Trauma-informed approach for unaccompanied refugee minors: a multiple baseline case series

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48643

Source
ToetsingOnline

Brief title
Trauma-informed approach for URMs: A multiple baseline case series

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
Symptoms of posttraumatic stress and symptoms of depression

Health condition

psychische stoornissen - depressieve symptomen

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Centrum 45 (Oegstgeest)
Source(s) of monetary or material Support: Asylum Migration and Integration Fund

Intervention

Keyword: Multiple baseline case series, Trauma-informed approach, Unaccompanied Refugee Minors

Outcome measures

Primary outcome

Main study parameters are standardized questionnaires measuring on symptoms of posttraumatic stress and depression. These measures will be employed during the waiting period, treatment and follow-up. Moreover, URMs will be asked to define their request for help.

Secondary outcome

Secondary objectives are determining the request for help of URMs.

Study description

Background summary

Unaccompanied refugee minors (URMs) are at increased risk of developing mental health issues, such as symptoms of posttraumatic stress disorder (PTSD) and depression (e.g., Derluyn, Broekaert and Schuyten, 2008). However, few studies have evaluated trauma-informed interventions for URMs that address these issues (Demazure, Gaultier, & Pinsault, 2017). The current study evaluates a culturally-sensitive trauma-informed approach for URMs.

Study objective

The primary objective of this study is to measure the effectiveness of the TFT for URMs living in the Netherlands. The research question is as follows: is this TFT effective in decreasing symptoms of posttraumatic stress and depression in URMs living in the Netherlands?

Study design

The current study design concerns a non-concurrent multiple baseline design in which repeated assessments will be conducted during a randomized waiting period, during treatment, and during follow-up. Standardized questionnaires are used.

Intervention

Participants of the study will receive approximately seven sessions of a culturally sensitive trauma-informed approach for URMs.

Study burden and risks

Participants will receive approximately seven sessions of an eclectic, culturally-sensitive trauma-informed approach which is currently offered at Centrum *45 (treatment as usual for URMs referred to Centrum *45). The approach includes elements from EMDR, KIDNET and CBT - frequently used treatments for treating symptoms of PTSD and depression (de Roos et al., 2017; Neuner et al., 2008). As the treatment is already offered, it is not likely that this study will be counterproductive and we consider the burden of the study to be reasonable. Moreover, in a pilot implementation and evaluation with 26 URMs the trauma-informed approach was positively evaluated by minors, Cultural Mediators and therapists involved in the study. Participants will receive the trauma-informed approach with a randomized waiting period. The longest possible waiting period (8 weeks) is in line with the average waitlist period in the setting where the study takes place (Centrum *45). Additional assessments include short standardized questionnaires conducted weekly during baseline period, treatment and follow-up (4 weeks). None of the procedures is invasive.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Being a URM under the guardianship of Nidos, living in the Netherlands;
- Aged between 13 and 18 years old;
- With traumatic stress symptoms
- With consent (of minor and her/his guardian)

Exclusion criteria

- Acute suicidality;
- Acute psychosis;
- If there is a need to consult or involve a psychiatrist, for example when medication/crisis intervention is required.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2019
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-06-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24895
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66525.058.18
OMON	NL-OMON24895