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

Trial Description

Title

Euthymic Therapy: a Randomised Controlled Trial

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Investigation of a cognitive behavioural resource-strengthening group intervention program which aims to increase hedonic experiences such as joy and happiness. We hope to find a comparable effect in treatment of patients with remaining depression symptoms.

Brief Summary in Scientific Language

Evaluation of a patient's ressource srengthening psychotherapeutic intervention in treatment of residual depression symptoms

Organizational Data

- DRKS-ID: **DRKS00003690**
- Date of Registration in DRKS: **2012/04/02**
- 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.: **EA1/172/06 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Euthymic therapy, group intervention, 7 weekly sessions à 50 min**
- Arm 2: **psychoeducation, group therapy, 7 weekly sessions à 50 min**

Characteristics

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

Primary Outcome

Our project thus aimes to assess the effects of ET on reduction of depressive symptoms (HAMD-21, BDI), anhedonia (TAF) and a patient's health resources (MR FSF) in a randomized, controlled, parallel-group design. We expect ET to reduce depressive residual symptoms and anhedonia and improve self care as effectively as the validated reference treatment (psychoeducation). 3 measuring times: baseline, post intervention an follow-up (after 3 month).
Following questionaires were used:
•Hamilton Depression Scale (HAMD)

Secondary Outcome

Additionally we expect an increase in following parameters: leisure activities (Checkliste der Freizeitaktivitäten, CFA), liefe-satisfaction (Lebenszufriedenheitsbogen, LZF), pleasure (Genussfragebogen, SFS), general state of health (Fragebogen zum allg. Gesundheitszustand), SF-36), self-efficacy (Fragebogen zum Selbstwirksamkeitserleben, SWE), locus of control (Fragebogen zur Erhebung von Kontrollüberzeugungen zu Krankheit und Gesundheit, KKG), sense of coherence (Marburger Skalen zum Kohärenzsinn, MR SOC).

3 measuring times: baseline, post intervention an follow-up (after 3 month).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Psychiatrie und Psychotherapie der Charité, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/10/24**
- Target Sample Size: **44**
- 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

Diagnosis of depression (ICD-10: F32, F33) partialremission (HAMD-21 depression score of </= 9) or a reduction of depression severity by 50% (HAMD) from the peak during inpatient treatment. Psychiatric treatment as usual remained, and it was ensured that no change in medication occurred within two weeks prior to the start of the group intervention.

Exclusion criteria

History of bipolar disorder, cyclothymia, schizophrenia, schizoaffective disorder, organic brain damage or substance abuse/dependence. Participation in a pharmaceutical study and ongoing individual psychotherapy were further exclusion criteria as well as borderline (ICD-10: F60.3) or antisocial personality disorders (ICD-10: F60.2).

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

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URL: **www.charite.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2009/05/15**

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.*