Supplementary Online Content

de Zwaan M, Herpertz S, Zipfel S, et al. Effect of internet-based guided self-help vs individual face-to-face treatment on full or subsyndromal binge eating disorder in overweight or obese patients: the INTERBED randomized clinical trial. *JAMA Psychiatry.* Published online August 2, 2017. doi:10.1001/jamapsychiatry.2017.2150

This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix. Supplementary Information

Binge Eating Disorder in DSM-IV and DSM-5

In this study the DSM-IV research criteria for BED[1] were used. The new formal DSM-5 criteria[2] are almost identical; however, a lower diagnostic threshold in terms of frequency and duration than formerly used was accepted. In the shift from provisional to formal diagnosis for BED, APA experts changed the criterion for frequency of BED from twice per week to once per week and the duration criterion from 6 months to 3 months, bringing the criteria in line with those for bulimia nervosa (BN).

Inclusion and Exclusion Criteria[3]

Inclusion

- Diagnostic criteria for BED according to DSM-IV-TR or subsyndromal BED. Subsyndromal BED was defined as follows: patients had to meet the criteria for objective binge-eating episodes (OBEs), but could lack one of the other DSM-IV criteria (a frequency of less than 2 days with OBEs in 6 months, no marked distress, or the presence of only 2 instead of 3 of the 5 associated criteria).
- Age 18 years and older
- German speaking
- BMI between 27 and 40 kg/m²
- Private access to the Internet

It is of note that a sizable number of screened patients did not meet our inclusion criteria for BMI < 40 kg/m^2, so that future studies may consider broadening the inclusion criteria to include patients with obesity grade 3.

Exclusion

- Serious unstable medical problems or conditions that influence weight or eating (e.g., type 1 diabetes mellitus, untreated thyroid problems)
- Pregnancy or lactation
- Ongoing psychotherapy
- Current bulimia nervosa
- Current substance abuse
- Psychotic disorder
- Current suicidal ideation
- Current intake of antipsychotic or weight-affecting drugs

Assessment Instruments

Primary outcome

Binge eating: The German version of the EDE interview (EDE-I)[4,5] was administered at baseline, mid-treatment, end of treatment, 6-month, and 1.5-year follow-up by independent and trained assessors, blind to treatment condition. The EDE is a well-established semi-structured interview for eating disorder diagnosis and assessment. The primary outcome variable derived from the EDE-I was the number of days with OBEs over the last 28 days.

Secondary outcomes

Secondary eating-related outcome variables: The EDE was further used for determining the presence of a diagnosis of BED, abstinence from binge eating (0 OBEs over the last 28 days), and eating disorder psychopathology as measured with the EDE subscales restraint, and eating, shape, and weight concern, as well as the global EDE score, derived from the 4 subscales (Cronbach's $\alpha = 0.87$ in this study's sample).

Comorbid psychopathologic findings: Secondary outcomes measured by the SCID-I/P[1,6] included the presence of an affective or anxiety disorder (i.e., social phobia, generalized anxiety disorder, specific phobia, posttraumatic stress disorder, and obsessive compulsive disorder) at each time point. Depression severity was measured with the Beck Depression Inventory (BDI-II), a 21-item self-report questionnaire[7,8], with good internal consistency in this sample ($\alpha = 0.91$). Self-esteem was measured with the Rosenberg Self-Esteem (RSES) Scale [9,10] ($\alpha = 0.91$ in this sample).

Quality of life: Quality of life was measured by the Impact of Weight on Quality of Life-Lite (IWQOL-Lite)[11,12] and the Clinical Impairment Assessment (CIA)[13]. The IWQOL-Lite is a 26-item health-related quality of life questionnaire designed specifically for use with obese patients. Internal consistency was excellent ($\alpha = 0.93$ in this sample). The CIA is a 16-item, self-report instrument for the measurement of impairment due to eating disorder psychopathology ($\alpha = 0.90$ in this study's sample).

