PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Project CP2: "Recruiting, Assessment, and Biobanking" in the clinical research unit 256 with the title " Mechanisms of Disturbed Emotion Processing in Borderline-Personality Disorder"

Trial Acronym

KFO256 - CP2

URL of the trial

http://www.kfo256.de/de/teilnahme/studienteilnehmer.html

Brief Summary in Lay Language

The project is responsible for the central recruitment and diagnostic assessment as well as biobanking of blood for DNA ,for all individual projects of the clinical research group 256, according to legal, ethical and data security standards. Participants of the study are patients with Borderline-Personality Disorder (current and remitted), with Posttraumaticstress Disorder, Fibromyalgia and Healthy Controls. The biomaterial will be available for methylation and genotyping studies.

Brief Summary in Scientific Language

The project CP2 of the clinical research unit 256 (CRU256) is responsible for the central recruitment and diagnostic assessment as well as biobanking of blood for DNA for all other projects of the CRU256 according to legal, ethical and data security standards of the Organisation For Economic Co-Operation And Development (OECD) and the Technologie- und Methodenplattform für die vernetzte medizinische Forschung (TMF) e.V. The biomaterial will be available for methylation and genotyping studies. CP2 also includes training and inter-rater reliability assessments of the diagnosticians. Psychometric data of all patients will be monitored in a central data bank, providing access for all participating researchers. Biomaterial will be centrally processed, stored and managed in a pseudonomyzed way at the Department of Genetic Epidemiology in Psychiatry (Central Institut of Mental Health; CIMH). In close cooperation with the Department of Biostatistics (CIMH) and the Institute of Medical Biometry and Informatics (Heidelberg), the CP2 will further provide support in biometric and statistical analyses.

The project CP2 of the clinical research unit 256 (CRU256) is responsible for the central recruitment and diagnostic assessment as well as biobanking of blood for DNA for all other projects of the CRU256 according to legal, ethical and data security standards of the Organisation For Economic Co-Operation And Development (OECD) and the Technologie- und Methodenplattform für die vernetzte medizinische Forschung (TMF) e.V. The biomaterial will be available for methylation and genotyping studies. CP2 also includes training and inter-rater reliability assessments of the diagnosticians. Psychometric data of all patients will be monitored in a central data bank, providing access for all participating researchers. Biomaterial will be centrally processed, stored and managed in a pseudonomyzed way at the Department of Genetic Epidemiology in Psychiatry (Central Institut of Mental Health; CIMH). In close cooperation with the Department of Biostatistics (CIMH) and the Institute of Medical Biometry and Informatics (Heidelberg), the CP2 will further provide support in biometric and statistical analyses.

Organizational Data

- DRKS-ID: **DRKS00010146**
- Date of Registration in DRKS: **2016/03/16**
- 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.: **2011-255N_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]**
- ICD10: **F43.1 - Post-traumatic stress disorder**

Interventions/Observational Groups

- Arm 1: **All participants have to do a diagnostic in two steps. First a telephone screening to clear up the in- and exclusion criteria (1 hour), followed by a on-site diagnostic assessment with trained psychologists (5 hours) and several questionnaires at home. The following questionnaires are used: IPDE, SCID-I, Raven, ZAN-BPD, ADHS-SB, AQ, BDI, BIS, BSL-23, CAARS-S:L, CTQ, DERS, FDS, HEXACO, PIV, SCL-90, STAI-G, STAXI, SVV-CL, WURS-k**
  Additionally blood samples (50 ml) and a drug test were taken.
  In addition the inter-rater reliability of the diagnosticians is beeing monitored.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The planned outcome is the recruitment and diagnostic assessment of participants as described below. Furthermore biomaterial will be processed and stored for later genetic analyses.

Incusion into study occures after positive telephone screening followed by on-site diagnostic assessment with trained psychologists (IPDE, SKIC I) and self ratings (questionnaires: ADHS-SB, AQ, BDI, BIS, BSL-23, CAARS-S:L, CTQ, DERS, FDS, HEXACO, PIV, SCL-90, STAI-G, STAXI, SVV-CL, WURS-k).

Period of recruiting: 01.04.2012-31.03.2018.

Participant groups:
current Borderline-Personality Disorder (age 18-45, female): 267;
current Borderline-Personality Disorder (age 15-17, female): 35;
current Borderline-Personality Disorder (age 18-45, male): 87;
remitted Borderline-Personality Disorder (age 18-45): 85;
Fibromyalgia (age 18-45, female): 35;
Posttraumatic Stress Disorder (age 18-45, female): 60;
Social Anxiety Disorder (age 18-45, female): 40;
Autism Spectrum Disorder (age 18-45, female and male): 40;
Healthy Controls (age 15-17, female): 35;
Healthy Controls (age 18-45, female): 240;
Healthy Controls (age 18-45, male) 95;

Secondary Outcome

The inter-rater reliability is been verified by quarterly video recordings of all diagnosticians. The videos will be rated by all other diagnosticians to compaire the results. The rating of the following questionnaires will be verified: IPDE, SCID-I

Countries of recruitment

- DE **Germany**
- AT **Austria**
- CH **Switzerland**

Locations of Recruitment

- Medical Center **Zentralinstitut für Seelische Gesundheit, Mannheim**
- University Medical Center **Klinik für Allgemeine Psychiatrie Zentrum für Psychosoziale Medizin Lehrstuhl für Allgemeine Psychiatrie, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/04/01**
- Target Sample Size: **1054**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **15 Years**
- Maximum Age: **45 Years**

Additional Inclusion Criteria

Current Borderline Personality disorder:
min. 5 criteria IPDE (International Personality Disorder Examination);

Remitted Borderline Personality disorder:
max. 3 criteria IPDE about the last 2 years and min. 5 criteria at an earlier time point, as diagnosed by IPDE;

Posttraumaticstress Disorder (PTSD):
PTSD according to DSM-IV (SCID I); sexual abuse during childhood according to Childhood Trauma Questionnaire (CTQ);

Fibromyalgia: Criteria of the American College of Rheumatology (Wolfe et al., 2010);

Healthy Controlls:
No psychiatric Axis I disorder according life span; no BPD (SCID I and IPSE);

Exclusion criteria

- psychotropic medication
- lifetime diagnosis schizophrenia or bipoloar I disorder
- substance dependence within two years prior to study, current substance abuse (veryfied by negative urine drug screening)
- pregnancy
- history of epilepsy, brain trauma, brain tumor, or other significant neurological or medical condition

For imaging studies, additionally:
- metal implants or electric implants that cannot be removed
- claustrophobia

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.)**

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Kennedyallee 40
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Germany

Telephone: **[---]***
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E-mail: **[---]***
URL: **http://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.*