

# IMPULS: Impulsivity-Focused Group Intervention to Reduce Binge Eating Episodes in Patients with Binge Eating Disorder – A Randomised Controlled Trial

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## Keywords

Binge eating disorder · Cue exposure · Cognitive behavioural therapy · Eating disorders · Impulsivity · Obesity · Randomised controlled trial · Self-control

## Abstract

**Background:** Impulsivity is a risk factor for binge eating disorder, and binge eating (BE) equates to impulsive eating behaviour. Hence, we developed IMPULS, a cognitive behavioural group intervention focusing on impulsive eating. **Methods:** We randomised 41 patients to the IMPULS group and 39 to the control group. The IMPULS group participated in the IMPULS treatment, while both groups completed weekly self-observations. We compared both groups concerning BE episodes in the past 4 weeks at the end of treatment (primary outcome). As secondary outcomes, we investigated eating pathology, depression, general impulsivity and body mass index (BMI) at the end of treatment and in a 3-month follow-up. **Results:** The primary outcome failed, because BE episodes in the past 4 weeks were reduced in both groups at the end of treatment. At follow-up, the IMPULS

group showed further improvement, contrary to the control group. The BE days/episodes in the 2 months before were overall reduced in both groups. Eating pathology was reduced in the IMPULS group at the end of treatment and partly in both groups at the follow-up. Depression was only reduced in the IMPULS group. General impulsivity and BMI did not change. **Conclusions:** The IMPULS study has a negative primary outcome. However, secondary outcomes indicate that the IMPULS treatment might be promising, as BE, eating pathology and depression were reduced in the IMPULS group. The initially reduced BE in the control group might represent a short-term effect from the self-observations. General impulsivity and BMI might need a longer time or more intensive treatment to change. © 2019 S. Karger AG, Basel

## Introduction

Binge eating disorder (BED) is the newest defined and most frequent eating disorder with a significant mental burden and a high comorbidity with obesity and subse-

quent somatic diseases [1]. The main criterion of BED according to DSM-5 [2] is the occurrence of binge eating (BE) episodes, at least once a week in 3 months, accompanied by a subjective loss of control. This loss of control is represented by a specific eating pattern that patients with BED eat large amounts of food in a short period of time and even without being hungry, that they cannot stop eating and regret eating afterwards. This eating behaviour strongly overlaps with the impulsivity concept. Impulsivity is a multidimensional personality trait that consists of two main factors [3, 4]. The first factor is increased reward sensitivity, which means that affected people perceive specific environmental stimuli as particularly rewarding and show increased approach behaviour towards those stimuli. For example, patients with BED are craving strongly for food and enjoy eating so that they are highly attracted by food advertisements, store signs and restaurants, which is also described as increased cue reactivity [5]. The second factor is decreased inhibitory control which is reflected by fast and spontaneous behaviour and without regarding possible negative consequences. Thus, patients with BED eat very fast and have difficulties to stop eating, even if they know that they will gain weight and regret eating afterwards. Taken together, a BE episode can be understood as impulsive eating behaviour.

Several reviews of cross-sectional studies show that people with BED are characterised by increased general (trait) impulsivity [6–8], and especially by impulsivity concerning eating behaviour [9–11]. Additionally, longitudinal studies deliver evidence that impulsivity represents a predictor for the development, maintenance and treatment success of BED [12–16]. Hence, impulsivity constitutes a risk factor for BED. Furthermore, impulsivity can be altered according to first studies in healthy volunteers, and this modification directly influences eating behaviour [17–19]. Conversely, the treatment of eating disorder symptoms is accompanied by the reduction of impulsivity [20, 21]. Therefore, we developed a psychotherapeutic treatment approach that is particularly focusing on food-related impulsivity with the aim to reduce BE in BED.

Concerning psychotherapy in BED, cognitive behavioural treatment (CBT) is deemed the evidence-based treatment of choice [22–24] with comparable outcomes for individual and group therapy [22, 25, 26]. However, the treatment factors that contribute to the efficacy of CBT should be identified, and there is still a need to improve current CBT treatment as BED remission rates are about 50% [23] and CBT does not affect body weight [24].

An impulsivity-focused treatment could constitute such an improvement (according to Gerlach et al. [6] and Gearhardt et al. [27]), because it is based on evidence from mechanisms research, and conventional CBT manuals for BED [28, 29] do hardly rely on the impulsivity concept. There is preliminary evidence from previous studies indicating that impulsivity-focused interventions are useful to reduce impulsive eating behaviour. As impulsivity is a multifactorial concept, these studies target different subcomponents of impulsivity and have used a range of different intervention techniques; however, all of them have in common that they use behavioural treatment approaches aiming at behavioural change in facets of impulsivity as the concept underlying the treatment. A few pilot studies indicate that patients with BED [30], bulimia nervosa [31] or obesity [32–34] benefit from self-control strategies and from food cue exposure with response prevention. Likewise, one randomised controlled trial (RCT) with food cue exposure and subsequent neurofeedback combined with self-regulation strategies showed treatment success compared to mental imagery after cue exposure in people with subclinical BE [35]. Food cue exposure in virtual reality was also superior in reducing BE as a second-level treatment compared with ongoing CBT in a sample consisting of patients with bulimia nervosa or BED [36]. In a sample of obese patients with an included subgroup of patients with BED (33%), a group intervention delivering strategies concerning inhibitory control and emotion regulation combined with a computer-based training of inhibitory control was comparable with usual CBT concerning overeating [37]. To summarise, self-control strategies and food cue exposure seem fruitful to reduce BE and might be helpful in patients with BED.

Thus, we conducted the first RCT of a CBT group intervention that is focusing on food-related impulsivity in a pure sample of patients with BED. We used food cue exposure with response prevention and self-control strategies in this impulsivity-focused manualised outpatient intervention called IMPULS [38].

We hypothesised that IMPULS can reduce BE frequency. Specifically, we expected as primary hypothesis a significant reduction of BE episodes in the past 4 weeks after treatment versus pretreatment in the IMPULS group versus the control group [39]. Our hypotheses concerning the secondary outcomes comprise (a) a significant reduction after treatment versus pretreatment in the IMPULS group versus the control group concerning further eating pathology and food-related and general impulsivity and (b) a significant reduction in the 3-month follow-

up concerning BE episodes in the past 4 weeks, further eating pathology, body mass index (BMI, weight in kilograms per height in squared metres) and general and food-related impulsivity. We compared the performance of the IMPULS treatment group with a control group that consisted of BED patients who did not take part in IMPULS, but both groups did weekly self-observations about BE and other impulsive behaviours in an online questionnaire.