Validated German versions of all instruments are available, except for the CIA that was translated by AH and MdZ for this study, controlled by a back translation procedure by a licensed translator.

Details regarding design, methods, and treatment of the study have been published previously[3]. The study was conducted in accordance to ICH-GCP and CONSORT 2010[14] criteria. Extensions of the CONSORT 2010 statement for non-inferiority trials[15] and e-health trials[16,17] were taken into account.

Treatment Interventions

Prior to the start of treatment and repeatedly over the course of the study, therapists received training for the GSH-I (provided by TL) as well as training for the CBT program (provided by AH). Regular supervision by a senior clinician was provided at each site. All therapists (n=29) were clinical psychologists (n=23) or residents in psychosomatic medicine (n=6) with at least 2 years of postgraduate training in psychotherapy. A detailed list of therapeutic interventions and techniques used has been published before[3].

Internet-based guided self-help (GSH-I)

For this study, the Self-Help Guide (Copyright © NetUnion & University Hospital of Geneva HUG) was used. This program is based on an online program for bulimia nervosa following CBT principles that was developed in the European Research Program SALUT by HUG and NetUnion and adapted to specifically address BED[18]. It consists of 11 modules. Participants worked through the modules sequentially. After predefined time intervals, the next module was made accessible to the participants by the coach.

Participants were instructed to contact their coach at least once weekly by e-mail, and they received feedback by e-mail once weekly on a fixed day from the coach (asynchronous communication). Coaches provided support and encouragement, and reinforced program participation through motivational messages. Structure and content of the e-mails were outlined in a coaches' manual (written by TL and FS), including sample e-mails, and giving instructions on how to handle unexpected emergencies (e.g., suicidality).

To ensure confidentiality and data protection, the online program used a password-protected server, which was located at NetUnion, Lausanne, Switzerland. Participants received a pseudonym and a password to access the online program. For security reasons, they had to change their password at first connection. An integrated messaging system enabled secured message exchange between coaches and participants. E-mail addresses were protected by one-way encryption. The program meets Health on the Net Foundation (HON) quality and ethics standards (http://www.hon.ch/).

Noninferiority of GSH-I with respect to face-to-face psychotherapy is of interest considering that Internet-based treatment has some advantages over face-to-face treatment: it can be offered with minimum delay and at low cost, it respects patients' privacy and avoids embarrassment about needing psychotherapy, allows patients to work on their own pace, and allows patients to renew or update treatment as often as they wish, and at no extra cost.

Cognitive-behavioral therapy (CBT)

For the face-to-face therapy, the German evidence-based manual, "Binge Eating and Obesity: Cognitive-Behavioral Therapy Manual for Binge-Eating Disorder" published by Hilbert and Tuschen-Caffier[19,20] was used. The manual comprises the following phases: (1) initial treatment phase for motivational enhancement; (2) intensive treatment phase, including modules on eating behavior, body image, and stress; and (3) self-management phase for relapse prevention. Participants received therapy twice weekly for the first month and once weekly from month 2 to month 4. All CBT sessions were audiotaped if participants gave their consent. One of four consecutive audiotapes of each participant was randomly chosen and checked with regard to manual adherence using a checklist on content, the material worked on, and formal (e.g., session duration) characteristics. Therapist adherence was generally very good with 74% of all CBT sessions fulfilling the criteria for excellent therapist adherence[21].

Severe Adverse Events

Four patients reported transient suicidal ideation during the course of the study (3 GSH-I and 1 CBT). Of those, three (2 GSH-I, 1 CBT) received additional treatment sessions (crisis intervention; see Flow Diagram Figure 1) and were withdrawn from the study. Suicidality resolved in all cases. One patient experienced a heart attack after the first session with the coach (GSH-I) and required hospitalization, no death occurred. Serious adverse events were reported to the IRB and the Data Safety Monitoring Board for the study.

