Online Supplementary Material for:

Hilbert, A., Petroff, D., Neuhaus, P., & Schmidt, R. Cognitive-Behavioral Therapy for Adolescents with an Age-Adapted Diagnosis of Binge-Eating Disorder: A Randomized Clinical Trial.

Supplementary Text

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1. Supplementary Methods

The Binge-Eating Disorder in Adolescents (BEDA) study
The BEDA study is a single-center, assessor-blind, prospective, randomized superiority trial, evaluating the efficacy of cognitive-behavioral therapy (CBT, experimental condition) compared to a wait-list (WL) control condition in adolescents with an age-adapted diagnosis of binge-eating disorder (BED).[1] The BEDA study was registered at the German Clinical Trials Register (https://www.drks.de; Identifier: DRKS00000542). Ethical approval was granted by the Ethics Committee of Leipzig University (235-10-23082010).

Definition of binge-eating disorder in adolescence
In the BEDA study, age-adapted diagnostic criteria of BED were used, as it is still controversial as to whether the newly defined entity of BED in the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5)[1] and the former BED research criteria in the previous Fourth Edition DSM-IV-TR[2] adequately capture the presentation in youth.[3] Regarding the size of a binge, outside of objective binge-eating episodes which are definitional of BED in the DSM-5,[1] a substantial proportion of adolescents report subjective binge-eating episodes. Both objective and subjective binge-eating episodes, involving a sense of loss of control (LOC) over eating an objectively or subjectively large amount of food, also termed LOC eating or binge eating, have been demonstrated to be psychopathologically relevant,[4] and have been proposed for an age-adapted diagnosis of BED in youth, in addition to a lower frequency threshold of binge eating.[5] Thus, in the BEDA study, age-adapted diagnosis of BED (DSM-IV-TR, DSM-5) or BED of low frequency and/or limited duration (DSM-5) was based on binge eating (i.e. objective and/or subjective binge eating).

Inclusion and exclusion criteria
Inclusion criteria:
- Age 12-20 years
- Written informed consent of parent and assent of adolescent for adolescents ages <18 years, written informed consent of adolescent at ages ≥18 years
- Diagnosis of BED according to age-adapted criteria of (a) the DSM-IV-TR and (b) DSM-5, and (c) DSM-5 BED of low frequency and/or limited duration

(a) At least 2 days with binge eating (i.e., objective and/or subjective episodes of binge eating) per week over the past 6 months; at least 3 out of 5 behavioral indicators; marked distress; absence of regular compensatory behaviors to avoid weight gain; absence of anorexia nervosa and bulimia nervosa
(b) At least 1 episode of binge eating (i.e., objective and/or subjective binge eating) per week over the past 3 months; at least 3 out of 5 behavioral indicators; marked distress; absence of regular compensatory behaviors to avoid weight gain; absence of anorexia nervosa and bulimia nervosa
(c) All age-adapted DSM-5 criteria for BED are met, except the binge eating occurs on average less than once a week or for less than 3 months

Exclusion criteria:
- Current bulimia nervosa
- Current substance abuse
- Current suicidal ideation
- Psychotic disorder
- Bipolar disorder
- Serious unstable medical problems or conditions (e.g., type 1 diabetes mellitus or thyroid problems)
- Current intake of antipsychotic or weight-affecting drugs
- Current psychotherapy
- Current inpatient treatment
- Current behavioral weight loss treatment
- Pregnancy or lactation
- Lack of compliance with major study procedures
- Current participation in other intervention trials

Sample size calculation
Based on literature available at the time of trial design,[6,7] an effect size d = 1.0 for binge-eating improvement was assumed, meaning that 30 patients per group were to be recruited and 27 analyzed to have a power of 95%, using a *t* test as a conservative approximation. Because of a higher drop-out than anticipated, the sample size was increased to 72.

Randomization
After baseline assessment, patients were centrally randomized to CBT or WL at the Clinical Trial Center of the University of Leipzig, ensuring concealment of allocation. Using Pocock's minimization algorithm with a stochastic component,[8] the computer-assisted randomization was stratified by sex and age (12-15 and 16-20 years), with an allocation ratio of 1:1. A total of $n = 37$ adolescents were randomized into the CBT and $n = 36$ were randomized into the WL arm (see Table S1 for baseline characteristics).

Recruitment
Recruitment followed a population-based (e.g., sending information letters to households with children in the targeted age range, study website), school-based (e.g., educational classes, screening), and clinic-based strategy (e.g., placing flyers in the waiting area of pediatricians, psychiatrists, and the Outpatient Unit of the Integrated Research and Treatment Center AdiposityDiseases at Leipzig University Medical Center). The majority of included patients were recruited through population-based (55%, 40/73) and school-based (36%, 27/73) approaches, while a minority was recruited via medical institutions (10%, 7/73). Recruitment took place between April 2012 and August 2014, with final follow-up in April 2017.

Changes in relation to the published study protocol
- Omission of the secondary outcome "number of days with binge-eating episodes in the past 28 days" to reflect the changing focus of research and diagnostic criteria of BED.[1] Accordingly, it is not the days with binge-eating episodes that are relevant for diagnosis, but the number of binge-eating episodes (i.e., objective and/or subjective binge-eating episodes; amendment no. 5 to study protocol).
- The assessment time point "2 months after randomization/mid-treatment" is not reported in the present study, but will be reported in a treatment process analysis on CBT for adolescent BED. However, data on the number of binge-eating episodes at "2 month after randomization/mid-treatment" were used to model follow-up analyses for optimization of estimates.
- In addition to the 6- and 12-month follow-up, a 24-month follow-up is reported. The 24-month assessment was added after publication of the study protocol to document long-term efficacy of adolescent BED (amendment no. 5 to study protocol).
- The sample size was increased from $N = 60$ to $N = 73$, because drop-out rates were higher than anticipated (30 versus 20%) which was first observed over the course of the study and after publication of the study protocol (amendment no. 6 to study protocol).
- The exclusion criterion "inpatient psychiatric treatment within the past 3 months prior to screening" was changed to "ongoing inpatient treatment" to enable direct subsequent outpatient treatment after inpatient stay (amendment no. 3 to study protocol).
- Post-treatment data were only made available after the 24-month follow-up and not after the 12-month follow-up as the 24-month follow-up was added after publication of the study protocol (amendment no. 5 to study protocol).
- The Dutch Eating Behavior Questionnaire[9] was not analyzed as a secondary outcome in the current paper in order to reduce the number of variables tapping into the same construct (eating disorder psychopathology), which would require an alpha adjustment. Results on the DEBQ will be reported in a follow-up paper.
- The primary analysis of binge-eating episodes was changed and now follows common and accepted practice by using the number of binge-eating episodes at post-assessment as the dependent variable and the baseline value as one of the covariates. The ratio of binge-eating episodes at post-assessment to baseline is now used as the dependent variable in a sensitivity analysis, as technical considerations and accepted analysis techniques prohibited its use in the primary analysis.

