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

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ednet-essstoerungen.de/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/07/2010

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^2
4. Signed consent form

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
175

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 (Bundeministerium für Bildung und Forschung [BMBF]) (Germany)

Sponsor details
Projektträger im Deutsches Zentrum für Luft- und Raumfahrt (DLR) e.V.
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Sponsor type
Not defined

Website
http://www.gesundheitsforschung-bmbf.de

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	21/11/2012		Yes	No
Results article	results	01/10/2017		Yes	No