Randomization and Masking
Individuals who met the inclusion criteria and gave written informed consent were randomized. Randomization was performed at a 1:1 ratio (without stratification) centrally by the independent Coordination Center for Clinical Trials (KKS) in Marburg, using a computer-generated randomization sequence. Treatment and assessment were separated: therapists and coaches were not involved in assessing treatment outcome and assessors were not involved in treatment. Assessors were blinded to treatment assignment. The statistician who conducted the statistical analyses (AM) was not involved in randomization. Treatment allocation was not disclosed to the statistician until all data checks were completed.

Sample Size Estimation
The primary outcome is the difference (delta, Δ) in the number of OBE days over the past 28 days between baseline (T0) and end of treatment (T2). To test for non-inferiority, we specified a non-inferiority margin of one OBE day in favor of CBT. The non-inferiority of GSH-I compared to CBT would be shown, if the upper boundary of the corresponding 95% CI of the difference between Δ in CBT and Δ in GSH-I (Δ CBT minus Δ GSH-I) would be less than 1 OBE day. Given a lack of research supporting an evidence-based non-inferiority margin at the time of study design, this margin has been agreed upon in discussions with international clinical experts. Assuming a standard deviation of 2.1 days in both groups for the number of OBE days over the evaluation period and a drop-out rate up to 20% from T0 to T2, a total of 175 participants needed to be recruited to guarantee a statistical power of at least 80% when testing for noninferiority in the confirmatory analysis.

Allegiance effects
Allegiance effects are very difficult to be addressed[22]. A sensitivity analysis including the therapists (n=29) as random effect instead of study center in the mixed model was conducted. Both adjustments did not change the results in anyone direction (eTable 1).

By having the same therapists offering both treatments we hoped to mitigate the influence of potential therapist confounders such as gender, age, differences in the ability to form therapeutic alliances, differences in therapist's competence, adherence to the treatment protocol, and attachment styles.

It is well known that the allegiance outcome association is weaker when the methodological quality of a study is high[23]. In a meta-analysis allegiance effects (inflation of the reported effect) were not statistically significant when the analyses were limited to studies where authors have assessed the integrity of the delivered treatments[22]. In our study both treatments were highly structured, the CBT was manualized as was the timing and content of the messages exchanged with the patients in the GSH-I condition. To ensure standardization of treatment all treatment staff was trained by the developer of the Internet-based program (TL) and the developer of the CBT program (AH). In addition, therapist adherence to both the CBT and the email content was rated by 2 experienced therapists who gave regular feed-back. Finally, assessors were blinded to treatment condition.

Adherence with GSH-I

Markers of adherence were selected in accordance with other studies using this program in patients with BED[18,25]. .NetUnion, the company that developed the Internet program provided us with an exported script of the data. The following indicators of adherence were used:

- the number of modules completed,
- the number of days completed in the diary.
- the number of messages exchanged,

We analyzed the correlations of these 3 markers of adherence with our main outcome (change in OBE days) in the per protocol sample and in the mITT sample. By using the per protocol and mITT samples we followed the procedure proposed by Manwaring et al.[26] who included only patients with posttest data in their analyses Correlational analyses between the indicators of adherence and the main outcome did not reveal any significant associations (eTable 6).

eTable 1. Sensitivity Analyses for the Primary Outcome (Changes in OBE Days Between T0 and T2)

	GSH-I	CBT	Statistics	
	Mean (SD)	Mean (SD)	Adj. rel. effect (95% CI)	p-value
Per-protocol: Study center fixed effect	10.4 (8.7)	11.7 (7.8)	1.55 (0.05 to 3.04)	.04
mITT: Study center fixed effect	10.2 (8.8)	11.5 (7.7)	1.70 (0.23 to 3.17)	.02
mITT: Baseline imputation (8 of 169)	9.2 (8.8)	11.3 (7.8)	2.42 (0.76 to 4.05)	.005
mITT: Without imputation (n = 161)	10.1 (8.8)	11.4 (7.8)	1.50 (0.04 to 2.96)	.05
Per-protocol: Therapist as random effect instead of study center	10.4 (8.7)	11.7 (7.8)	1.45 (0.03 to 2.87)	.05
mITT; Therapist as random effect instead of study center	10.2 (8.8)	11.5 (7.7)	1.58 (0.16 to 3.01)	.03

