

The effectiveness of EMDR in young children (1,5 to 8 years) with PTSD

Published: 23-09-2019

Last updated: 15-05-2024

It is investigated whether EMDR is effective in reducing post-traumatic stress reactions in young children (1.5 to 8 years), reducing co-morbid emotional and behavioral problems and whether the results will be maintained 3 months after treatment. In...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON52705

Source

ToetsingOnline

Brief title

EMDR for young children

Condition

- Psychiatric and behavioural symptoms NEC

Synonym

Post-traumatic stress disorder (PTSD), trauma

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Privéfond

Intervention

Keyword: EMDR, PTSD, young children

Outcome measures

Primary outcome

The severity of the child's post-traumatic stress symptoms are measured by a clinical interview, a questionnaire and diary measurements.

Secondary outcome

In addition, 2 questionnaires will be taken that measure behavioral and emotional problems of the child (CBCL) and parenting stress (OBVL). The latter questionnaires are already purchased as standard within the healthcare package.

Study description

Background summary

After experiencing traumatic events, a significant proportion of children (16%) develop post-traumatic stress disorder (PTSD) which increases the risk of developmental delay in various areas (physical, emotional, social, cognitive, biological and neurological) . Reducing symptoms at an early stage is important, especially with young children, so that developmental delay and suffering for the child and family remain limited. In addition, adequate treatment of PTSD will lead to a reduction in healthcare costs.

Eye Movement Desensitization and Reprocessing (EMDR) is an evidence based treatment for PTSD in adults and children from 8 to 18 years. EMDR for young children is "care as usual", but scientific research into the effectiveness of EMDR in young children (<8 years) is scarce. The main aim of the current study is to increase the empirical support of EMDR for young children with PTSD. If time-limited trauma treatment proves to be effective in reducing PTSD at an early age, it provides an important tool for the prevention of chronic psychopathology, the reduction of suffering for children and families and will lead to cost savings in health care.

Study objective

It is investigated whether EMDR is effective in reducing post-traumatic stress

reactions in young children (1.5 to 8 years), reducing co-morbid emotional and behavioral problems and whether the results will be maintained 3 months after treatment. In addition, it will be investigated whether EMDR treatment of the child leads to a reduction of parenting stress.

Study design

A Single Case Experimental Design (SCED) with a multiple baseline is used to answer the research questions. A baseline phase is started, followed by a treatment phase. In this way every participant has his / her own control condition (SCED). To increase the power, the length of the baseline phase will be varied (20 options, children are randomly assigned to a starting point of treatment), making it possible to differentiate between time effects and effects of the intervention. During the study, an app is filled out daily with regard to the 3 most important post-traumatic stress reactions. In addition, there are three measurement moments (before, after treatment and at follow-up 3 months after treatment), at which a clinical interview and questionnaires are conducted.

Intervention

The children receive EMDR treatment performed by experienced GZ psychologists, psychotherapists and clinical psychologists working at the MOC 't Kabouterhuis.

Study burden and risks

There are no risks associated with participating in the study. In clinical practice, EMDR is *care as usual* in young children with PTSD. No adverse effects of treatment with EMDR are known from both literature and clinical practice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Babies and toddlers (28 days-23 months)

Inclusion criteria

To be eligible to participate in the current study, a participant must meet the following criteria:

1. Children aged 1.5 to 8 years.
2. The main diagnosis is a Posttraumatic Stress disorder (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 diaries can be installed.
5. Parents have sufficient knowledge of the Dutch language.

Exclusion criteria

A potential participant who meets one of the following criteria will be excluded from participating in the current study:

1. There are signs of a lack of security/ 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 type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

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

Ethics review

Approved WMO	
Date:	23-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	12-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO
Date: 21-06-2021
Application type: Amendment
Review commission: METC Amsterdam UMC

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: 23648
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL69997.018.19
OMON	NL-OMON23648