

# Internet-based guided self-help for overweight and obese patients with binge eating disorder

<b>Submission date</b>	<b>Recruitment status</b>	[X] Prospectively registered
04/05/2010	No longer recruiting	[X] Protocol
<b>Registration date</b>	<b>Overall study status</b>	[ ] Statistical analysis plan
18/05/2010	Completed	[X] Results
<b>Last Edited</b>	<b>Condition category</b>	[ ] Individual participant data
04/08/2017	Mental and Behavioural Disorders	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

01GV0601

## Study information

### Scientific Title

Internet-based guided self-help for overweight and obese patients with binge eating disorder: a multicentre randomised controlled trial

**Acronym**

INTERBED

**Study objectives**

Internet-based guided self-help will be equally effective in reducing the number of binge eating days as individual cognitive-behavioural therapy (CBT).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Board of the Faculty of Medicine, University of Erlangen-Nuremberg, 22/09/2009, ref: 4081

**Study design**

Multicentre prospective randomised non-inferiority trial with two parallel arms

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Binge eating disorder

**Interventions**

Participants will be randomised to:

1. GSH: internet-based guided-self-help for BED. The program contains 11 modules delivered within 4 months. During this time the participants will be contacted weekly via e-mail, discussing progress or potential problems with a therapeutic coach.
2. CBT: 20 sessions of individual cognitive-behavioral therapy will be delivered over 4 months. A published manual will be used.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Difference of the number of binge eating days over the last 28 days. Number of days with binge eating episodes will be measured with the German version of the Eating Disorder Examination, a semi-structured interview which is regarded as the gold standard assessment of eating pathology. Comparisons will be done between baseline (randomisation), mid-treatment (2 months after randomisation) and the end of treatment (4 months after randomisation). In addition, maintenance of treatment outcome will be assessed 6 months after treatment completion in the two intervention groups.

**Key secondary outcome(s)**

Measured at baseline (randomisation), mid-treatment (2 months after randomisation), the end of treatment (4 months after randomisation) and 6 months follow-up:

1. Associated eating-disorder psychopathology
2. General psychopathology, psychiatric disorders
3. Severity of depression
4. Self-esteem
5. Quality of life
6. Impulsivity, impulse control
7. Weight, BMI
8. Process measure: working alliance inventory, eating behaviour, assessed on a weekly basis
9. Health economy

#### **Completion date**

31/03/2013

## **Eligibility**

#### **Key inclusion criteria**

1. Binge eating disorder (BED) according to DSM-IV criteria or subsyndromal BED (lacking one diagnostic criterion)
2. Age 18 years or older, either sex
3. Body mass index (BMI) between 27 and 40 kg/m<sup>2</sup>
4. Signed consent form

#### **Participant type(s)**

Patient

#### **Healthy volunteers allowed**

No

#### **Age group**

Adult

#### **Lower age limit**

18 years

#### **Sex**

All

#### **Key exclusion criteria**

1. Bulimia nervosa
2. Current substance abuse
3. Current suicidal ideation
4. Psychotic disorder
5. Mania
6. Ongoing psychotherapy
7. Medical conditions (type I diabetes or thyroid problems) that influence weight or eating
8. Pregnancy and lactation

#### **Date of first enrolment**

01/07/2010

**Date of final enrolment**

31/03/2013

## Locations

**Countries of recruitment**

Germany

Switzerland

**Study participating centre**

**University of Erlangen-Nuremberg**

Erlangen

Germany

91054

## Sponsor information

**Organisation**

Federal Ministry for Education and Research (Bundesministerium für Bildung und Forschung [BMBF]) (Germany)

**ROR**

<https://ror.org/04pz7b180>

## Funder(s)

**Funder type**

Government

**Funder Name**

Bundesministerium für Bildung und Forschung

**Alternative Name(s)**

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Germany

## Results and Publications

### Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2017		Yes	No
<a href="#">Protocol article</a>	protocol	21/11/2012		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes