

## Trial Description

### Title

**Neural mechanisms of trust and dyadic interaction in borderline personality disorder**

### Trial Acronym

**BPDTrust**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The aim of the study is to investigate the biological mechanisms of trust and interpersonal interaction of Borderline Personality Disorder (BPD). Distrust and dysfunctional regulation of emotions are core symptoms of patients with BPD. Because trust is one of the major foundations of successful human relations, the distrust observable in BPD patients substantially impairs their interpersonal interactions and relationships. Recent findings have identified neurobiological reasons for varying social behavior and trust. In order to identify these neurobiological mechanisms, fMRI studies and the investigation of oxytocin, a neuropeptide, are conducted. Thereby the participants are asked to engage in a social interaction while the interacting partners are simultaneously scanned. With regard to the aforementioned symptoms, it is hypothesized that patients with BPD show different activity in brain systems associated with trust linked to altered oxytocin levels. In order to investigate these hypotheses, patients with a Borderline Personality Disorder, between the age 19 and 60, will be tested.**

### Brief Summary in Scientific Language

**A constant instability in interpersonal relationships, impulse control and regulation of affect are the key symptoms of Borderline personality disorder (BPD). A core dysfunctional attitude that characterizes BPD patients is distrust. Because trust is one of the major foundations of successful human relations, the distrust observable in BPD patients substantially impairs their interpersonal interactions and relationships. Recent neurobiological advances have brought the neurobiology of prosocial behaviour and trust into focus. Neural systems and molecular mediators of prosocial behaviour and trust have been identified, with a key role of prefrontal regulation of the amygdala, modulated by the prosocial neuropeptide, Oxytocin (OT). While the amygdala and modulating structures have been previously assessed in BPD, much less is known about the OT system, and the link between OT and neural systems implicated in trust is unknown. In the present study, we hypothesize that BPD patients exhibit abnormal activity and connectivity in brain systems associated with trust linked to an altered OT system. To test this hypothesis we plan to investigate dyadic trust-related social interactions while the interacting partners are simultaneously scanned in a hyperscanning environment. We expect to observe specific neural signatures during these interactions that predict reduced trust as well as reduced OT levels in the patients.**

## Organizational Data

- DRKS-ID: **DRKS00003281**
- Date of Registration in DRKS: **2011/12/14**
- 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.: **2011-222N-MA , Medizinische Ethik-Kommission II  
Medizinische Fakultät Mannheim der Universität Heidelberg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **F60.3 - Emotionally unstable personality disorder**
- Free text: **Healthy Volunteer**

## Interventions/Observational Groups

- Arm 1: **Patients**

To test the hypothesis dyads of participants will be studied. Participants will participate in three different paradigms:

1. A basic emotion processing paradigm.
2. A simple shared attention paradigm to measure basal social interaction mechanisms
3. multi-round economic exchange trust game.

Paradigms 2 and 3 will be conducted in a hyperscanning context while experiment 1 will be conducted separately for both participants, but in the same session.

Before the sessions participants will give a urine sample for measurement of oxytocin levels afterwards.

Both before and after each scanning sessions, participants' current emotional states will be assessed the state versions of the State-Trait Anger Expression Inventory (STAXI-S) (Spielberger, 1988) and State-Trait Anxiety Inventory (STAI-S) (Spielberger et al., 1983) to determine potential effects of vasopressin on current levels of anger and anxiety, respectively. Valence, arousal, and dominance will also be assessed before and after the scanning sessions using the Self-Assessment Manikin (Bradley & Lang, 1994).

- Arm 2: **Healthy Controls**

Healthy Controls and participants with a Borderline Personality Disorder will be tested within the same experimental context.

To test the hypothesis dyads of participants will be studied. Participants will participate in three different paradigms:

1. A basic emotion processing paradigm.
2. A simple shared attention paradigm to measure basal social interaction mechanisms
3. multi-round economic exchange trust game.

Paradigms 2 and 3 will be conducted in a hyperscanning context while experiment 1 will be conducted separately for both participants, but in the same session.

Before the sessions participants will give a urine sample for measurement of oxytocin levels afterwards.