Adj. rel. effect = adjusted relative effect, adjusting for age, sex, objective binge eating days at baseline, body mass index, Beck Depression Inventory, and Eating Disorder Examination-Interview global score; CBT = cognitive-behavioral therapy; GSH-I = Internet-based guided self-help; mITT = modified intention-to-treat sample

eTable 2. Effect Sizes for Secondary Outcomes

	End of treatment			6-month follow-up		
	GSH-I N=77	**CBT N=85**	**Cohen d**	**GSH-I N=70**	**CBT N=80**	**Cohen d**
Primary Outcome						
OBE days, mean (SD)	3.9 (5.5)	2.0 (4.1)	0.38	5.3 (6.9)	2.8 (5.2)	0.42
Secondary Outcomes						
Abstinence from binge eating, No./total patients (%)	27/76 (36)	52/85 (61)	0.48	26/68 (38)	46/79 (58)	0.39
BED full diagnosis, No./total patients (%)	35/72 (49)	24/83 (29)	0.49	20/66 (30)	20/78 (26)	0.11
Eating Disorder Examination (EDE), mean (SD)						
Global	2.0 (1.2)	1.9 (1.2)	0.12	2.0 (1.2)	1.7 (1.1)	0.29
Restraint	1.4 (1.4)	1.5 (1.4)	0.05	1.6 (1.4)	1.3 (1.3)	0.21
Eating concern	1.1 (1.2)	0.9 (1.1)	0.11	1.1 (1.3)	0.9 (1.1)	0.17
Shape concern	2.9 (1.6)	2.6 (1.6)	0.17	2.8 (1.5)	2.4 (1.5)	0.26
Weight concern	2.6 (1.5)	2.3 (1.5)	0.18	2.5 (1.4)	2.1 (1.5)	0.31
Body mass index, mean (SD), kg/m^2	32.9 (3.9)	34.2 (4.5)	0.31	33.1 (4.2)	33.5 (4.6)	0.10
Mental comorbidity						
Affective disorders, No./total patients (%)	21/69 (30)	16/85 (19)	0.32	15/61 (25)	18/76 (24)	0.02
BDI-II, mean (SD)	11.7 (12.4)	9.0 (10.8)	0.23	10.0 (11.9)	9.0 (10.0)	0.10
Anxiety disorders, No./total patients (%)	9/69 (13)	16/85 (19)	0.17	9/61 (15)	18/76 (24)	0.23
RSES, mean (SD)	20.4 (8.3)	21.5 (6.9)	0.14	21.4 (7.9)	22.1 (7.1)	0.10
Quality of life						
IWQOL-Lite, mean (SD)	65.8 (25.6)	63.8 (22.6)	0.05	61.8 (26.3)	59.5 (24.1)	0.10
CIA, mean (SD)	12.1 (10.9)	11.9 (11.1)	0.01	11.9 (11.5)	10.5 (10.9)	0.14

BDI-II = Beck Depression Inventory-II, CBT = cognitive-behavioral therapy, CIA = Clinical Impairment Assessment, GSH-I = Internet-based guided self-help, IWQOL-Lite = Impact of Weight on Quality of Life- Lite, OBE = objective binge eating, RSES = Rosenberg Self-esteem Scale

Cohan d: 0.2 = small effect, 0.5 = medium effect, 0.8 = large effect[24]

eTable 3. Within-Group Changes of the Primary Outcome (OBE Days) Using the Intention-to-Treat Sample Without Imputations

	GSH-I (n=83)	**CBT (n=86)**
	Adj. rel. effect (95% CI)	Adj. rel. effect (95% CI)
Mid-treatment (T1)	0.46 (0.38 to 0.57)	0.32 (0.22 to 0.46)
End of treatment (T2)	0.29 (0.22 to 0.38)	0.10 (0.07 to 0.15)
6-month follow-up (T3)	0.45 (0.33 to 0.59)	0.13 (0.09 to 0.19)

