Effectiveness of a Brief Intensive Trauma Treatment for adolescents with (subclinical) PTSD: a multi-center randomized controlled trial

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The aim of the study is:1) To test the effectiveness and cost-effectiveness of KIT for adolescents with (s)PTSD and comorbid symptoms. 2) To compare the outcomes from the current study with outcomes we have collected in two previous randomized...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON51843

Source
ToetsingOnline

Brief title
Effect of a BITT for adolescents with (s)PTSD: a multi-center RCT

Condition

- Psychiatric disorders NEC

Synonym
Post-traumatic stress disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Stichting tot steun VCVGZ

Intervention

Keyword: Adolescents, Brief intensive treatment, Post-traumatic stress disorder, Trauma treatment

Outcome measures

Primary outcome

All study parameters will be assessed by questionnaires and structured interviews by the research-psychologist, blinded to the group condition of participants. PTSD symptoms will be assessed by the Child and Adolescent Trauma Screening (In Dutch Kind en Jeugd Trauma Screener (KJTS)) and the Clinician Administered PTSD Scale for Children and Adolescents (CAPS-CA).

In the substudy there are the following primary outcome measures: (1) PTSD symptoms are measured daily using questions from the KJTS and (2) the Cultural Formulation Interview (CFI) is administered to adolescents and parents. The CAPS-CA and SDQ will also be administered in the context of regular care.

Secondary outcome

Depression symptoms, anxiety symptoms and anger will be measured with the PROMIS pediatric item bank v2.0 and the Structured Clinical Interview for DSM-5 Childhood Disorders (SCID-5 Junior, module: 3, 6 and 12 resp.). Quality of life will be measured with the EuroQol-5D Youth and proxy (EQ-5D-youth and /proxy). Cost-effectiveness will be measured with the Treatment Inventory of Costs in Psychiatric clients (TiC-PY/proxy) and the (EQ-5D-youth and /proxy).
Risk-behavior and safety will be measured with a questionnaire developed by

Hendriks et al. (2017).

Study description

Background summary

The majority of children and adolescents experience one or more traumatic life events while growing up. Up to one in five of these youngsters suffers from posttraumatic stress disorder (PTSD) symptoms. An even larger group suffers from subclinical (s)PTSD. (S)PTSD can cause extreme suffering and impairment in functioning, comparable to full-blown PTSD. Moreover, (s)PTSD coincides with high numbers of comorbid somatic and psychiatric illnesses and high-risk behavior (self-harm and suicidality. Untreated (s)PTSD often maintains or worsens comorbid psychopathology. (s)PTSD can be treated effectively in youth through weekly sessions of eye movement desensitization and reprocessing (EMDR) or trauma-focused cognitive behavioral therapy (TF-CBT). Despite availability of these treatments, a large group does not receive EMDR or TF-CBT. This may be because patients and clinicians do not recognize or underestimate the impact of (s)PTSD. Also, clinicians seem hesitant to address trauma symptoms due to fear of deterioration of present high-risk behavior. Moreover, current trauma treatment trajectories take at least several months. This treatment delay and/or prolonged treatment trajectories interfere with healthy development (e.g. school dropout, reduced social contacts and/or hobbies) and lead to high dropout rates in treatment. These findings underline the need for innovative and brief trauma treatment strategies. A first pilot study has shown that Brief Intensive Traumatreatment (in Dutch Korte Intensieve Traumabehandeling (KIT)) (BI-TFT) can be a safe, effective treatment for youth with (s)PTSD. Based upon these first positive experiences we have developed a one-week KIT-program for adolescents.

Study objective

The aim of the study is:
1) To test the effectiveness and cost-effectiveness of KIT for adolescents with (s)PTSD and comorbid symptoms.
2) To compare the outcomes from the current study with outcomes we have collected in two previous randomized controlled trials (RCTs), comparing regular (and thus prolonged) TF-CBT and EMDR in adolescents with (s)PTSD (n=70) on effectiveness, cost-effectiveness, and drop-out rates.
3) To test the effectiveness of a KIT for Papiamento-speaking adolescents with (s)PTSD and comorbid symptoms.
4) To describe cultural differences in PTSD between Papiamento-speaking adolescents in the Dutch Caribbean and adolescents in the Netherlands.

Study design

The current study is a multi-center, single-blinded RCT which will be conducted at the Amsterdam UMC. Adolescents (12-18 years old) with (s)PTSD will be randomly allocated by an independent researcher to the KIT (n=50) versus a waitlist control group (WLCG; n=50), stratified by age . Measurements are done at comparable time intervals for both groups: at pre-treatment (T0), directly after KIT or WLCG (T1) and at 3 (T2), 6 (T3) and 9 (T4) months follow-up. The WLCG follows the KIT after the 3 months follow-up.

The sub study will be conducted using a single case experimental design (SCED). The SCED will consist of multiple phases: phase A (baseline; 2 weeks), phase B (BITT; 5 days); phase C (post-treatment follow-up; 9 days); phase D (3-month follow-up; 9 days). Throughout the different phases, participants will complete short daily assessments. In addition, participants will complete larger assessments before phase A and after phase C.

Intervention

KIT is an outpatient, intensive, one-week individual trauma therapy program. KIT is based on well-established protocols, consisting of two 90-minutes trauma therapy sessions a day (trauma exposure in the morning and EMDR in the afternoon), two 60-minutes psychomotor therapy sessions a day, one 90-minutes psychoeducation session for parents a day, and a 90-minutes family therapy session at the end of the week (sharing the trauma narrative).

Study burden and risks

Currently, a large group of adolescents with (s)PTSD does not receive adequate treatment. Participation in this study provides an extras treatment opportunity. Furthermore, current trauma treatment takes at least several months. The current study intends to significantly reduce the burden on adolescents and their parents by offering effective treatment in a short period of time. The risks associated with the current study are comparable to those of standard treatment and the burden is presumably less to regular therapy considering its brief duration. To prevent extra risks, a so called *crisis prevention plan* will be developed together with all participants (and their caregiver(s)) before the treatment (KIT or WLCG) phase. This is in line with regular care for youngsters vulnerable to crisis and high-risk behaviour. A first pilot study has shown that brief intensive trauma treatment can be a safe, effective treatment for adolescents with (s)PTSD. Assessments are, overall, comparable to those in regular care thus form no extra burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

- 12-18 years of age;
- With a history of psychological trauma (conform the Life Events Checklist of the Clinician Administered PTSD Scale for Children and Adolescents DSM-5 (CAPS-CA)
- At least subthreshold PTSD criteria, conform the CAPS-CA DSM-5, i.e.:
o fully meeting criterion A, F and G and at least one symptom of criteria B, C, D and E;
o or fully meeting criterion A, F, G and at least the B, C, D or E symptom clusters;
- A written informed consent must be provided by the adolescent and, for adolescents aged 12-15 years, all legal guardians.

Exclusion criteria

- unable to speak and write Dutch;
- estimated or determined mental retardation (IQ <70);
- suffering from ongoing trauma by a parent who is part of the adolescent*s current primary-care system.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-10-2022
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL81121.018.22