Both before and after each scanning sessions, participants' current emotional states will be assessed the state versions of the State-Trait Anger Expression Inventory (STAXI-S) (Spielberger, 1988) and State-Trait Anxiety Inventory (STAI-S) (Spielberger et al., 1983) to determine potential effects of vasopressin on current levels of anger and anxiety, respectively. Valence, arousal, and dominance will also be assessed before and after the scanning sessions using the Self-Assessment Manikin (Bradley & Lang, 1994).  
</style>

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]\***
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Primary Outcome will be the analysis of fMRI data. Thereby the aim is to identify brain regions with emotional processing (paradigm 1) joint attention (paradigm 2) and trust of fairness (paradigm 3).**

**Hyperscanning will be conducted on two identical Siemens 3 Tesla Trio scanners at the Central Institute of Mental Health.**

**Data sets will be analyzed stepwise.**

**First, preprocessing of the data will proceed using our standard published techniques and the software package SPM8.**

**Second, the data will be analyzed separately using the general linear model and statistical parametric mapping (again in SPM8). Thereby the aforementioned brain regions in association with the paradigms are aimed to be identified. For this, a general linear model to the data sets, using our experimental events as predictors, is applied. Contrast images from each subject will then be introduced**

**to a second level group analysis to test for group differences. These contrast groups can also be used to investigate correlations between individual brain activation and behavioral or oxytocin data (see Secondary Outcome).**

**Third, the focus of the experiment is the characterization of interpersonal neural systems supporting dyadic interaction across both brains simultaneously. This is a current research frontier in neuroimaging data analysis, so three new approaches will be explored.**

### Secondary Outcome

**Secondary outcome measures can be classified in 1. behavioral data , 2. Oxytocin measurements and 3. emotional state data.**

#### 1. Behavioral Data

**For the matching task, reaction times can be used to quantify processing speed. For the joint attention task, reaction times are a relevant behavioral readout of the efficacy of cooperation. In the trust game, a detailed analysis of the investment and repayment time courses has been provided by King-Casas et al. (King-Casas et al., 2008), which we will follow in this hyperscanning experiment to provide measures of trust, cooperation and perceived fairness over the course of the game.**

#### 2. Oxytocin Measurements

**Before the scanning sessions, subjects will give an urine sample for measurement of Oxytocin.**

#### 3. Emotional state data

**Participants' current emotional states, both before and after each of the scanning sessions, will be assessed with the state versions of the State- Trait Anger Expression Inventory (STAXI-S) (Spielberger, 1988) and State-Trait Anxiety Inventory (STAI-S) (Spielberger et al., 1983) to determine potential effects of vasopressin on current levels of anger and anxiety, respectively. Valence, arousal, and dominance will also be assessed before and after the scanning sessions using the Self-Assessment Manikin (Bradley& Lang, 1994).**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

### Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2012/03/01**
- Target Sample Size: **360**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Planned**

(Anticipated or Actual) Date of First Enrollment: **2012/03/01**

Target Sample Size: **360**

Monocenter/Multicenter trial: **Monocenter trial**

■ National/International: **National**

### Inclusion Criteria

■ Gender: **Female**

■ Minimum Age: **19 Years**

■ Maximum Age: **60 Years**

### Additional Inclusion Criteria

- **Sufficient knowledge of German language**

- **Able to give informed consent**

**For patients:**

**Borderline personality disorder according to DSM IV**

### Exclusion criteria

- **MR exclusion criteria (metal parts in body, brain surgery, permanent make up)**

- **pathological gambling**

**For controls:**

- **any psychiatric disorder**

### Addresses

#### ■ Primary Sponsor

**Zentralinstitut für Seelische Gesundheit**

**Mr. Prof. Dr. med. Andreas Meyer-Lindenberg**

**J 5**

**68159 Mannheim**

**Germany**

Telephone: **0621 1703-2001**

Fax: **0621 1703-2005**

E-mail: **a.meyer-lindenberg at zi-mannheim.de**

URL: **www.zi-mannheim.de**

#### ■ Contact for Scientific Queries

**Zentralinstitut für Seelische Gesundheit**

**Mr. Prof. Dr. phil. Peter Kirsch**



### Contact for Scientific Queries

**Zentralinstitut für Seelische Gesundheit**

**Mr. Prof. Dr. phil. Peter Kirsch**

**J 5**

**68159 Mannheim**

**Germany**

Telephone: **0621 1703-6501**

Fax: **0621 1703-6505**

E-mail: **peter.kirsch at zi-mannheim.de**

URL: **www.zi-mannheim.de**

### ■ Contact for Public Queries

**Zentralinstitut für Seelische Gesundheit**

**Mr. Prof. Dr. phil. Peter Kirsch**

**J 5**

**68159 Mannheim**

**Germany**

Telephone: **0621 1703-6501**

Fax: **0621 1703-6505**

E-mail: **peter.kirsch at zi-mannheim.de**

URL: **www.zi-mannheim.de**

## 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**

**Kennedyallee 40**

**53175 Bonn**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **www.dfg.de**

## Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): [---]\*

DRKS-ID: **DRKS00003281**

Date of Registration in DRKS: **2011/12/14**

Date of Registration in Partner Registry or other Primary Registry: [---]\*



Deutsches Register  
Klinischer Studien

German Clinical  
Trials Register

## 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.*