

Diagnosis and management of binge eating disorder

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This paper addresses current issues regarding the diagnosis and management of binge eating disorder (BED). Controversies in diagnosis include the lack of empirically validated criteria, the lack of a universally recognized operational definition of a "binge episode", and the lack of age-appropriate assessment instruments in light of growing reports of BED among children and adolescents. For adults with BED, several pharmacological and behavioral treatments have shown promise in reducing binge frequency and related psychological symptoms of disordered eating (i.e., disinhibition, hunger, depressed mood). Second-generation antidepressants and cognitive behavioral therapy are among the most widely studied treatments. However, no behavioral interventions have demonstrated efficacy with respect to weight loss (which is a critical concern for many BED sufferers who are overweight). Furthermore, randomized controlled trials for BED have been plagued by high drop out and placebo response rates, as well as by insufficient follow-up after active treatment ends to determine long-term outcomes. Therefore, the long-term utility of the various intervention strategies studied thus far remains unclear. More research is needed on innovative medications and behavioral treatments that explore novel modalities to reduce the subjectively reinforcing properties of binge eating. In addition, expanded use of information technologies may be particularly instrumental in the treatment of patients who experience marked shame, denial, and interpersonal deficits, or who face limited access to specialty care. Ultimately, examining BED within the broader context of the current obesity epidemic will be an important area of study.

Key words: Binge eating disorder, diagnostic criteria, antidepressants, behavioral therapy, information technologies

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The symptom of binge eating was first identified by Stunkard in 1959 (1). However, the syndrome of binge eating disorder (BED) has not yet achieved official diagnostic recognition and remains a syndrome in need of further study in the DSM-IV-TR (2).

DIAGNOSIS OF BED: CONTROVERSIES AND EVOLVING ASSESSMENT STRATEGIES

The diagnostic criteria for BED are listed in Table 1. Similar to bulimia nervosa (BN), the definition of a binge eating episode requires the consumption of an unusually large amount of food coupled with a sense of feeling out of control. Also as in BN, the frequency criterion is twice per week, although this criterion is not well supported by the literature for BN and has not been validated for BED (3,4). Where BN and BED diverge is that individuals with BED do not regularly engage in compensatory behaviors (i.e., purging, laxative abuse, excessive exercise), although the precise boundary between BED and non-purging BN is far from clear. In addition, to meet criteria for BED, the binge episodes are associated with at least three of the following criteria: a) eating more rapidly than normal; b) eating when not physically hungry; c) eating until uncomfortably full; d) eating alone because of shame; and e) feeling disgusted with oneself, depressed or guilty after overeating (2). Finally, the individual experiences marked distress regarding binge eating. Although some of these criteria date back to the DSM-III criteria for bulimia, none have been empirically validated for BED.

Given the concern with proliferation of categories in the DSM, experts have proposed guidelines to consider before adding a syndrome to the DSM. Blashfield et al (5) pro-

Table 1 DSM-IV-TR diagnostic criteria for binge eating disorder

A. Recurrent episodes of binge eating

An episode of binge eating is characterized by both of the following:

1. Eating, in a discrete period of time (e.g., within any 2-hour period), an amount of food that is definitely larger than most people would eat in a similar period of time under similar circumstances
2. The sense of lack of control over eating during the episode (e.g., a feeling that one cannot stop eating or control what or how much one is eating)

B. Binge-eating episodes are associated with three (or more) of the following:

1. Eating much more rapidly than normal
2. Eating until feeling uncomfortably full
3. Eating large amounts of food when not feeling physically hungry
4. Eating alone because of being embarrassed by how much one is eating
5. Feeling disgusted with oneself, depressed, or very guilty after overeating

C. Marked distress regarding binge eating is present

D. The binge eating occurs, on average, at least 2 days a week for 6 months

(Note: The method of determining frequency differs from that used for bulimia nervosa; future research should address whether the preferred method of setting a frequency threshold is counting the number of days on which binges occur or counting the number of episodes of binge eating)

E. The binge eating is not associated with the regular use of inappropriate compensatory behavior (e.g., purging, fasting, excessive exercise, etc.) and does not occur exclusively during the course of anorexia nervosa or bulimia nervosa

posed five taxonomic guidelines: a) there should be sufficient journal and empirical articles published on the proposed syndrome within the last 10 years; b) explicit diagnostic criteria should have been proposed in the literature and measurement procedures exist for assessing the syndrome; c) at least two empirical studies (by independent research groups) demonstrate good inter-rater reliability; d) the category represents a syndrome of frequently co-occurring symptoms; and e) at least two independent, empirical studies demonstrate that the proposed category can be differentiated from other categories with which it may be con-

fused. Although substantial work has been done on BED, not all of these guidelines have been adequately addressed.