## Materials and Methods

### Design

The IMPULS trial is a parallel-group RCT with stratified randomisation that was conducted at the Department of Psychosomatic Medicine and Psychotherapy, Tübingen, Germany. It has been approved by the ethics committee of the Medical Faculty of the Eberhard Karls University Tübingen and the University Hospital Tübingen, Germany, and is registered at the German Clinical Trials Register (ID: DRKS00007689, [www.drks.de](http://www.drks.de)). The IMPULS trial was carried out between March 2015 and September 2017. The data assessment and the treatment were performed by trained and regularly supervised data assessors and psychotherapists. The therapists were blind to the assessment outcomes, and the data assessors were blind to the randomisation outcome. The data were externally monitored by the Centre of Clinical Studies, University Hospital Tübingen, Germany. The independent randomisation and support concerning data analysis was done by the Institute for Clinical Epidemiology and Applied Biometry, Tübingen, Germany. The full study protocol with a detailed description of the study design, sample size calculation, data management and safety aspects [39], as well as the IMPULS intervention [38], have been published before.

### Participants and Patient Flow

For study inclusion, the patients had to be adult and fulfil the diagnostic criteria for BED according to DSM-5 [2]. They were excluded if they showed (i) current suicidality, (ii) current substance addiction, psychotic disorders or bipolar I disorder, (iii) received current psychotherapy, (iv) were pregnant or breastfeeding, and (v) had somatic conditions which influence eating behaviour or body weight (e.g., diabetes, thyroid diseases) and in which medication had been adapted in the last 3 weeks.

The patient flow is presented in Figure 1 according to the Consolidated Standards of Reporting Trials (CONSORT). The stratified randomisation included the factors BE episodes in the past 4 weeks (cut-off 12) and BMI (cut-off 35) to balance the severity of BED and weight status. As can be seen in Figure 1, the study dropout rate was low. No severe adverse events occurred.

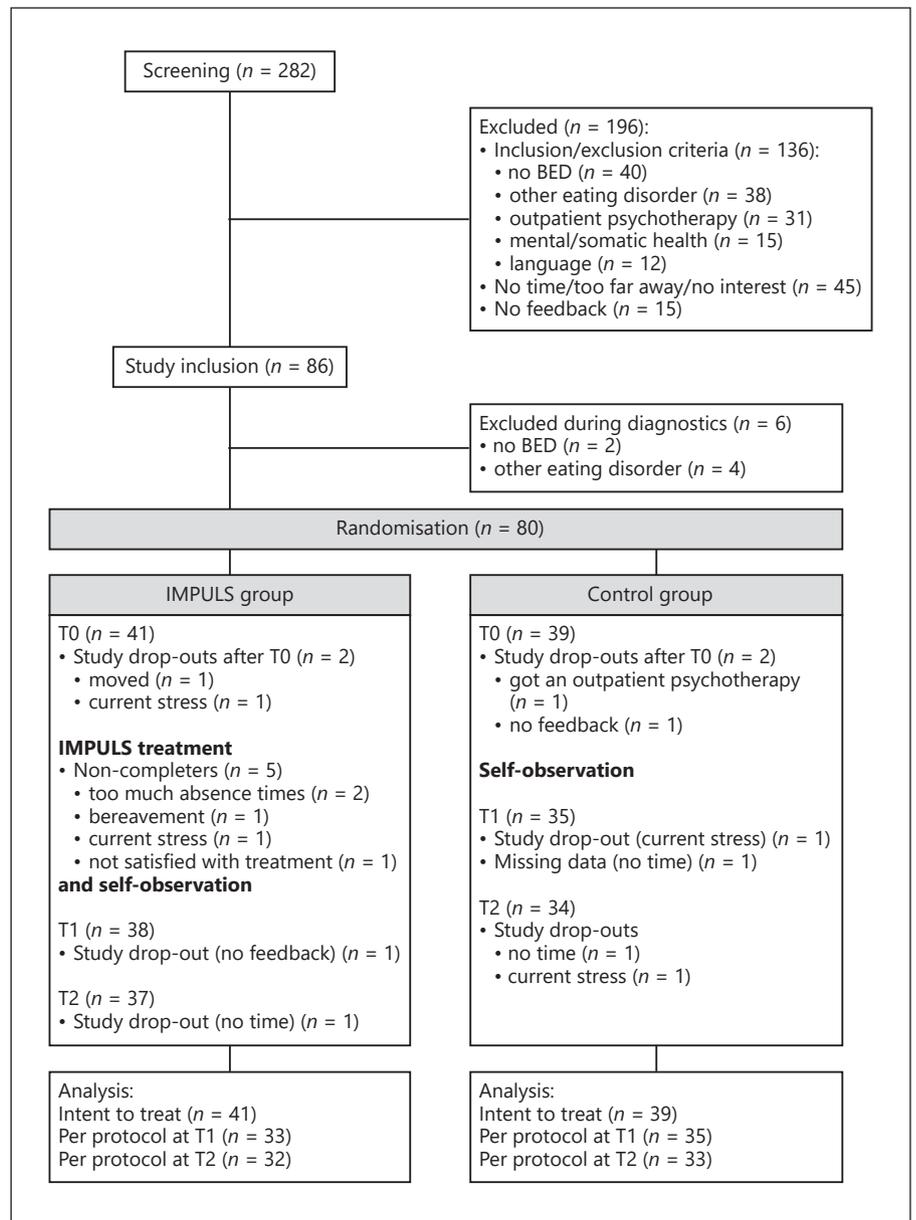
### Procedure

For recruitment, the study information was distributed with e-mail bulletins, flyers, press releases and in our outpatient department in Tübingen, Germany. Individuals interested in study participation were screened for eligibility by phone. Afterwards, all patients gave written informed consent before the first diagnostic appointment at baseline (T0), where the clinical interviews and

