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The effectiveness of an intensive trauma treatment for adolescents

Submission date
28/07/2022

Recruitment status
No longer recruiting

Registration date
18/08/2022

Overall study status
Completed

Last Edited
05/08/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Without treatment, posttraumatic stress disorder (PTSD) can severely disrupt a child's cognitive and psychosocial functioning. Therefore, it is important that adolescents quickly recover from their trauma complaints. For adults, it is known that by increasing the frequency of treatment sessions and combining them with physical activity, PTSD treatment outcomes significantly improve and dropout rates are lower. The aim of this study is to investigate the effects of such an intensive trauma treatment on trauma complaints, treatment motivation and dropout in adolescents aged 12-18 years.

Who can participate?
Adolescents from 12 to 18 years diagnosed with posttraumatic stress disorder

What does the study involve?
Adolescents are randomly allocated to one of three baseline conditions: the two-week intensive trauma treatment begins after 2, 3 or 4 weeks. After the baseline period, all adolescents will receive the intensive trauma treatment. The intensive trauma treatment program consists of 2 weeks with four (half-)days of treatment each week. Treatment consists of 90 minutes of individual Prolonged Exposure (PE) and 90 minutes of individual Eye Movement Desensitization and Reprocessing (EMDR) therapy, with a brief break in between. After EMDR, a 15 minutes handover and psycho-education will take place for the adolescent and his/her network. Thereafter, participants have lunch and finish their treatment day with an hour of physical activity, guided by a coach.
PTSD is diagnosed before treatment and after a follow-up of 1 and 3 months. Participants complete a questionnaire on trauma complaints before the treatment, directly after the treatment, and after a follow-up of 1 and 3 months. Treatment tolerability is assessed with an interview after treatment. During the baseline and intervention phase adolescents also complete questionnaires on trauma complaints and tolerability of the treatment on a daily basis.

What are the possible benefits and risks of participating?
Participants may recover faster than with care as usual. A possible risk is that a participant will have mild symptoms for a short time after the trauma treatment, such as concentration problems, overstimulation and fatigue. These complaints last for a maximum of 3 days. However,

this risk is also present with regular trauma treatment. Participating in the study takes extra time because we administer questionnaires to participants more often than with care as usual.

Where is the study run from?
De Opvoedpoli Amsterdam (The Netherlands)

When is the study starting and how long is it expected to run for?
January 2021 to September 2023

Who is funding the study?
1. Vereniging EMDR Nederland (Netherlands)
2. De Opvoedpoli Amsterdam (Netherlands)
3. iHUB (Netherlands)

Who is the main contact?
Irene Tijsseling, irene@opvoedpoli.nl

Contact information

Type(s)
Principal Investigator

Contact name
Mrs Irene Tijsseling

Contact details
Rode Kruisstraat 32
Amsterdam
Netherlands
1025 KN
+31 (0)623026460
irene@opvoedpoli.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

The effectiveness and tolerability of an intensive outpatient trauma treatment program for adolescents with PTSD: a multiple baseline study

Acronym
ITB

Study objectives
1. It is hypothesized that the intensive trauma treatment program for adolescents leads to a reduction in PTSD symptoms as measured by the Children's Revised Impact of Event Scale (CRIES-13) in the intervention phase compared to the baseline phase. The researchers expect that the scores on the CRIES-13 questionnaire will decrease from the moment the intensive trauma treatment program for an adolescent starts.
2. It is hypothesized that the intensive trauma treatment program for adolescents leads to a reduction in PTSD symptoms as measured by the CRIES-13. The researchers expect that the score on the CRIES-13 questionnaire will be significantly lower at the post-treatment evaluation, at the follow-up at 1 month and at the follow-up at 3 months compared to pretest.
3. It is expected that the adolescents are free from PTSD diagnoses as measured by the Clinician Administered PTSD Scale for Children and Adolescents (CAPS-CA) at 1-month follow-up and 3-month follow-up.
4. The researchers expect the dropout rate from the intensive trauma treatment program for adolescents to be low (below 5%), comparable to other intensive trauma treatment programs as studied in adults (Hendriks et al., 2017; Schottenbauer et al., 2008).
5. The researchers expect that the intensive trauma treatment program will be well tolerated by both adolescents and therapists. This is the case when the adolescents score 36 points or more on the Session Rating Scale during each treatment day of the intensive trauma treatment program. In addition, after the 2 weeks of intensive trauma treatment, adolescents and therapists will indicate by means of a semi-structured interview that they tolerate the form of this trauma therapy well.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/08/2021, ethics committee of the Faculty of Social and Behavioral Sciences of the University of Amsterdam of the Faculty of Social and Behavioral Sciences (Nieuwe Achtergracht 129B, 1018 WS Amsterdam, The Netherlands; +31 (0)20 525 6686; w.p.m. vandenwildenberg@uva.nl), ref: ERB number 2021-CDE-13283

Study design
Single-center interventional randomized multiple baseline study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Posttraumatic stress disorder in adolescents

Interventions
If there is a suspicion of PTSD in an adolescent during intake, the adolescent will complete the CRIES-13 to screen for the presence of (symptoms of) PTSD. If the adolescent scores ≥30 on the CRIES-13, research information and informed consent will be sent to the adolescent and his/her parents. If the adolescent is willing to participate, and his/her parent(s) give(s) permission (in case the adolescent is <16), the CAPS-CA will be administered by a trained independent psychologist. If there is a PTSD diagnosis, and the adolescent meets the inclusion criteria, the adolescent will join the study. Participants will be randomized to one of three baseline conditions: the intensive trauma treatment starts after 2, 3 or 4 weeks after baseline. Block randomization is carried out by a colleague who is not involved in the study and who works in a different department.