Relevant publication: Hilbert A. Cognitive-behavioral therapy for binge eating disorder in adolescents: study protocol for a randomized controlled trial. Trials. 2013;14:312.

Measures
Primary outcome
Number of binge-eating episodes. The German version of the Eating Disorder Examination (EDE)[10,11] was used to assess the number of binge-eating episodes (i.e., objective and/or subjective binge-eating episodes) over the past 28 days at *post-assessment*, representing the end of treatment for those in CBT and the end of the waiting period for those in WL. The EDE is a semi-structured interview with established reliability and validity.[12] For the present sample, interrater reliability for binge-eating episodes was determined based on a random sample of $n = 19$ (26%) audiotaped EDEs which were independently coded by a trained research assistant. Interrater reliability for the number of objective and subjective binge-eating episodes was almost perfect with intra-class correlation (ICC) coefficients of .96 and 1.00, respectively. If necessary for younger patients, age-adapted language was used from the validated child version of the EDE.[13-15]

Secondary outcomes

Secondary outcomes included the number of binge-eating episodes (i.e., objective and/or subjective binge-eating episodes) over the past 28 days at 6, 12, and 24 months following CBT, as well as the number of objective binge-eating episodes over the past 28 days, abstinence from binge eating, remission from BED, eating disorder psychopathology, depressive symptoms, self-esteem, and quality of life as measured 4 months after randomization (*post-assessment*), and at *6-, 12-, and 24- month follow-up* after treatment. In addition, the wait-list (WL) control group received a diagnostic assessment following delayed CBT; thus, for both the CBT and the WL arm, a *post-treatment* assessment was available.

Number of objective binge-eating episodes. The EDE was used to determine the number of objective binge-eating episodes over the past 28 days.

Abstinence. Abstinence from binge eating was defined as zero binge-eating episodes (i.e., objective and subjective binge-eating episodes) over the past 28 days assessed through the EDE.

Remission. Remission from BED diagnosis was derived from the EDE and defined as not meeting age-adapted diagnostic criteria for BED according to DSM-5 and BED of low frequency and/or limited duration according to DSM-5. As the treatment and waiting phase were 4 months in duration, only the DSM-5 diagnoses, covering the past 3 months, and not the DSM-IV-TR diagnosis, covering the past 6 months, were considered at post-assessment in order to mirror treatment effects only, and not pre-study diagnoses.

Eating disorder psychopathology. Beyond its diagnostic items, 22 items of the EDE, answered on a 7-point Likert scale ranging from 0 to 6, with higher values indicating greater eating disorder psychopathology, measure restraint eating, eating concern, weight concern, and shape concern, were used to form a global mean score (α = .84, 95% CI .77 to .88). The ICC coefficient for the EDE global score indicated perfect interrater reliability with ICC = 1.00.

Depressive symptoms. The 21-item self-report Beck Depression Inventory-II[16,17] was used to measure depressive symptoms on a 4-point Likert scale. A higher global sum score, ranging from 0 to 63, indicates more severe depression (α = .93, 95% CI .88 to .95).

Self-esteem. The 10-item self-report Rosenberg Self-Esteem Scale (RSES)[18,19] was used to assess adolescents' self-esteem on a 4-point Likert scale. A higher global sum score, ranging from 10 to 40, indicates higher self-esteem (α = .90, 95% CI .87 to .93).

Quality of life. Responses on the 12-item Short Form Health Survey (SF-12)[20,21] were used to provide composite scores for physical (α = .32, 95% CI -.01 to .50) and mental health (α = .71, 95% CI .62 to .76) ranging from 0 to 100, with higher scores indicating higher level of health. Due to inacceptable internal consistency of the SF-12 physical composite score, only the SF-12 mental health composite score was reported.

Body Mass Index-standard deviation score. Body mass index (BMI, kg/m²) was derived from objectively measured body weight and height using calibrated instruments. By calculating BMI-standard deviation scores (SDS), BMI was standardized based on age- and sex-specific German reference data.[24] For the purpose of unification, patients aged 18-20 years (at baseline, 12/73 patients) were treated as if they were 18.0 years old when calculating BMI-SDS.

Mental disorders. The structured clinical interview Diagnostic Interview for Mental Disorders in Children and Adolescents (K-DIPS)[22] was used to determine current and lifetime comorbid mental disorders based on adolescents' report according to DSM-IV-TR. The K-DIPS was administered at baseline and 6- and 12-month follow-up. Mental disorders were classified into the following three categories: (1) attention, activity or social disorders including attention-deficit/hyperactivity disorder, oppositional defiant disorder, and conduct disorder; (2) anxiety disorders including separation anxiety disorder, selective mutism, specific phobia, social anxiety disorder, panic disorder, agoraphobia, generalized anxiety disorder, and posttraumatic stress disorder; and (3) affective disorders including major depressive disorder and dysthymia. Interrater reliabilities of the K-DIPS were substantial to almost perfect for current diagnoses and ranged between $.89 \leq \kappa \leq .98$.[23]

Treatment expectation and motivation. The expectation of the treatment to be successful and motivation were assessed prior to therapy on a scale ranging from 0 not at all to 10 very much.

The clinical interviews EDE and K-DIPS were conducted by trained raters. All raters were blind to the randomization and had no therapeutic relationship with the patients. They underwent extensive training for conducting the interviews and received ongoing supervision for standardized administration (drift prevention).

Treatment
Age-adapted CBT was derived from the evidence-based manual by Hilbert and Tuschen-Caffier.[25] All adolescents received individual CBT with 20 sessions of 50 minutes over 4 months. CBT consisted of an initial treatment phase for motivational enhancement; an intensive treatment phase with modules on eating behavior, body image, and stress; and a self-management phase for relapse prevention. Within the first month of treatment, 2 sessions per week were scheduled (sessions 1-8), while in months 2 to 4, 1 session per week was held (sessions 9-20). The age-adapted manual for adolescents with BED differed from the adult manual[25] by having: a greater number of motivating behavioral exercises with a low level of complexity; a decreased focus on cognitive interventions; a concentration on age-specific maintenance factors (e.g., difficulties in identity development) including familial factors (e.g., familial eating patterns); and a greater focus on enhancing an autonomous motivation for treatment, as treatment may be sought by third parties (e.g., parents). In the adolescent-focused treatment, parents received standardized information letters about BED, general intervention topics, and recommendations for daily routine on a monthly basis. Previous clinical trials suggested efficacy of adolescent-focused specialist treatment of BED symptomatology with limited or no parental involvement.[26-28] CBT was provided by 4 master's level female clinical psychologists with advanced training in CBT and specific training in CBT of BED, and was conducted under regular supervision by AH. Treatment fidelity and therapist adherence were further established using adherence control forms[29] based on audio documentation of the CBT sessions by two independent, trained raters using five randomly-selected tapes per patient (25% of sessions). Therapist adherence across CBT sessions was excellent.[30]

Wait-List control condition
After a waiting period of 4 months, patients of the WL arm were guaranteed CBT. They were instructed not to seek any other medical or psychological treatment for BED or obesity during the waiting period without informing the study team.