questionnaires were assessed. In the second part of the baseline assessment, we assessed food-related impulsivity with eye tracking methodology and associated brain activity with near infrared spectroscopy [39]. After the diagnostic appointment at baseline, the patients were randomised to the IMPULS group and control group. Next, the IMPULS treatment lasting 8 weeks was provided to the IMPULS group. The time lag between the baseline assessment and the beginning of the IMPULS treatment was on average 3.6 ( $\pm 1.6$ ) weeks. During this time, the patients were waiting for the start of the intervention and did not receive any other treatment. The time lag between the last IMPULS treatment session and assessment at the end of treatment (T1) was on average 2.8 ( $\pm 2.5$ ) weeks. During the intervention period, both the IMPULS group and the control group patients completed weekly self-observations using a brief online questionnaire to assess the treatment process. After the IMPULS treatment, the procedure from baseline was repeated at the end of treatment ( $12.7 \pm 2.6$  weeks after baseline) and in the 3-month follow-up ( $13.9 \pm 3.2$  weeks after the end of treatment). There was no treatment delivered between the end of treatment and the 3-month post-treatment follow-up. All participants received remuneration for the participation at the 3 measurement points.

### Treatment

Patients from the IMPULS group participated in the IMPULS treatment consisting of 8 weekly group sessions (90 min each). The groups included 4–6 patients each and were held in the evening by trained and regularly supervised psychologists or physicians according to the highly standardised IMPULS manual [38, 39]. IMPULS is focusing on the reduction of impulsive eating behaviour and consists of modified CBT interventions that were adapted from addiction and eating disorder treatments [29, 40–42]. We believe that the IMPULS treatment complements and expands on current CBT interventions for eating disorders by including techniques specifically targeting impulsivity (i.e., self-monitoring and exposure techniques). The sessions included psychoeducation and the development of an impulsivity-based BED model (session 1), development of individual treatment goals (session 2), self-monitoring as homework and the development of self-control strategies (stimulus control, response control; sessions 2–8), food cue exposure with response prevention in the group and as homework (sessions 3–7) and the reflection and maintenance of achieved goals (session 8). One central part of the treatment consists of self-monitoring with behaviour analysis and protocols which were used on a weekly basis by each patient throughout the intervention. Self-monitoring was focused on the occurrence of BE episodes, risk situations in which patients felt the urge to binge and situations in which they successfully suppressed their urges. Based on the behavioural analyses of these situations, trigger and consequences of BE were identified and methods of stimulus and reaction control were introduced. Another central intervention of the IMPULS trial consists of food cue exposure which is introduced and conducted in the main part of the treatment (sessions 3–7). The introduction of this pivotal intervention comprises psychoeducation about the technique as well as preparation of a hierarchy of difficult food items. Patients are then guided through several food exposure tasks using their preferred binge food. The tasks vary in difficulty to ensure generalizability and transfer to everyday life and are also conducted as homework.



**Fig. 1.** CONSORT patient flow chart of the IMPULS trial. T0, baseline; T1, end of 8-week intervention; T2, 3-month postintervention follow-up.

The patients from the control group did not receive any treatment and were not on a waiting list to receive IMPULS later on. Both groups, the control group and the IMPULS group did the 8 weekly online self-observations during the intervention period and received additional information and support concerning further treatment options; however, they were not allowed to seek out treatment during the active IMPULS phase (see exclusion criteria). In the self-observations, BE and “other impulsive behaviours” like compulsive buying, irritability and excessive substance use were assessed. These other impulsive behaviours were extracted from the impulse control and borderline personality disorder chapters from ICD-10 [43] and DSM-5 [2]. The patients rated the frequency for (a) the BE episodes and other impulsive behaviours in the past 7 days, (b) situations in which they were able to inhibit such

impulsive behaviours and (c) alternative behaviours that were executed instead of impulsive behaviours. These self-observations could be understood as a “mini-intervention” received by the control group.

#### Assessment

The data assessors were trained in the diagnostic assessment and regularly supervised from the principal investigator.

The following interviews were conducted:

- *Eating Disorder Examination* (EDE; German version [44]): standardised interview to verify the BED diagnosis, exclude other eating disorders, and to assess the primary outcome, i.e. the frequency of BE episodes in the past 4 weeks, as well as the abstinence rate [45], the frequency of patients with clinically

relevant change (min. 50% reduction of BE episodes in the past 4 weeks) and the deterioration rate (50% increase in BE episodes in the past 4 weeks [46, 47]), the frequency of BE days in the past 4 weeks, and the BE days and episodes in the 2 months before, i.e. in months 2 and 3. The EDE comprises 4 subscales (restraint, eating concern, weight concern, shape concern). Arithmetic means can be calculated for each subscale and also for all items of the interview (total score). Higher EDE scores represent higher symptom severity

- *Structured Clinical Interview for DSM-IV Disorders* (German version [48]) to assess other mental disorders and to exclude patients with comorbid disorders according to the exclusion criteria (see above)

The BMI was calculated from height and body weight, which were measured in light clothing and without shoes.

Several validated self-report measures were used to assess:

- Sociodemographic and clinical baseline data: here, we assessed age, sex, nationality, marital status, family situation and education
- Eating pathology with the *Eating Disorder Examination Questionnaire* (EDE-Q [49]) and the *Dutch Eating Behaviour Questionnaire* (DEBQ; [50]). The EDE-Q is the self-report version of the EDE interview (see above) and contains the same subscales and scoring scheme with high scores indicating high symptom severity. The DEBQ comprises the three subscales *restrained eating*, *emotional eating* and *external eating*. Particularly the subscale *external eating* is addressing impulsive eating behaviour. Arithmetic means are calculated for each subscale as well as the total score. Higher DEBQ scores represent stronger endorsement of the respective eating behaviour
- Addiction-related concepts such as withdrawal symptoms or development of tolerance (only at baseline) with (a) the *Yale Food Addiction Scale* [51] that is investigating whether a patient is addicted to food or not according to modified criteria for addictive disorders and (b) the *Food Craving Questionnaire Trait, short version* [52], investigating the intensity of the general desire to eat. Items of the Yale Food Addiction Scale are recoded and are weighted according to the fulfilment of 7 underlying addiction criteria. Fulfilled addiction criteria are summed up. A diagnosis of food addiction according to the Yale Food Addiction Scale is fulfilled if at least 3 criteria are fulfilled and the person additionally reports clinically significant impairment. The Food Craving Questionnaire Trait, short version, is a one-factor questionnaire. Item scores are summed up to a total score with higher scores indicating a higher general desire to eat
- General impulsivity with the *Barrat Impulsiveness Scale, short version* (BIS-15 [53]) and the *Behavioral Inhibition System/Behavioral Activation System questionnaire* (BIS/BAS [54]). The BIS-15 comprises the subscales nonplanning, motor impulsiveness and attentional impulsiveness. Item scores are summed up to a total score with higher scores indicating higher impulsiveness. The BIS/BAS questionnaire is based on the personality theory by Gray who suggested the existence of a behavioural inhibition system (BIS) and a behavioural approach system (BAS). Item scores for each subdomain (BIS vs. BAS) are calculated as arithmetic means. Higher scores on the BIS scale indicate a stronger tendency of behavioural inhibition, while higher scores in the BAS scale indicate stronger tendencies of behavioural activation

