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Randomized controlled trial of an Internet-based cognitive-behavioral treatment program for binge-eating disorder

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Abbreviations: BED: binge-eating disorder, BMI: body-mass index, CBT: cognitive-behavioral therapy, OBE: objective binge-eating episode. TG: treatment group, WL: waiting list control group

Abstract

Binge-eating disorder (BED) is a prevalent health condition associated with obesity. Few people with BED receive appropriate treatment. Personal barriers include shame, fear of stigma, geographic distance to mental health services, and long wait lists. The aims of this study were to examine the efficacy of an Internet-based cognitive-behavioral intervention for adults with threshold BED (DSM-IV) and to examine the stability of treatment effects over 12 months. Participants were randomly assigned to a 16-week Internet-based cognitive-behavioral intervention (n= 69) or a waiting list condition (n= 70). Binge eating frequency and eating disorder psychopathology were measured with the Eating Disorder Examination-Questionnaire and the Eating Disorder Examination administered over the telephone. Additionally, body weight and body mass index, depression, and anxiety were assessed before and immediately after treatment. Three-, six-, and twelve-month follow-up data were recorded in the treatment group. Immediately after the treatment the number of binge-eating episodes showed significant improvement (d = 1.02, between group) in the treatment group relative to the waiting list condition. The treatment group had also significantly reduced symptoms of all eating psychopathology outcomes relative to the waiting list condition ($0.82 \leq d \leq 1.11$). In the treatment group, significant improvement was still observed for all measures one the year after the intervention to relative to pretreatment levels. The Internet-based intervention proved to be efficacious significantly reducing the number of binge-eating episodes and eating disorder pathology long-term. Low-threshold e-health interventions should be further evaluated to improve treatment access for patients suffering from BED.

Key words: binge-eating disorder, Internet-based, randomized controlled trial, cognitive behavioral therapy, efficacy

Introduction

Binge-eating disorder (BED) is characterized by recurrent episodes of eating large amounts of food accompanied by feelings of loss of control over eating. BED can cause a substantial disease burden and is associated with high personal and social costs (Smink, van Hoeken, & Hoek, 2012). The life-time prevalence of BED according to DSM-IV is estimated to be 1.9 % (Kessler et al., 2013). Many individuals with BED are likely to experience comorbid psychiatric disorders (Hudson, Hiripi, Pope Jr, & Kessler, 2007) and to attempt or complete suicide (Sansone & Levitt, 2002). Lifetime BED has also been found to be associated with current severe obesity (BMI ≥40kg/m²) (Hudson et al., 2007). Although efficacious treatments for BED are available (Vocks et al., 2010), individuals with BED do not necessarily seek treatment. Hart and colleagues (2011) found in their systematic review that only 23% of people suffering from eating disorders have sought treatment. Specific personal barriers to psychological treatment include shame, fear of stigma, or self-discrimination (Griffiths, Mond, Murray, Thornton, & Touyz, 2015), as well as lack of time, long waiting times, lack of skilled therapists, geographic distance to mental health services, and unwillingness to disclose psychological problems (Bell & Newns, 2004). Low-threshold interventions such as self-help programs (Beintner, Jacobi, & Schmidt, 2014) or Internet-based interventions (Dölemeyer, Tietjen, Kersting, & Wagner, 2013) can help to overcome these obstacles.

A growing body of research has examined the effects of self-help interventions for BED and bulimia nervosa (BN) (Carter & Fairburn, 1998; Grilo & Masheb, 2005). These interventions are offered in different treatment modalities. “Overcoming Binge Eating” (Fairburn, 1995) is one of the best-researched self-help books for BED. It was evaluated in a number of clinical trials and the findings suggest that cognitive-behavioral therapy administered through guided or unguided self-help is an effective treatment for BED (Carter & Fairburn, 1998; Ghaderi & Scott, 2003; Wells, Garvin, Dohm, & Striegel-Moore, 1997). An increasing number of Internet-based interventions have been developed as the digitalization process and general use of the Internet have expanded (Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004;

Webb, Joseph, Yardley, & Michie, 2010). Originally based on bibliotherapy, Internet-based interventions provide more sophisticated treatment tools (e.g. online eating diaries) and are often therapist-assisted. In their meta-analysis of BED and BN self-help interventions, Beintner et al. (2014) found that Internet-based interventions showed lower treatment dropout rates than CD-ROM and bibliotherapy interventions. Furthermore, personalized guidance generally improved treatment adherence, especially when given by a specialist.

Several Internet-based interventions have been conducted for BED over the past few years (Carrard et al., 2011a, 2011b; Ljotsson et al., 2007; Robinson & Serfaty, 2008). Medium to large effect sizes from pre- to post-treatment were found in the intervention groups of controlled studies for binge-eating episodes, ranging from 0.41 to 0.77 (Dölemeyer, Tietjen, et al., 2013). These effect sizes are comparable to those found for face-to-face therapies (Vocks et al., 2010).

Ljotsson et al. (2007) conducted a 12-week randomized controlled trial using the Swedish translation of the book "Overcoming Binge Eating" (Fairburn, 1995) among patients with threshold and subthreshold bulimia or BED. The participants were assigned homework based on each book chapter and received weekly feedback on their completed homework by e-mail. The treatment dropout rate was 31%. The rate of abstinence was 37% and improvements were maintained during 6 months post-treatment. Robinson and Serfaty (2008) used an e-mail therapy for BED and BN that did not follow a structured treatment program for their 12-week randomized controlled trial. Even though the model of therapy varied among therapists, all interventions included collecting a personal eating history, identification of problematic eating behaviors and dysfunctional thoughts, and encouragement of eating diaries. On average, the frequency of contact with the therapist was two e-mails per week. The study dropout was 47% and the rate of abstinence 23%. Carrard et al. (2011a; 2011b) conducted two Internet-based studies of BED based on the same guided self-help program. They included participants with BED or subthreshold BED in the first study (Carrard et al., 2011a), and obese participants who suffered from BED or subthreshold BED in the second (Carrard et

al., 2011b). The length of both interventions was 6 months and participants were in contact with their coaches at least once a week. In study 1, 38% completed all 11 modules and 24% stopped before completing 50% of the treatment. In study 2, 14% completed all treatment modules and 18% stopped before completing 50% of the treatment. The rate of abstinence also differed between the studies. For study 1 it was 35% and for study 2 it was 45%. In both studies (Carrard et al. 2011a, Carrard 2011b) improvements in eating disorder symptoms were maintained during 6 months after treatment.

Overall, these first results of Internet-based interventions for BED are promising with regard to treatment efficacy and short-term stability of treatment effects. However, two of these interventions were intended for patients suffering from BED or BN. Only two studies solely addressed BED. These studies included sub-threshold BED as well (Carrard et al., 2011a; 2011b; Ljotsson et al., 2007). Therefore it remains unknown whether similar effects would be observed among individuals meeting the criteria for full-syndrome BED according to DSM-IV. Furthermore, treatment completion rates were rather modest, and it still remains unclear whether or not intensive therapist support could improve treatment completion and outcomes. A recently published meta-analysis (Johansson & Andersson, 2012) analyzed the intensity of therapist contact using data from 25 controlled trials for depression. The authors categorized the studies by type of human contact. The results indicated that higher levels of human contact yield larger effect sizes. This matches other studies' findings that indicate a significant correlation between the amount of therapist time per participant and the between-group effect sizes of internet-based interventions (Palmqvist, Carlbring, & Andersson, 2007). Furthermore, little is known about the long-term effects of Internet-based interventions for BED as previous studies did not assess eating pathology any later than six months post-treatment (Carrard et al., 2011a; 2011b; Ljotsson et al., 2007).