Data management
Data management was performed by the Clinical Trial Center of the University of Leipzig. Data were monitored for completeness, consistency, and plausibility. Post-treatment data were released after study completion only, and interim analyses were not conducted. Data analysis was performed between February 2018 and February 2019.

Safety
Adverse events were evaluated at each CBT session in verbal form. They were reviewed annually by an independent Data Monitoring and Safety Committee, composed of 2 experts in eating disorders and clinical studies conduct and 1 data analyst.
A total of 64 adverse events were reported in 25 patients, 2 of which were "serious adverse events" that were reported from the same patient (wrist-cutting). Both events were considered severe without being life-threatening and unrelated to CBT. The remaining adverse events were classified as severe (n = 12), moderate (n = 23), and mild (n = 27). Nine of the severe events were from a single patient reporting nausea, vomiting, migraine (twice), headache (thrice), cold, and a bug bite. Two of the remaining severe events were traffic accidents, and there was one instance of appendicitis, see Table S3.

Definition and sample characteristics of analyses sets
Intent-to-treat (ITT) sample. The ITT sample included all randomized patients (N = 73), regardless of whether or not they provided data.

Complete case (CC) sample. In the CC set, the number of binge-eating episodes was analyzed for all patients who provided data. At 4 months after randomization, n = 63 patients (CBT n = 28, WL n = 35) provided data on the primary outcome (cf. Table S2).

Modified complete case (mCC) sample. The modified CC set was used for follow-up analyses and included all patients who provided data at all assessment points with a maximum of 1 missing assessment point that was not baseline and 24-month follow-up. Since the mixed models used for follow-up analyses are largely unaffected by small numbers of missing data points in the middle of a time series, this allowed us to increase sample size while retaining the principle and certainty of a standard CC analysis.

Per protocol (PP) sample. The PP set was made up of the CC patients who attended at least 10 CBT sessions, provided binge-eating episode data at the end of treatment, and whose end of treatment visit was not more than 6 weeks later than the planned 4 months. The notion of PP is thus not applicable during the waiting period, and the CC set was used for a secondary analysis of the between-group treatment effects. Of the 37 patients in the CBT arm, 28 (76%) attended at least 10 therapy sessions. Of them, 23 patients additionally provided post-treatment

assessments within the time stipulated. In the WL arm, 29 (78%) patients started therapy after the waiting period, of whom 22 (61%) patients attended at least 10 therapy sessions. Of those, 19 patients provided post-treatment data as specified. Thus, the PP set was made of $n = 42$ patients (cf. Table S2).

Imputation methods
The between group comparison at post-assessment followed an ITT principle meaning that the analyses took into account all randomized patients. Missing data were treated with multiple imputation with the R package 'multiple imputation using chained equations (mice)':[31] Imputation was performed with 50 sets using the imputation variables age, sex, baseline value of the dependent variable, and the last therapy session attended. Patients with missing post-assessment data for the binary variables of abstinence from binge eating and remission from BED were treated as non-abstinent and without remission. Numeric data were imputed with predictive mean matching, ensuring that values remained within the observed range. Multiple sets were combined using the standard rules derived by Rubin,[32] which then yielded confidence intervals and *p* values.

Statistical methods
The primary outcome, the number of binge-eating episodes at post-assessment, was examined with analysis of covariance for a linear model using the baseline value and stratification variables (sex, age > 15 years) as covariates, and group as factor. For sensitivity analyses, relative change in binge eating was estimated[33] and a negative binomial model for count data with overdispersion was calculated.
Secondary metric outcomes at post-assessment were analyzed analogously to the primary outcome. Binary outcomes were analyzed with logistic regression using the number of binge-eating episodes at baseline and stratification variables as covariates, and group as factor.
Mixed models with random intercept served to examine metric follow-up data with sex as a covariate and time as a factor. Confidence intervals used Tukey's all-pairwise comparisons.
To measure effect size, *d* was estimated for metric variables and the natural logarithm was divided by 1.81 for odds ratios.[34] All analyses were performed using the statistics software R version 3.4.1.[35] Two-tailed $p < .05$ was considered significant.

2. Supplementary Results

Mental comorbidity
Of the 73 patients at baseline, 22 patients had an anxiety disorder, 5 patients had an affective disorder, and none of the patients had an attention, activity, or social disorder. At 6- and 12-month follow-ups, only 6 and 4 patients, respectively, had an anxiety disorder, and at 6 months, 2 patients had an affective disorder. No other diagnoses were made at any time point.

Longitudinal analyses for the primary and secondary outcomes at 6-, 12-, and 24-month follow-up
Raw data of the primary and secondary outcomes at post-treatment as well as 6-, 12-, and 24-month follow-up are presented in Table S4.

Sensitivity analyses for the primary outcome
Sensitivity results with the negative binomial distribution and the assumption of the likeness between CBT and control arms corroborated the main results and showed a difference between groups of 4.5 (95% CI 1.8 to 11.7, $p = .0023$) and 4.7 (95% 1.4 to 8.0, $p = .0062$), respectively. The model with the ratio of binge-eating episodes from post-assessment to baseline estimated that the CBT arm had 3.9 (95% CI 0.9 to 7.6) less binge-eating episodes than the WL arm, $p = .0089$.

Complete case analyses for the primary and secondary outcomes at post-assessment
Both the CC and ITT analyses showed a reduction in the number of binge-eating episodes in the CBT arm of 4.7 episodes more than in the WL arm. Regarding secondary outcomes, the reduction in the number of objective binge-eating episodes was analogous for the CC and ITT sets, with a difference between groups of 3.1 episodes for both analyses. Abstinence and remission rates were considerably greater for the CC (68% and 78%) versus ITT set (51% and 57%) in the CBT arm, whereas abstinence and remission rates did not differ between the CC (34% and 34%) and ITT sets (33% and 33%) for the WL arm. The results on other secondary outcomes were consistent for the CC and ITT sets, as shown in Tables S5 and S6.

