KIDNET vs EMDR vs Waitlist in refugeechildren with PTSD (symptoms) in the Netherlands

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22679

Source
Nationaal Trial Register

Brief title
KIEM

Health condition

Posttraumatic Stress Disorder (PTSD; partial-)

Sponsors and support

Primary sponsor: Vereniging EMDR Nederland (VEN); EMDR Europe; ZONMW; Stichting tot steun VCVGZ
Source(s) of monetary or material Support: Vereniging EMDR Nederland (VEN); EMDR Europe; ZONMW; Stichting tot steun VCVGZ

Intervention

Outcome measures

Primary outcome

Posttraumatic stress symptoms (CAPS-CA, CRIES-13 children and parents)

Secondary outcome

Behavioral and emotional symptoms (SDQ)
Quality of life (Kidscreen-27)
Treatment satisfaction (interview with participant)
Anxiety of the caregiver (BAI)

Study description

Background summary

Background: Prevalence of Posttraumatic stress disorder (PTSD) in refugees is reportedly higher in comparison to the general population. Refugee children specifically are challenged by developmental tasks, adjustment and integration, whilst often coping with trauma and loss. With staggering numbers of people seeking refuge around the world, and 50% being under 19 years of age, research examining the effects of trauma-focused therapies for refugee children with PTSD is lagging behind. EMDR and Kid-NET are both promising methods, although studies so far have been methodologically weak and treatment methods have not been compared.
Objective: The aim of the current study is to investigate the preliminary effectiveness of EMDR and Kid-NET, compared to a waitlist control group, offered to refugee children, combining qualitative and quantitative data, using a rigorous design.
Method: A randomized controlled trial has been designed. Primary outcome is PTSD symptom severity assessed with the Clinician-Administered PTSD Scale for Children DSM-5 (CAPS-CA) at baseline (T1), after eight sessions of treatment or waiting (T2) and at follow-up (T3). Additionally, self-report instruments to assess traumasymptoms, behavioural responses and quality of life perceptions in both children and their parents, are conducted at T1, T2 and T3. After treatment, participants are being interviewed about their perception of treatment process and effectiveness.
Discussion: This is the first RCT that examines the effectiveness of EMDR and Kid-Net in refugee children specifically, compared to a waitlist control group, intended to reduce PTSD complaints in a growing and challenging population.

Study objective

1) EMDR is more effective in reducing symptoms of PTSD behavioral and emotional symptoms and improving quality of life in refugee children and adolescents currently living in the Netherlands, when compared to a waiting list control group.
2) KIDNET is more effective in reducing symptoms of PTSD, behavioral and emotional symptoms and improving quality of life in refugee children and adolescents currently living in the Netherlands, when compared to a waiting list control group.
3) Both trauma-focused interventions equally reach efficacy in refugee children.
4) Which factors are predictive of treatment outcome (e.g., gender, age, type of traumatic experience, decision on asylum request, caregiver’s level of anxiety and their beliefs with

regard to therapy)?
5) Is there a difference in treatment satisfaction between EMDR and KID NET? And is treatment satisfaction as verbalized by the minors, associated with treatment outcome? (no hypothesis)

Study design

T1 start treatment; T2 end of treatment; T3 3-month follow-up

Intervention

EMDR, KIDNET

Contacts

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Eligibility criteria

Inclusion criteria

Eligible participants for this study must meet all of the following criteria:(1) children and adolescents of ages 8 and 18 years; (2) partial or full PTSD as reported by the child (interviewed with the Clinician-Administered PTSD Scale for DSM 5 - Child/Adolescent Version (CAPS-CA-5; Pynoos et al., 2015)). Partial PTSD is defined as either fulfilling three of the four symptom clusters or one symptom present in each of the four symptom clusters. Participants will be included when they (3) are accompanied by at least one caregiver; (4) applied for asylum in the Netherlands or are residing in the Netherlands since January 2015 or later; (5) elementary reading and writing level.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study: (1) intelligence level (<80); (2) acute interfering psychiatric disorder that needs to be treated first; (4) brain damage; (5) acute threat of deportation or moving within intervention period; (6) anti-epileptic and neuro epileptic medication; or (7) current severe substance abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2017
Enrollment:	93
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44793
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9559
CCMO	NL40769.058.13
OMON	NL-OMON44793

Study results