- Depression levels with the *Beck Depression Inventory, second version* [55]. Items of the Beck Depression Inventory comprise core symptoms of depression. Item scores are summed up to a total score with higher scores indicating higher symptom severity

#### Statistical Analysis

Data were analysed with the Statistical Package of Social Sciences version 25 (SPSS). Multiple imputations on a single-item level were done according to Rubin [56] and Ibrahim et al. [57] with 5 imputations.

For sample comparisons at baseline, we computed parametric *t* tests or non-parametric tests ( $\chi^2$  tests, Mann-Whitney U tests) in the case of initially complete data, and *t* tests or logistic regressions in the case of imputed data. Concerning the primary and secondary outcomes, we changed our data analysis strategy from analyses of variance to generalised estimating equations [58] to analyse estimated group differences (IMPULS group vs. control group) at the end of treatment and follow-up adjusted for baseline, and within-group time effects, because this approach is a robust method to adjust for dependency of measurements in the same subject [58, 59]. In the generalised estimating equations, all variables concerning BE episodes including the primary outcome, log-transformed values were used (transformation  $x \rightarrow \lg_{10}(x + 1)$ ) to obtain normally distributed values (skewness and kurtosis between  $-1$  and  $+1$ ). The remaining variables were normally distributed. Thus, for each outcome a linear model with normal distribution and identity link could be used. We report *p* values for the estimated group differences (adjusted for baseline) of the BE episodes in the past 4 weeks, whereby statistical significance was set at an  $\alpha$ -level of 0.05. We report regression coefficients and 95% Wald confidence intervals for all estimated group differences (adjusted for baseline) and within-group time effects. Concerning BE episodes, the logarithmised values and the original values are presented for terms of easier interpretability. Confidence intervals that do not contain 0 indicate significant results. For the abstinence rate, the frequency of clinically relevant change and the deterioration rate that have per definition constant values at baseline, we tested only for estimated group differences (adjusted for baseline) at the end of treatment and postintervention follow-up with logistic regressions. For all outcomes, we performed intent-to-treat (ITT) analyses and additionally per-protocol (PP) analyses. As most of the PP results are consistent with the ITT results, all values of the PP analyses are reported as supplementary material (online suppl. Table S1; see [www.karger.com/doi/10.1159/000499696](http://www.karger.com/doi/10.1159/000499696) for all online suppl. material), and only deviations from the ITT analyses are mentioned in the main text.

## Results

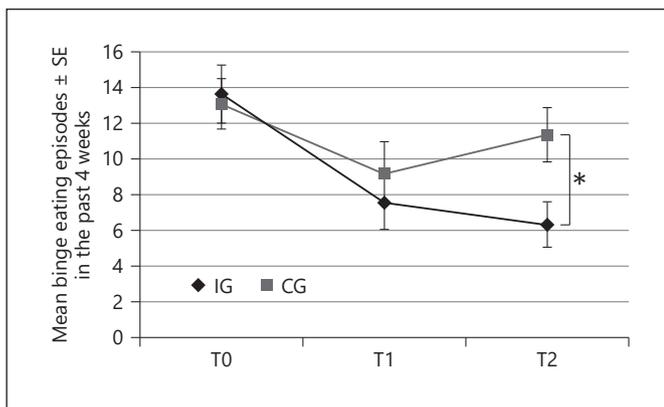
### Sample Characteristics

The sample characteristics are presented in Table 1. The sample did show sociodemographic and clinical data that are comparable to other outpatient BED samples, e.g. the sample investigated in the INTERBED trial [45]. The groups did not differ from each other at all assessed variables at baseline. Most of the diagnosed current mental

**Table 1.** IMPULS sample characteristics at baseline (T0)

	IMPULS group (n = 41)	Control group (n = 39)	p
Age (mean ± SD), years	40.1±12.1	40.5±13.5	0.82
Female sex, n (%)	36 (87.8)	31 (79.5)	0.31
Nationality, n (%)			
German	33 (80.5)	34 (87.2)	0.42
Other	8 (19.5)	5 (12.8)	
Living in relationship, n (%)	27 (65.9)	25 (64.1)	0.87
Children, n (%)	20 (48.8)	16 (42.1)	0.55
Education (school graduation), n (%)			
No/low	8 (19.5)	3 (7.7)	0.13
Medium/high	33 (80.5)	36 (92.3)	
BMI (mean ± SD)	36.2±8.9	37.7±10.2	0.47
Duration of illness (mean ± SD), years	15.9±11.4	15.5±12.2	0.77
Current mental comorbidities acc. to SCID I, n (%)	14 (34.1)	12 (30.8)	0.75
Lifetime mental comorbidities acc. to SCID I, n (%)	34 (82.9)	27 (69.2)	0.15
Current psychotropic drug use, n (%)	5 (12.2)	6 (15.4)	0.58
BDI II total score (mean ± SD)	16.1±12.7	12.6±9.2	0.16
EDE total score (mean ± SD)	2.6±0.8	2.4±0.8	0.30
EDE-Q total score (mean ± SD)	2.9±1.0	2.7±1.0	0.26
DEBQ total score (mean ± SD)	3.5±0.5	3.4±0.5	0.42
FCQ-T-R total score (mean ± SD)	62.1±14.6	61.0±12.2	0.72
YFAS diagnosis, n (%)	29 (71.7)	28 (70.8)	0.93
BIS-15 total score (mean ± SD)	33.9±7.3	35.3±7.8	0.40
BIS total score (mean ± SD)	3.1±0.5	3.1±0.6	0.62
BAS total score (mean ± SD)	3.0±0.3	3.0±0.3	0.62

BAS, Behavioral Activation System; BIS, Behavioral Inhibition System; BIS-15, Barratt Impulsiveness Scale (short version); BDI II, Beck Depression Inventory (second version); DEBQ, Dutch Eating Behaviour Questionnaire; EDE, Eating Disorder Examination Interview; EDE-Q, Eating Disorder Examination Questionnaire; FCQ-T-R, Food Craving Questionnaire Trait (short version); SCID I, Structured Clinical Interview for DSM-IV Disorders, Axis I; YFAS, Yale Food Addiction Scale.