Per protocol set. Longitudinal analyses on the number of binge-eating episodes using the PP set corroborated the results of the ITT longitudinal analysis, with significant reductions of 9.2 to 10.1 in the PP set and 9.6 to 10.2 binge-eating episodes in the ITT set over time (see Tables S5 and S8). For objective binge-eating episodes, PP

analyses showed comparable effects to the ITT set with significant reductions of 6.2 to 6.7 episodes in the PP and reductions of 7.0 to 7.1 episodes in the ITT set. Follow-up abstinence and remission rates were greater for the PP (52 to 67% and 67 to 81%) versus ITT set (45 to 51% and 59 to 70%) across all follow-up time points. The results on other secondary outcomes were consistent for the PP and ITT sets, as shown in Tables S5 and S8.

Modified complete case set. Longitudinal analyses on the number of binge-eating episodes using the mCC set revealed somewhat lower reductions compared to the ITT set, with reductions of 7.1 to 8.6 binge-eating episodes over time (see Tables S5 and S7), while the results on objective binge-eating episodes were similar for the ITT and mCC sets. Abstinence and remission rates at 6-, 12-, and 24-month follow-ups were greater for the mCC set compared to the ITT set with abstinence rates between 60 and 76% (versus 45 to 51% in the ITT set) and remission rates between 76 and 90% (versus 59 to 70% in the ITT set). The results on other secondary outcomes were consistent for the mCC and ITT sets, as shown in Tables S5 and S7.

3. Supplementary Discussion

Clinical significance of therapeutic effects on eating disorder symptomatology

Regarding the primary outcome, binge-eating episodes were significantly reduced to under 2 episodes per month, which was maintained through 24-month follow-up. Similar results were found for objective binge-eating episodes with under 1 episode per month throughout follow-up. Thus, on average, a subclinical level of binge-eating episodes and objective binge-eating episodes was reached when considering the DSM-5 diagnostic criteria of BED and age adaptation. Regarding secondary outcomes, abstinence from binge eating as an indicator of full remission from binge eating was reached in 51% of patients, which is consistent with abstinence from objective binge eating following adult CBT.[36,37] Remission from age-adapted diagnosis of BED amounted to 57%. Therapeutic gains in these outcomes and in global eating disorder psychopathology remained constant through 24-month follow-up. When compared with EDE norms from a population-based twin sample of adolescent girls aged 12-16 years,[38] global eating disorder psychopathology fell from above to below the 95th percentile at post-treatment and follow-ups, suggesting that a subthreshold, albeit above average, level of eating disorder psychopathology was sustainably attained. Altogether, these results speak for the clinical significance of change in eating disorder outcomes. Notwithstanding, in light of the residual eating disorder symptoms, further exploration to maximize treatment effects in CBT of adolescent BED is warranted.

Strengths and limitations

Beyond the well-controlled design, there was a low risk of bias in selection (random sequence generation, allocation concealment), detection (assessor-blind), and reporting (published study protocol).[33] Although recruitment initially followed a mixed strategy, including adolescents from the population and those seeking treatment at clinical institutions (e.g., pediatricians, outpatient weight loss treatment), 90% of the sample was recruited population- and school-based, indicating relative homogeneity in recruitment. Other potential confounding biases relating to the sample might be the overrepresentation of male patients, presumably due to gender-specific health-care seeking and consistent with psychotherapy studies on adults with BED,[37] and cultural homogeneity as most patients had German nationality - limiting the generalizability to more diverse populations. The lack of blinding of patients and therapists – a general limitation in psychotherapy studies – may have increased the chance for performance bias. Regarding attrition, assessment completion appeared to be lower than in adults with BED,[36] although comparable to that in other CBT trials in adolescents with BED symptomatology.[6,27] For preventing an attrition bias given the differential loss in CBT versus WL at post-assessment, analyses were conducted by ITT, with sensitivity analyses underscoring the robustness of the results. The fact that overall retention in the present treatment was lower than in CBT of adult BED[36,37] may reflect a tendency of spontaneous remission from BED in adolescents.[39] Despite high self-rated treatment expectations and motivation, not all of the randomized adolescents actually started CBT and this concerned mostly the WL arm (19% versus 5% in CBT), probably related to the 33% abstinence rate from binge eating after WL. Of those starting therapy, 22% dropped out of treatment prematurely, which is comparable to psychotherapy of adult BED.[37] Finally, it should be noted that comparisons between CBT and WL did not extend beyond the 4-month duration, after which WL patients were offered CBT as well. In addition to ethical considerations, according to which withholding treatment for a long time in clinical trials is problematic, it was thereby possible to obtain a larger database for longitudinal analyses. Nevertheless, longer-term comparisons between CBT and untreated patients would be particularly informative to evaluate the long-term efficacy of CBT beyond BED's increased tendency of spontaneous remission and recurrence in adolescence.[39]

Table S1. Baseline sociodemographic and clinical characteristics

	CBT (n = 37)		Control (n = 36)		Total (N = 73)	
	Mean or No.	*SD* or %	Mean or No.	*SD* or %	Mean or No.	*SD* or %
Sex, female	30	81	30	83	60	82
Age, y	15.3	2.5	15.4	2.6	15.3	2.5
Pubertal stage						
I Pre-puberty	1	3	0	0	1	2
II Early puberty	1	3	3	9	4	6
III Midst of puberty	6	18	5	15	11	17
IV Advanced puberty	11	33	16	48	27	41
V Post-puberty	14	42	9	27	23	35
Nationality						
German	34	92	35	97	69	95
Other	3	8	1	3	4	5
Winkler index	11.9	3.8	12.2	4.1	12.0	4.0
Socioeconomic status						
Low	6	18	7	22	13	20
Medium	18	55	14	44	32	49
High	9	27	11	34	20	31
Body mass index-standard deviation score	1.93	0.83	1.94	1.10	1.93	0.97
Weight status						
Normal weight	7	19	10	28	17	23
Overweight	12	32	7	19	19	26
Obesity	18	49	19	53	37	51
BED diagnosis[a]						
DSM-IV-TR	14	38	14	39	28	38
DSM-5	8	22	12	33	20	27
DSM-5 low frequency and/or limited duration	7	19	6	17	13	18
DSM-IV-TR age-adapted	3	8	2	6	5	7
DSM-5 age-adapted	5	14	2	6	7	10
Binge-eating episodes past 28 days[a]	11.8	9.8	11.2	8.9	11.5	9.3
Objective binge-eating episodes	7.9	9.6	7.4	7.4	7.7	8.5
Subjective binge-eating episodes	3.8	6.1	3.8	6.3	3.8	6.1
Mental comorbidity[b]						
Anxiety disorders	12	32	10	28	22	30
Affective disorders	4	11	1	3	5	7
Attention disorders	0		0		0	
Therapy expectations[c]						
Expectation	8.1	1.1	8.2	1.3	8.1	1.2
Motivation	8.7	1.5	8.5	1.5	8.6	1.5

Note. Percentages calculated from valid cases. CBT, cognitive-behavioral therapy; BED, binge-eating disorder; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders (4th ed., text revision); DSM-5, Diagnostic and Statistical Manual of Mental Disorders (5th ed.); age-adapted BED diagnosis refers to the presence of both objective and/or subjective binge-eating episodes; pubertal stage derived from the Pubertal Development Scale.