Over the past decade, the magnitude of research focusing on BED has increased substantially (6). A variety of self-report inventories, such as the Binge Eating Scale (BES) (7), the Three Factor Eating Questionnaire (8) and the Body Shape Questionnaire (9), as well as interview methods, such as the Structured Clinical Interview for the Diagnosis of DSM Disorders (SCID, 10) and the Eating Disorders Examination (EDE) (11), have been developed to assess binge eating in adults. However, attempts are still ongoing to refine the definition of a binge episode and to develop valid and reliable diagnostic criteria for BED. Researchers and clinicians are often unsuccessful in assessing what is an *unusually large amount of food* (12). First, they are inconsistent in recognizing bouts of overeating from grazing (i.e., eating continuously throughout the day instead of eating planned meals) and in deciphering what constitutes a truly large portion size from normal behavior, overindulgence, or circumstances (e.g., holiday). These inconsistencies make it difficult to determine the true number of binge episodes experienced by a patient or research participant. Second, researchers and clinicians (as well as patients) are unreliable in determining if loss of control was present during the binge eating episode (12). Because of subjective differences in the definition, loss of control is difficult to measure. Some individuals may report loss of control after eating a small amount of food (e.g., one cookie), whereas others may only experience a sense of loss of control after a much larger amount of food (e.g., a box of cereal). The EDE has a method for classifying types of overeating. An objective binge episode is one in which the amount eaten would be defined as relatively large (judged by the interviewer) and includes the patient's report of loss of control during the episode. A subjective binge episode is not viewed as large by the interviewer but the patient still reports loss of control. For example, the patient may have eaten a regular size candy bar but may have intended to only eat half of it. Alternatively, subjects may be classified with overeating episodes (either objective or subjective) when they do not experience loss of control over eating.

Although initially conceptualized primarily to be a disorder of adulthood, there is growing recognition that BED also occurs in adolescents and children. Such recognition has propelled the development of age-appropriate and age-relevant assessment measures. Assessment measures for children include the Eating Disorders Examination adapted for children (ChEDE) (13) and the Questionnaire of Eating and Weight Patterns - Adolescent version (14). Researchers have posited that broader, flexible criteria be used to measure BED in children (15-17), and Marcus and Kalarchian (15) recently proposed provisional criteria for measuring BED in children (see Table 2) based on a review and synthesis of findings from previous research studies. On the basis of these criteria, Shapiro et al (18) developed a brief structured, interviewer-administered scale (Chil-

Table 2 Provisional research criteria for diagnosing binge eating disorder in children (from 15)

A. Recurrent episodes of being eating

An episode of binge eating is characterized by both of the following:

1. Food seeking in absence of hunger (e.g. after a full meal)
2. A sense of lack of control over eating (e.g., endorse that "When I start to eat, I just can't stop")

B. Binge episodes are associated with one or more of the following:

1. Food seeking in response to negative affect (e.g., sadness, boredom, restlessness)
2. Food seeking as a reward
3. Sneaking or hiding food

C. Symptoms persist over a period of 3 months

D. Eating is not associated with the regular use of inappropriate compensatory behaviors (e.g., purging, fasting, excessive exercise) and does not occur exclusively during the course of anorexia nervosa or bulimia nervosa

dren's Binge Eating Disorder Scale, C-BEDS) to measure BED in children aged 5-13. Results showed a strong association between diagnoses from the C-BEDS and SCID. However, the C-BEDS may be more developmentally appropriate for children and better able to identify subsyndromal BED. If used by physicians and other health providers, this brief measure may assist with identifying early onset binge eating behaviors and avoiding the associated consequences, including adult BED, obesity, and associated comorbidities.

MANAGEMENT OF BED

Goals for treatment

The primary goal for BED treatment is to achieve abstinence from binge eating. In overweight individuals with BED, treatment goals are often twofold: abstinence from binge eating and sustainable weight loss. Given comorbidity profiles, treatment must also often target anxiety and depression commonly associated with BED.