**Fig. 2.** Time course of the primary outcome, i.e. mean and standard error (SE) of the frequency of binge eating episodes in the past 4 weeks according to EDE in the IMPULS group (IG) and the control group (CG). \*  $p < 0.05$ , representing significant group differences. T0, baseline; T1, 8-week intervention; T2, 3-month postintervention follow-up.

comorbidities were anxiety disorders (57.1%), affective disorders (36.7%), and a small proportion were pain disorders (6.1%).

### BE Symptomatology

All results for the primary and secondary outcomes of the ITT analyses are presented in Tables 2 and 3, and for the PP analyses as online supplementary material in Table S1. The primary outcome, i.e. the frequency of BE episodes in the past 4 weeks according to EDE, is additionally presented in Figure 2.

Concerning the primary outcome, the estimated group difference at the end of treatment (adjusted for baseline) was not significant ( $p = 0.524$ ). Both groups reduced the primary outcome from baseline to the end of treatment with confidence intervals below 0 (IMPULS group  $-0.46$  to  $-0.22$ , control group  $-0.45$  to  $-0.09$ ). At follow-up however, the group difference was significant ( $p = 0.005$ ).

**Table 2.** Binge eating episodes in the past 4 weeks including the primary outcome and other secondary outcomes by treatment group (IMPULS group, control group) and measurement point (baseline (T0), end of 8-week intervention (T1), 3-month postintervention follow-up (T2))

	IMPULS group (n = 41)			Control group (n = 39)		
	T0	T1	T2	T0	T1	T2
<i>Primary outcome</i>						
Binge eating episodes in the past 4 weeks (mean ± SD)	13.6±10.4	7.5±9.4	6.3±8.1	13.1±8.8	9.2±10.8	11.4±9.3
<i>Secondary outcomes</i>						
Abstinence rate, n (%)	0 (0)	6 (14.6)	14 (34.1)	0 (0)	7 (17.9)	4 (10.3)
Clinically relevant change, n (%)	0 (0)	26 (63.4)	25 (61.0)	0 (0)	16 (41.0)	15 (38.5)
Deterioration rate, n (%)	0 (0)	5 (12.2)	6 (14.6)	0 (0)	8 (20.5)	9 (23.2)
Binge eating days in the past 4 weeks (mean ± SD)	11.5±7.3	5.5±5.4	5.4±6.9	11.4±7.4	7.4±7.3	9.6±8.3
Binge eating episodes in month 2 (mean ± SD)	12.7±10.4	8.1±7.2	5.5±5.9	13.5±11.3	8.9±8.9	8.0±8.5
Binge eating days in month 2 (mean ± SD)	10.1±6.2	6.7±5.1	4.9±5.3	11.4±7.9	7.4±6.6	7.1±8.1
Binge eating episodes in month 3 (mean ± SD)	13.1±12.5	9.1±7.7	6.1±7.9	15.8±12.5	10.3±8.6	8.1±10.4
Binge eating days in month 3 (mean ± SD)	10.2±6.6	7.2±4.5	5.4±6.4	12.7±8.2	8.6±6.7	7.0±7.4
BMI (mean ± SD)	36.2±8.9	36.2±8.7	35.7±8.2	37.7±10.2	38.6±10.2	37.9±10.2
EDE total score (mean ± SD)	2.6±0.8	2.1±0.8	2.1±0.8	2.4±0.8	2.3±0.7	2.2±0.7
EDE-Q total score (mean ± SD)	2.9±1.0	2.2±1.0	2.2±1.0	2.7±1.0	2.5±0.9	2.5±1.0
DEBQ total score (mean ± SD)	3.5±0.5	3.1±0.6	2.9±0.6	3.4 (0.5)	3.2±0.5	3.1±0.5
DEBQ external eating (mean ± SD)	3.7±0.6	3.2±0.7	3.0±0.7	3.6 (0.6)	3.5±0.7	3.4±0.7
BDI II total score (mean ± SD)	16.1±12.7	11.2±8.4	10.1±8.6	12.6±9.2	12.4±8.7	13.7±10.2
BIS-15 total score (mean ± SD)	33.9±7.3	33.0±5.9	33.0±6.5	35.3±7.8	34.4±8.3	34.4±7.3
BIS total score (mean ± SD)	3.1±0.5	3.1±0.5	3.1±0.4	3.1±0.6	3.1±0.4	2.9±0.5
BAS total score (mean ± SD)	3.0±0.3	3.0±0.4	3.0±0.4	3.0±0.3	3.0±0.4	3.0±0.3

Imputed data of: abstinence rate, no binge eating (BE) episodes in the past 4 weeks; BAS, Behavioral Activation System; BIS, Behavioral Inhibition System; BIS-15, Barratt Impulsiveness Scale (short version); BDI II, Beck Depression Inventory (second version); BMI, body mass index; clinically relevant change, min. 50% reduction of BE episodes in the past 4 weeks; DEBQ, Dutch Eating Behaviour Questionnaire; deterioration rate, min. 50% increase in BE episodes in the past 4 weeks; EDE, Eating Disorder Examination Interview; EDE-Q, Eating Disorder Examination Questionnaire.

This is representing the reduction of BE episodes in the IMPULS group (confidence interval  $-0.33$  to  $-0.15$ ), whereas the control group shows no change between baseline and postintervention follow-up (confidence interval  $-0.15$  to  $0.01$ ). The PP analysis was consistent to the ITT analysis in the primary outcome (see online suppl. Table S1).

