PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

PRO*MDD: Effectiveness of outpatient treatment PROgrams for Major Depressive Disorder: Metacognitive Therapy vs. Behavioral Activation

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Major depressive disorder (MDD) is a highly prevalent, often recurrent or chronic, disabling psychiatric disease, which is associated with low quality of live, high treatment costs and impaired psychosocial functioning and participation. Psychotherapy plays a key role in the treatment of MDD. Treatment has been significantly improved by intensive research of psychotherapeutic methods, however there is still room for optimization.
Metacognitive therapy (MCT) is an innovative therapeutic method that has shown high effect in several smaller studies. Behavioral Activation (BA) is an treatment with high scientific evidence. MCT and BA target different psychological mechanism that maintain depression and hardly overlap in the employed treatment techniques. Thus, they appear especially suitable for a comparison in regard to effectiveness and development of treatment methods.
In the planned study these two treatments will be compared for the first time within the routine clinical setting of an outpatient clinic. 128 depressed patients will be included (64 per treatment condition). In both conditions, patients receive one group therapy session and one individual therapy session per week for a maximum of six months. Treatment may stop earlier if patients recover. The primary outcome is the severity of depressive symptoms. Further outcome measures address general psychiatric symptoms, quality of life, comorbidity with other psychiatric disorders as well as psychosocial functioning and participation. Primary and secondary outcomes will be assessed before the start of treatment, three, six, 12, 18 and 30 months after the start of treatment.

Brief Summary in Scientific Language

Major depressive disorder (MDD) is a highly prevalent, often recurrent or chronic, disabling psychiatric disease, which is associated with low quality of live, high treatment costs and impaired psychosocial functioning and participation. Psychotherapy plays a key role in the treatment of MDD. Treatment has been significantly improved by intensive research of psychotherapeutic methods, however there is still room for optimization.
Metacognitive therapy (MCT) is an innovative therapeutic method that targets

metacognitive processes underlying depression like rumination and threat monitoring. MCT has shown high effect sizes within less than ten treatment sessions in case studies and smaller randomized controlled trials. Behavioral Activation (BA) is an evidence based therapeutic method grounded in the reward deficit theory. MCT and BA target different psychological mechanism that maintain depression and hardly overlap in the employed treatment techniques. Thus, they appear especially suitable for a comparison in regard to effectiveness, development of treatment methods, specific indication ("what works for whom") and research of treatment process.
The PROMDD trial will be the first randomized controlled trial to examine the effectiveness of MCT and BA within the routine clinical setting of an outpatient clinic. 128 consecutive patients with a severe or moderate depressive episode will be randomly assigned to either MCT or BA (64 per treatment condition). In both conditions, patients receive one group therapy session and one individual therapy session per week for a maximum of six months. Treatment may stop earlier if patients recover. The primary outcome is the severity of depressive symptoms assessed by the Hamilton Rating Scale for Depression (HRSD). Further outcome measures address general, MDD-specific and method-specific process parameters, quality of life, comorbidity with other psychiatric disorders as well as psychosocial functioning and participation.
Primary and secondary outcomes will be assessed before the start of treatment, three, six, 12, 18 (one year follow-up) and 30 months (two year follow-up) after the start of treatment. In addition, selected method-specific process parameters and severity of depression will be collected weekly during treatment.
By means of an explorative data analysis, possible moderator and mediator variables (e.g. psychological change specific for the method used, sex, age, severity of symptoms, course of depression, comorbidity, traumatic experiences during childhood) will be addressed.

Organizational Data

- DRKS-ID: **DRKS00011536**
- Date of Registration in DRKS: **2017/02/13**
- 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.: **16-176 , Ethik-Kommission Universität zu Lübeck Medizinische Fakultät des Universitätsklinikums Schleswig-Holstein**

Secondary IDs

Health condition or Problem studied

- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F32 - Depressive episode**

Interventions/Observational Groups

- Arm 1: **outpatient Metacognitive therapy -programm (MCT) with one individual and one group session per week for 6 months**
- Arm 2: **outpatient Behavioral Activation-programm (BA) with one individual and one group session per week for 6 months**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

primary outcome: severity of depressive symptoms assessed by the Hamilton Rating Scale for Depression (HRSD) at the end of treatment (6 months assessment)

Secondary Outcome

Secondary outcomes address general psychopathology (BSI), quality of life (SF-12), psychosocial functioning and participation (WHODAS), course of other psychiatric disorders (SKID I und II), metacognitions, rumination and worying (MDD-S, MCQ-30, RSQ-D) as well as behavioral activation (BADS).Secondary Outcomes will be assessed at baseline as well as 3, 6, 12, 18 and 30months after start of treatment

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Psychiatrische Institutsambulanz, Lübeck**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/09/27**
- Target Sample Size: **128**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Primary Diagnosis of MDD according to DSM-IV (SCID-I-Interview)
severity of depression > 16 Punkte in HRSD-Interview.
willingness to participate in the study (informed consent)
willingness to participate over a maximum of 6 months in the study and take part in the therapy session regularly (no plans to move or to have inpatient treatment)

Exclusion criteria

lifetime diagnosis of psychotic disorder
lifetime diagnosis of bipolar disorder
IQ below 85
acute sucidality
acute serious substance abuse disorder, that calls for detoxication
Inadequate german language skills

Addresses

- **Primary Sponsor**

  Klinik für Psychiatrie und Psychotherapie, Universität zu Lübeck
  Ratzeburger Allee 160
  23538 Lübeck
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

Contact for Scientific Queries

Klinik für Psychiatrie und Psychotherapie, Universität zu Lübeck
Ms. Dr. med. Eva Faßbinder
Ratzeburger Allee 160
23538 Lübeck
Germany

Telephone: **0451-50098702**
Fax: **0451-50098710**
E-mail: **eva.fassbinder at uksh.de**
URL: **[---]***

- **Contact for Public Queries**

Klinik für Psychiatrie und Psychotherapie, Universität zu Lübeck
Ms. Dr. med. Eva Faßbinder
Ratzeburger Allee 160
23538 Lübeck
Germany

Telephone: **0451-50098702**
Fax: **0451-50098710**
E-mail: **eva.fassbinder at uksh.de**
URL: **[---]***

Sources of Monetary or Material Support

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

Klinik für Psychiatrie und Psychotherapie, Universität zu Lübeck
Ratzeburger Allee 160
23538 Lübeck
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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.*