The aims of this study were (1) to investigate the efficacy of an Internet-based cognitive-behavioral intervention for adults with BED, meeting the full criteria according to DSM-IV-TR, within a randomized controlled trial comparing with a waiting list condition, and (2) to

examine the stability of the intervention effects up to 12 months after the end of the intervention in the treatment group. The primary outcome was the number of objective binge-eating episodes (OBE) over the past 28 days. We expected that participants in the treatment group (TG) would have significantly reduced OBE after treatment compared to the waiting list group (WL); and that the improvements in the TG would remain evident at 3-month, 6-month and 12-months follow-up assessments.

Materials and methods

Participants

The trial was registered in the German Clinical Trials Register (DRKS: 00000590). The study protocol was approved by the Ethical Committee of the University of Leipzig. Participants were only included if they provided written informed consent.

Participants were recruited between April 2011 and May 2012 via the Internet, through the Integrated Research and Treatment Center AdiposityDiseases, and through press information, as well as advertisements and links posted on psychology websites and the websites of organizations for people suffering from eating disorders. We also contacted eating disorder treatment centers throughout Germany. Inclusion criteria were 1) a diagnosis of BED according to the DSM-IV, 2) access to the Internet, 3) age between 18 and 65, 4) fluency in German, 5) residency in Germany, Austria or Switzerland, and 6) written informed consent. Exclusion criteria were the following: 1) current bulimia or anorexia nervosa, 2) severe major depressive symptoms or acute suicidal ideation, 3) history of psychotic or dissociative symptoms, 4) any severe substance abuse or dependence disorder, 5) any serious medical conditions influencing weight or eating (e.g., type 1 diabetes mellitus, thyroid problems), 6) ongoing psychotherapy, 7) current pregnancy, 9) bariatric surgery.

Screening procedure

Inclusion and exclusion criteria were assessed in an extensive online diagnostic survey and a telephone interview (Figure 1). Eating disorder pathology was assessed using the *Eating Disorder Examination-Questionnaire (EDE-Q)* (Fairburn & Belgin, 1994; Hilbert & Tuschen-Caffier, 2006b). Depression was measured using the *Beck Depression Inventory* (BDI) (Hautzinger, Bailer, Worall, & Keller, 1995) and participants were excluded if the BDI sum score exceeded a cutoff of 26. Suicidality was measured with the five screening items of the *Beck Suicide Ideation Scale* (BSIS) (Beck, Brown, & Steer, 1997). If patients scored above 1 on any screening item, further suicide screening was conducted via telephone. The *Dutch Screening Device for Psychotic Disorder* (SDPD) (Lange, Schrieken, Blankers, van de Ven, & Slot, 2000) was used to assess psychotic or dissociative symptoms and the risk of psychosis. The Dutch norm data were used and patients were excluded if the sum score exceeded a cutoff of 13. All other inclusion and exclusion criteria were assessed in a biographical questionnaire.

The BED diagnosis was validated in a telephone interview using the German version of the semi-structured *Eating Disorder Examination (EDE)* (Fairburn & Cooper, 1993; Hilbert, Tuschen-Caffier, 2006a). The EDE has demonstrably good psychometric quality indicated by a high interrater reliability ($\kappa \geq 0.80$) (Hilbert, Tuschen-Caffier & Ohms, 2004) and satisfactorily distinguishes between cases and non-cases of eating disorders (Berg, Peterson, Frazier & Crow, 2012).

After completing the online assessment and the EDE, eligible patients gave their informed consent. If candidates did not meet the inclusion criteria, or if the screening revealed severe psychosocial liability, they were given a telephone or email consultation about treatment options and further help seeking treatment.

Outcome measures

The primary outcome was the number of objective binge-eating episodes (OBE) over the last 28 days. OBE are characterized by eating an amount of food in a discrete period of time that

is larger than what most people would eat under similar circumstances accompanied by loss of control over eating (APA, 2000). Eating disorder-related attitudes and behavior, general psychopathology (depression and anxiety), and body weight and body mass index (BMI) were secondary outcomes.

Eating Disorder Examination-Questionnaire (EDE-Q). The EDE-Q (Fairburn & Belgin, 1994; Hilbert & Tuschen-Caffier, 2006b) is a 28-item self-report version of the EDE covering the last 28 days prior to the assessment. Twenty-two items assesses the frequency and intensity of eating disorder psychopathology in four dimensions "restraint", "eating concern", "weight concern", and "shape concern" along with a global score. The subscales and the total score range from 0 to 6 with higher scores reflecting higher severity of eating disorder psychopathology. Six additional diagnostic items assess the frequency of core behaviors of eating disorders. These items include different forms of overeating and compensatory behavior and are not included in the subscales or the total score. Of these diagnostic items, we focused on the number of OBE during the last 28 days prior to assessment which is the core symptom of BED. Reas, Grilo & Masheb (2006) report the following reference values for the EDE-Q among treatment-seeking patients with BED: global score M = 3.5 (SD = 0.8), restraint: M = 2.0 (SD = 1.4), eating concern: M = 3.2 (SD = 1.2), weight concern: M = 4.0 (SD = 1.0), shape concern: M = 4.9 (SD = 0.9), number of OBE: M = 13.7 (SD = 11.7). The German version of the EDE-Q has good internal consistency (subscales: $0.85 \leq \alpha \leq 0.93$, global score: $\alpha = 0.97$) and retest-reliability (subscales: $0.67 \leq r_{tt} \leq 0.85$, global score: r_{tt} = 0.88; number of OBE: $\tau = 0.45$, all p-values < 0.001), as well as sensitivity to change after therapeutic interventions (Hilbert, Tuschen-Caffier, Karwautz, Niederhofer, & Munsch, 2007).

Beck Depression Inventory (BDI). Depression was measured using the German version of the Beck Depression Inventory (Beck & Steer, 1987; Hautzinger, Bailer, et al., 1995). It consists of 21 multiple-choice items assessing symptoms of depression during the last 14 days. The BDI total score ranges from 0 to 63 with higher scores reflecting higher severity of depressive

symptoms. Pearl, White & Grilo (2014) report a BDI total score of *M* = 15.1 (*SD* = 18.7) among treatment-seeking patients with BED. Several studies have documented the reliability and validity of the BDI (Beck, Steer, & Carbin, 1988; Hautzinger, 1991). In their review on the BDI, Beck, Steer, et al. (1988) report a mean internal consistency estimate of α = 0.87 and a mean retest-reliability of r_{tt} = 0.60.