Accordingly, the abstinence rate, clinically relevant change and deterioration rate in the IMPULS group and control group did not differ from each other at the end of treatment in the ITT and consistently in the PP analysis (Table 3 and online suppl. Table S1). At follow-up however, the abstinence rate was higher and the deterioration rate lower in the IMPULS group compared to the control group in the ITT analyses with the respective confidence intervals below 0, and in the PP analysis, the abstinence rate and clinically relevant change were higher.

Concerning the frequency of BE days in the past 4 weeks, there was no group difference at the end of treatment (confidence interval  $-5.94$  to  $1.99$ ) as both groups

reduced BE days in the past 4 weeks (both confidence intervals below 0). At follow-up, the groups did not differ either (confidence interval  $-4.29$  to  $0.01$ ), though only the IMPULS group decreased BE days in the past 4 weeks (confidence interval IMPULS group  $-4.50$  to  $-1.56$ ; control group  $-2.48$  to  $0.70$ ). The results from the PP analysis are similar but showed no reduction of BE days in the control group at the end of treatment and a group difference at follow-up (see online suppl. Table S1).

The ITT and PP analyses of the frequencies of BE episodes and days in the 2 months before, i.e. months 2 and 3, showed overall no group differences at the end of treatment and follow-up (all confidence intervals containing 0), because both groups reduced BE behaviour. The only exceptions in the ITT analysis were no reduction of BE episodes in month 2 in the control group and in month 3 in the IMPULS group at the end of treatment, and in the PP analysis in BE days in month 3 in the control group.

**Table 3.** Regression coefficients and 95% Wald confidence intervals for the binge eating episodes in the past 4 weeks including the primary outcome and other secondary outcomes

Variable	Group difference T0/T1	Group difference T0/T2	Time effect in IMPULS group T0/T1	Time effect in control group T0/T1	Time effect in IMPULS group T0/T2	Time effect in control group T0/T2
<i>Primary outcome</i>						
Binge eating episodes in the past 4 weeks, logarithmised values	-0.07 (-0.28 to 0.15)	-0.17 (-0.29 to -0.05)	-0.34 (-0.46 to -0.22)	-0.27 (-0.45 to -0.09)	-0.24 (-0.33 to -0.15)	-0.07 (-0.15 to 0.01)
Binge eating episodes in the past 4 weeks, original values	-2.24 (-7.15 to 2.67)	-2.80 (-5.45 to -0.14)	-6.09 (-9.01 to -3.17)	-3.85 (-7.78 to 0.09)	-3.66 (-5.49 to -1.72)	-0.86 (-2.68 to 0.96)
<i>Secondary outcomes</i>						
Abstinence rate <sup>1</sup>	0.21 (-0.99 to 1.40)	-1.51 (-2.73 to -0.29)	-	-	-	-
Clinically relevant change <sup>1</sup>	-0.83 (-1.74 to 0.09)	-0.85 (-1.79 to 0.08)	-	-	-	-
Deterioration rate <sup>1</sup>	0.78 (-0.48 to 2.04)	-1.69 (-2.56 to -0.82)	-	-	-	-
Binge eating days in the past 4 weeks	-1.98 (-5.94 to 1.99)	-2.14 (-4.29 to 0.01)	-5.96 (-7.99 to -3.92)	-3.98 (-7.39 to -0.57)	-3.03 (-4.50 to -1.56)	-0.89 (-2.48 to 0.70)
Binge eating episodes in month 2, logarithmised values	-0.01 (-0.25 to 0.24)	-0.09 (-0.21 to 0.03)	-0.20 (-0.35 to -0.06)	-0.20 (-0.39 to 0.00)	-0.22 (-0.30 to -0.14)	-0.13 (-0.22 to -0.04)
Binge eating episodes in month 2, original values	0.03 (-5.58 to 5.64)	-0.82 (-3.32 to 1.69)	-4.59 (-8.30 to -0.87)	-4.62 (-8.82 to -0.41)	-3.59 (-5.22 to -1.96)	-2.77 (-4.67 to -0.87)
Binge eating days in month 2	0.63 (-3.50 to 4.75)	-0.46 (-2.45 to 1.52)	-3.39 (-5.74 to -1.04)	-4.02 (-7.41 to -0.62)	-2.62 (-3.83 to -1.40)	-2.15 (-3.73 to -0.58)
Binge eating episodes in month 3, logarithmised values	0.07 (-0.20 to 0.33)	-0.03 (-0.14 to 0.09)	-0.14 (-0.32 to 0.05)	-0.20 (-0.39 to -0.02)	-0.20 (-0.28 to -0.12)	-0.18 (-0.26 to -0.10)
Binge eating episodes in month 3, original values	1.57 (-4.74 to 7.89)	0.36 (-2.32 to 3.04)	-3.99 (-8.43 to 0.46)	-5.56 (-10.03 to -1.09)	-3.47 (-5.23 to -1.72)	-3.84 (-5.85 to -1.82)
Binge eating days in month 3	1.06 (-3.21 to 5.32)	0.45 (-1.41 to 2.31)	-3.02 (-5.38 to -0.65)	-4.07 (-7.62 to -0.52)	-2.40 (-3.50 to -1.30)	-2.85 (-4.36 to -1.35)
BMI	-0.87 (-2.48 to 0.75)	-0.33 (-1.19 to 0.52)	0.02 (-0.85 to 0.89)	0.88 (-0.54 to 2.30)	-0.24 (-0.78 to 0.30)	0.10 (-0.55 to 0.74)
EDE total score	-0.38 (-0.72 to -0.04)	-0.13 (-0.31 to 0.04)	-0.51 (-0.75 to -0.27)	-0.13 (-0.36 to 0.10)	-0.26 (-0.39 to -0.14)	-0.13 (-0.25 to -0.01)
EDE-Q total score	-0.52 (-0.85 to -0.20)	-0.25 (-0.45 to -0.05)	-0.66 (-0.90 to -0.42)	-0.14 (-0.36 to 0.09)	-0.33 (-0.49 to -0.18)	-0.09 (-0.21 to 0.04)
DEBQ total score	-0.21 (-0.39 to -0.03)	-0.14 (-0.24 to -0.03)	-0.33 (-0.46 to -0.21)	-0.13 (-0.26 to 0.01)	-0.26 (-0.34 to -0.17)	-0.12 (-0.19 to -0.05)
DEBQ external eating	-0.41 (-0.71 to -0.11)	-0.24 (-0.39 to -0.09)	-0.53 (-0.70 to -0.36)	-0.12 (-0.36 to 0.12)	-0.34 (-0.45 to -0.24)	-0.10 (-0.21 to 0.00)
BDI II total score	-4.75 (-8.25 to -1.24)	-3.58 (-5.48 to -1.67)	-4.93 (-7.60 to -2.27)	-0.19 (-2.47 to 2.10)	-3.03 (-4.62 to -1.44)	0.55 (-0.54 to 1.64)
BIS-15 total score	0.04 (-2.53 to 2.60)	0.00 (-1.22 to 1.22)	-0.91 (-2.60 to 0.79)	-0.94 (-2.99 to 1.10)	-0.44 (-1.38 to 0.50)	-0.44 (-1.28 to 0.39)
BIS total score	-0.09 (-0.29 to 0.10)	-0.04 (-0.07 to 0.15)	-0.07 (-0.19 to 0.06)	0.03 (-0.13 to 0.18)	-0.04 (-0.12 to 0.04)	-0.08 (-0.16 to 0.00)
BAS total score	-0.03 (-0.17 to 0.10)	0.00 (-0.06 to 0.07)	-0.03 (-0.13 to 0.06)	-0.00 (-0.09 to 0.09)	-0.01 (-0.06 to 0.04)	-0.02 (-0.06 to 0.03)

