Trial Description

Title

Sensory-affective interaction and body perception in borderline personality disorder

Trial Acronym

KFO IP4 II

URL of the trial

http://www.kfo256.de/de/projekte/sensorik.html

Brief Summary in Lay Language

We will examine the relationship between dissociation, body experiences and sensory processing in borderline personality disorder. Further, we explore the underlying neuronal mechanisms.

Brief Summary in Scientific Language

Our project aims at the elucidation of psychobiological mechanisms of dissociative states and the evaluation of their importance for the psychopathology of BPD. In study 1, after the induction of dissociation or a neutral control condition, we will perform experiments that use of the processing of pain and pleasant touch. In study 2, we will facilitate or inhibit the activity of certain brain regions using a neuronavigated transcranial magnetic stimulation (TMS) protocol. We will examine its effects on sensory integration associated with body perception and the processing of somatosensory stimuli with positive or negative valence, and their association with dissociation.

Organizational Data

- DRKS-ID: **DRKS00007929**
- Date of Registration in DRKS: **2015/09/18**
- 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.: **2014-609N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Subjects with borderline personality disorder: Study 1: The subjects will listen to autobiographic stories with a negative emotional content. Afterwards, we will assess their pain perception (by a thermode) as well as the processing of non-painful stimuli (touch stimuli). Further, we will test their body perception by a bodily illusion paradigm. Study 2: We will perform the same experiments after transcranial magnetic stimulation of a target or control region.**
- Arm 2: **Healthy controls: Study 1: The subjects will listen to autobiographic stories with a negative emotional content. Afterwards, we will assess their pain perception (by a thermode) as well as the processing of non-painful stimuli (touch stimuli). Further, we will test their body perception by a bodily illusion paradigm. Study 2: We will perform the same experiments after transcranial magnetic stimulation of a target or control region.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- 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

Study 1: We will assess alterations in sensory perception (pain, touch) by self-developed questionnaires after the induction of dissociation.
Study 2: We will assess alterations in sensory perception (pain, touch) by self-developed questionnaires after transcranial magnetic stimulation of certain brain regions.

Secondary Outcome

Study 1: We will assess alterations in body perception by self-developed questionnaires after the induction of dissociation.
Study 2: We will assess alterations in body perception by self-developed questionnaires after transcranial magnetic stimulation of certain brain regions.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/10/01**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **50 Years**

Additional Inclusion Criteria

unmedicated, female human subjects with diagnosed current borderline personality disorder, age between 18 and 50 as well as healthy participants

Exclusion criteria

epilepsy and other seizures, unusual circulatory reactions, traumatic brain injuries, metal implants in the head area, heart diseases, and cervical myelopathy.

Addresses

- **Primary Sponsor**

  Institut für Neuropsychologie und Klinische PsychologieZentralinstitut für Seelische GesundheitMedizinische Fakultät Mannheim,Heidelberg

Primary Sponsor

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■ **Contact for Scientific Queries**

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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.)**

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Kennedyallee 40
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URL: **www.dfg.de**

Status

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

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.*