Symptom Checklist-90 revised (SCL-90-R). The 10-item anxiety subscale of the German version of the well-validated SCL-90-R (Franke & Derogatis, 1995) assesses cognitive and somatic symptoms of anxiety during the last seven days prior to the assessment. The subscale total score ranges from 0 to 40 with higher scores indicating higher severity of anxiety symptoms. Vancampfort et al. (2014) report a total score of *M* = 20.4 (*SD* = 7.5) for the SCL-90-R anxiety subscale among treatment-seeking patients with BED. The German version of the SCL-90-R has good psychometric properties (Cronbach *α* for anxiety subscale = 0.84 (Hessel, Schumacher, Geyer, & Brähler, 2001), retest-reliability for anxiety subscale: r_{tt} = 0.85 (Franke & Derogatis, 1995)).

Body weight and body mass index (BMI). Body weight and height were assessed via self-report. BMI was calculated using the formula BMI = weight (kg)/height (m)².

Study design

Participants were randomly assigned either to the TG or WL. The computer-assisted randomization procedure was conducted by the Center of Clinical Trials (University of Leipzig) and stratification by the number of OBE was implemented. Immediately after randomization, patients in the TG received access to the encrypted Internet-based communication system. The treatment lasted 16 weeks. Participants in the WL started delayed treatment after a 16-week waiting period. For ethical reasons, the WL started treatment immediately after the end of the TG treatment period instead of waiting until the follow-up assessments had been completed. Baseline assessment (t0) was conducted during the screening. Further assessment points in the TG were: post-treatment (t1), and 3 (t2), 6 (t3),

and 12 (t4) months after the end of treatment. Assessment points in the WL were baseline (t0) and after the 16-week waiting period (t1). A priori sample size calculations indicated that a sample size of 51 would be sufficient to detect medium between-group effects at post-treatment assuming an alpha of 0.05 and a power of 80% (Faul, Erdfelder, Lang, & Buchner, 2007). Assuming a dropout rate of 25% between baseline and post-treatment assessment, our goal was to have a sample size of 68 per group at baseline.

Internet-based intervention

The 16-week Internet-based cognitive-behavioral treatment program was developed based on existing evidence-based German- and English-language cognitive-behavioral face-to-face treatment and self-help programs for BED (Fairburn, 1995; Hilbert & Tuschen-Caffier, 2010) and an Internet-based intervention for bulimia nervosa (Ruwaard et al., 2013). The intervention was conducted as a guided therapy with intensive therapist contact, based on the principles of structured writing as applied in a number of previous studies (Lange et al., 2003; Ruwaard et al., 2013; Wagner, Knaevelsrud, & Maercker, 2006). The intervention consisted of 11 personalized structured writing assignments and individualized feedback from trained therapists, complimentary daily eating and activity diaries, week plans, and psychoeducation as applied in cognitive-behavioral treatments (Figure 2).

A webpage containing general information about the intervention and an outline of the study was developed. All communication between the patient and the therapist was asynchronous and text-based, and took place exclusively via the Internet. Writing assignments were designed to be completed in 45 minutes. The manual involved different elements and modules concentrating for instance on the identification of individual eating patterns, binge eating triggers and distraction strategies, cognitive restructuring of automatic negative eating- or weight-related thoughts, development of a regular and balanced eating behavior, as well as implementation of sporting activities and exercise. Further writing assignments focused on body image, problem solving, and relapse prevention. Alongside these modules, patients

wrote online eating protocols and activity diaries, as well as short weekly reports detailing weight, number of OBE, and hours of activity. Patients were required to turn their writing assignments according to a pre-agreed time schedule. They received a written response from their therapists within two working days. Psychoeducation also played an important role and patients were provided with detailed information about the background and the meaning of each module and the significance of the specific writing assignment.

Throughout the study, participants were encouraged to call or email their therapist anytime if they were distressed or in crisis. In cases of crisis or severe distress, patients were contacted by telephone.

Three therapists (clinical psychologists) conducted the treatments. Each of them was trained specifically in psychotherapy and CBT for BED for this study. They were given special training in therapeutic writing for the online treatment and received regular supervision. It took them 20 to 50 minutes per text when giving individualized feedback.

Data analyses

Statistical analyses were conducted using SPSS, Version 20. Significance level was set to $\alpha < 0.05$. Patients who did not provide post-treatment or post-waiting period data as well as patients in the TG who did not complete follow-up assessments were considered dropouts. TG patients who did not complete at least 80% of the treatment modules (until week 13) were not followed-up. Statistical analyses were based on intention-to-treat. Considering the rather stable nature of eating disorders (Pope et al., 2006), missing data at post-treatment and follow-up assessments were imputed using the "last observation carried forward" method (LOCF).

The equivalence of the randomized groups with regard to demographic and clinical characteristics at baseline was examined using two-tailed independent sample t-tests for continuous variables and Pearson χ^2-tests for categorical variables. We conducted 2x2 repeated measures analyses of variance (ANOVA) using time (pre vs. post) as within-subjects

factor and group (TG vs. WL) as between-subjects factor to test for differences between the two groups in changes from pre- to post-treatment in the main and all secondary outcomes. Post-hoc within-group comparisons were conducted separately for each group using two-tailed paired sample t-tests and Bonferroni correction (α_{corr} = 0.025) in case of significant intervention effects.

We examined the stability of the treatment effects in the TG with separate two-tailed paired sample t-tests assessing differences between pretreatment and 3-, 6-, and 12-month follow-ups as well as between post-treatment and follow-up assessments and changes between follow-up assessments. The significance level was Bonferroni corrected resulting in α_{corr}= 0.007. We calculated between-group [$d = t \times \sqrt{(1/n1+1/n2)}$, $t=\sqrt{F_{interaction\ Group*Time}}$] and within-group [$d = t \times \sqrt{(2x(1-r)/n)}$] effect sizes (Cohen's *d*).

Clinical significance of change was defined using the number of OBE after treatment according to the more conservative DSM-5 criteria for BED (APA, 2013). Recovery from binge eating was defined as less than four OBE. Remission from binge eating was operationalized as no OBE. We compared rates of recovery and remission from binge eating between TG and WL using Pearson χ^2-tests. Baseline predictors of recovery and remission from binge eating in the TG were examined in exploratory logistic regression models adjusted for age, gender and educational level using a stepwise forward procedure. We conducted two separate models: 1) using the variable "remission from binge eating" (=no binge eating) after treatment as the dependent variable, 2) using the variable "recovery from binge eating" (<4 OBE) after treatment as the dependent variable. The following predictors indicating the severity of the eating disorder psychopathology and general psychopathology at baseline were examined: the frequency of OBE (EDE-Q), mean values of the EDE-Q subscales restraint, eating concern, weight concern, shape concern, and sum scores of anxiety (SCL-90-R) and depression (BDI). To keep the models sparse, only predictors that were significantly correlated with the dependent variable ($p < 0.05$) were included in regression models.

Results

Demographic and clinical characteristics

Overall, 691 patients registered on the study homepage and were sent screening questionnaires. Of those, 69.5% filled out screening questionnaires. After the confirmation of the BED diagnosis, 139 participants were randomized to the TG (*n*=69) and the WL (*n*=70) (Figure 1).

