

## Trial Description

### Title

**Neural Correlates of Overvaluation of Shape and Weight in Binge Eating Disorder**

### Trial Acronym

[---]\*

### URL of the trial

<http://www.uni-tuebingen.de/de/60844>

### Brief Summary in Lay Language

**Dissatisfaction with one's own body is very common in overweight individuals with and without eating disorders, and is often associated with considerable impairment. Since high body dissatisfaction can substantially limit quality of life for those concerned, treatment is very important. In this context, first studies show remarkable efficiency of so-called "body confrontation trainings" to improve body satisfaction. The objective of this study is the investigation of mechanisms of action of these body confrontation trainings in overweight women with Binge Eating Disorder by functional magnetic resonance imaging (fMRI).**

### Brief Summary in Scientific Language

**With the new release of the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5; American Psychiatric Association [APA], 2013a) in May 2013, binge eating disorder (BED) graduated from the DSM-IV category of "disorders needing further research" into its own diagnostic label. BED is characterized by recurrent binge eating episodes in the absence of compensatory behavior. With a prevalence rate of 2% to 5% (Hudson et al., 2007), BED is the most prevalent eating disorder and is linked to overweight and obesity (Yanovski, 2003). Moreover, BED is associated with high levels of comorbid mental disorders, substantial medical, psychological and psychosocial sequelae (Hudson et al., 2007), reduced health-related quality of life (De Zwaan et al., 2002; Rieger et al., 2005), and an increased mortality risk (Fichter et al., 2008). Empirical evidence suggests that schema-driven processes seem to maintain overvaluation of shape and weight in BED (Svaldi et al., 2011, 2012). However, the underlying functional neuroanatomy of overvaluation of shape and weight, and the corresponding body dissatisfaction in BED is yet to be understood. In fact, no study directly tested whether overvaluation of shape and weight in BED is based on dysfunctional body-image-processing brain circuits. The characterization of these neuronal underpinnings might help to broaden our understanding of the etiology of BED, and in terms of a biomarker might further help to improve the diagnostic differentiation between disorders of the same cluster or between subgroups within the same disorder. Indirect first evidence that body image disturbance in BED may be associated with dysfunctional body-image-processing brain circuits comes from functional magnetic resonance imaging (fMRI) studies conducted with patients with anorexia nervosa (AN; e.g., Friederich et al., 2010; Mohr et al., 2010; Uher et al., 2005; Wagner, Ruf, Braus, & Schmidt, 2003) and bulimia nervosa (BN;**



e.g., Mohr et al., 2011; Vocks, Busch, et al., 2010). However, given that the functional neuronal correlates of body image disturbance seem to be different between AN and BN, knowledge from these two eating disorders has only limited validity for BED and neuroimaging research for this disorder is urgently needed. We will combine established methods for investigating causal relationships: First, we will use two established fMRI paradigms to test differences in the neural processing of the self- and a weight-matched control body in women with BED and weight-matched female controls without BED. Comparisons will include (a) activations within the body image processing neural network (extrastriate and fusiform body areas) and (b) body image induced activity within the emotion processing network (including amygdala, insula, medial prefrontal cortex) as well as correlations between these activations and questionnaire scores. Second, within the BED group, half of study participants will be randomly assigned to a repeated mirror exposure (4 sessions), the other half to a wait-control list (WCL). Group and time comparisons will examine cognitive and affective changes with regard to body perception assessed via questionnaires. Third, the previously mentioned fMRI paradigms will be administered once more in the BED group. Comparisons will thereby include (a) the modification of neuronal processing when viewing the self- and the other-body after mirror exposure and (b) differences with regard to neuronal processes when viewing the self- and the other-body between BED patients in the mirror exposure group and the WCL.

## Organizational Data

- DRKS-ID: **DRKS00008107**
- Date of Registration in DRKS: **2015/06/29**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **296/2015BO2 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **F50.9 - Eating disorder, unspecified**
- Free text: **Binge Eating Disorder**

## Interventions/Observational Groups

- Arm 1: **Mirror confrontation training - 1 cognitive preparation, 4 mirror exposure sessions (1 session per week for 5 weeks), duration per session between 60 and 90 minutes**



- Arm 2: **Waiting list (training after appr. 4 months)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Control group receives no treatment**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Activity in extrastriate and fusiform body areas as well as limbic areas during self-body exposure (assessed with fMRI pre and within two weeks post mirror exposure/waiting period)**

## Secondary Outcome

**Self-report data on eating behaviour, body dissatisfaction, and shape/weight concerns (assessed with questionnaires pre and post mirror exposure/waiting period)**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- other **Universität, Tübingen**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/11/22**
- Target Sample Size: **60**

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Target Sample Size: **60**

- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **69 Years**

### Additional Inclusion Criteria

**Diagnosis of BED according to DSM-V criteria as the primary diagnosis, BMI between 25 and 45, ability and willingness to provide informed consent.**

### Exclusion criteria

**High risk of suicide; Co-occurring psychotic or bipolar disorder, alcohol/substance dependence within the past six months, and/or Borderline Personality Disorder; Medical disorder that would affect weight and/or ability to participate; Insufficient German language skills; Current participation in psychotherapeutic treatment other than that offered in the study; Current participation in a weight-control program; Taking medication that would affect weight; Pregnancy; History of metal or metal fragments in the body (e.g. through accident or traumatic injury); Irremovable medical devices (e.g. pacemaker, cochlea implant); Past head or heart surgery; History of untreated claustrophobia or panic attacks in confined spaces; Non-removable metal attached to the body (e.g. piercings); Large tattoo in the head or neck area and/or tattoo where the use of metallic ink cannot be excluded; No consent to be informed of incidental findings that may come to light as a consequence of participation in the study**

### Addresses

- **Primary Sponsor**

**Eberhard Karls Universität Tübingen  
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Germany**

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### Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

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URL: **http://www.ekfs.de/de/start.html**

### Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]\*

### 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.