[a]Determined using the Eating Disorder Examination.

[b]Determined using the Diagnostic Interview for Mental Disorders in Children and Adolescents.

[c]Assessed on a rating scale ranging from 1 to 10 with higher scores indicating higher expectations.

Table S2. Baseline demographic and clinical characteristics for full analysis, complete case, and per protocol sets

	Full analysis set (*N* = 73)	Complete case set (*n* = 63)	Per protocol set (*n* = 42)	*p*
Sex, No. (%) of females	60 (82)	52 (83)	32 (76)	.12
Age, mean (SD), years	15.3 (2.5)	15.3 (2.5)	15.2 (2.5)	.68
Pubertal stage, No. (%), (PDS score)				.32
I Pre-puberty	1 (2)	1 (2)	1 (3)	
II Early puberty	4 (6)	4 (7)	4 (11)	
III Midst of puberty	11 (17)	10 (18)	8 (21)	
IV Advanced puberty	27 (41)	23 (40)	14 (37)	
V Post-puberty	23 (35)	19 (33)	11 (29)	
Winkler index, mean (SD)	12.0 (4.0)	12.0 (4.1)	12.2 (3.9)	.76
Socioeconomic status, No. (%)				
Low	13 (20)	11 (19)	7 (18)	
Medium	32 (49)	28 (49)	20 (50)	
High	20 (31)	18 (32)	13 (32)	
Body mass index-standard deviation score, mean (SD)	1.93 (0.97)	1.91 (0.99)	2.03 (0.92)	.33
Weight status, No. (%)				
Normal weight	17 (23)	15 (24)	8 (19)	.32
Overweight	19 (26)	16 (25)	10 (24)	.62
Obesity	37 (51)	32 (51)	24 (57)	.20
Diagnosis, No. (%)[a]				.38
DSM-IV-TR	28 (38)	25 (40)	16 (38)	
DSM-5	20 (27)	16 (25)	10 (24)	
DSM-5 low frequency/limited duration	13 (18)	11 (17)	6 (14)	
DSM-IV-TR age-adapted	5 (7)	4 (6)	4 (10)	
DSM-5 age-adapted	7 (10)	7 (11)	6 (14)	
Binge-eating episodes past 28 days, mean (SD)	11.5 (9.3)	11.2 (9.1)	11.2 (8.4)	.77
Objective binge-eating episodes	7.7 (8.5)	7.5 (7.9)	7.1 (8.1)	.48
Subjective binge-eating episodes	3.8 (6.1)	3.7 (6.0)	4.1 (6.2)	.59
Mental comorbidity, No. (%)[b]				
Anxiety disorders	22 (30)	19 (30)	12 (29)	.73
Affective disorders	5 (7)	5 (8)	3 (7)	1.00
Attention disorders	0	0	0	1.00
Therapy expectations, mean (SD)				
Treatment expectation	8.1 (1.4)	8.0 (1.4)	8.1 (1.4)	.71
Motivation	8.6 (1.4)	8.5 (1.6)	8.6 (1.5)	.45

Note. Percentages calculated from valid data. *p* values refer to the comparison between the per protocol and the full analysis set. DSM, Diagnostic and Statistical Manual of Mental Disorders; PDS, Pubertal Development Scale. Age-adapted BED diagnosis refers to the presence of both objective and/or subjective binge-eating episodes.

[a]Determined using the Eating Disorder Examination.

[b]Determined using the Diagnostic Interview for Mental Disorders in Children and Adolescents.

Table S3. List of adverse events and their severity

	No. of adverse events	Severity		
		Mild	Moderate	Severe
Abdominal discomfort	2		2	
Appendicitis	1			1
Asthma	1		1	
Crying	1	1		
Cystitis	1		1	
Depression	1		1	
Diarrhea	1	1		
Dysmenorrhea	1	1		
Foot fracture	1		1	
Gastrointestinal disorder	1	1		
Gastrointestinal infection	3	1	2	
Headache	5	2		3
Illusion	1		1	
Influenza	1		1	
Intentional self-injury	4		2	2
Intestinal obstruction	1		1	
Intracranial pressure increased	1			1
Joint dislocation	1		1	
Ligament sprain	1	1		
Lung disorder	1		1	
Micturition urgency	1	1		
Migraine	3		1	2
Nasopharyngitis	14	10	3	1
Nausea	3	2		1
Pyelonephritis	1		1	
Road traffic accident	1			1
Spider bite	1			1
Viral infection	1		1	
Visual impairment	1	1		
Vomiting	6	5		1
Wisdom teeth removal	2		2	

Table S4. Raw longitudinal data

	Baseline (*n* = 72)	Post-treatment (*n* = 54)	6 months (*n* = 53)	12 months (*n* = 56)	24 months (*n* = 47)
Eating Disorder Examination					
Binge-eating episodes past 28 days, mean (SD)	11.2 (9.3)	1.3 (2.8)	1.8 (4.7)	1.3 (3.6)	1.1 (2.7)
Objective binge-eating episodes past 28 days, mean (SD)	7.7 (8.5)	0.6 (1.7)	0.5 (1.1)	0.7 (2.4)	0.7 (2.4)
Abstinence from binge eating, No. (%)	—	35 (65)	33 (63)	37 (69)	36 (77)
Remission from BED, No. (%)	—	43 (80)	47 (89)	51 (91)	42 (89)
Global eating disorder psychopathology, mean (SD)	2.2 (0.8)	1.4 (0.9)	1.2 (0.9)	1.2 (0.7)	1.1 (0.7)
Beck Depression Inventory-II, mean (SD)	14.9 (10.5)	12.7 (14.6)	8.5 (10.4)	6.3 (8.1)	6.1 (6.3)
Rosenberg Self-Esteem Scale, mean (SD)	27.5 (6.3)	29.3 (8.3)	30.7 (7.7)	32.5 (6.4)	33.9 (5.3)
SF-12 Mental quality of life, mean (SD)	43.0 (13.6)	46.5 (14.0)	50.0 (11.9)	51.8 (10.2)	51.3 (10.4)
Body mass index-standard deviation score, mean (SD)	1.9 (1.0)	2.0 (0.9)	1.9 (1.1)	2.0 (1.1)	1.9 (1.1)

Note. For the mean differences with 95% confidence intervals, a negative sign indicates improvement. Confidence intervals are computed using Tukey's honest differences. BED, binge-eating disorder; SF-12, Short-Form Health Survey.

