Trial Description

Title

The efficacy of Narrative Exposure Therapy for Children (KIDNET) as a Treatment for Traumatized Young Refugees versus Treatment as Usual: A Multi-Center Randomized Controlled Trial

Trial Acronym

YOURTREAT

URL of the trial

http://www.uni-bielefeld.de/yourtreat

Brief Summary in Lay Language

Many young refugees hosted in Germany made adverse and traumatic experiences in their home country and on the flight. So far, the evidence regarding effective treatment options for traumatized young refugees is limited. The aim of the study YOURTREAT is to investigate if a specific trauma treatment called Narrative Exposure Therapy for Children (KIDNET) can reduce symptoms of Posttraumatic Stress Disorder (PTSD) in young refugees. Therefore, treatment with KIDNET will be compared to treatment as usual for young refugees within the German health care system. Young refugees aged 10 -18 years can participate in the study. Participants will be allocated randomly to the two conditions of the study.

Brief Summary in Scientific Language

Background: Germany hosts a large number of refugees from war-affected countries. The integration of refugees, in particular young refugees from the Middle East, is one of the major current social challenges in Germany. Mental disorders, first of all posttraumatic stress disorder (PTSD) that results from war experiences, are common among young refugees and interfere with quality of life as well as functional integration. Evidence regarding effective treatment options for this population is scarce. In this trial, we aim to evaluate a pragmatic, short-term treatment with Narrative Exposure Therapy for Children (KIDNET) for the treatment of young refugees in Germany.

Methods/design: In a rater-blinded multicenter randomized-controlled trial, KIDNET is compared to treatment as usual (TAU) within the general health care system. A total number of 80 young refugees who fulfill the diagnostic criteria of PTSD will be randomized to either KIDNET or TAU. Diagnostic interviews take place at baseline before treatment, and six and 12 months thereafter, and will assess exposure to traumatic events, PTSD and comorbid symptoms, as well as parameters of integration.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017222**
- Date of Registration in DRKS: **2019/05/15**
- 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.: **122018 , Ethikkommission der Deutschen Gesellschaft für Psychologie (DGPs)**

Secondary IDs

Health condition or Problem studied

- Free text: **Posttraumatic Stress Disorder**

Interventions/Observational Groups

- Arm 1: **Narrative Exposure Therapy for Children (KIDNET), 11 sessions**
- Arm 2: **Treatment as Usual (TAU) within the German Health System**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
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Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

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

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

Control: **Other**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **N/A**

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

Primary Outcome

The change in PTSD symptom severity from the diagnostic interview before treatment initiation to the follow-up assignments after 6 and 12 months. PTSD symptoms will be measured at each assessment by a structured clinical interview by expert clinicians using the Clinician-Administered PTSD Scale for DSM-5 – Child/Adolescent Version (CAPS-CA-5; Pynoos et al., 2015). The change in PTSD Symptoms will be evaluated by a mixed linear model.

Secondary Outcome

The following continuous secondary outcomes will be assessed before treatment (baseline) and at each follow-up assessment (after 6 and 12 months). The change of these secondary outcomes will be also evaluated by mixed linear models. (1) Depressive symptoms and internalizing and externalizing behavior, assessed by the Hopkins symptom checklist-37 for refugee adolescents (HSCL-37A; Bean, Derluyn, Eurelings-Bontekoe, Broekaert, & Spinhoven, 2007), (2) Suicidal ideation, assessed by the Columbia Suicide Severity Rating Scale (C-SSRS; Posner et al., 2011), and (3) Physical health, assessed by 17 items selected from the Screening for Somatoform Symptoms 7 (SOMS-7) based on their frequency and sensitivity to change (Rief & Hiller, 2003).

In addition, the rate of participants who still meet the diagnostic criteria of PTSD according to the CAPS-CA-5, as well as the PTSD response rate will be assessed at each follow-up assessment (after 6 and 12 months).
The PTSD response rate will be defined as the number of participants who show clinical significant symptom improvement on the CAPS-CA5, according to the reliable change index (RCI).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Universität Bielefeld, Bielefeld**
- other **Katholische Universität Eichstätt-Ingolstadt, Eichstätt-Ingolstadt**
- other **Universität Konstanz, Konstanz**
- University Medical Center **Universitätsklinikum Hamburg-Eppendorf, Hamburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/07/16**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **10 Years**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

• being a refugee allocated to the community close to one of the participating centers but not necessarily with a permanent permit to stay
• PTSD diagnosis according to CAPS-CA-5
• Age 10-18 years
• Informed consent obtained from participant (if participant is ≥16) or participant and caregiver/legal guardian (if participant is <16)

Exclusion criteria

• Acute risk of harm of self or others requiring inpatient treatment
• Clinical signs of acute psychotic disorder
• Clinical signs of mental retardation which would prevent effective psychotherapy
• Concurrent psychotherapeutic treatment
• Anxiolytic treatment with benzodiazepines as this medication is known to interfere with exposure-based psychotherapy (other medication is allowed and will be monitored).
• High alcohol or drug consumption (≥ 2-3 days of consumption per week) represents an exclusion criterion if participants cannot assure their preparedness and confidence to control their consumption in favor of the treatment they will receive in the framework of the trial

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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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.*