In total, 96.4% of the participants were female and the mean age was 35.1 years (SD=9.9). The majority of the participants (71.1%) were well-educated and married or living with a partner (59.7%). 37 patients (26.6%) had a history of previous psychotherapeutic treatment and the mean number of OBE at baseline was 16.5 (SD=5.9). The TG and the WL did not differ in any of the demographic variables at baseline or with regard to binge-eating frequency, other eating disorder symptoms, depression, anxiety, and body weight or BMI at baseline (Table 1).

Attrition and program use

In the TG, 19 (27.5%) participants dropped out between pretreatment and post-treatment assessment. In the WL, 6 patients (8.6%) did not complete the post-waiting assessment (Figure 1). The dropout rate in the TG was significantly higher compared to the WL (χ^2 (1, N = 139) = 8.47, p = 0.004). No differences between dropouts and completers were found any of the clinical baseline characteristics (e.g., eating disorder symptoms, depression, and anxiety). Dropouts were more likely to have a lower level of education (χ^2 (1, N = 139) = 8.49, p = 0.004).

Participants in the TG attended on average 13.8 (*SD* = 4.2) or 86% of 16 weekly sessions. Forty-nine (71.0%) patients completed all sessions and 51 (73.9%) completed at least 80% of the treatment. Two patients (2.9%) did not respond to the treatment invitation link. Sixty-two (89.9%) completed at least 8 weeks of treatment; i.e. at least 50% of the sessions and 5 patients (7.3%) stopped treatment between 3 and 5 weeks. In most cases treatment

discontinuation was initiated by the patient (89.5%). Four patients stopped therapy without giving any reason as they could no longer be reached and another four patients preferred face-to-face therapy. Three stated that the internet-based therapy was not the appropriate approach for them and five patients stopped treatment for other reasons, e.g. lack of time. Two patients had to be excluded due to unreliableness.

Treatment efficacy

Changes on symptom levels from pre- to post-treatment in all outcomes along with the results of the intention-to-treat repeated measures ANOVA are shown in Table 2.

Binge-eating and eating disorder symptoms. The treatment led to a significantly greater reduction in the number of OBE as indicated by a significant Group*Time interaction. Between-group effect size was large (d = 1.02). Post-hoc within group analyses revealed that the number of OBE decreased significantly between pre- and post-treatment assessment in both the TG and the WL. While a small effect size was found for the WL (d = 0.31), effect size in the TG was large (d = 1.36). Significant Group*Time interaction effects were also found for all EDE-Q subscales and the global score. Between-group effect sizes were large, ranging from d = 0.82 for restraint to d = 1.18 for the EDE-Q global score. Post-hoc *t*-tests showed a significant reduction from pre- to post-treatment assessment for restraint, weight concern and shape concerns in the TG ($0.95 \leq d \leq 1.18$), while no significant changes were found in the WL. Levels of eating concern and the EDE-Q global score significantly improved in both groups, with small effect sizes in the WL ($0.25 \leq d \leq 0.29$) and large effect sizes in the TG ($1.19 \leq d \leq 1.33$).

General psychopathology. A significant Group*Time interaction was found for depression but not for anxiety. The decrease of depressive symptoms was significantly greater in the TG than in the WL (d = 0.53). Post-hoc *t*-tests revealed significant changes from pre- to post-treatment in both groups with a small effect size in the WL (d = 0.35) and a large effect size in the TG (d = 0.88).

Anthropometrics. In the TG, body weight decreased to a greater extent compared to the WL (d = 0.41). Post-hoc t-tests showed a significant but very small reduction of body weight in the TG (d = 0.06), while no changes were found in the WL. No treatment effect was found for BMI.

Clinical significance

At post-treatment assessment, 33 (47.8%) patients in the TG and only three (4.3%) patients in the WL were recovered from binge eating. The recovery rate was significantly higher in the TG compared to the WL (X^2(1, N = 139) = 34.33, p < 0.001). 10 patients (14.6%) showed a remission from binge eating in the TG whereas none of the WL patients went into remission (X^2(1, N = 139) = 10.93, p < 0.001) (Figure 3).

Predictors of treatment outcome

Depression was the only significant predictor for the likelihood of recovery from binge eating (B = -0.12, Wald = 6.14, p = 0.01). Participants with higher levels of depression at baseline were less likely to be recovered from binge-eating post-treatment (OR = 0.89, 95% CI [0.84-0.98]). Eating concern was found to significantly predict remission from binge eating (B = 0.82, Wald = 4.66, p=0.03). Participants with higher levels of eating concern at baseline were more likely not to binge-eat at all after treatment (OR = 2.28, 95% CI [1.08-4.81]).

Stability of treatment effects

In the TG, 14 patients dropped out during the follow-up period resulting in a total dropout-rate from pre-treatment to 12-month follow-up of 47.8% (n=33, Figure 1). The results from paired t-tests examining the within-group differences between pretreatment and follow-up assessments (intention-to-treat) are displayed in Table 3.

Binge eating and eating disorder symptoms. The reduction in the number of OBE from pretreatment to post-treatment assessment was sustained through the follow-up period. Scores

at each follow-up were significantly lower compared to the pretreatment score. Within group effect sizes were large ($1.05 \leq d \leq 1.31$). No significant changes were observed between any of the follow-up assessments ($p > 0.007$) after Bonferroni correction. We observed similar findings for all EDE-Q subscales and the global score. At 3-, 6- and 12-month follow-up assessments, we found significantly lower scores compared to pretreatment. Large effect sizes were still found 12 months after treatment ($0.79 \leq d \leq 1.11$) and no significant changes were observed between any of the follow-up assessments ($p > 0.007$) after Bonferroni correction.

Recovery and remission from binge-eating: At the 3-month follow-up 33 (47.8%) patients showed a recovery from binge-eating and 13 (18.8%) were remitted. 29 (42.0%) patients were recovered six months after treatment and 15 (21.7%) were remitted. At the 12-month follow-up the recovery rate was 44.9% ($n = 31$) and the remission rate was 24.6% ($n = 17$). Conditional probabilities for recovery during follow-ups among those who were recovered at post-treatment were 81.8% at 3 months, 69.7% at 6-month follow-up and 72.7% at 12 months after treatment. Conditional probabilities for remission were 60.0% at all follow-ups.

General psychopathology. Improvements in depressive symptomatology were maintained throughout the follow-up period as indicated by significantly decreased BDI scores at every follow-up compared to pretreatment. Within effect sizes were medium ($0.63 \leq d \leq 0.74$). No significant changes were observed between any of the follow-up assessments after Bonferroni correction. ($p > 0.007$).

Anthropometrics. Reductions in body weight were maintained during the follow-up period and no significant further changes were observed between follow-ups. Within group effect sizes were small ($0.09 \leq d \leq 0.13$).