All values adjusted for baseline, not adjusted for multiple comparisons. Abstinence rate, no binge eating (BE) episodes in the past 4 weeks; BAS, Behavioral Activation System; BIS, Behavioral Inhibition System; BIS-15, Barratt Impulsiveness Scale (short version); BDI II, Beck Depression Inventory (second version); BMI, body mass index; clinically relevant change, min. 50% reduction of BE episodes in the past 4 weeks; DEBQ, Dutch Eating Behaviour Questionnaire; deterioration rate, min. 50% increase in BE episodes in the past 4 weeks; EDE, Eating Disorder Examination Interview; EDE-Q, Eating Disorder Examination Questionnaire; T0, baseline; T1, end of 8-week intervention; T2, 3-month postintervention follow-up. <sup>1</sup> No time effects per group computed as data were analysed with logistic regressions instead of generalised estimating equations due to constant values at baseline.

### Eating Pathology

For the total score from the EDE interview, the groups differed from each other at the end of treatment (confidence interval -0.72 to -0.04), where the IMPULS group (-0.75 to -0.27), but not the control group (-0.36 to 0.10), decreased in EDE total score. At follow-up, there were no group differences (confidence interval -0.31 to 0.04) as both groups reduced the EDE total score with confidence intervals below 0. In the PP analyses, the results were consistent except for no group difference at the end of treatment.

In the ITT analysis of the EDE-Q total score, the groups differed at the end of treatment and follow-up (both confidence intervals below 0) with only the IMPULS group showing decreased scores (confidence interval -0.90 to -0.42 at the end of treatment and -0.49 to -0.18 at follow-up). In the PP analyses, the groups did not differ at follow-up, as the control group also reduced the EDE-Q total score at the end of treatment and follow-up.

In the ITT analysis of the DEBQ total score, both groups differed at the end of treatment and follow-up (both confidence intervals below 0) with the IMPULS group showing decreased scores at both measurement

points (confidence intervals  $-0.70$  to  $-0.36$  and  $-0.45$  to  $-0.24$ ), but the control group only at follow-up ( $-0.19$  to  $-0.05$ ). In the PP analyses, the groups did only differ at follow-up, and the control group did also show decreased scores at the end of treatment. The reported group differences from the DEBQ total score were mainly driven by the DEBQ subscale external eating with group differences at the end of treatment and follow-up in the ITT and PP analyses (all confidence intervals below 0), whereas concerning the other two subscales restrained eating and emotional eating, the groups did not differ.

#### *Body Mass Index*

In the ITT and PP analyses, the groups did not differ from each other and no group did change the BMI at the end of treatment and follow-up (all confidence intervals containing 0).

#### *Depression*

Concerning BDI II total score, both groups differed at the end of treatment and follow-up (both confidence intervals below 0) with only the IMPULS group showing decreased scores (confidence interval  $-7.60$  to  $-2.27$  at the end of treatment and  $-4.62$  to  $-1.44$  at follow-up). The results from the PP analyses were consistent, except for no group difference at the end of treatment.

#### *General Impulsivity*

In the ITT and PP analyses, the groups did not differ from each other, and no group did change BIS-15 total score, BIS total score and BAS total score at the end of treatment and follow-up (all confidence intervals containing 0).

## **Discussion**

The IMPULS study is the first RCT in patients with BED that examines the efficacy of a group intervention which focuses especially on impulsive eating behaviour as compared to a control group receiving no intervention. In this trial, we carried out a manualised treatment that was regularly supervised, therapists and data assessors were blinded, data were externally monitored, randomisation was independent and data analysis was externally supported. This is in line with the current methodological recommendations for clinical trials from Guidi et al. [46]. According to the low drop-out rate, the IMPULS treatment is feasible and highly accepted in patients with BED.

The data did not support our primary hypothesis, this means that with respect to the primary outcome of this study (BE frequency over the past 4 weeks), we could not show a superiority of the IMPULS treatment as compared to the control condition. Taking a closer look at the results from the primary outcome of the IMPULS trial, data shows that the patients from the IMPULS group reduced BE episodes in the past 4 weeks in the treatment period, and this effect continues until 3 months after treatment, whereas the control group did only reduce BE episodes between baseline and end of treatment but then relapsed to the initial level of BE episodes at the postintervention follow-up. Accordingly, we found no group difference at the end of treatment, but at the follow-up. Thus, the intervention group significantly reduced the core symptoms of BED as compared to the control group in the longer observation period. These results indicate that the IMPULS treatment is effectively targeting the main symptom of BED, i.e. BE episodes. Similar results can be seen concerning the BE *days* in the past 4 weeks. This pattern was also mirrored by the abstinence and deterioration rates with no group differences at the end of treatment, but higher abstinence and lower deterioration rates in the IMPULS group compared with the control group at the postintervention follow-up. Concerning BE episodes and days in the 2 months before, we also found a reduction from baseline to the end of treatment and from baseline to postintervention follow-up in both groups. Taken together, IMPULS seems a useful treatment for BED with sustaining effects, whereas the effects in the control group disappear rapidly after the end of treatment. The initial amelioration of BE in the control group might be due to the weekly self-observations that have been completed by both groups and are in line with results from Hilbert et al. [60] who report a 70% rate of patients with BED who show a so-called “rapid response” within the first 4 treatment weeks. However, without more elaborated and guided care, the patients from the control group seemed not to be able to maintain their achievements like the patients in the IMPULS group. In sum, these results speak for a more powerful and enduring effect in the IMPULS group resulting from our IMPULS treatment.

