Trial Description

Title

Objective Markers of Posttraumatic Dissociation – Assessment of Spontaneously Occurring Dissociation

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Individuals, who made traumatic experiences in their life, can suffer from the consequences long after the experience (e. g. in form of a trauma-related disorder). Persons suffering from a chronical trauma-related disorder sometimes additionally report alterations in their perception and sensation, like e. g. the feeling, as if the world can only be seen through a fog or as if the own body seems to be strange and foreign. This kind of symptoms are mostly assessed via self-report. Up to now, it lacks of physiological markers to objectively measure the severity of these symptoms. One possible marker is the cardiac muscle activity. If trauma-associated triggers provoke alterations in perception and sensation, they also can provoke bodily reactions. This happens through the stress response mediated by the vegetative nervous system, which is responsible for the involuntary regulation of our organs. Therefore, we want to assess the occurrence and the intensity of such kind of phenomena via a smartphone app over a maximum of 10 work days in patients in a specialized inpatient treatment center. Simultaneously participating patients will carry a mobile device to measure the electronic heart muscle activity. With this study, we want to examine, if there will be changes in the activity of the heart muscle, while patients report the symptoms described above.

Brief Summary in Scientific Language

Dissociation describes a psychological phenomenon, which may occur to a pathological degree within the scope of mental disease. Recurring posttraumatic dissociation, long after the traumatic event is a known phenomenon in patients suffering from chronic posttraumatic stress disorder (PTSD). Especially symptoms of depersonalization (the feeling that the own body doesn’t belong to oneself or out-of-body experiences) and derealization (characterized by the feeling, that the surrounding seems unreal) as well as alterations in time perception and emotional experiences were reported by these patients. Essentially this can be seen as negative symptoms, what refers to an attenuation in the sensory and emotional self-experience.
The majority of published research regarding posttraumatic dissociation used subjective introspection of participants to identify such alterations. But it is assumed that the core feature of this negative symptomatic compromises introspection itself. To this date, no objective (psychophysiological) markers were identified to quantify the severity of dissociation.

Asking patients about their dissociative experiences, they partially mention symptoms, which refer to cardiovascular changes. That is in line with laboratory studies, which report a declined heart rate during dissociation. Further support for a negative correlation between the intensity of dissociation and the heart rate is given by analogue studies on healthy subjects. However, there is only few empirical literature assessing objective changes in heart rate in PTSD-patients. Heart rate as well as heart rate variability are ambulatory easily assessable via new wearable devices. We want to focus on that as a potential marker for dissociation.

The main target of this study is to examine dissociations and associated physiological reactions (namely heart rate and heart rate variability). Especially, we assess spontaneous dissociation under natural conditions, to make a contribution to the ecological validity as a supplement of present studies. To investigate this issue, these hypotheses will be tested:
H1: Spontaneous dissociative episodes are characterized through significant changes in heart rate or heart rate variability compared to baseline values.
H2: The perceived intensity of dissociation correlates with changes in heart rate and heart rate variability.

After obtaining informed consent of the study participants a psychopathological Assessment – complementary to our clinical routine diagnostics – is conducted.

Subsequent participating inpatients from the specialized trauma-station get a smartphone with a pre-installed application, which should always be activated, if a patient registers a dissociative phenomenon on herself (event-based assessment design). Patients carry the Smartphone and a mobile ECG device over a maximum of 10 days (from 7 am to 7 pm each day).
Besides the timeframes of perceived dissociation (via button clicking, when the symptom is perceived as well as when the end of the symptom is perceived), the smartphone application asks question about the description and intensity of the phenomenon, possible triggers, if the patient herself set the timestamps of the dissociation and which activity she was doing shortly before the symptom was perceived.

Organizational Data

- DRKS-ID: **DRKS00016307**
- Date of Registration in DRKS: **2018/12/18**
- 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.: **EK229062018 , Ethikkommission der Medizinischen Fakultät der Technischen Universität Dresden**

Secondary IDs

Health condition or Problem studied

- ICD10: **F43.1 - Post-traumatic stress disorder**

Interventions/Observational Groups

- Arm 1: **During the observation period up to 10 days patients carry a mobile ECG and smartphone from 7 am to 7 pm. Are they perceiving dissociative symptoms, they activate the App and answer short questions.**

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

Changes in heart rate and heart rate variability under reported dissociation (time-dependent analysis of the ECG sequence given by timestamps integrated in the smartphone application).

Secondary Outcome

Intensity of reported dissociation and the relationship to changes in heart rate and heart rate variability dissociation (time-dependent analysis of the ECG sequence given by timestamps integrated in the smartphone application; assessment of intensity via smartphone application).
Frequency and duration of reported dissociation (via timestamps and programmed smartphone application).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Psychotherapie und Psychosomatik, Dresden**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/02/11**
- Target Sample Size: **70**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Informed consent; Inpatient stay in hospital; Good German language skills; Diagnosis of a posttraumatic stress disorder (PTSD)

Exclusion criteria

− Severe head injuries as well as neurological disorders
− Diagnosis of comorbid: Organic, including symptomatic, mental disorders (F00-F09); Mental and behavioural disorders due to psychoactive substance use (F10-F19); Schizophrenia, schizotypal and delusional disorders (F20-F29); Emotionally unstable personality disorder – borderline (F60.31)
− Beta blocker therapy within the last 4 weeks

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

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- **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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  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.*