Reductions in the number of OBE were also maintained between post-treatment and the 12-month follow-up assessment as indicated by non-significant paired t-tests between post-treatment and 12-month follow-up. Similar findings were observed for restraint, eating concern, shape concern, and body weight. Increases between post-treatment and 12-month follow-up, however not statistically significant ($p > 0.007$) after Bonferroni correction, were

found for weight concern ($t(68) = -2.45$, $p = 0.02$), EDE-Q global score ($t(68) = -2.33$, $p = 0.02$), and depression ($t(68) = -2.43$, $p = 0.02$).

Discussion

The aim of this study was to evaluate whether an Internet-based intervention for patients meeting the full criteria of BED according to DSM-IV-TR was efficacious in reducing binge-eating frequency and associated eating pathology, as well as general psychopathology. We also sought to evaluate longer-term symptom reduction by conducting follow-up assessments up to one year after treatment. According to our hypotheses our intervention led to a strong improvement of BED core symptoms and eating disorder psychopathology which could be largely maintained during one year after treatment. The most important finding was that the intervention significantly reduced the number of OBE over the last 28 days in the TG compared to the WL showing a large between group effect size ($d = 1.02$). Reductions in the number of OBE could be maintained from post-treatment to 12-month follow-up. Furthermore, the intervention significantly reduced scores on all secondary eating psychopathology outcomes with large between group effect sizes. Reductions on EDE-Q scales also proved sustainable. We also evaluated clinically significant change. At post-treatment, 48% of our patients experienced recovery from binge-eating as they did not meet the number of OBE required in the DSM-5. A total of 15% of patients showed a remission from binge-eating, i.e. they did not binge at all after the treatment. The majority of those recovered or remitted at post-treatment were still recovered or remitted one year after the end of the treatment.

During the follow-up period, considerable symptom fluctuation was found, e.g., the number of OBE and eating concerns increased between the 3- and 6-month follow-ups. We found a slight decrease in the eating pathology on some subscales between the 6-month follow-up and the 12-month follow-ups whereas on other scales slight increases were found. These changes showed that eating pathology might change throughout the time course. It remains unclear

why these fluctuations were found. Most long-term face-to-face interventions for BED did not report findings throughout the year following treatment completion (Fischer, Meyer, Dremmel, Schlup, & Munsch, 2014; Hilbert et al., 2012); therefore, it remains unclear whether these changes are specific to Internet-based interventions.

The treatment was also effective in reducing body weight relative to the WL and reductions were maintained during the one-year follow-up period. However, between and within group effect sizes were small and no treatment effect was found for BMI. Because the intervention for BED was not aimed at losing weight, but rather at learning to eat healthier and more regularly, large effects for weight loss or changes in BMI were not expected. Still, as also observed in other Internet-based treatment studies among patients with BED (Carrard et al., 2011a), our participants were often ambivalent about whether they would rather work on their eating pathology or on weight loss. The therapists encouraged participants to focus more on dealing with their BED than on losing weight.

Symptoms of depression were significantly reduced in the TG post-treatment relative to the WL, a result which was still evident in medium effect sizes one year after treatment completion. No additive effect of the intervention was found for anxiety. The improvements with regard to depression might be due to the affected patients having regained self-esteem and a better sense of control over their eating psychopathology. However, these findings are not consistent with those from a meta-analysis on the efficacy of interventions for BED, which showed only small to no effects on comorbid depression (Vocks et al., 2010).

Contrary to many other Internet-based trials, we used a conservative attrition rule. Therefore, the attrition rate of 27% from pre- to post-treatment can be considered satisfactory and is in line with other studies on Internet-based BED interventions (Carrard et al., 2011a; Ljotsson et al., 2007; Robinson & Serfaty, 2008). When looking at treatment completion rates, our intervention revealed more favorable results compared to previous Internet-based interventions (Carrard et al., 2011a, 2011b; Ljotsson et al., 2007; Robinson & Serfaty, 2008). While in Carrad et al. (2011a, 2011b) 62%-86% of participating patients discontinued an

Internet-based guided self-help intervention, only 29% of the included patients stopped treatment prematurely in our study. In Ljotsson et al. (2007), a comparable proportion of patients discontinued treatment, however, more patients dropped out before completing 50% of the treatment (17% vs. 7% in our study). This finding supports the assumption that intensive therapist contact may improve treatment adherence and completion rates (Beintner et al. 2014).

The Internet-based CBT was delivered through structured writing tasks and the patients received manualized writing assignments about their eating pathology. The content of these writing tasks was based on established CBT self-help and treatment manuals. Some individuals with eating disorders are likely to avoid thinking about their eating behavior. Structured therapeutic writing about disordered eating may enhance emotional processing. Writing can be a first step toward recognizing and communicating about painful and embarrassing experiences related to their eating behavior (Schmidt, Bone, Hems, Lessem, & Treasure, 2002). Specifically, individuals who have experienced high levels of shame about their OBE can benefit from structured writing. Indeed, Johnston and colleagues (Johnston, Startup, Lavender, Godfrey, & Schmidt, 2010) found that bulimic patients with a lot of body shame benefited the most from e-mail based writing assignments. The advantages of writing are manifold. Not only do many people find it less embarrassing or shaming than talking face-to-face (Aardoom, Dingemans, Spinhoven, & Van Furth, 2013), it can also help to structure fearful dysfunctional thoughts and foster reflection. Another important aspect of the intervention was that the patients received intensive feedback on their written texts from their therapists. The improvement in eating disorder psychopathology in our study is comparable with results of other Internet-based interventions with intensive therapeutic contact (Ruwaard et al., 2013). The therapeutic alliance in this study was reported to be positive and stable. Significant correlations were found between the working alliance and the EDE-Q subscales but not for the OBE (Dölemeyer, Klinitzke, Steinig, Wagner, & Kersting, 2013). Alongside

these writing tasks, patients filled out daily diaries of eating behavior which are supposed to play and important role in the reduction of OBEs (Fairburn, 1995).

The results from our study are of importance in the light of the lately revised diagnostic criteria for BED in the DSM-5 in which a lower frequency and a shorter duration of regular binge-eating is required for a BED diagnosis. This change may lead to an increase of BED prevalence and therefore evidence-based and reachable low-threshold treatments need to be made available. Internet-based interventions may be an efficacious alternative to cover this need and may serve as a first step treatment for BED. Furthermore, some of the individuals who discontinued our intervention preferred face-to-face therapy. For those patients, Internet-based interventions could help to lower thresholds to take up face-to-face therapy or may be a useful adjunct to face-to-face treatment as well (Schmidt, Bone, et al., 2002).

