# Trial Description

## Title

**Developmentally Adapted Cognitive Processing Therapy for Adolescents and Young Adults with PTSD Symptoms after Physical and Sexual Abuse**

## Trial Acronym

**D-CPT**

## URL of the trial

**http://www.traumatherapie-jugendliche.de/**

## Brief Summary in Lay Language

**We aim to study an intervention for Posttraumatic Stress Disorder (PTSD) related to sexual and/or physical abuse (SA/PA). Therefore, parts of different treatments were extracted and combined into a new intervention specially adapted for adolescents and young adults. This programme is called developmentally adapted Cognitive Processing Therapy (D-CPT; Matulis, Resick, Rosner & Steil, in prep). It has been successfully evaluated in a pilot study (Matulis, Resick, Rosner & Steil, 2013).**
**To evaluate the treatment's efficacy, half of the patients is assigned to the D-CPT and the other half to the TAU-condition (Treatment as Usual = treatment which adolescents usually receive in the German health system).**
**Participation in our study is possible for adolescents and young adults (14 to 21 years old) who suffer from PTSD after SA/PA.**

## Brief Summary in Scientific Language

**We aim to evaluate a developmentally adapted Cognitive Processing Therapy (D-CPT; Matulis, Resick, Rosner & Steil, in prep) for Posttraumatic Stress Disorder (PTSD) after sexual and/or physical abuse (SA/PA) in adolescents and young adults. It is based on the Cognitive Processing Therapy (CPT; Resick, Monson & Chard, 2008) – an intervention that has been proven to be very effective for adults. Developmental adaptations concern emotion processing, therapy format and addressing typical developmental tasks. The D-CPT has already been successfully piloted: Nearly all of the participating patients showed improvement (Matulis, Resick, Rosner & Steil, 2013).**
**Additionally, we will assess moderators of treatment response, epigenetic profiles, direct and indirect costs of the disorder and neurophysiological processing of threat cues in PTSD and their respective changes in the course of these two treatments (D-CPT and TAU). Results will provide data on treatment efficacy, as well as exploring associations to epigenetic profiles and the neurobiological processing of threat cues.**

## Do you plan to share individual participant data with other researchers?

**[---]***

### Description IPD sharing plan

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00004787**
- Date of Registration in DRKS: **2013/03/18**
- 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.: **D-CPT , Ethikkommission der Philosophisch-Pädagogischen Fakultät der Katholischen Universität Eichstätt-Ingolstadt**

## Secondary IDs

## Health condition or Problem studied

- Free text: **DSM-IV: 309.81 - Posttraumatic Stress Disorder**
- ICD10: **F43.1 - Post-traumatic stress disorder**

## Interventions/Observational Groups

- Arm 1: **D-CPT-arm: Psychotherapeutic intervention with 30 to 36 sessions (50 min each) within 16 to 20 weeks. The treatment is a developmentally adapted Cognitive Processing Therapy (D-CPT). It is organized in four phases: committment, emotion regulation training, intensive trauma-focuesd treatment and developmental tasks training.**
- Arm 2: **TAU-arm (Treatment As Usual): Patients allocated to TAU will be either encouraged to continue their current treatment or will be referred to institutions of public mental healthcare. If TAU-patients are dissatisfied with their treatment after 7 months, they will be offered D-CPT.**

## Characteristics

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

Who is blinded: **assessor**

- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Severity of PTSD**
**Measure: German version of the Clinician Administered PTSD Scale for Children and Adolescents (CAPS-CA, in German IBS-P-KJ; Steil & Füchsel, 2006)**
**Measurement points: Pretest (before starting the treatment), Posttest (after ending the treatment, approx. 16 weeks), Follow-Up I (3 months after ending the treatment), Follow-Up II (6 months after ending the treatment; for patients of the TAU-arm only those, who didn’t choose D-CPT after Follow-Up I)**

