



## Trial Description

### Title

**Neuronal Correlates of Emotion Regulation in patients with Borderline Personality Disorder before and after Treatment with Dialectical Behavior Therapy**

### Trial Acronym

**EmoReg\_L**

### URL of the trial

**<http://www.zi-mannheim.de/831.html>**

### Brief Summary in Lay Language

**Patients with Borderline Personality Disorder (BPD) suffer from intense and rapidly changing emotions, and they have difficulties to regulate these emotions. These symptoms might be due to a hyperreactivity in the limbic system, a brain system involved in the processing of emotions. Current research leads to the assumption that painful stimuli might serve as a possibility to distract attention from emotional contents. However, negative emotions can be attenuated by directing the attentional focus away from aspects of a situation, for example by solving mental arithmetics or other cognitive tasks.**

**We will investigate two emotion regulation strategies, namely reappraisal and attentional distraction. Both strategies are targeted within Dialectical Behaviour Therapy (M. Linehan), teaching patients' behavioral skills to establish functional emotion regulation strategies. In this longitudinal study, we aim to investigate the effect of Dialectical Behaviour Therapy on improvement of emotion regulation and underlying neural processes.**

**We will investigate 30 female BPD patients using three emotion regulation paradigms, each before and after three month of inpatient DBT treatment. The same paradigms will be used with 30 untreated female BPD patients and 30 healthy female controls with a test interval of three months. In every paradigm, we present neutral and negative pictures, which are supposed to elicit emotions. In each paradigm, a different strategy should be used to regulate these emotions: reappraisal, cognitive attentional shift or sensory attentional shift. Furthermore, pain sensitivity will be measured at all time points. We expect a normalization of the elevated pain thresholds and changes in brain systems involved in emotion regulation in patients with BPD after DBT treatment, depending on treatment outcome.**

### Brief Summary in Scientific Language

**Affective instability and self-injurious behavior are important features of Borderline Personality Disorder (BPD). These symptoms might be due to a pattern of limbic hyperreactivity paired with dysfunctional prefrontal regulation mechanisms. Current research leads to the assumption that painful stimuli might serve as a possibility to distract attention from emotional contents. According to general emotion regulation models by James Gross and colleagues, negative affect can be attenuated by directing the attentional focus away from aspects of a situation (attentional shift), or by cognitive regulation strategies (reappraisal).**

**Both strategies are targeted within Dialectical Behaviour Therapy (M. Linehan), teaching patients' behavioral skills to establish functional emotion regulation strategies. In this longitudinal study, we aim to investigate the effect of Dialectical Behaviour Therapy on improvement of emotion regulation and underlying neural processes.**

**We will investigate 30 female BPD patients using three emotion regulation paradigms, each before and after three month of inpatient DBT treatment. The same paradigms will be used with 30 untreated female BPD patients and on 30 healthy female controls with a test interval of three month. In every paradigms, we present neutral and negative pictures, which are supposed to elicit emotions. In each paradigm, a different strategy should be used to regulated these emotions: reappraisal, cognitive attentional shift or sensory attentional shift. Furthermore, pain sensitivity will be measured at all time points. We expect a normalization of the elevated pain thresholds and of the neural correlated of malfunctioning emotion regulation in patients with BPD after DBT treatment, depending on treatment outcome.**

## Organizational Data

- DRKS-ID: **DRKS00000778**
- Date of Registration in DRKS: **2011/06/09**
- 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.: **2010-243N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

## Secondary IDs

- Other Secondary-ID: **SCHM 1526/8-2 (Studien-ID des Geldgebers DFG)**

## Health condition or Problem studied

- ICD10: **F60.31 - [generalization F60.3: Emotionally unstable personality disorder]**