All within-group effects $p < .001$

Adj. rel. effect = adjusted relative effect, adjusting for age, sex, objective binge eating days at baseline, BMI, Beck Depression Inventory, and Eating Disorder Examination-Interview global score; CBT = cognitive-behavioral therapy; GSH-I = Internet-based guided self-help; OBE = objective binge eating

eTable 4. Exploratory Longitudinal Analysis for the Number of OBE Days During the Previous 28 Days Also Containing the 1.5-Year Follow-up Data

	GSH-I	CBT	Statistics	
	Mean (SD)	**Mean (SD)**	**adj. rel. effect (95% CI)**	**p-value[a]**
T0	14.1 (7.8)	13.5 (7.5)	0.99 (0.82 to 1.19)	.92
T1	6.6 (7.3)	5.0 (7.1)	0.79 (0.58 to 1.09)	.15
T2	3.9 (5.5)	2.0 (4.1)	0.43 (0.28 to 0.67)	<.001
T3	5.3 (6.9)	2.8 (5.2)	0.40 (0.25 to 0.63)	<.001
T4	5.1 (8.2)	4.2 (6.3)	0.91 (0.54 to 1.50)	.70

T0=baseline, T1=mid-treatment, T2=end of treatment, T3=6-month follow-up, T4=1.5-year follow-up

Adj. rel. effect = adjusted relative effect, adjusting for age, sex, objective binge eating days at baseline, BMI, Beck Depression Inventory, and Eating Disorder Examination-Interview global score;

[a]based on random coefficients modeling (mixed effect models) with the negative binomial as outcome distribution

eTable 5. Exploratory Longitudinal Analysis for the Number of OBE Days During the Previous 28 Days Including Only the 116 Patients for Whom 1.5-Year Follow-up Data Are Available (Completer)

	GSH-I	CBT	Statistics	
	Mean (SD)	**Mean (SD)**	**adj. rel. effect (95% CI)**	**p-value[a]**
T0	14.9 (8.3)	14.0 (7.7)	1.00 (0.76 to 1.30)	.97
T1	7.2 (7.5)	5.5 (7.5)	0.77 (0.53 to 1.11)	.16
T2	4.1 (5.9)	2.2 (4.0)	0.48 (0.29 to 0.79)	.004
T3	5.4 (7.1)	3.0 (5.4)	0.56 (0.34 to 0.90)	.02
T4	5.1 (8.2)	4.2 (6.3)	0.92 (0.58 to 1.45)	.71

T0=baseline, T1=mid-treatment, T2=end of treatment, T3=6-month follow-up, T4=1.5-year follow-up

Adj. rel. effect = adjusted relative effect, adjusting for age, sex, objective binge eating days at baseline, BMI, Beck Depression Inventory, and Eating Disorder Examination-Interview global score;

[a]based on random coefficients modeling (mixed effect models) with the negative binomial as outcome distribution

eTable 6. Comparison of Dropout Rates Using Different Definitions (Whole Sample n = 178)

Definitions of drop-out	**GSH-I**	**CBT**	**Statistics**	
	N (%)	**N (%)**	**OR (95% CI)**	**p-value[c]**
Insufficient treatment dose[a]	9 (10.1%)	7 (7.9%)	1.27 (0.40 to 4.22)	.79
No post-baseline measurement	6 (6.7%)	3 (3.4%)	1.99 (0.41 to 12.73)	.50
Excluded from per protocol set[b]	17 (19.1%)	8 (9%)	2.30 (0.87 to 6.56)	.08
No end of treatment rating	13 (14.6%)	4 (9%)	3.49 (1.02 to 15.37)	.04
No 6-month follow-up rating	21 (23.6%)	9 (11.2%)	2.64 (1.07 to 7.04)	.03