Limitations of this study are related to the generalizability of the findings, as 96% of our participants were female, even though the treatment was aimed at both male and female participants. We also had a total dropout rate of 28% during the follow-up period among those who had completed post-treatment assessment. To overcome this limitation we analyzed the data by intention-to-treat. Additionally no EDE interview was conducted after therapy or during follow-up and the outcome was exclusively based on self-report (EDE-Q). The EDE-Q shows high correlations with EDE-interview on the four subscales (Mond, Hay, Rodgers, Owen, & Beumont, 2004) but lower correlations on the behavior frequencies with some studies suggesting an overestimation (Fairburn & Beglin, 1994) and others an underestimation of the frequency of OBE (Mond, Hay, et al. 2004). As the primary outcome and secondary eating disorder psychopathology was assessed using the EDE-Q at all assessment times the risk of bias should be limited. Furthermore, BED diagnosis was validated using the EDE before the start of therapy. However, due to the use of self-report measures, the comparability of our results with studies using semi-structured interviews assessing OBE frequency (e.g., EDE) as an outcome is limited. Assessors were not blinded with regard to treatment allocation. However, treatment allocation was done after the telephone interview and

thereafter assessments were conducted via self-report. Therefore bias should be limited. Furthermore, 72% of the participants had received a higher education. This is comparable with other Internet-based mental health interventions (Kersting et al., 2013; Knaevelsrud & Maercker, 2007; Wagner et al., 2006). Generally, Internet-based interventions are reaching a better-educated group of people. Therefore, future Internet-based interventions should specifically address the treatment access needs of poorer and less educated people (Lampe, 2011). Finally, due to our strict exclusion criteria regarding co-morbidity and other eating disorders, a large number of applicants were excluded from the study, further limiting the generalization of our conclusions. Major strengths of our study are the use of a randomized controlled as well as a longitudinal design that made it possible to assess the stability of treatment effects up to one year after treatment completion. The therapy offered was based on well-established manuals and followed a structured procedure. Acceptance of our intervention and compliance with the treatment were satisfactory.

Conclusions

The results of this randomized controlled trial indicate that an Internet-based intervention for patients meeting the full criteria of BED (DSM-IV-TR) with intensive therapeutic support is an efficacious intervention. Furthermore, the intervention led to stable effects up to one year after the end of the treatment. The program was well accepted by the participants and it provoked significant symptom reductions for key factors of BED. Treating patients via the Internet could thus be a solution for providing low-threshold psychological support in a more cost-effective way than traditional face-to-face therapies. Many patients suffering from BED feel ashamed and tend to avoid face-to-face therapy. Internet-based interventions therefore offer new ways to disseminate adequate psychological intervention for BED. Even though the intervention was generally efficacious, 29% of the participants discontinued treatment. This proportion is still higher than that normally found in face-to-face interventions (Fischer et al., 2014; Hilbert et al., 2012). Thus, future research should focus on the evaluation of additive

modules (e.g. motivational interviewing) as these can improve readiness to change and confidence to control binge-eating (Vella-Zarb, Mills, Westra, Carter, & Keating, 2014).

Conflicts of interest

The authors declare that they have no competing interests.

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Table 1. Baseline demographic and clinical characteristics of the study sample with test statistics

	Total sample (*N* = 139)	Treatment (*n* = 69)	Waitlist (*n* = 70)	Test statistic	*p*
Age, M (SD, range),	35.1 (9.9, 18-61)	34.9 (10.1, 18-59)	35.3 (9.7, 19-61)	-0.22[a]	n.s.
Females, n (%)	134 (96.4)	65 (94.2)	69 (98.6)	1.91[b]	n.s.
Married/ cohabiting, n (%)	83 (59.7)	43 (62.3)	40 (57.1)	0.39[b]	n.s.
Children, n (%)	63 (45.3)	30 (43.5)	33 (47.1)	0.19[b]	n.s.
Education, n (%)				0.80[c]	n.s.
Low	11 (8.0)	4 (5.9)	7 (10.0)		
Medium	28 (20.3)	14 (20.6)	14 (20.0)		
High	99 (71.7)	50 (73.5)	49 (70.0)		
Body weight (kg), M (SD)	93.7 (22.6)	91.9 (21.0)	95.42 (24.1)	-0.91[a]	n.s.
BMI (kg/m²), M (SD)	32.4 (7.4)	31.9 (6.7)	32.8 (8.1)	-0.76[a]	n.s.
Eating disorder symptoms (EDE-Q)					
Number of OBE, M (SD)	16.5 (5.9)	16.0 (5.6)	17.1 (6.1)	-1.13[a]	n.s.
Restraint, M (SD)	2.7 (1.4)	2.9 (1.4)	2.8 (1.4)	0.62[a]	n.s.
Eating concern, M (SD)	3.7 (1.2)	3.7 (1.2)	3.8 (1.2)	-0.46[a]	n.s.
Weight concern, M (SD)	4.3 (0.9)	4.3 (0.8)	4.3 (1.0)	0.01[a]	n.s.
Shape concern, M (SD)	4.7 (0.7)	4.7 (0.7)	4.6 (0.8)	0.83[a]	n.s.
Global score, M (SD)	3.9 (0.8)	3.9 (0.8)	3.9 (0.7)	0.29[a]	n.s.
General psychopathology					
Depression (BDI), M (SD)	16.2 (5.8)	15.9 (5.6)	16.6 (5.9)	-0.66[a]	n.s.
Anxiety (SCL-90-R), M (SD)	4.4 (4.2)	4.3 (4.4)	4.4 (3.9)	-0.26[a]	n.s.

n.s. = not significant
[a] two-tailed t-test for independent samples, [b]Pearson χ^2, 2x2 table (df=1), [c]Pearson χ^2, 3x2 table (df=2)
BDI: Beck Depression Inventory, BMI: Body mass index, EDE-Q: Eating Disorder Examination Questionnaire, SCL-90-R: Symptom Checklist 90 revised

Table 2. Means, standard deviations, effect sizes and test statistics of repeated-measures ANOVAs and post-hoc t-tests for intention-to-treat data

	Group	Pretreatment		Post-treatment		Between group analyses			Within group analyses		
		M	*SD*	*M*	*SD*	Interaction effect Group*Time (repeated measures ANOVA)	*p*	$d_{between}$ (95%CI)	Post-hoc paired samples t tests	*P* [a]	d_{within} (95%CI)
Primary outcome											
Number of OBE over the last 28 days (EDE-Q)	TG	15.8	5.6	6.8	7.5	*F* (1, 139) = 94.53	<0.001	1.02 (0.73-1.41)	*t* (68) = 10.51	<0.001	1.36 (1.13-1.60)
	WL	17.1	6.1	14.9	7.7				*t* (67) = 2.79	0.007	0.31 (0.10-0.54)
Eating disorder symptoms (EDE-Q)											
Restraint	TG	2.9	1.4	1.6	1.4	*F* (1, 139) = 45.41	<0.001	0.82 (0.35-1.02)	*t* (68) = 7.49	<0.001	0.95 (0.70-1.21)
	WL	2.8	1.4	2.6	1.4				*t* (67) = 1.53	0.130	0.16 (-0.04-0.33)
Eating concern	TG	3.7	1.2	2.0	1.6	*F* (1, 139) = 71.76	<0.001	0.96 (0.68-1.35)	*t* (68) = 8.67	<0.001	1.19 (0.92-1.47)
	WL	3.8	1.2	3.4	1.2				*t* (67) = 2.45	0.017	0.29 (0.05-0.52)
Weight concern	TG	4.3	0.8	3.0	1.3	*F* (1, 139) = 72.39	<0.001	1.12 (0.74-1.41)	*t* (68) = 9.01	<0.001	1.18 (0.96-1.50)
	WL	4.3	1.0	4.2	0.8				*t* (67) = 1.74	0.087	0.20 (-0.03-0.42)
Shape concern	TG	4.7	0.7	3.4	1.4	*F* (1, 139) = 59.92	<0.001	1.11 (0.65-1.32)	*t* (68) = 8.05	<0.001	1.17 (0.91-1.51)
	WL	4.6	0.8	4.5	0.8				*t* (67) = 1.31	0.196	0.15 (-0.08-0.37)
Gobal score	TG	3.9	0.8	2.5	1.2	*F* (1, 139) = 89.91	<0.001	1.18 (0.76-1.45)	*t* (68) = 9.49	<0.001	1.33 (1.07-1.64)
	WL	3.9	0.9	3.7	0.8				*t* (67) = 2.48	0.016	0.25 (0.05-0.46)
General psychopathology											

