The effectiveness of Eye Movement Desensitization and Reprocessing in preschoolers (ages 4-8) with posttraumatic stress disorder.

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The aim of this research is to investigate the treatment outcome of EMDR in preschoolers (4-8 years) with PTSD.Primary objectives:Does EMDR ameliorate post-traumatic stress symptoms in young children (4-8 years)?Do participants after treatment no...

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

Summary

ID

NL-OMON46105

Source
ToetsingOnline

Brief title
EMDR in preschoolers

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic stress disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Delfland (Delft)

Source(s) of monetary or material Support: GGZ Delfland

Intervention

Keyword: -Eye movement desenisitization and Reprocessing, -preschoolers, -SCED, -treatment outcome

Outcome measures

Primary outcome

Primary outcome measures:

-post-traumatic stress symptoms, measured by daily diary and a questionnaire

for parents (Trauma Symptom Checklist for Young Children, TSCYC).

DSM-V PTSD diagnostic status, assessed by a semi-structured diagnostic

interview with parents (Diagnostic Infant and Preschool Assessment, DIPA)

Analysis of the diary measurements (time-series design) by randomization test.

Analysis of the questionnaires using the Reliable Change Index (RCI

Secondary outcome

Emotional and behavioral problems, measured by 2 questionnaires for parents

(Trauma Symptom Checklist for Young Children, TSCYC; Strengths and Difficulties

Questionnaire, SDQ).

Study description

Background summary

Meta-analyses indicate that approximately 16% of traumatically exposed children develop posttraumatic stress disorder (PTSD; Alisic et al, 2014). One of the evidence based trauma treatments for children is Eye Movement Desensitization and Reprocessing (EMDR). EMDR is a brief, trauma focused treatment, that has been regularly applied in the Netherlands since 2000 in children and

adolescents with PTSD, and also in young children. Research has shown that EMDR is an effective treatment for children aged 8-18 years old. However, few trials have studied the effect of EMDR on preschoolers. The current research proposal aims to strengthen the evidence for EMDR as treatment for PTSD in children and to fill the gap of evidence for young children (<8 years old).

Study objective

The aim of this research is to investigate the treatment outcome of EMDR in preschoolers (4-8 years) with PTSD.

Primary objectives:
Does EMDR ameliorate post-traumatic stress symptoms in young children (4-8 years)?
Do participants after treatment no longer meet the diagnostic criteria of a post-traumatic stress disorder as described in DSM V?

Secondary objectives:
Does EMDR ameliorate emotional and behavioral problems in young children with PTSD?

Will these above-mentioned results be maintained at follow-up 3 months after treatment?

Study design

We intent to investigate this in a Single Case Experimental Design (SCED). A multiple baseline with an AB-design is used (A= baseline, B= treatment), the start of the treatment will be randomised for each participant. Measurements consist of i) daily diary measurement of the 2 most severe post-traumatic stress symptoms and ii) Three single-time point measurements (baseline, posttreatment, and 3- month follow-up) of:
- post-traumatic stress symptoms;
- DSM-V PTSD diagnostic status;
- emotional and behavioural problems.

Intervention

Participants receive EMDR treatment as they would receive if they did not participate in the study (up to 6 weekly sessions of 1 hour). Only the measurements (with parents) are extra.

Study burden and risks

There are no known risks of EMDR. EMDR is a brief and well-tolerated treatment

method that is proven effective for children and adolescents between the ages of 8 and 18 with PTSD, without negative side effects. There is no reason to assume that there would be side effects or other adverse effects of EMDR for young children with PTSD.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Participants are a) regular referrals to GGZ Delfland aged 4-8 years; and b) meeting full DSM-V diagnostic criteria for PTSD established through the Diagnostic Infant and Preschool Assessment (DIPA); c) written parental consent; d) parents are in possession of a smartphone to install the diary app on. Participants are to refrain from another form of psychological treatment during the treatment phase of the trial.

Exclusion criteria

Exclusion criterium is ongoing trauma (abuse, threats by perpetrator), in that case the primary goal is safety for the child, before trauma treatment can take place.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-10-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL66334.078.18