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

Trial Description

Title

Treatment of posttramaumatic stress disorders in patients in in-patient addiction rehabilitation with the EMDR-method - a randomized controlled trial

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In patients with addiction, other additional mental disorders contribute significantly to a difficult course of the disease and worse treatment outcomes. Patients with addiction offen additionally suffer from post-traumatic stress disorder (PTSD): 15-40% of addicted patients are affected by PTSD. Most institutions that consider PTSD in the treatment of addicted patients use a stabilizing approach, such as enhancing competencies to cope with burdening symptoms or to develop individual resources. However, the guidelines for the treatmnet of PTSD recommend a trauma-focused PTSD treatment. 'Eye Movement Desensitization and Reprocessing (EMDR)' is a trauma-focused treatment approach, which has been shown to yield better treatment outcomes than stabilizing procedures. Although the effectiveness of EMDR is well documented for patients with PTSD only, there is rare evidence of the efficacy of EMDR in addicted patients with PTSD. The objective of this randomized controlled trial is to compare the effectiveness of EMDR with the effects of a stabilizing therapy. Both groups will receive addtional stabilizing group-therapy. 158 patients with addiction and PTSD admitted to a rehabilitation clinic will be randomized to either EMDR or the stabilizing treatment. Patients in the EMDR group are expected to show less PTSD symptoms six months after treatment, compared with the control group.

Brief Summary in Scientific Language

Patients with substance use disorders, comorbid psychiatric disorders contribute to a worse course of the diseases and a worse treatment outcomes. One of the most common comorbidities is post-traumatic stress disorder (PTSD) which affects 15-40% of the addicted patients. In the stationary addiction rehabilitation, a comorbid PTSD is most often treated by a stabilizing therapy, such as enhancing competencies to cope with burdening symptoms or to develop individual resources. However, guidelines for the treatment of PTSD recommend a trauma-focused treatment approach, such as "Eye Movement Desensitization and Reprocessing (EMDR)", which has shown higher effect sizes compared with stabilizing therapies. Although the effectiveness of EMDR is well documented for

patients with PTSD only, there is rare evidence of the efficacy of EMDR in addicted patients with PTSD. The objective of this randomized controlled trial is to compare the effectiveness of EMDR with the effects of a stabilizing therapy. Both groups will receive addtional stabilizing group-therapy. 158 patients with addiction and PTSD admitted to a rehabilitation clinic will be randomized to either EMDR or the stabilizing treatment. Patients in the EMDR group are expected to show less PTSD symptoms 6 months after treatment, compared with the control group.

Organizational Data

- DRKS-ID: **DRKS00009007**
- Date of Registration in DRKS: **2016/06/01**
- 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.: **PV4853 , Ethik-Kommission der Ärztekammer Hamburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1172-9213**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Stabilizing PTBS treatment (Treatment as usual)**
- Arm 2: **Stabilizing PTBS treatment (Treatment as usual) and EMDR**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
-

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **assessor, data analyst**

Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Parallel**

- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

PTBS-symptoms, measured by the Clinician Administered PTSD Scale at 6-month-follow-up

Secondary Outcome

Secondary outcomes 6 months after treatment:
PTBS-Symptoms (PTSD Checklist for DSM-5); Alcohol use (mean amount of alcohol per day, number of abstinent days in the last month; Timeline Follow Back); Alcohol /substance use (Alcohol Use Disorders Identification Test; Drug Use Disorders Identification Test); Addiction-related problems (Addiction Severity Index)
Depressive symptoms (Beck Depression Inventory II); Dissociative symptoms (Dissociative Experiences Scale); Emotion regulation (Difficulties in Emotion Regulation Scale); Health-related quality of life (Short-Form 12-Item Health Survey)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Dormagen**

Recruitment

- Planned/Actual: **Actual**

Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2015/09/09**
- Target Sample Size: **158**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

Substance use disorder according to DSM5 (305.00, 303.90, 291.9); at least subsyndromal PTSD according to DSM5, 309.81 (criteria A and B and at least one more criterion of C to E), assessed with the Clinician Administered PTSD-Scale; patient provided informed consent

Exclusion criteria

Severe dissociative symptomatology (Dissociative Experiences Scale > 40); acute suicidality; acute psychotic symptomatology; severe cognitive impairments

Addresses

- **Primary Sponsor**

  Gesellschaft für Rehabilitationswissenschaften Nordrhein-Westfalen e.V. (GfR)
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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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E-mail: **[---]***
URL: **[---]***

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.*