The literature on BED treatment covers a wide range of putative therapeutic agents and modalities. Those with the most substantial empirical support to date include the use of certain medications and certain behavioral interventions, alone or in combination. Evidence supporting self-help and other approaches is less strong (19,20).

Treatment approaches

Pharmacotherapy

The medications most widely studied thus far in randomized controlled trials (RCTs) include second-generation antidepressants (21-25), tricyclic antidepressants (26), anticonvulsants (27), and sibutramine (28). However, the majority of published RCTs have been limited in scope,

with samples being relatively small (fewer than 500 total participants in eight medication RCTs comprising primarily Caucasian women over age 18).

Among selective serotonin reuptake inhibitors (SSRIs), fluoxetine and fluvoxamine have received the most attention thus far. After 12 weeks, both fluoxetine (average dose 71.3 mg/day) (21) and fluvoxamine (average dose 239 mg/day) (22) were associated with reduced binge frequency and depressed mood. Using a larger sample (85 BED patients) but a shorter treatment period (9 weeks), Hudson et al (24) reported a significantly greater rate of reduction in binge frequency and body mass index (BMI) as well as greater improvement in illness severity with fluvoxamine (50-300 mg/day) compared to placebo. However, fluvoxamine did not demonstrate superiority over placebo in terms of remission rate or change in depression scores. Moreover, end-point BMI was not reported. Thus, the group receiving fluvoxamine experienced more rapid reductions in binge eating and weight than the placebo group, but these changes did not appear to yield clinically significant effects with respect to binge abstinence and weight loss.

Sertraline and citalopram also show some promise in the treatment of BED. In two 6-week treatment trials, McElroy et al studied the effects of sertraline (mean dose 187 mg/day) versus placebo (23) and citalopram (40-60 mg/day) versus placebo (25) on binge frequency, weight, and mood in individuals with BED. Compared with placebo, both sertraline and citalopram were associated with reduced binge eating, weight loss, and illness severity ratings, but neither medication was clearly superior to placebo in terms of remission rate, and the initial rapid response in binge eating observed with citalopram was not sustained over time. Citalopram, but not sertraline, was associated with reduced depression ratings compared to placebo.

Tricyclic antidepressants are also of interest in the treatment of BED. Laederach-Hoffmann et al (26) studied 31 overweight individuals with BED over a 32-week period, providing standard bi-weekly diet counseling and psychological support augmented with either imipramine (25 mg three times a day) or placebo. At 8 and 32 weeks, binge eating episodes, depressed mood, and body weight decreased significantly in the imipramine-treated group. However, abstinence rates from binge eating were not reported.

Medications that suppress appetite directly or that are associated with weight loss as a side effect have also been examined in the treatment of BED. Examples include the anticonvulsant agent topiramate, which is associated with weight loss in some patients, and sibutramine, which is marketed for the treatment of obesity. In a recent study, topiramate (average dose 212 mg/day) was administered for 14 weeks to obese individuals with BED with a score greater than 15 on the Yale-Brown Obsessive Compulsive Scale for Binge Eating (YBOCS-BE) (27). Relative to placebo, topiramate yielded a significantly greater percentage reduction in binge episodes, binge days per week, and YBOCS-BE score, but did not differ with respect to weight loss, illness severity,

or depression. Appolinario et al (28) studied the effects of 12 weeks of sibutramine treatment (15 mg/day) in individuals with BED and a BES score of at least 17. The sibutramine-treated group showed significantly greater decreases in binge days per week, BES scores, and self-reported depression scores compared to the placebo group. At week 12, the sibutramine group had lost on average 7.4 kg, whereas the placebo group had gained weight.

In summary, pharmacotherapy can be useful in the treatment of BED. Specifically, certain second-generation antidepressants, anticonvulsants, and anti-obesity medications have been associated with reduced binge frequency and in some cases reduced negative affect in individuals with BED. However, overall, studies have been hampered by high drop out and placebo response rates and by the failure to measure abstinence as a primary outcome and to report long-term post-intervention data. These limitations make it difficult to estimate the magnitude of clinical significance of any observed effects attributed to medication. Further study will be needed to determine the full utility and limitations of pharmacotherapy in the treatment of BED.