[a] < 12 of 20 CBT sessions; logged in until < week 10 in GSH-I

[b] no post-baseline measurement available, insufficient treatment dose, and/or crisis intervention; including study dropouts (5 in the GSH-I and 2 in the CBT group)

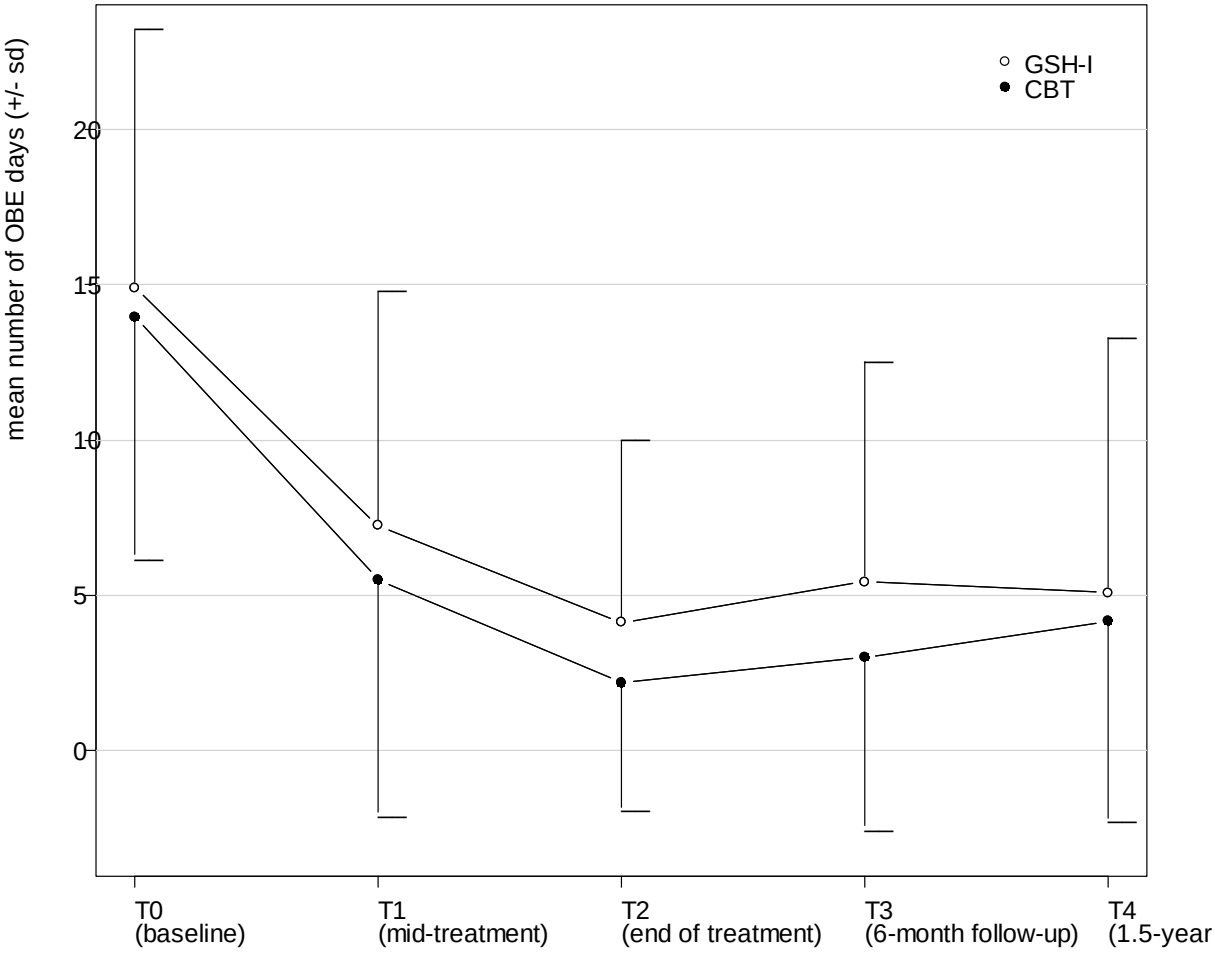
[c]p-values based on Fisher's exact test for independence.

