Trial Description

Title

Efficacy of CBT-E and DBT-E in the treatment of eating disordered patients with high comorbidity

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with eating disorders and further mental disorders receive one out of two specific treatments. One treatment focuses on individual eating disorder specific thoughts and maintaining factors (CBT-E). The other treatment is based on emotion regulation and mindfulness skills (DBT-E). The study compares the efficacy of both treatments. We expect both treatment as being equally high efficient. Furthermore we hypothesized differential effects: Patients with deficts in emotion regulation benefit more from DBT-E while patients with core low self-esteem are better suited by CBT-E.
Patients get randomly assigned to the treatment form. Female patients with all types of eating disorders (anorexia, bulimia, atypical eating disorders, binge eating) and additional mental disorders e.g, clinical depression, personality disorders are included.

Brief Summary in Scientific Language

In the treatment of eating disorders patients with high comorbidity have been rarely scientifically studied. CBT (Cognitive Behavioral Therapy) developed by Fairburn is considered the gold standard of treatment for Bulimia nervosa. According to the transdiagnostic model of eating disorders this treatment has been revised. CBT-Expanded (CBT-E) now constitutes a treatment for patients with all subtypes eating disorders and also includes elements that addresses associated comorbid psychopathology. In the treatment of patients with severe behavioural dysregulation Dialectic Behavioral Therapy (DBT) developed by Linehan has found valuable results. Now, it has been proposed to apply DBT also for the treatment of eating disorders (DBT-E).
The proposed study compares the efficacy of both treatments in a sample of eating disordered patients with high comorbidity. A randomized controlled design is used with a planned sample size of 178 patients for each form of treatment and 42 patients in a waiting control group (treatment as usual). Therapy is conducted by two well-trained teams that work in a similar university setting with an inpatient treatment of 12 weeks.
Primary outcome is the remission of the eating disorder pathology measured by EDE (within one standard deviation of population mean) at a follow-up 6 months after the start of the treatment. Secondary outcomes are the changes in divers questionnaires: on eating disorder psychopathology (EDE-Q), emotion regulation (DERS, ICARUS, ERQ), general psychopathology (BSL, SF-12, BSI, QIDS, HADS-D)

and psychosocial functioning. Additionally, circadian profiles of cortisol are sampled and body fat is assessed by bioelectrical impedance analysis.

Organizational Data

- DRKS-ID: **DRKS00000519**
- Date of Registration in DRKS: **2010/10/07**
- 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.: **AZ 09/124 , Ethik-Kommission Universität zu Lübeck Medizinische Fakultät des Universitätsklinikums Schleswig-Holstein**

Secondary IDs

Health condition or Problem studied

- ICD10: **F50 - Eating disorders**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F60 - Specific personality disorders**
- ICD10: **F40 - Phobic anxiety disorders**
- ICD10: **F41 - Other anxiety disorders**
- ICD10: **F42 - Obsessive-compulsive disorder**
- ICD10: **F43 - Reaction to severe stress, and adjustment disorders**
- ICD10: **F44 - Dissociative [conversion] disorders**
- ICD10: **F45 - Somatoform disorders**
- ICD10: **F34 - Persistent mood [affective] disorders**
- ICD10: **F32 - Depressive episode**

Interventions/Observational Groups

- Arm 1: **One-to-one sessions and group therapy of 12 week inpatient setting specific cognitive interventions to change overevaluation of shape, weight and their control according to the individual formulation;**
  cognitive concept;
  dieting as a typical core problem due to low self-esteem;
  joined information on eating disorder specific themes;
  high individualization of the therapy

Arm 1: **One-to-one sessions and group therapy of 12 week inpatient setting specific cognitive interventions to change overevaluation of shape, weight and their control according to the individual formulation;
cognitive concept;
dieting as a typical core problem due to low self-esteem;
joined information on eating disorder specific themes;
high individualization of the therapy**

- Arm 2: **One-to-one sessions and group therapy of 12 week inpatient setting focus on relation of emotional regulation and eating behavior;
dysfunctional emotion regulation as core problem;
dialectical strategies (balance of acceptance and change, validation, commitment strategies, pro/cons lists)
mealtime as mindfulness exercise
joined information;
systematic skills training;
limited individualization**

- Arm 3: **wait control group: treatment-as-usual, e.g. practical doctor**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **[---]***
- Control: **Active control, Other**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Primary outcome is the remission of the eating disorder assessed by EDE three months after the end of treatment (EDE-Score within one standard deviation of population mean).

Secondary Outcome

**Eating Disorder Examination Questionnaire (EDE-Q)
Borderline Symptom List (BSL)
Questionnaire on general health status (SF-12)
Diagnosis (ICD-10)
Brief Symptom Inventory (BSI)
Quick Inventory of Depressive Symptomatology (QIDS)
Anxiety (HADS-D)
Emotion regulation questionaires (ICARUS, DERS, ERQ)
metabolic parameter: cortisol profile, biometrical data**

pre, pre II, start of the treatment, end of the treatment, post (3 months after end), follow-up (9 months after end)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2011/01/15**
- Target Sample Size: **398**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Main inclusion criterion is the diagnosis an eating disorder, indication for inpatient treatment (e.g. failed outpatient treatment, high psychosocial impairment, conditions unfavourable to treatment in the immediate environment) in combination with every possible form of comorbidity. Further inclusion criteria are being female, age above 18 years, and first treatment in our hospital.

Exclusion criteria

Patients who are not able to receive a psychotherapeutic treatment (dementia, psychosis) are excluded. Furthermore, substance abuse as the dominant present diagnosis is excluded.

Addresses

■ **Primary Sponsor**

Universitätsklinikum Schleswig-Holstein Campus Lübeck
Ratzeburger Allee 160
23538 Lübeck
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uk-sh.de**

■ **Contact for Scientific Queries**

Universitätsklinikum Schleswig-Holstein Campus Lübeck
Mr. Prof. Dr. Ulrich Schweiger
Ratzeburger Allee 160
23538 Lübeck
Germany

Telephone: **0451-5002450**
Fax: **[---]***
E-mail: **Ulrich.Schweiger at psychiatrie.uk-sh.de**
URL: **www.uk-sh.de**

■ **Contact for Public Queries**

psychiatrische Hochschulambulanz des UKSH, Campus Lübeck
Ms. Sibylle Grell
Ratzeburger Allee 160
23538 Lübeck
Germany

Telephone: **0451 500 2910**
Fax: **[---]***
E-mail: **Sibylle.Grell at psychiatrie.uk-sh.de**
URL: **[---]***

Sources of Monetary or Material Support

■ **Institutional budget , no external funding (budget of sponsor/PI)**

Universitätsklinikum Schleswig-Holstein Campus Lübeck
Ratzeburger Allee 160
23538 Lübeck
Germany

Telephone: **[---]***
Fax: **[---]***

Institutional budget , no external funding (budget of sponsor/PI)

Universitätsklinikum Schleswig-Holstein Campus Lübeck
Ratzeburger Allee 160
23538 Lübeck
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uk-sh.de**

Status

- Recruitment Status: **Recruiting planned**
- 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.*