Behavioral therapy

Cognitive-behavioral therapy (CBT) has been the most commonly tested behavioral therapeutic approach for BED (29-31). Other approaches include dialectical behavior therapy (DBT), self-help, exercise, and virtual reality therapy (32-38). Studies have examined the effect of CBT alone as well as in combination with other manipulations concerning the level of spousal or therapist involvement or complementary body exposure treatment. The majority of behavioral therapy trials have enrolled relatively small samples of individuals with BED, usually female and over 18 years of age.

CBT for BED is rooted in the idea that inaccurate thoughts (about body image, for example) lead to inappropriate food consumption (i.e., excess quantity in a short time with accompanying feelings of loss of control), and that learning to adjust or restructure one's binge-triggering thoughts can reduce binge behavior. CBT can be delivered one-on-one or in a group setting, independently or in combination with other psychotherapy approaches.

Several studies have shown that CBT reduces binge frequency, related psychological aspects of binge eating (restraint, disinhibition, and hunger), depressed mood, and ratings of illness severity in individuals with BED (29-31). CBT may also increase the likelihood of abstinence from binge eating (31). However, CBT does not appear to lead to significant changes in body weight. Moreover, augmentation strategies such as CBT plus increased spousal involvement with therapy (31) or body exposure treatment (30) have not revealed any clear advantages over CBT alone. Thus, as currently conceptualized, CBT may be effective in helping patients improve their sense of control over binge eating behavior, but not over their weight concerns.

DBT fosters the development of skills in the domains of mindfulness, emotion regulation, interpersonal effectiveness, and distress tolerance. One study suggests that DBT principles may be useful in the management of BED. Telch et al (32) studied 20 weeks of DBT versus waiting list control in 44 women with DSM-IV BED. DBT led to greater reduction in binge days and binge episodes and in weight, shape, and eating concerns. However, the two groups did not differ in weight loss or in change in depression or anxiety.

Several studies have examined the effect of self-help strategies in BED. Interventions have been delivered in various formats, including with and without a facilitator or therapist, with or without structure, etc. Carter and Fairburn compared self-help using a book (33) with waiting list control in 72 women with BED and weekly binges (34). Self-help (both with and without a facilitator) led to greater reductions in the mean number of binge days and in clinical severity, while also improving abstinence and cessation rates and EDE scores. However, self-help did not produce significant weight loss in either group. Adding a facilitator had no appreciable effect over self-help alone. Similarly, Peterson et al (35,36) found self-help, regardless of the degree of facilitator involvement, to be beneficial in terms of reduced binge behavior, improved eating attitudes, and higher abstinence rates, but not in terms of reducing depression scores or BMI.

Other “alternative” approaches such as exercise (37,38) and virtual reality therapy (39) are beginning to be explored in the treatment of BED, but currently sufficient data do not exist to make any recommendations.

In summary, behavioral therapies offer some promise in the treatment of BED. CBT, DBT and self-help approaches are all associated with reductions in binge behavior, but the clinical significance of these findings remains uncertain in the absence of data on abstinence during active treatment and longer-term follow-up. Moreover, as examined to date, these behavioral therapies do not result in marked weight loss, which is a critical concern for the significant number of BED sufferers who are overweight. Somewhat paradoxically, there is some indication that drop out during self-help intervention may be inversely related to the degree of involvement by a professional facilitator/therapist. Further studies are needed to clarify these observations.

Combining pharmacotherapy and behavioral therapy

Several studies have examined the potential benefit of combining medication with behavioral treatment vs. either therapy delivered alone in the management of BED.

In their 16-week trial, Grilo et al (40) compared fluoxetine (60 mg/day) versus placebo either alone or with CBT. Results indicated that CBT plus fluoxetine (as well as CBT alone) was superior to fluoxetine alone and placebo in remission rate and in reducing binge frequency, eating and shape concerns, disinhibition, and depression. Weight loss did not differ across groups, however.

Agras et al (41) evaluated the effects of traditional weight loss therapy alone vs. CBT supplemented with weight loss therapy vs. CBT supplemented with weight loss therapy plus desipramine (300 mg/day). Binge eating was significantly reduced after 12 weeks in both groups receiving CBT; however, this effect did not persist at 36 weeks of treatment. Average weight loss was greatest in the weight loss therapy group in the early stages of treatment, but over time (i.e., at 3-month follow-up) the group receiving desipramine lost the most weight. Desipramine showed no clear advantage in reducing symptoms of depression.

