Trial Description

Title

Treating Psychosocial and Neural Consequences of Childhood Interpersonal Violence in Adults

Trial Acronym

RELEASE

URL of the trial

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Brief Summary in Lay Language

Patients with Posttraumatic Stress Disorder (PTSD) after experiences of interpersonal violence during childhood and adolesence often suffer from co - occuring psychiatric disorders e.g Borderline Personality Disorder (BPD). BPD often comprises complex symptom patterns.
At the Central Institute of Mental Health in Mannheim a new treatment for patients with PTSD after childhood sexual or physical abuse and co - occuring borderline symptoms was developed and evaluatet. The main aim of the present study is to test the efficacy of this treatment approach in comparison to the well established Cognitive Processing Therapy. In addition, we investigate factors which are responsible for a successful therapy. A third aim of the study is to investigate neural mechanisms and correlates of therapy and their consequences on re-experiencing.

Brief Summary in Scientific Language

Experiences of childhood interpersonal trauma (CIT) such as sexual or physical abuse have powerful and often additive associations with the occurrence of mental disorders throughout the course of life. The highest odds ratios (ORs) in females who have been victims of such experiences are found for alcohol and drug abuse (OR=8.9), borderline personality disorder (BPD; OR=7.6), and posttraumatic stress disorder (PTSD; OR=7.25) (Cutajar et al., 2010). The latter two disorders frequently co-occur, and often result in complex conditions with severe psychopathology, pervasive problems in emotion regulation, non-suicidal self-injurious behaviours, and low remission rates. Unfortunately, the empirical database on psychosocial treatments for survivors of CIT is quite limited. Furthermore, the few existing studies have mostly excluded subjects with current self-harm behaviours, suicidal ideation, dissociative disorders, substance abuse, or BPD—hence, a large group of patients suffering from PTSD after CIT. Thus, researchers are still trying to identify efficacious treatment programmes for this group of patients.
We recently developed a three-month residential treatment programme that tailors dialectical behavioural therapy (DBT) to the specific needs of such patients. The effects of this programme, termed DBT-PTSD, were evaluated in a randomised controlled trial (RCT) that was funded by the German Research Foundation (DFG).

Data revealed significant reduction of posttraumatic symptoms, with large between-group effect sizes when compared to a treatment-as-usual wait list condition (Cohen's d=1.5) (Bohus et al., 2012a). However, residential treatment is expensive and can be provided for only a limited number of patients. Therefore, we have modified the DBT-PTSD approach for outpatient conditions, and have collected promising pilot data.
The first aim of the research collaboration RELEASE is to evaluate the efficacy of this new outpatient treatment programme. The second aim is to identify the major therapeutic variables mediating treatment efficacy. The third aim is to study the neural mechanisms and treatment sensitivity of two of the most serious sequelae of PTSD after CIT: intrusions and dissociation. To address these questions, we will recruit 180 female patients who experienced CIT and who currently fulfil the DSM-IV criteria for PTSD plus severe emotion dysregulation. Participants will be randomised to one year of outpatient psychotherapy with either DBT-PTSD or cognitive processing therapy (CPT-C; Resick et al. 2008).

Organizational Data

- DRKS-ID: **DRKS00005578**
- Date of Registration in DRKS: **2013/12/19**
- 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.: **2013-635N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F43.1 - Post-traumatic stress disorder**
- ICD10: **F60.31 - [generalization F60.3: Emotionally unstable personality disorder]**

Interventions/Observational Groups

- Arm 1: **Outpatient Dialectical Behavioral Therapy for PTSD. 90 women with Postraumatic Stress Disorder after interpersonal violence during childhood or adolescence will be randomly assigned to this treatment arm.
Individual treatment for each participant takes place once a week (50 minutes) for one year.**
- Arm 2: **Outpatient Cognitive Processing Therapy - Cognitive. 90 women with Postraumatic Stress Disorder after interpersonal violence during childhood or adolescence will be randomly assigned to this treatment arm. Individual treatment for each participant takes place once a week (50 minutes) for one**

year.

Characteristics

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

Primary Outcome

Severity of Posttraumatic Stress Disorder
Assessment: Clinician Administered PTSD Scale (CAPS, Blake et al. 1995)
Assessment points:
Baseline
3 months after baseline
6 months after baseline
9 months after baseline
12 months after baseline (end of the study)
3 months follow-up

Secondary Outcome

Symptom-severity of borderline personality disorder
Assessment: Borderline Symptom List (BSL-23, Bohus et al. 2009)
Assessment points:
Baseline
3 months after baseline
6 months after baseline
9 months after baseline
12 months after baseline (end of the study)
3 months follow-up

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Zentralinstitut für Seelische Gesundheit, Klinik für Psychosomatik und Psychotherapeutische Medizin , Mannheim**
- other **Institut für Psychologie, Göthe Universität Frankfurt am Main, Frankfurt a.M.**
- other **Institut für Psychologie, Humboldt Universität zu Berlin, Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/04/01**
- Target Sample Size: **180**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

PTSD after childhood sexual or physical abuse before the age of 18 years, sexual or physical assault must be the index trauma, at least 3 criteria of BPD (including criterion 6: affective instability), commitment and possibilty to attend weekly therapy sessions for one year; no planned absence for more than 4 weeks in this period, participant has the ability to understand character and consequences of the study, informed consent

Exclusion criteria

**Lifetime diagnosis of schizophrenia, lifetime diagnosis of bipolar I disorder, mental retardation, severe psychopathology which needs to be treated immediately in another setting (e. g. BMI < 16), medical conditions making exposure based treatment impossible, current alcohol - or drug addiction,
suicide attempt within the last 2 months, inpatient treatment planned, instability of the current life conditions (e.g. homelessness, ognoing contact with offender), pregnancy, 1 year DBT-PTSD or CPT-C treatment before inclusion**

Addresses

- **Primary Sponsor**

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  Klinik für Psychosomatik und Psychotherapeutische Medizin
  Mr. Prof. Dr. med. Martin Bohus
  J5

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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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Status

- Recruitment Status: **Recruiting planned**
- 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.*