevel models described in primary aim, and allowed to interact with component, to determine whether baseline scores on the same component moderate the effect of each MABT component on the primary outcomes (Andrew F Hayes & Rockwood, 2017).

3.3.4 | Exploratory aim: Evaluating component interaction effects

To test component interaction effects, higher-order interaction terms (e.g., three-way interaction between mindful awareness, distress tolerance, and time) will be added to the multilevel models outlined in primary aim.

4 | CONCLUSIONS

The current study will provide critical information regarding the independent and interacting effects of specific MABT components on ED symptoms, the mechanisms of action of MABTs for individuals with binge eating, and for whom these MABT components may confer the greatest benefit.

CONFLICT OF INTEREST
The authors declare no potential conflict of interest.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID
Christina R. Felonis https://orcid.org/0000-0002-9964-2331

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