Grilo et al (42) investigated the effect of CBT alone and in combination with the lipase inhibitor orlistat (120 mg three times/day) in 50 obese individuals with BED. CBT plus orlistat was associated with greater initial weight loss and a greater remission rate after 12 weeks of treatment. However, these potential benefits were not accompanied by any improvements in eating-related measures or depression, and they were not maintained at 2-month follow-up.

Taken together, these studies suggest that augmentation of CBT with certain medications may provide additional benefit over CBT alone or medication alone strategies in the early stages of BED treatment. However, the long-term benefit of such combined approaches is less certain.

Treatment harms and factors contributing to treatment efficacy

Throughout the BED treatment literature, the most commonly reported harms were those associated with the side effects of second-generation antidepressants, such as sedation, dry mouth, headache, and sexual dysfunction/decreased libido (43). In the studies reviewed here, for example, compared to placebo, insomnia was more pronounced in those receiving fluvoxamine or sertraline, and constipation was more pronounced in those receiving sibutramine or imipramine. Other side effects, such as nausea, sweating and fatigue, dry mouth, blurred vision, and gastrointestinal upset, were also reported. Notably, 24% of individuals treated with desipramine and 20% of individuals treated with topiramate dropped out due to medication side effects. Harms associated with psychotherapy are not reported as frequently, but may include increased mood dysregulation after cessation of active treatment, and should be monitored and given appropriate attention.

Specific factors that contribute to treatment efficacy in BED are not well understood. Limited data suggest that early abstinence from binge eating is associated with significantly greater weight loss (41), and that higher initial self-esteem may account for a small but significant percent of variance in outcome (33). There are deficiencies in the research literature regarding treatment efficacy by subgroups, as well. In general, males, ethnic minorities, and children are understudied. Initial findings require replication, and larger more culturally diverse samples need to be

studied before an accurate picture of individual difference factors in BED outcome can emerge.

Treatment drop out and placebo response

Our understanding of treatment options for BED is limited by several consistent methodological problems in the research literature: drop out and placebo response rates that are often high and unevenly distributed across treatment groups, and the failure to report abstinence rates and long-term follow-up data. Among pharmacotherapy trials reviewed here, drop out rates ranged from a low of 7% (with imipramine) to a high of 57% (with fluoxetine); rates for citalopram (16%), fluvoxamine (20%), sibutramine (23%), orlistat (24%), sertraline (28%), and topiramate (47%) were intermediate. Placebo response rates were also highly variable (6% to 39%). In psychotherapy trials, drop out was also extensive and highly variable, and not always consistent with hypothesized effects of the therapeutic manipulation (i.e., facilitator involvement). Across studies, drop out from CBT (14% to 34% in studies reviewed), DBT (18%), and self-help (0% to 27%) was on par with or perhaps slightly lower compared to certain pharmacotherapies, particularly fluoxetine, suggesting good acceptability of these treatment approaches to most patients. Evidence that combination therapies are more or less acceptable and tolerable for patients is mixed, including improved drop out from weight loss therapy plus CBT vs. weight loss alone (41), but not from treatment with fluoxetine plus CBT vs. fluoxetine alone (40). Lastly, the vast majority of published treatment trials have not followed participants for extended periods after acute treatment ends, so that the utility of these interventions in the long-term management of BED is uncertain.

CONCLUSIONS

Several issues regarding the diagnosis and management of BED remain open to research. Controversies in diagnosis include the lack of empirically validated criteria, the lack of a universally recognized operational definition of a "binge episode", and the lack of age-appropriate assessment instruments to be used in children and adolescents with BED.

Short-term, placebo-controlled medication-only trials provide limited evidence that SSRIs can be useful in reducing target eating, psychiatric, and weight symptoms in individuals with BED. However, this evidence must be viewed tentatively, because it is derived from a collection of studies plagued by high drop out and placebo response rates. Non-SSRI agents such as sibutramine and topiramate may also be beneficial in terms of weight reduction among individuals with BED, but definitive conclusions about their longer-term clinical utility await further details regarding abstinence and remission. Similarly, more stud-

ies are needed to confirm the therapeutic potential of low-dose imipramine to augment more traditional weight management and psychotherapy strategies.