Depression (BDI)	TG	15.9	5.6	9.8	7.8	F (1, 139) = 56.13	0.002	0.53 (0.20-0.87)	t (68) = 7.55	<0.001	0.88 (0.67-1.15)
	WL	16.6	5.9	14.0	8.1				t (67) =3.08	0.003	0.35 (1.13-0.59)
Anxiety (SCL-90-R)	TG	4.3	4.4	3.4	3.5	F (1, 139) = 2.76	0.235	0.20 (0.10-0.57)	--	--	--
	WL	4.4	3.9	4.3	4.1				--	--	--
Anthropometrics											
Body weight (kg)	TG	91.9	21.0	90.6	21.3	F (1, 139) = 2.78	0.033	0.37 (0.12-0.55)	t (68) = 2.31	0.024	0.06 (0.01-0.12)
	WL	95.4	24.1	95.6	24.7				t (67) = -0.46	0.648	-0.01 (-0.04-0.03)
Body Mass Index (kg/m²)	TG	31.9	6.7	31.4	6.9	F (1, 139) = 3.63	0.094	0.29 (0.15-0.52)	--	--	--
	WL	32.8	8.1	32.8	8.3				--	--	--

Total n = 139, TG n = 69, WL n = 70

[a] Significance level after Bonferroni correction: $\alpha = 0.025$

BDI: Beck Depression Inventory, BMI: Body mass index, EDE-Q: Eating Disorder Examination Questionnaire, OBE: objective binge-eating episode, SCL-90-R: Symptom Checklist 90 revised

-- no significant Group*Time interaction effect in higher-order analyses

Table 3. Means and standard deviations, effect sizes and t-test results of symptom levels at follow-ups in treatment group (intention-to-treat, *n* = 69)

	Pre-treatment	**Post-treatment**	**3-month follow up**				**6-month follow up**				**12-month follow up**			
			Within group analyses (Pretreatment to 3-month FU)				Within group analyses (Pretreatment to 6-month FU)				Within group analyses (Pretreatment to 12-month FU)			
	M (SD)	*M (SD)*	*M (SD)*	*t*(68)	*p* [a]	*d* (95%CI)	*M (SD)*	*t*(68)	*p* [a]	*d* (95%CI)	*M (SD)*	*t*(68)	*p* [a]	*d* (95%CI)
Primary Outcome (EDE-Q)														
Number of OBE	16.0 (5.6)	6.8 (7.5)	7.1 (7.6)	10.08	<0.001	1.31 (1.06-1.59)	8.4 (8.2)	8.44	<0.001	1.05 (0.83-1.34)	7.8 (7.9)	9.00	<0.001	1.18 (0.94-1.47)
Eating disorder symptoms (EDE-Q)														
Restraint	2.9 (1.4)	1.6 (1.4)	1.7 (1.3)	6.66	<0.001	0.92 (0.64-1.19)	1.7 (1.3)	6.63	<0.001	0.90 (0.63-1.18)	1.9 (1.4)	5.89	<0.001	0.79 (0.52-1.06)
Eating concern	3.7 (1.2)	2.0 (1.6)	2.1 (1.6)	8.04	<0.001	1.12 (0.86-1.43)	2.2 (1.6)	6.77	<0.001	0.97 (0.69-1.27)	2.1 (1.7)	7.20	<0.001	1.04 (0.76-1.34)
Weight concern	4.3 (0.8)	3.0 (1.3)	3.0 (1.4)	8.35	<0.001	1.12 (0.89-1.44)	3.1 (1.5)	7.20	<0.001	0.98 (0.74-1.31)	3.3 (1.4)	6.49	<0.001	0.89 (0.64-1.21)
Shape concern	4.7 (0.7)	3.4 (1.4)	3.5 (1.3)	7.90	<0.001	1.17 (0.90-1.51)	3.6 (1.4)	6.69	<0.001	1.02 (0.74-1.37)	3.6 (1.4)	6.84	<0.001	1.00 (0.74-1.34)
Global Score	3.9 (0.8)	2.5 (1.2)	2.7 (1.2)	9.11	<0.001	1.31 (1.04-1.63)	2.7 (1.3)	7.88	<0.001	1.15 (0.88-1.47)	2.7 (1.3)	7.84	<0.001	1.11 (0.85-1.43)
General psychopathology														
Depression (BDI)	15.9 (5.6)	9.8 (7.8)	10.6 (8.3)	5.82	<0.001	0.73 (0.49-1.41)	11.2 (8.7)	4.82	<0.001	0.63 (0.38-0.92)	10.9 (7.6)	5.83	<0.001	0.74 (0.49-1.01)
Anthropometrics														
Body weight (kg)	91.9 (21.0)	90.6 (21.3)	90.2 (21.0)	2.95	0.004	0.09 (0.03-0.14)	90.0 (21.4)	2.69	0.009	0.09 (0.02-0.16)	89.3 (21.0)	3.06	0.003	0.13 (0.04-0.21)

BDI: Beck Depression Inventory, BMI: Body mass index, EDE-Q: Eating Disorder Examination Questionnaire, OBE: objective binge-eating episode, SCL-90-R: Symptom Checklist 90 revised
[a] Significance level after Bonferroni correction: $\alpha = 0.007$

Figure 1. CONSORT flowchart showing the progression of participants through the study