## Secondary Outcome

**Each at Pretest (before starting the treatment), Posttest (after ending the treatment, approx. 16 weeks), Follow-Up I (3 months after ending the treatment), Follow-Up II (6 months after ending the treatment; for patients of the TAU-arm only those, who didn’t choose D-CPT after Follow-Up I):**
**1.Self-rating of PTSD symptoms : German version of the UCLA PTSD INDEX for DSM IV (Arbeitsgruppe Psychotraumatologie KJP Ulm, 2008), German version of the Trauma Symptom Checklist for Children (Matulis & Steil, 2010)**
**2.Axis I and II comorbidity: German version of the Structured Clinical Interview for DSM Disorders (SKID; Wittchen, Zaudig & Fydrich, 1997), further important parts of the Diagnostic Interview for Mental Disorders in Childhood and Adolescence (Kinder-DIPS; Schneider, Unnewehr & Margraf, 2009), nicotine section of the Expert System for Diagnosing Mental Disorders (DIA-X, Wittchen & Pfister, 1997)**
**3.Depressive symptoms: German version of the Beck Depression Inventory (BDI-II; Hautzinger, Keller & Kühner, 2006)**
**4.Dissociative symptoms: German version of the adolescent Dissociative Experiences Scale (HDI; Brunner, Resch, Parzer & Koch, 2008)**
**5.Symptoms of emotional disregulation: German version of the Borderline Symptom Checklist 23 (BSL-23; Bohus, Kleindienst, Limberger, Stieglitz, Domsalla, Chapman et al., 2009)**
**6.General pathology and impairment: German version of the Youth-Self-Report (YSR; Döpfner, 1998)**
**7.Service use and quality of life: Client Sociodemographic and Service Receipt Inventory (CSSRI; Chisholm et al., 2000), EuroQol 5 Dimensions (EQ-5D; Dolan, 1997)**

**Each at Pretest (before starting the treatment) and Follow-Up I (3 months after ending the treatment):**
**1.Assessment of psychophysiological parameters by Electroencephalogram (EEG)**
**2.Epigenetic micro-array analyses of DNA saliva samples**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- other **Psychotherapeutische Hochschulambulanz der Katholischen Universität Eichstätt-Ingolstadt, Ingolstadt**
- other **Hochschulambulanz der Freien Universität Berlin, Berlin**
- other **Verhaltenstherapie-Ambulanz der Goethe-Universität Frankfurt, Frankfurt a.M.**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/07/09**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **14 Years**
- Maximum Age: **21 Years**

### Additional Inclusion Criteria

**Sexual or physical abuse after the age of three (definition according to the American Psychological Association Committee on Professional Practice and Standards, 1999)**
**PTSD (according to CAPS-CA: meeting 1 B-criterion, 2 C-criteria, 2 D-criteria) persisting for longer than one month**
**PTSD as primary diagnosis**
**Living in safe conditions**
**Sufficient knowledge of German language**
**Informed consent from parents/legal guardians (if under 18) and participant**
**Stable psychopharmacological medication at study entry (in the last 3 weeks there was either no or a constant psychopharmacological medication)**

### Exclusion criteria

**Acute suicidality within the last 6 months**
**Life threatening self-harming behavior within the last 6 months**
**Substance related or organic mental disorder**
**Pervasive developmental disorder**
**Current or lifetime diagnosis of a psychotic disorder according to DSM-IV**
**Current or lifetime diagnosis of a bipolar disorder according to DSM-IV**
**Current diagnosis of substance dependence according to DSM-IV (abstinence < 6 months)**
**Mental retardation (IQ ≤ 75)**
**Simultaneous psychotherapeutic treatment**

## Addresses

- **Primary Sponsor**

  **Katholische Universität Eichstätt-Ingolstadt;**
  **Lehrstuhl Klinische und Biologische Psychologie**
  **Ms. Prof. Dr. Dipl.-Psych. Rita Rosner**
  **Ostenstr. 25**
  **85072 Eichstätt**
  **Germany**

  Telephone: **+49 8421 93 - 1958**
  Fax: **+49 8421 93 - 2902**
  E-mail: **rita.rosner at ku.de**
  URL: **http://www.ku.de/ppf/psychologie/psych1/**

- **Contact for Scientific Queries**

  **Katholische Universität Eichstätt-Ingolstadt;**
  **Lehrstuhl Klinische und Biologische Psychologie**
  **Ms. Prof. Dr. Dipl.-Psych. Rita Rosner**
  **Ostenstr. 25**
  **85072 Eichstätt**
  **Germany**

  Telephone: **+49 8421 93 - 1958**
  Fax: **+49 8421 93 - 2902**
  E-mail: **rita.rosner at ku.de**
  URL: **http://www.ku.de/ppf/psychologie/psych1/**

- **Contact for Public Queries**

  **Katholische Universität Eichstätt-Ingolstadt; Lehrstuhl Klinische und Biologische Psychologie**
  **Ms. Dipl.-Psych. Eline Rimane**
  **Levelingstr. 7**
  **85049 Ingolstadt**

**Contact for Public Queries**

**Katholische Universität Eichstätt-Ingolstadt; Lehrstuhl Klinische und Biologische Psychologie**
**Ms. Dipl.-Psych. Eline Rimane**
**Levelingstr. 7**
**85049 Ingolstadt**
**Germany**