eTable 7. Indicators of Adherence to GSH-I and Correlations of Adherence Measures With Primary Outcome (Change in OBE Days)

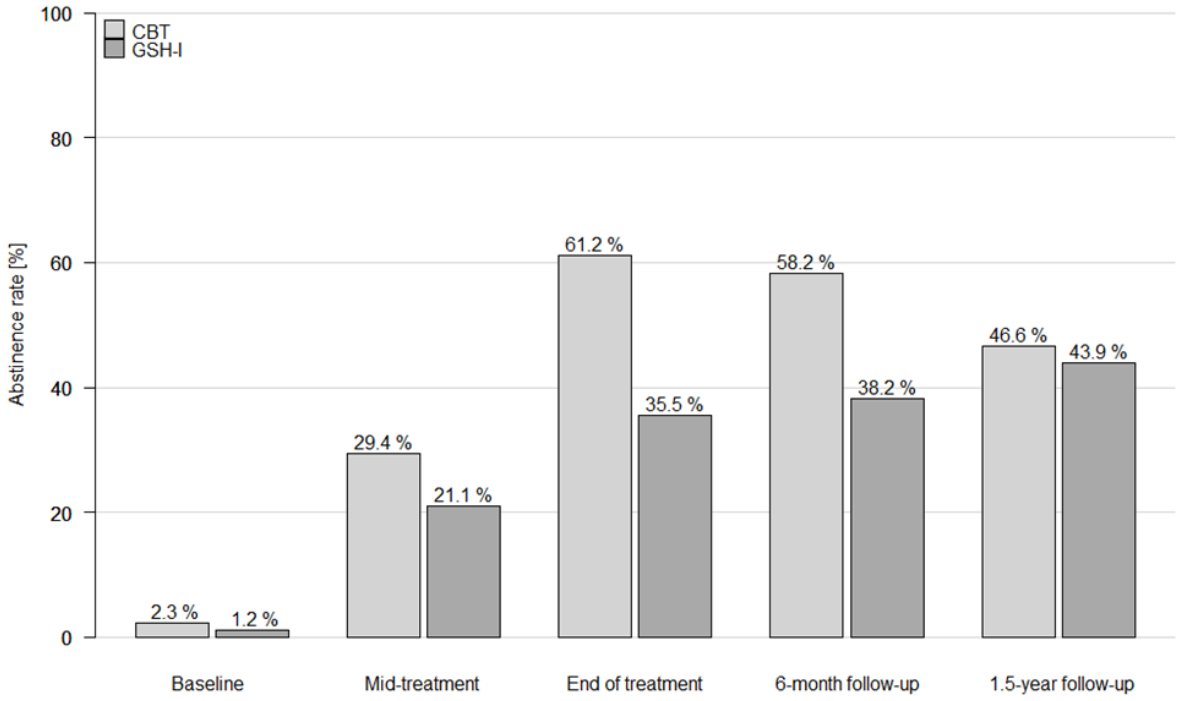
	Per protocol (n=72)			mITT (n=83)		
	Mean (SD) Range	corr. coeff.	p-value	Mean (SD) Range	corr. coeff.	p-value
Number of modules completed	8.7 (2.8)[a] 1-11	0.06	.62	8.4 (3.2)[b] 0-11	0.08	.47
Number of days completed in the diary	108 (32.2) 3-163	0.10	.41	104.4 (37.4) 0-163	0.13	.26
Number of messages exchanged	16.4 (2.3) 8-21	-0.16	.18	15.9 (3.4) 0-21	-0.04	.74

[a] mean percent in per protocol sample: 79.5%
[b] mean percent in mITT sample: 76%

eFigure 1. Course of OBE Days Also Containing the Follow-up Data at T4



eFigure 2. Abstinence Rates (Percentages of Patients With Zero OBE Days During the Last 28 Days) by Time and Treatment Condition



OBE = objective binge eating

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