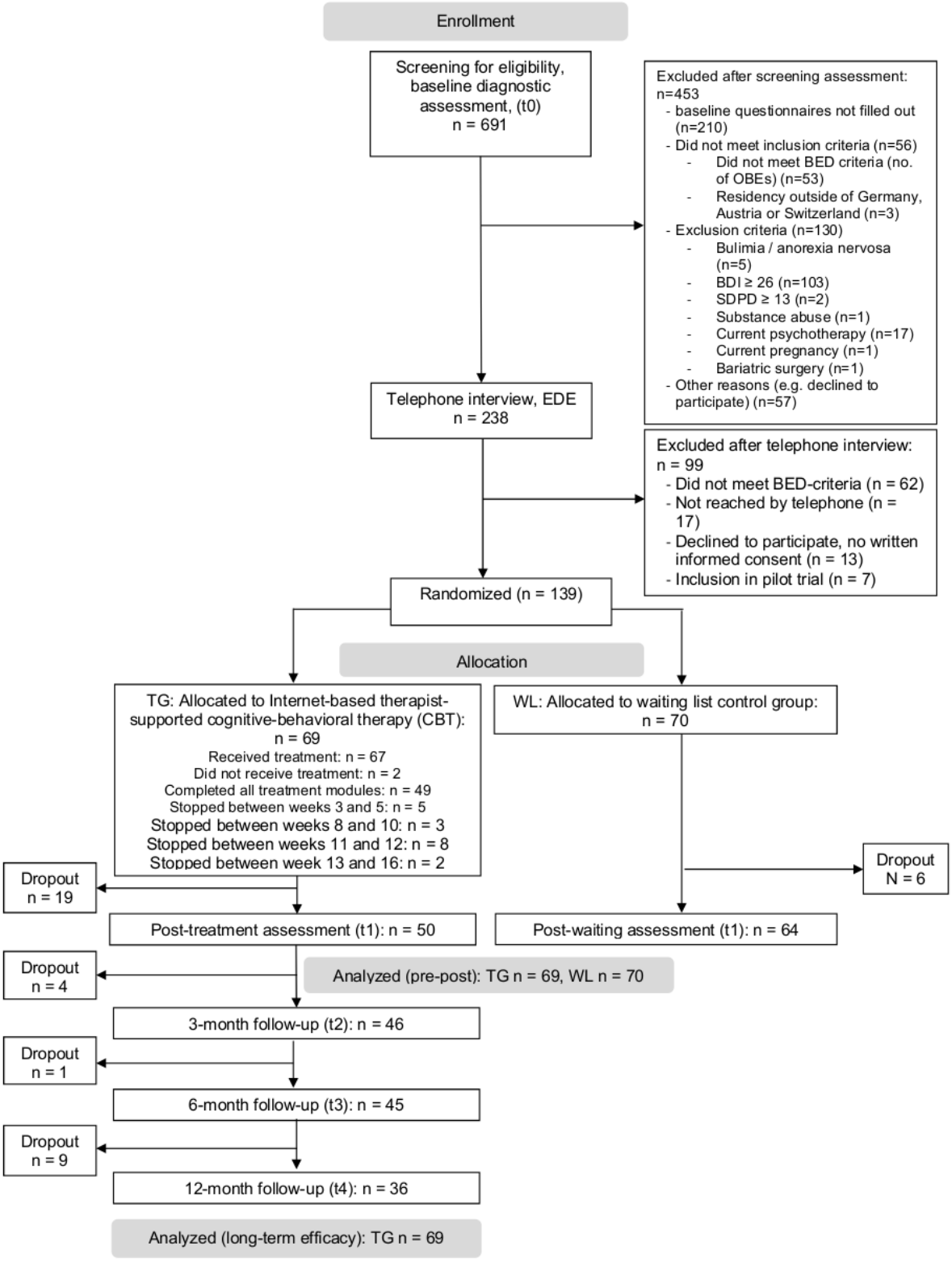


Figure 2. Overview of treatment modules and content of the internet-based cognitive-behavioral treatment program

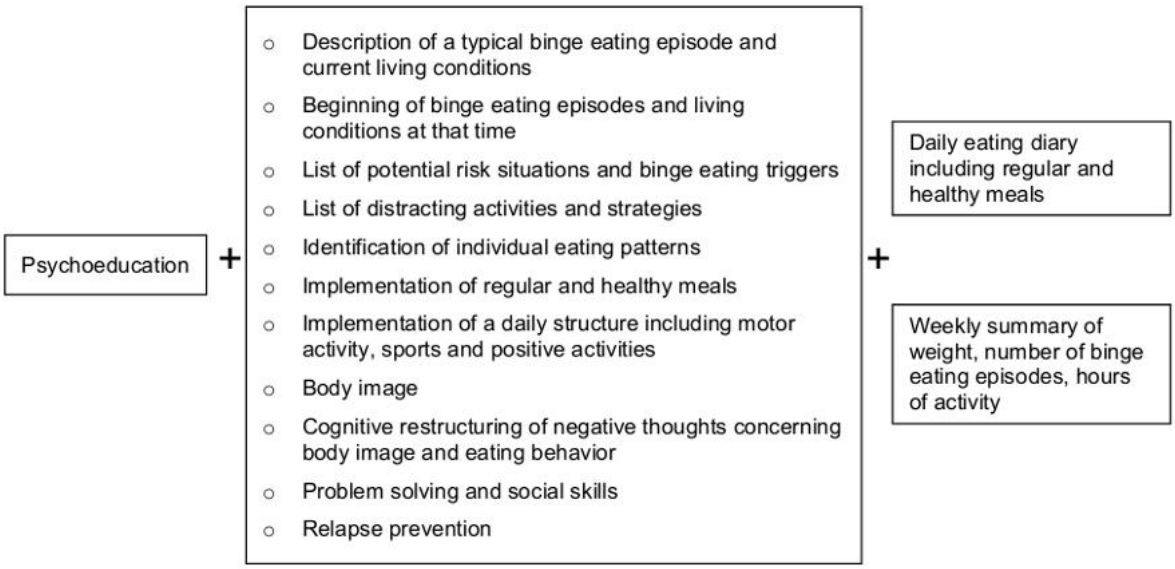
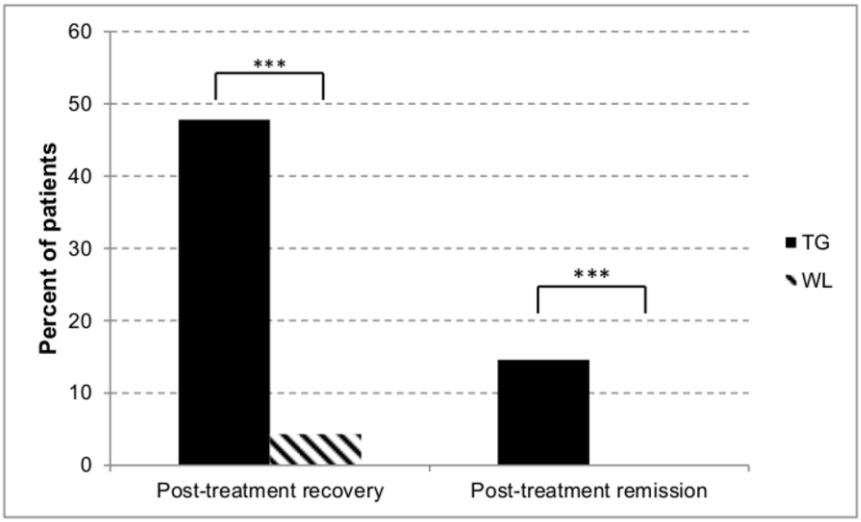


Figure 3. Post-treatment % of patients in remission and recovery from binge-eating for treatment and waiting list control groups



Highlights

- Cognitive behavioral therapy is effective for treatment of binge-eating disorder
- The guided Internet therapy led to a substantial reduction of BED symptoms
- Depression was significantly reduced after treatment
- Treatment effects were maintained over a one-year follow-up period