Table S5. Intent-to-treat analyses for longitudinal effects from mixed effects models (*N* = 73)

		Baseline	Δ Post-treatment	Δ 6 months	Δ 12 months	Δ 24 months	Test	*p*
Eating Disorder Examination								
Binge-eating episodes	Mean	11.5	−10.0	−9.6	−10.2	−10.1	$F(6, 284) = 46.3$	< .001
	95% CI		−12.5 to −7.5	−12.1 to −7.1	−12.7 to −7.7	−12.6 to −7.5		
Objective binge-eating episodes	Mean	7.7	−7.1	−7.0	−7.0	−7.0	$F(6, 283) = 31.0$	< .001
	95% CI		−9.2 to −4.9	−9.2 to −4.9	−9.2 to −4.8	−9.2 to −4.8		
Abstinence from binge eating	No.	—	35	33	37	36	—	—
	%		48	45	51	49		
Remission from BED	No.	—	45	48	51	43	—	—
	%		62	66	70	59		
Global eating disorder psychopathology	Mean	2.2	−0.9	−1.0	−1.0	−1.1	$F(6, 267) = 36.4$	< .001
	95% CI		−1.2 to −0.6	−1.3 to −0.7	−1.3 to −0.8	−1.4 to −0.9		
Beck Depression Inventory-II	Mean	14.9	−3.3	−6.0	−7.8	−8.7	$F(6, 260) = 13.3$	< .001
	95% CI		−7.1 to 0.5	−9.6 to −2.4	−11.5 to −4.2	−12.4 to −5.0		
Rosenberg Self-Esteem Scale	Mean	27.5	−2.5	−3.1	−4.5	−5.8	$F(6, 257) = 12.9$	< .001
	95% CI		−4.8 to −0.1	−5.4 to −0.9	−6.8 to −2.2	−8.1 to −3.5		
SF-12 Mental quality of life	Mean	43.0	−3.9	−5.8	−7.8	−7.4	$F(6, 242) = 8.3$	< .001
	95% CI		−8.8 to 0.9	−10.5 to −1.2	−12.6 to −3.1	−12.1 to −2.7		
Body mass index-standard deviation score	Mean	1.93	0.02	−0.03	−0.01	0.11	$F(6, 150) = 1.7$	.14
	95% CI		−0.08 to 0.13	−0.03 to 0.09	−0.16 to 0.14	−0.12 to 0.35		

Note. For the mean differences with 95% confidence intervals, a negative sign indicates improvement. Confidence intervals were computed using Tukey's honest differences. BED, binge-eating disorder; SF-12, Short-Form Health Survey.

Table S6. Complete case analyses for the primary and secondary outcomes (*n* = 63)

	Baseline		Post-assessment				
	CBT	**Control**	**CBT**	**Control**	**Adjusted effect (95% CI)**	**Effect size**	***p***
Eating Disorder Examination							
Binge-eating episodes, mean (SD)	11.1 (9.2)	11.3 (9.1)	1.3 (2.9)	6.1 (8.6)	4.7 (1.5 to 8.0)	0.34	.0052
Objective binge-eating episodes, mean (SD)	7.6 (8.5)	7.4 (7.5)	0.6 (1.9)	3.7 (5.2)	3.1 (1.0 to 5.2)	0.35	.0044
Abstinence from binge eating, No. (%)	—	—	19/28 (68)	12/35 (34)	7.3 (2.0 to 33.6)	1.10	.0048
Remission from BED, No. (%)	—	—	21/27 (78)	12/35 (34)	10.7 (2.9 to 51.4)	1.31	< .001
Global eating disorder psychopathology, mean (SD)	2.3 (0.9)	2.2 (0.8)	1.4 (1.0)	2.0 (0.9)	0.7 (0.3 to 1.0)	0.33	< .001
Beck Depression Inventory-II, mean (SD)	16.4 (12.2)	15.7 (10.3)	13.5 (15.9)	12.3 (11.0)	−0.6 (−5.8 to 4.5)	-0.02	.81
Rosenberg Self-Esteem Scale, mean (SD)	27.0 (7.0)	26.8 (5.5)	29.1 (9.1)	27.5 (8.0)	1.3 (−1.9 to 4.6)	0.08	.42
SF-12 Mental quality of life, mean (SD)	42.7 (15.1)	41.1 (14.5)	46.4 (14.5)	42.2 (15.0)	3.2 (−3.2 to 9.6)	0.11	.32
Body mass index-standard deviation score, mean (SD)	1.9 (0.8)	2.1 (1.0)	1.9 (0.9)	2.1 (1.0)	0.1 (−0.1 to 0.2)	0.03	.35

Note. For metric outcomes, positive values of the adjusted effect and effect size d indicate superiority of CBT. For categorical outcomes, an odds ratio > 1.0, used as effect size, indicates superiority of CBT. BED, binge-eating disorder; CBT, cognitive-behavioral therapy; SF-12, Short-Form Health Survey.

Table S7. Modified complete case analyses for longitudinal effects from mixed effects models (*n* = 42)

	Baseline Mean	Δ Post-treatment (95% CI)	Δ 6 months (95% CI)	Δ 12 months (95% CI)	Δ 24 months (95% CI)	$F(df_1, df_2)$	*p*
Eating Disorder Examination							
Binge-eating episodes past 28 days	11.2	-7.6 (-10.2 to -4.9)	-7.1 (-9.8 to -4.5)	-8.6 (-11.3 to -6.0)	-8.2 (-10.8 to -5.6)	$F(6, 196) = 24.7$	< .001
Objective binge-eating episodes past 28 days	7.1	-6.3 (-8.7 to -3.9)	-6.3 (-8.7 to -3.9)	-6.7 (-9.1 to -4.3)	-6.4 (-8.8 to -4.1)	$F(6, 191) = 19.1$	< .001
Abstinence from binge eating, No. (%)	—	27 (64)	25 (60)	26 (62)	32 (76)	—	—
Remission from BED, No. (%)	—	32 (76)	37 (88)	37 (88)	38 (90)	—	—
Global eating disorder psychopathology	2.2	-0.8 (-1.2 to -0.5)	-1.0 (-1.3 to -0.6)	-1.0 (-1.4 to -0.7)	-1.2 (-1.6 to -0.9)	$F(6, 187) = 25.7$	< .001
Beck Depression Inventory-II	13.9	-2.9 (-7.6 to 1.7)	-5.9 (-10.4 to -1.4)	-7.1 (-11.7 to -2.6)	-8.3 (-12.7 to -3.9)	$F(6, 181) = 8.4$	< .001
Rosenberg Self-Esteem Scale	28.7	-2.2 (-5.0 to 0.7)	-2.5 (-5.3 to 0.3)	-4.2 (-7.0 to -1.4)	-5.2 (-8.0 to -2.5)	$F(6, 182) = 8.5$	< .001
SF-12 Mental quality of life	44.0	-3.7 (-9.7 to 2.3)	-6.4 (-12.1 to -0.7)	-7.4 (-13.1 to -1.4)	-7.8 (-13.5 to -2.2)	$F(6, 174) = 5.9$	< .001
Body mass index-standard deviation score	1.89	0.00 (-0.18 to 0.18)	-0.06 (-0.24 to 0.11)	-0.05 (-0.22 to 0.13)	0.05 (-0.14 to 0.23)	$F(6, 172) = 0.8$	.53