The intensive trauma treatment program consists of 2 weeks with four (half-)days of treatment each week. Treatment on the first day consists of psycho-education about trauma and trauma treatment, as well as the case conceptualization, ending with an hour of physical activity. Next, participants receive six (half-)days of trauma treatment, where each day starts with 90 minutes of individual Imaginary Exposure (IE) and Exposure in Vivo (EiV), followed by a 15-minute break and then 90 minutes of individual Eye Movement Desensitization and Reprocessing (EMDR) therapy. After EMDR, the therapist will reflect on the treatment day with the adolescent and a support figure (e.g., parent or best friend) and will provide additional psycho-education. Then participants have lunch and finish their treatment day with an hour of physical activity. The last treatment day of the program consists of a 1.5-hour session in which the adolescent shares his /her trauma story and treatment achievements with the full self-selected support group (e.g., parents, siblings, friends).

During baseline and the 2-week intervention phase, the CRIES-13 will be administered daily. To monitor the client's and therapist's tolerability of the treatment, participants and therapists complete the Session Rating Scale (SRS) after each treatment day. At a follow-up of 1 month and 3 months after the intervention phase, the CAPS-CA will be administered to determine the PTSD diagnosis (yes or no), and measure the change in the severity of PTSD symptoms. During these measurements, the adolescent will again complete the CRIES-13. After the 1-month follow-up, the adolescent and his/her parents decide with a therapist if further treatment is needed. At a 3-month follow-up, an inventory will be made of what treatment has been offered in the interim period.

Intervention Type
Behavioural

Primary outcome measure
Trauma complaints measured with the CRIES-13 daily during the baseline and 2-week intervention period

Secondary outcome measures
1. Tolerability of the intensive trauma therapy measured with the Session Rating Scale (SRS) on each treatment day during the intervention period (eight times)
2. Tolerability of the intensive trauma treatment measured using a self-developed semi-structured interview at posttest
3. PTSD diagnosis measured with the Clinician Administered PTSD Scale for Children and Adolescents (CAPS-CA) at pretest and at 1 and 3-months follow-up
4. Trauma complaints measured with the CRIES-13 at pretest, posttest, 1-month and 3-months follow-up

Overall study start date
01/01/2021

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Adolescents from 12 to 18 years old seen at the mental health outpatient policlinics of the Opvoedpoli or Care-Express in Amsterdam. They are referred by their general practitioner, the Ouder- en Kindteam or Jeugdteam, or medical specialist.
2. 30 points or more on the Dutch version of the Children's Revised Impact of Events Scale (CRIES-13; Verlinden et al., 2005)
3. A PTSD diagnosis as measured by the Dutch version of the CAPS-CA (Van Meijel et al., 2019)
4. At least four traumatic experiences that give rise to reliving and fear, type II trauma (Terr, 1991)
5. Sufficient knowledge of the Dutch language to undergo treatment
6. Involvement of at least one support figure from the network
7. Abstinence from soft drugs and alcohol during the 2-week period of the intensive trauma treatment

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
15 participants will participate in this study; five participants per baseline condition

Total final enrolment
15

Key exclusion criteria
1. Severe intellectual disability defined as an estimated IQ of 70 or less
2. Not being able or unwilling to recall the traumatic memories
3. Not being able or unwilling to follow intensive trauma treatment
4. Unsafe home situation, for example with ongoing abuse at home
5. Suicidality is only an exclusion criterion if there are concrete plans or if this requires medical care

Date of first enrolment
01/10/2021

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Opvoedpoli Amsterdam
Rode Kruisstraat 132
Amsterdam
Netherlands
1025 KM

Sponsor information

Organisation
Opvoedpoli

Sponsor details
Rode Kruisstraat 32
Amsterdam
Netherlands
1025 KN
+31 (0)6 23026460
vereniging@emdr.nl

Sponsor type
Hospital/treatment centre

Website
https://www.opvoedpoli.nl/

Funder(s)

Funder type
Research organisation

Funder Name
Vereniging EMDR Nederland

Funder Name
De Opvoedpoli Amsterdam

Funder Name
iHUB

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/05/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Aged 12 to 18 years		09/08/2022	No	Yes
Participant information sheet	Parents		09/08/2022	No	Yes
Protocol file			09/08/2022	No	No
Statistical Analysis Plan			09/08/2022	No	No
Results article		01/06/2024	02/08/2024	Yes	No