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

Submission date	Recruitment status	[ ] Prospectively registered
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

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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 x 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