Note. For the mean differences with 95% confidence intervals, a negative sign indicates improvement. Confidence intervals were computed using Tukey's honest differences. BED, binge-eating disorder; SF-12, Short-Form Health Survey

Table S8. Per protocol analyses for longitudinal effects from mixed effects models (*n* = 42)

	Baseline Mean	Δ Post-treatment (95% CI)	Δ 6 months (95% CI)	Δ 12 months (95% CI)	Δ 24 months (95% CI)	$F(df_1, df_2)$	*p*
Eating Disorder Examination							
Binge-eating episodes past 28 days	11.2	-9.7 (-12.3 to -7.0)	-9.2 (-11.9 to -6.5)	-10.1 (-12.9 to -7.3)	-9.8 (-12.7 to -7.0)	$F(6, 195) = 34.6$	< .001
Objective binge-eating episodes past 28 days	7.1	-6.4 (-8.7 to -4.0)	-6.4 (-8.8 to -3.9)	-6.2 (-8.7 to -3.7)	-6.7 (-9.3 to -4.2)	$F(6, 195) = 18.6$	< .001
Abstinence from binge eating, No. (%)	—	28 (67)	22 (52)	23 (55)	22 (52)	—	—
Remission from BED, No. (%)	—	34 (81)	35 (83)	35 (83)	28 (67)	—	—
Global eating disorder psychopathology	2.3	-0.9 (-1.2 to -0.6)	-0.9 (-1.2 to -0.6)	-1.0 (-1.3 to -0.7)	-1.1 (-1.5 to -0.8)	$F(6, 187) = 27.3$	< .001
Beck Depression Inventory-II	18.9	-4.3 (-8.7 to 0.1)	-5.1 (-9.5 to -0.7)	-7.4 (-12.0 to -2.9)	-9.3 (-13.9 to -4.6)	$F(6, 184) = 9.1$	< .001
Rosenberg Self-Esteem Scale	24.6	-2.9 (-5.5 to -0.2)	-2.6 (-5.3 to 0.0)	-4.6 (-7.3 to -1.9)	-6.0 (-8.8 to -3.2)	$F(6, 183) = 10.2$	< .001
SF-12 Mental quality of life	41.7	-3.1 (-8.9 to 2.6)	-3.4 (-9.0 to 2.3)	-7.2 (-13.1 to -1.3)	-7.5 (-13.4 to -1.6)	$F(6, 175) = 5.7$	< .001
Body mass index-standard deviation score	1.95	-0.02 (-0.18 to 0.19)	-0.06 (-0.23 to 0.12)	-0.07 (-0.25 to 0.10)	0.01 (-0.18 to 0.20)	$F(6, 179) = 0.5$	.76

Note. For the mean differences with 95% confidence intervals, a negative sign indicates improvement. Confidence intervals were computed using Tukey's honest differences. BED, binge-eating disorder; SF-12, Short-Form Health Survey.

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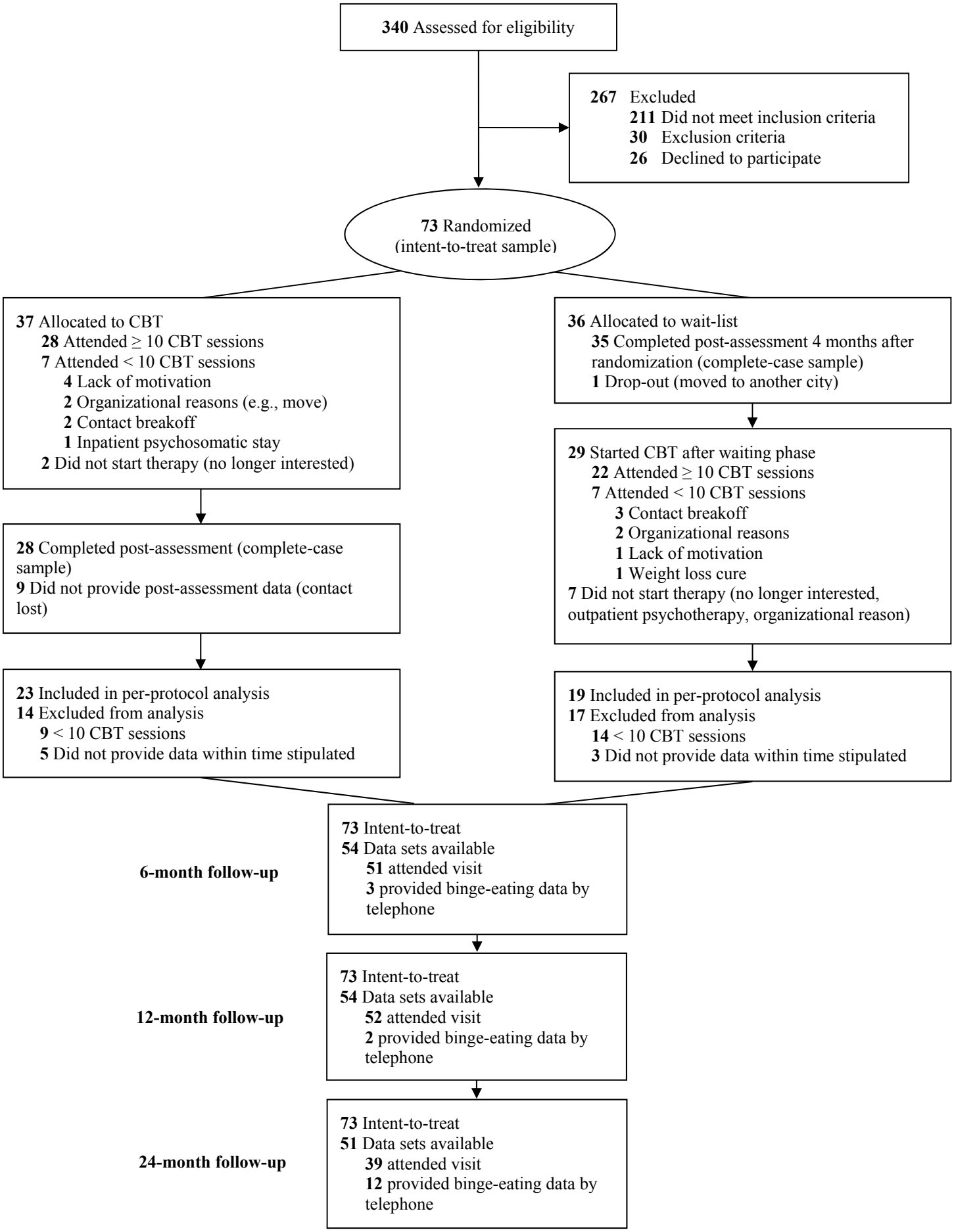

Figure S1. CONSORT flow chart.