Telephone: **+49 8421 93 - 1958**
Fax: **+49 8421 93 - 2902**
E-mail: **eline.rimane at ku.de**
URL: **http://www.ku.de/ppf/psychologie/psych1/**

■ **Collaborator, Other Address**

**Universitätsklinikum Hamburg-Eppendorf; Institut für Gesundheitsökonomie und Versorgungsforschung**
**Mr. Prof. Dr. med. Hans-Helmut König**
**Martinistr. 52**
**20246 Hamburg**
**Germany**

Telephone: **+49 40 7410 - 54464**
Fax: **+49 40 7410 - 54934**
E-mail: **h.koenig at uke.uni-hamburg.de**
URL: <style fontName='DejaVu Sans' isBold='true'>http://www.uke.de/index.php?id=-1_-1_-1&as_link=http%3A//www.uke.de/index.php</style>

■ **Collaborator, Other Address**

**Universität Bielefeld;**
**Arbeitseinheit für Klinische Psychologie und Psychotherapie**
**Mr. Prof. Dr. Dipl.-Psych. Frank Neuner**
**Universitätsstraße 25**
**33615 Bielefeld**
**Germany**

Telephone: **+49 521 106 - 6871**
Fax: **+49 521 106 - 89012**
E-mail: **frank.neuner at uni-bielefeld.de**
URL: **http://www.uni-bielefeld.de/psychologie/ae/AE11/**

■ **Collaborator, Other Address**

**Max-Planck-Institut für Psychiatrie**
**Ms. Dr. med. Ulrike Schmidt**
**Kraepelinstr. 2-10**
**80804**
**Germany**

**Collaborator, Other Address**

**Max-Planck-Institut für Psychiatrie**
**Ms. Dr. med. Ulrike Schmidt**
**Kraepelinstr. 2-10**
**80804**
**Germany**

Telephone: **+49 89 30622 - 0**
Fax: **+49 89 30622 - 605**
E-mail: **uschmidt at mpipsykl.mpg.de**
URL: **http://www.mpipsykl.mpg.de/index.html**

■ **Collaborator, Other Address**

**Goethe-Universität Frankfurt am Main;**
**Klinische Psychologie & Psychotherapie**
**Ms. Dr. Dipl.-Psych. Regina Steil**
**Varrentrappstr. 40-42**
**60486 Frankfurt am Main**
**Germany**

Telephone: **+49 69 798 - 23379**
Fax: **+49 69 798 - 23459**
E-mail: **steil at psych.uni-frankfurt.de**
URL: **http://www.psychologie.uni-frankfurt.de/abteilungen_und_bereiche/klinische_psychologie_und_psychotherapie/index.html**

■ **Collaborator, Other Address**

**Freie Universität Berlin;**
**Arbeitsbereich Klinische Psychologie und Psychotherapie**
**Ms. Univ.-Prof. Dr. Dipl.-Psych. Babette Renneberg**
**Habelschwerdter Allee 45**
**14195 Berlin**
**Germany**

Telephone: **+49 30 838 - 56188**
Fax: **+49 30 838 - 51233**
E-mail: **b.renneberg at fu-berlin.de**
URL: **http://www.ewi-psy.fu-berlin.de/einrichtungen/arbeitsbereiche/klinische_psychotherapie/index.html**

## 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.)**

**Bundesministerium für Bildung und Forschung (BMBF)**
**Dienstsitz Bonn**

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**Bundesministerium für Bildung und Forschung (BMBF)**
**Dienstsitz Bonn**
**Heinemannstr. 2**
**53175 Bonn**
**Germany**

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.bmbf.de**

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/08/31**

## Trial Publications, Results and other documents

- Paper <style fontName='DejaVu Sans' isBold='true'>Rosner, R., König, H.-H., Neuner, F., Schmidt, U., & Steil, R. (2014). Developmentally adapted cognitive processing therapy for adolescents and young adults with PTSD symptoms after physical and sexual abuse: study protocol for a randomized controlled trial. Trials, 15. doi: 10.1186/1745-6215-15-195.</style>
- Paper **Rosner, R., Rimane, E., Frick, U., Gutermann, J., Hagl, M., Renneberg, B., . . . Steil, R. (2019). Effect of Developmentally Adapted Cognitive Processing Therapy for Youth With Symptoms of Posttraumatic Stress Disorder After Childhood Sexual and Physical Abuse: A Randomized Clinical Trial. JAMA Psychiatry. Advance online publication. https://doi.org/10.1001/jamapsychiatry.2018.4349**

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