In terms of behavioral interventions, CBT is effective in reducing binge frequency (whether reported as binge days or binge episodes) and in improving the psychological features of BED such as restraint, hunger, and disinhibition. CBT's effect on binge frequency, in particular, apparently leads to greater rates of sustained (up to four months after treatment) abstinence. The validity of CBT for reducing symptoms of depression in this patient population is unclear. Likewise, additional studies are needed to confirm the findings of decreased binge eating, eating-related psychopathology, and negative mood with DBT. Self-help approaches may provide viable alternatives, as they have shown efficacy in decreasing binge eating and key psychological features associated with BED. Abstinence from binge eating may hinge on treatment expectancies about weight loss and improved mood – the practitioner must be savvy about these treatment limitations, convey them through patient education, and monitor their impact on long-term adherence. Although non-weight focused behavioral strategies may not promote significant weight loss, they may be associated with less weight gain over time in individuals with BED. The importance of weight maintenance vs. weight loss or gain in treatment adherence and remission warrants further study. Finally, to date, most behavioral studies have suffered from marked drop out, thus our understanding of CBT as well as other behavioral therapies for the treatment of BED is still limited. Specific unaddressed questions include whether calories previously consumed as binges become distributed over nonbinge meals after treatment, which would contribute to the absence of weight change in CBT, and whether treatment alters the way in which patients label binges and nonbinge meals.

Questions remain as to the added benefit of combining pharmacological and psychotherapy approaches (i.e., medication plus CBT), which improve both binge eating and weight loss outcomes. Specifically, additional studies are needed to determine which medications given under which circumstances and to which patients optimally produce and maintain weight loss. Because weight-loss medications generally exert their effects only during active treatment (44), questions remain about pharmacotherapy duration and its relation to remission of behavioral and psychological symptoms and to long-term weight outcome. In addition, further studies are needed to better understand factors that serve as binge triggers (i.e., food cravings, mood) (45).

In order to move our understanding of BED treatment forward, new methods that enhance motivation and retention in medication trials need to be developed, and optimal strategies for maintaining treatment gains must be determined. The metric by which we evaluate treatment success must also be refined and standardized to focus on abstinence from binge eating (not merely reduced binge frequency) as the critical outcome. In addition, abstinence

should be evaluated independent of weight loss, yet weight loss must not be overlooked as a potentially significant moderator of long-term adherence and treatment satisfaction. Studies that target relapse prevention in BED also warrant a high research priority. Future studies should also carefully document and control for placebo response, which has been shown to be high (yet possibly transitory) in BED (22,46,47). Advances regarding treatment-resistant BED patients are likely to build on lessons learned from recent depression-treatment trials regarding potential drug augmentation and sequential medication benefits (48), and from ongoing and future studies targeting CBT non-responders. Finally, additional studies of DBT (for example, which can articulate which aspects of DBT are most applicable to the complex emotional and behavioral features of BED) are warranted.

Research is needed on innovative medications and behavioral treatments that explore novel modalities to reduce the subjectively reinforcing properties of binge eating. This likely includes new information technologies (such as e-mail, the Internet, personal digital assistants, text messaging, and other technological advances) that can be used to enhance treatment, particularly for those patients experiencing shame, denial, and interpersonal deficits or facing limited availability of specialty care. Our group (49) recently compared preliminary feasibility and acceptability of CD-ROM-delivered cognitive-behavioral therapy (CD-ROM CBT) to 10 weekly group CBT sessions and to a waiting list control in 66 overweight individuals with BED. Results were promising in terms of drop out and continued use of the CD after treatment. Also, the majority of waiting list participants elected to receive CD-ROM CBT over group CBT treatment at the end of the waiting period. Thus, preliminarily, CD-ROM appears to be an acceptable and at least initially preferred method of CBT delivery for overweight individuals with BED. The use of technology as a means of treatment delivery is emerging (50); further studies are needed in order to bridge the gap between clinical research and population-based delivery for the treatment of BED.

In summary, individuals with BED can benefit from pharmacotherapy and psychotherapy both alone and in combination. Greater clarity is required to determine how best to achieve both abstinence from binge eating and sustainable weight loss. As these stories unfold, important insights will likely emerge regarding BED and its place within the broader context of our current obesity epidemic (51,52).

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