

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

Submission date
30/03/2011

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
07/07/2011

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
07/07/2011

Condition category
Mental and Behavioural Disorders

Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Matthias Berking

Contact details
University of Marburg
Institute of Psychology
Department of Clinical Psychology and Psychotherapy
Gutenbergstraße 18
Marburg
Germany
35032

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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 fourth 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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, The Swiss National Science Foundation (SNSF), 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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