**Trial Description**

**Title**

Approach Bias Modification Training In Bulimia Nervosa and Binge Eating Disorder: A Randomised Controlled Pilot Trial

**Trial Acronym**

ABBA

**URL of the trial**

[---]*

**Brief Summary in Lay Language**

The central aim of this pilot study is to examine whether 10 sessions of a specifically tailored computerised training (termed "approach bias modification") can reduce the core symptoms of bulimia nervosa and binge eating disorder. During this training, participants learn to make avoidance movements in response to images of high calorie food. In order to examine the efficacy of the training, we compare this training to a sham version in which participants are not trained to make avoidance movements towards food pictures. Additionally, we will investigate whether this training reduces food craving and food intake as well as the way how participants process visual food cues. Finally, we will assess treatment acceptance.

**Brief Summary in Scientific Language**

The principle aim of this randomised sham-controlled pilot trial is to examine whether a specifically tailored computerised cognitive bias modification (CBM) training (termed "approach bias modification") can reduce the number of subjective and objective binge eating episodes and other core bulimic symptoms in patients with bulimia nervosa or binge eating disorder. Participants will be randomly assigned to either 10 sessions of real CBM or 10 sessions of sham CBM (over a 4 weeks period). In the real CBM condition, participants will be trained to repeatedly show avoidance behaviour (via a joystick) in response to pictures of high calorie food. In contrast, the sham condition requires participants to make an equal number of approach and avoidance movements in response to the food images. In addition, we will examine whether (compared to the sham condition) real CBM alters trait-level and cue-elicited state-level food craving as well as approach and attentional bias towards food cues and actual food intake (in the laboratory). Finally, we will also examine treatment acceptance taking the attrition rate and feedback by the participants into account.

**Organizational Data**
Secondary IDs

ICD10: F50.2 - Bulimia nervosa
ICD10: F50.9 - Eating disorder, unspecified

Interventions/Observational Groups

Arm 1: real CBM (approach bias modification training): In an implicit learning paradigm, participants repeatedly make avoidance movements (via a joystick) in response to pictures of high calorie food (which makes the pictures shrink on the computer screen). The training involves 10 sessions over a period of 4 weeks, one session lasts 15 minutes.

Arm 2: sham CBM: Participants equally often make approach and avoidance movements in response to pictures of high calorie food (via a joystick which increases/decreases the pictures on the computer screen). Equivalent to the real CBM condition, this sham version involve 10 sessions (15 minutes each) over a period of 4 weeks.

Characteristics

Study Type: Interventional
Study Type Non-Interventional: [---]*
Allocation: Randomized controlled trial
Blinding: [---]*
Who is blinded: patient/subject, assessor
Control: Placebo
Purpose: Treatment
Assignment: Parallel
Phase: II
Study Type: Interventional
Study Type Non-Interventional: [---]*
Allocation: Randomized controlled trial
Blinding: [---]*
Who is blinded: patient/subject, assessor
Control: Placebo
Purpose: Treatment
Assignment: Parallel
Phase: II
Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

**Primary Outcome**

Number of subjective and objective binge eating attacks and global eating disorder psychopathology during the previous 2 months prior and after the intervention.

**Secondary Outcome**

(1) approach bias towards visual food cues prior/after the intervention.
(2) attentional bias towards visual food cues prior/after the intervention.
(3) trait food craving prior/after the intervention.
(4) state levels of cue-elicited food craving prior/after the intervention.
(5) food intake in the laboratory prior/after the intervention.
(6) treatment acceptance.

**Countries of recruitment**

- DE Germany
- UK United Kingdom

**Locations of Recruitment**

- University Medical Center Klinik für Allgemeine Innere Medizin und Psychosomatik, Zentrum für Psychosoziale Medizin, Universitätsklinik Heidelberg, Heidelberg
University Medical Center Section of Eating Disorders, Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2015/12/18
- Target Sample Size: 54
- Monocenter/Multicenter trial: Multicenter trial
- National/International: International

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

(a) age 18 years or above

(b) DSM-V diagnosis of Bulimia Nervosa or Binge Eating Disorder

Exclusion criteria

(a) age under 18 years

(b) medical (e.g. major electrolyte abnormalities) or psychiatric (e.g. acute suicidality) instability

(c) current or lifetime diagnosis of substance dependence, psychosis, bipolar disorder, ADHD, or borderline personality disorder

(d) psychotropic medication other than selective serotonin reuptake inhibitors (patients have to be on a stable medication, i.e. at least 14 days, of SRRI during participation in the trial)

Addresses

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Sources of Monetary or Material Support

Private sponsorship (foundations, study societies, etc.)

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Status

Recruitment Status: Recruiting complete, follow-up complete
Study Closing (LPLV): 2017/09/01
**Trial Publications, Results and other documents**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.