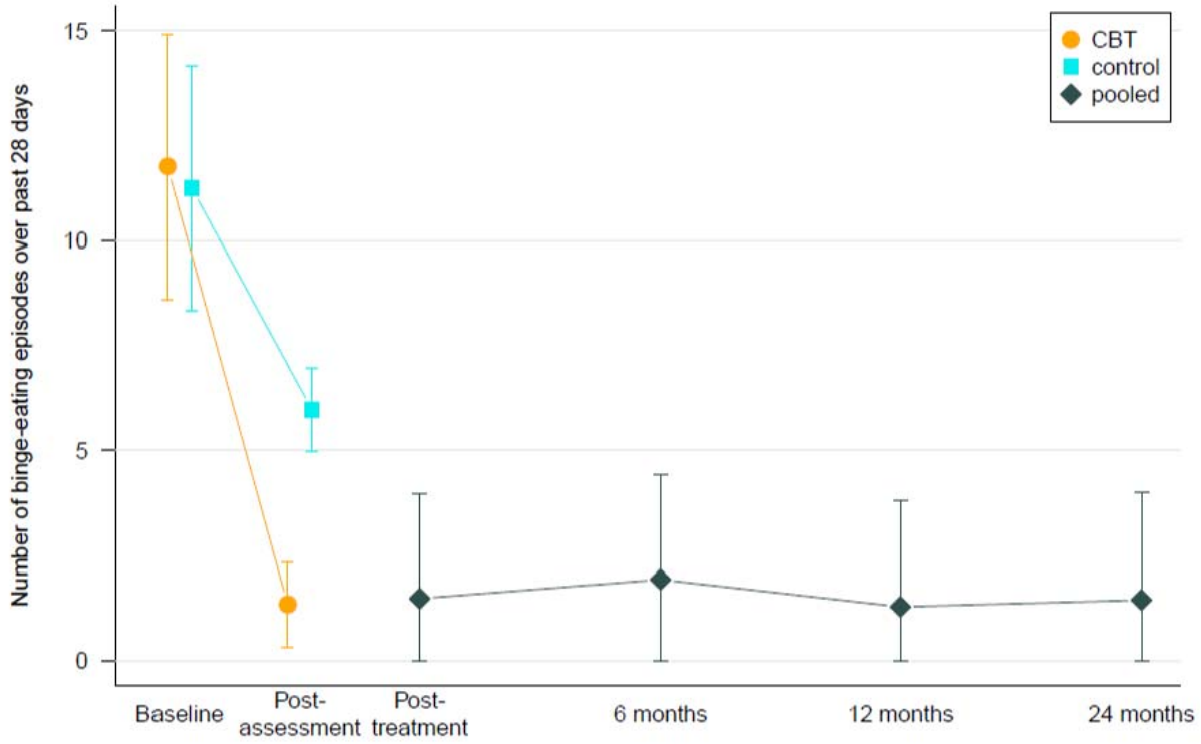

Figure S2. Binge-eating episodes from baseline to post-assessment and across 24-month follow-up determined using the Eating Disorder Examination. Displayed are means and 95% CI.

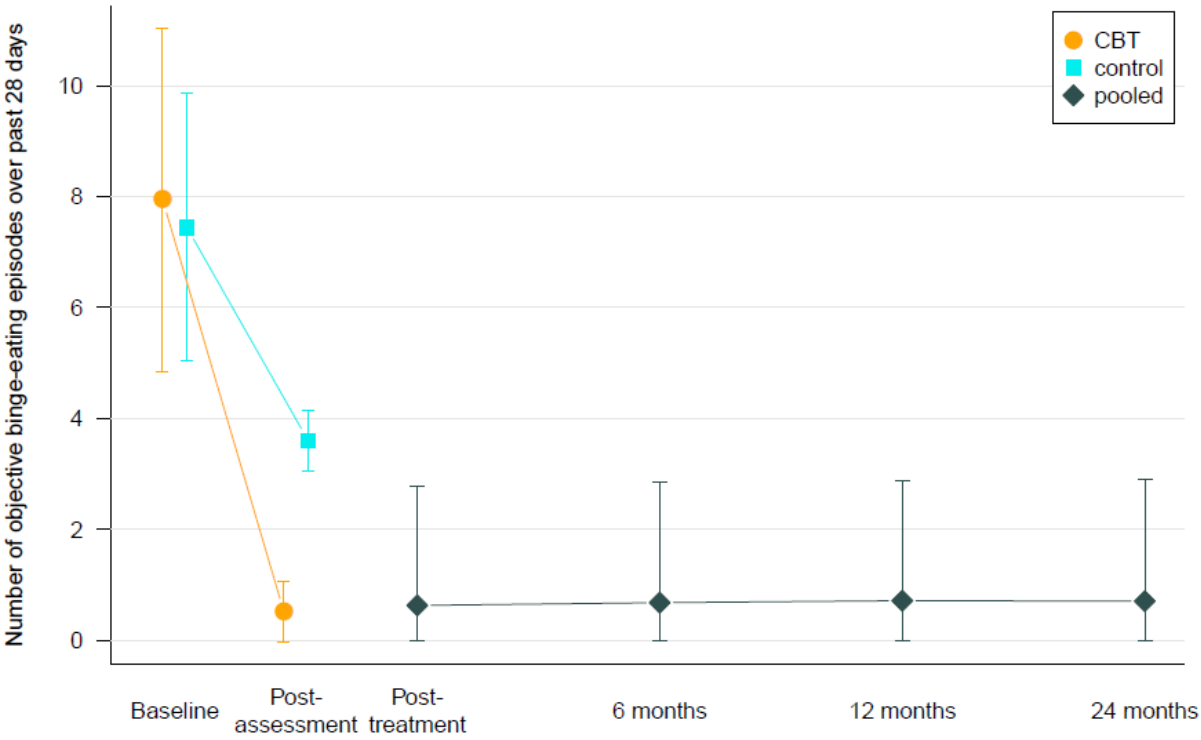

Figure S3. Objective binge-eating episodes from baseline to post-assessment and across 24-month follow-up determined using the Eating Disorder Examination. Displayed are means and 95% CI.

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