## Interventions/Observational Groups

- Arm 1: **In the first trial arm, 30 patients intending to participate in inpatient DBT treatment will be included. Patients will be measured at therapy start and about 12 weeks later (to assure being in the same menstruation phase). First, before the first measurement, diagnostic measures of axis 1 and 2 disorders will be obtained if not available from current treatment diagnostics. BPD diagnosis will be obtained with the international personality disorder examination (IPDE), symptom severity will be measured with the borderline symptom list (BSL-95, Bohus et al. 2007) and the Zanarini Rating-Scale (ZAN-BPD, Zanarini et al. 2003). Further psychometric measures are the Questionnaires on Dissociative Symptoms (Freyberger et al. 1998), the Beck**

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**Depression Inventory (Hautzinger et al. 2003), the State-Trait-Anxiety**

**Inventory (Laux et al. 1981) and the Questionnaire for Self-Injurious Behavior**

**(Kleindienst et al. 2008).**

**If inclusion criteria are met and informed consent is obtained, the participant may continue in the study. All dependent measures will be obtained at two time points three months apart. At each time point, individual pain stimuli for the sensory attentional shift paradigm will be determined first. Thermal stimulation is elicited via a heat eliciting device (Thermal Sensory Analyzer, Medoc, Israel). We apply sensory stimulation on the lower forearm. For each participant, a subjective pain intensity of 6 on a scale of 0 (not painful) to 10 (strongest pain imaginable) is determined. To do so, we apply thermal stimuli between 39°C und 50°C for three seconds each, increasing or decreasing successively the temperature by 0.5 °C until the participant rates the painfulness as 8 (for increasing stimuli) or 0 (for decreasing stimuli). This procedure is repeated four times, with decreasing and increasing trials alternating. In the sensory attentional shift paradigm, the temperature which is rated 6 most frequently will be used. Before starting the experiment, the determined temperature is presented once again in order to assure that the pain intensity is well tolerable.**

- **Arm 2: In the second trial arm, 30 outpatient BPD patients participate, who do**

**not have any DBT treatment between the two measurement time points. The untreated patients group are studied with the same procedure as described for arm 1.**

- **Arm 3: In the third trial arm, 30 healthy controls are studied. Meeting the inclusion and exclusion criteria, healthy controls are studied with the same procedure as described for arm 1.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: [---]\*
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

## Primary Outcome

**The primary outcome criterion is the change of borderline symptom severity measured by the borderline symptom list (BSL-95, Bohus et al. 2007) from measurement 1 to measurement 2.**

## Secondary Outcome

**The secondary outcome criterion is the change of borderline symptom severity measured by the Zanarini Rating- scale (ZAN-BPD, Zanarini et al. 2003) from measurement 1 to measurement 2.  
Also, change in emotion regulation abilities measured by the Difficulties in Emotion Regulation Questionnaire (DERS, Gratz & Roemer 2004).from measurement 1 to measurement 2.**

## Countries of recruitment

- **DE Germany**

## Locations of Recruitment

- **University Medical Center ZI Mannheim, Mannheim**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/05/25**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **45 Years**

## Additional Inclusion Criteria

**Inclusion criteria for all participants: Age 18 to 45 years, willingness to participate. Additional criteria for patients: Borderline personality disorder according to DSM IV, fulfilling the DSM IV criterion for emotional instability, fulfilling the DSM IV criterion for self-injurious behavior.**

## Exclusion criteria

**Exclusion criteria for all participants: Pregnancy, Lifetime diagnosis of psychotic disorder or bipolar I disorder, Major depressive episode at the time of measurement, Substance dependency in the preceding year, Organic brain diseases, Severe medical or neurological condition, Antecedent cranial or brain injuries, Metallic items in or on the body, Left-handedness, Claustrophobia. Additional exclusion criteria for the patient control group: Attendance of a DBT skill group within the test interval. Additional criteria for the healthy control group: Fulfilling more than one DSM IV criterion for BPD, Any psychiatric disease.**

## Addresses

### ■ Primary Sponsor

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## **Sources of Monetary or Material Support**

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**Deutsche Forschungsgemeinschaft DFG**

**Kennedyallee 40**

**53175 Bonn**

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## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/02/12**

## Trial Publications, Results and other documents

- Paper [---]\*

\* 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.