EMDR for young children with PTSD

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Based on the results of EMDR studies in older children aged 8-18 years and adults, it is hypothesized that EMDR will lead to reductions in post-traumatic stress symptoms, co-morbid emotional and behavioral problems. Additionally, we expect that EMDR...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON23648

Source
Nationaal Trial Register

Brief title
EMDR in young children with PTSD

Condition

- Anxiety disorders and symptoms

Synonym
PTSD

Health condition

Posttraumatic stress disorder (PTSD)

Research involving
Human

Sponsors and support

Primary sponsor:	Stichting Villa Johanna
Secondary sponsors:	EMDR Europe

Intervention

- Psychosocial intervention

Explanation

Outcome measures

Primary outcome

Daily diary app with the most frequent and intensive post-traumatic stress symptoms, parent reported PTSD diagnosis (Diagnostic Infant and Preschool Assessment, DIPA) and the severity of the child's post-traumatic stress symptoms (Kinder en Jeugd Trauma Screener, KJTS)

Secondary outcome

Behavioural and emotional problems of the child (Child Behaviour Check List, CBCL) and parenting stress (Opvoedingsbelasting Vragenlijst, OBVL).

Study description

Background summary

The purpose of the current study is to increase the empirical support of EMDR for young children with PTSD (1.5 to 8 years). Research questions are whether EMDR is effective in reducing post-traumatic stress reactions and comorbid emotional and behavioral problems in young children whether EMDR is effective in reducing parenting stress, and whether the results will be maintained 3 months after treatment. A single Case Experimental Design (SCED) with a multiple baseline is used to answer the research questions. Every case will start with a baseline phase, followed by a treatment phase and follow-up phase. In this way every participant has his/her own control condition (conform SCED). To increase the power, the length of the baseline will be varied (20 options, children are random assigned to a starting point of treatment), making it possible to differentiate between time effects and effects of the intervention.

Study objective

Based on the results of EMDR studies in older children aged 8-18 years and adults, it is hypothesized that EMDR will lead to reductions in post-traumatic stress symptoms, co-morbid emotional and behavioral problems. Additionally, we expect that EMDR treatment will lead to a reduction of parenting stress and that these effects will be maintained at 3 months follow-up.

Study design

At baseline (T0), pre-treatment (T1), post-treatment (T2) and follow-up (T3).

Intervention

Eye Movement Desensitization and Reprocessing (EMDR)

Contacts

Public
de Bascule
Carlijn de Roos

020-8901000
Scientific
de Bascule
Carlijn de Roos

020-8901000

Eligibility criteria

Age

Babies and toddlers (28 days-23 months)
Babies and toddlers (28 days-23 months)
Children (2-11 years)
Children (2-11 years)

Inclusion criteria

1. Children aged 1.5 to 8 years. 2. The main diagnosis is PTSD as described in the DSM 5 3. During the treatment process (phase A and B), no other ongoing (psychological) trauma treatment is allowed. 4. Parents must have access to a smartphone upon which the app for the daily measurements can be installed. 5. Parents have sufficient knowledge of the Dutch language.

Exclusion criteria

1. Insufficiënt safety/ ongoing traumatization. In this case, the safety of a child has priority

and traumatization has to be stopped before trauma treatment can take place. 2. If medication (for other disorders) was introduced less than 1 month ago or is not yet stabilized.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Single
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2020
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
n/a

Ethics review

Approved WMO

Date:	23-09-2019
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214

Postbus 22660

1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52705
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8426
Other	Medisch Ethische toetsingscommissie (METC-AMC). : METC 2019_114
CCMO	NL69997.018.19
OMON	NL-OMON52705

Study results

Summary results
not yet