# Evaluating the effectiveness of an adjunctive Emotion Regulation Training during inpatient treatment for Major Depressive Disorder

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
30/03/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
07/07/2011	Completed	[X] Results
Last Edited	Condition category	Individual participant data
07/07/2011	Mental and Behavioural Disorders	

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10104020-2

# Study information

#### Scientific Title

Evaluating the effects of integrating an Emotion Regulation Training in cognitive behavioral psychotherapeutic inpatient treatment for Major Depressive Disorder on the reduction of depressive symptoms - a randomized controlled trial

#### Acronym

**ERTMDD** 

#### **Study objectives**

Including an intensive emotion regulation training in inpatient cognitive-behavioral psychotherapeutic treatment (CBT) for depression enhances the treatment's effects on symptoms of depression

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Vogelsberg Clinic (Germany), March 2008

#### Study design

Prospective single center randomized controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Major depressive disorder as defined by DSM IV criteria

#### **Interventions**

- 1. Cognitive Behavioural Therapy (CBT) + Emotion Regulation Training (ERT): ERT is an abbreviated (5  $\times$  1.5 hs) version of the "Affect Regulation Training" developed by Berking (2010; German: Training emotionaler Kompetenzen).
- 2. The training aims to enhance emotion regulation skills with the help of a variety of methods including relaxation, acceptance of emotions, compassionate self-support, behavior analysis and

emotion-focused problem solving

- 3. It will be delivered in 1.5 hour sessions two times a week during the second, third and forth week of the inpatient treatment
- 4. Control condition: CBT-based treatment as usual including behavioral activation and cognitive restructuring

#### Intervention Type

Other

#### Phase

Phase IV

#### Primary outcome measure

Beck Depression Inventory (BDI; German version: Hautzinger, Bailer, Worall, & Keller, 1995) as assessed pre- and post treatment

#### Secondary outcome measures

- 1. Emotion Regulation Skills Questionnaire (ERSQ; German version: Berking & Znoj, 2008) as assessed pre- and post treatment
- 2. BDI scores as assessed at pre-treatment and at a 6-month follow-up
- 3. BDI scores as assessed at pre-treatment and at a 12-month follow-up
- 4. ERSQ scores as assessed at pretreatment and at a 6-month follow-up
- 5. ERSQ scores as assessed at pre-treatment and at a 12-month follow-up

#### Overall study start date

01/04/2008

#### Completion date

01/06/2011

# Eligibility

#### Key inclusion criteria

- 1. Diagnosis of Major Depressive Disorder according to DSM-IV criteria
- 2. Age: 18 or above
- 3. Ability and willingness to provide informed consent
- 4. Anticipated treatment length of six weeks or above

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

500

#### Key exclusion criteria

- 1. High risk of suicide
- 2. Co-occurring psychotic
- 3. Bi-polar disorders
- 4. Alcohol/substance dependence within the past six months
- 5. Insufficient German language skills (assessment and treatment will be in German)

#### Date of first enrolment

01/04/2008

#### Date of final enrolment

01/06/2011

### Locations

#### Countries of recruitment

Germany

# Study participating centre University of Marburg

Marburg Germany 35032

# Sponsor information

#### Organisation

Swiss National Science Foundation (Switzerland)

#### Sponsor details

Wildhainweg 3 P.O. Box 8232 Bern Switzerland CH-3001

#### Sponsor type

Research organisation

#### Website

http://www.snf.ch/E/Pages/default.aspx

#### **ROR**

https://ror.org/00yjd3n13

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Swiss National Science Foundation (PZ00P1-121576/1)

#### Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

Switzerland

#### Funder Name

University of Lüneburg, Germany

#### **Funder Name**

University of Marburg, Germany

#### **Funder Name**

Vogelsberg Clinic, Germany

### **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		17/04/2008		Yes	No
Results article	results	01/11/2008		Yes	No
Results article	results	01/09/2010		Yes	No