Concerning eating pathology, the patients in the IMPULS group showed earlier and stronger effects in comparison with the control group according to the standardised EDE interview, the EDE questionnaire and the DEBQ self-report. This could be explained by the fact that the IMPULS treatment has addressed BED pathology more comprehensively and promotes a deeper understanding of the mechanisms of the eating pathology,

whereas the patients of the control group were only instructed to observe concrete BE episodes and other impulsive behaviours by themselves without getting more background information. This interpretation is in line with De Zwaan et al.'s [45] RCT in patients with BED and with Zerwas et al.'s [61] RCT in patients with BN, both indicating that a guided online intervention is inferior to a face-to-face intervention. Moreover, it is supported by the result that particularly the DEBQ subscale "external eating" evoked the group difference in the DEBQ: this subscale is addressing the disposition of "eating in response to food-related stimuli" [62, p. 296] or cue reactivity [5], which is precisely what we have targeted in the food cue exposure exercises in the IMPULS treatment. Another point speaking for a deeper processing and progress in the IMPULS group are the decreased depression scores in the IMPULS group contrary to the control group, with mild depression symptoms in both groups at baseline. Despite a good group coherence and increased day structure, the reduced depression scores might mirror a general improvement in psychopathology as a positive side effect, because the patients in the IMPULS group are now better getting along with their eating disorder.

Unfortunately, the patients in the IMPULS group did not significantly reduce BMI and general impulsivity according to BIS-15 and BIS/BAS self-reports in the follow-up. These results indicate that general impulsivity is a relatively stable trait that is hard to change using a short-term intervention – however, it must be kept in mind that IMPULS was specifically designed to influence impulsive eating behaviour. Concerning BMI, IMPULS was not designed as a weight reduction programme either, and as De Zwaan et al. [45] put it, the failure of significant weight loss "may be reinterpreted as stabilization of weight and prevention of further weight gain" (p. 993). Further, it could be useful to make observations in a longer time span as the 3-month follow-up to detect significant changes in BMI and general impulsivity. We are currently addressing this question together with the long-term course of BED in a 3-year follow-up study.

Taken together, although the data did not support our primary hypothesis, the results from the IMPULS trial as a whole deliver evidence that a particular focus on impulsive eating behaviour might be a fruitful approach to reduce BE pathology in patients with BED. This interpretation is in line with a current methodological article from Pocock and Stone [63], who state in the abstract that the "labeling of all randomized trials as either positive or negative on the basis of whether the *p* value for the primary outcome is less than 0.05 (...) is overly simplistic. (...) the

interpretation of any trial should depend on the totality of the evidence (i.e., the primary, secondary, and safety outcomes), not just a single end point."

Some limitations of the RCT have also to be considered: first, the treatment administration was not blind for the patients, which is a limitation that is inherent to all RCTs of psychotherapy. Moreover, IMPULS is a monocentric trial with just a sufficient sample size according to the power analysis [39]. Hence, the results should be replicated in a larger multicentre trial. Clinically, it seems fruitful to enhance the IMPULS treatment. For example, disrupted emotion regulation strategies might be another promising risk factor for BED, particularly the interaction of negative emotions with impulsive eating behaviour [for reviews, see 64, 65]. We have used the DEBQ to assess facets of impulsive eating; however, this instrument has previously been subject to critique for difficulties with construct and discriminative validity [66, 67]. Another important point is that the treatment duration was short with only 8 sessions. Therefore, we speculate that a longer treatment might deliver the opportunity to work more intensively on the eating pathology, especially for those who are no "rapid responders" [60]. Such a longer enduring treatment might raise abstinence rates to rates from usual group CBT of about 50% [23]. However, the abstinence rate of 34%, the clinically relevant change of 61% and the low deterioration rate of 15% at the follow-up in the IMPULS group are indeed considerable (compare Lambert [47]). Moreover, the reduction of the BE frequency in the IMPULS trial was initially comparable and even somewhat higher at the follow-up in comparison with Boutelle et al.'s [30] pilot trial lasting 4 months with impulsivity-related interventions. In comparison with a clinical trial in patients with BED using also an 8-session, but usual group CBT [68], changes in abstinence rates, BE frequency and BMI were comparable to the IMPULS treatment. Taking these comparisons into account, it seems that IMPULS might be as effective as a CBT-based treatment as usual. This assumption is also in line with the conclusion that Preuss et al. [37] have drawn from their RCT concerning an impulsivity-based treatment in obese patients.

To conclude, to our knowledge IMPULS is the first RCT investigating the efficacy of an impulsivity-focused intervention in a pure BED sample. The IMPULS treatment seems capable of addressing the main issues of this often chronic disease with strong somatic comorbidities. As IMPULS was feasible and accepted in the group setting, it might constitute a helpful add-on treatment to individual psychotherapy. To get more insight into the neu-

ropsychological mechanisms, the treatment processes and mechanisms of action in IMPULS, we will in a next step examine the eye tracking and near-infrared spectroscopy data, the weekly self-observations and the evaluation of the IMPULS treatment. If these analyses support the here presented findings, impulsivity as the underlying concept of BED as well as self-control strategies and food-related cue exposure should be integrated into the usual treatment of BED.

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## Statement of Ethics

All patients gave written informed consent before the first diagnostic appointment at baseline.

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There are no competing interests.

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## Author Contributions

K.S., K.E.G., E.J.L., P.M., W.B. and S.Z. participated in the design of the study. K.S., E.J.L., S.B. and K.E.G. developed the treatment manual. E.-M.S. was therapist in all treatment groups, and S.B. supervised all treatment sessions. K.S. and P.M. performed the data analysis with support by S.K.R. K.S. drafted the manuscript, and all co-authors revised the manuscript critically and for important intellectual content. All authors read and approved the final version of the paper.

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