Eye Movement Desensitization and Reprocessing (EMDR) in children with a medically related trauma: a randomized controlled trial

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The objective of the study is to I. study the effectiveness of a standardized EMDR protocol for children with elevated PTSD symptoms (so-called subclinical/partial PTSD) with medically related trauma, and II. To identify factors predicting treatment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47373

Source
ToetsingOnline

Brief title
EMDR in children with medically related trauma

Condition

- Other condition
- Congenital cardiac disorders

Synonym
Congenital heart disease (being born with a heart defect) and acute internal or surgical conditions

Health condition

alle kinderen die via SEH acuut opgenomen worden i.v.m. een acute interne of chirurgische aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: InnovatieFonds;Vereniging EMDR Nederland en stichting Hartekind

Intervention

Keyword: children, EMDR, illness, trauma

Outcome measures

Primary outcome

Main study parameter/endpoint:

- Difference in PTSD symptoms (measured with the SPPC) between EMDR and CAU

group on T1 (baseline), T2 (2 weeks after the completion of EMDR therapy or

CAU) and T3 (6 months follow-up)

Secondary outcome

Secondary study parameters/endpoints, assessed at T1, T2, T3:

Psychosocial functioning

Quality of life

Sleep

Self-perception

Attention (problems):

School functioning

Medical consumption/adherence:

Predictor variables, assessed at T1:

demographic factors

cognitive coping styles

stressful life events, s

Somatic complaints,

information regarding surgery and painful procedures.

Study description

Background summary

(Please see METC protocol Par. 1, which includes also references)

Children admitted to the hospital often undergo invasive and painful medical procedures, possibly resulting in problems with working through these traumatic events or even a posttraumatic stress disorder (PTSD). About 1 in every 10 children develops a PTSD and circa 3 in every 10 children develop a partial/subclinical PTSD. This is associated with increased medical consumption, reduced medical adherence, unfavorable medical outcomes and mental health problems at long-term. According to research about 1 in 10 children develop a PTSD due to hospital admission or medical procedures. PTSD is characterized by disturbing recurring flashbacks, avoidance or numbing of memories of the event, hyperarousal (high levels of anxiety), and significant interference with their daily lives. A distinction is made between:
Trauma type I: when there is a single, sudden, unforeseen event (e.g. traffic accident);
Trauma type II: when there is an extreme event, of which the child knows it can re-occur. For example, repeated surgery or diagnostic procedure (e.g. heart catheterization) in a chronically ill child.

Until now, little research has been done into the treatment of PTSD in children. Currently, cognitive behavioral therapy (CBT) is the most evidence-based intervention for PTSD, in which the focus is on reducing and resolving anxiety. A drawback of this treatment is that reliving and replaying feared thoughts and memories are psychologically very intensive. An innovative and promising new method of treating PTSD is Eye Movement Desensitization and Reprocessing (EMDR). EMDR is a standardized treatment method for trauma,

consisting of a structured eight-phase approach to address the past, present, and future aspects of a traumatic or distressing memory. The difference between EMDR and CBT is that with EMDR the child does not have to relive the traumatic event, which may be very burdensome and extensive (this is done in CBT). Rather, in EMDR a child is asked to select a memory of the trauma that is currently emotionally painful.

The efficacy of EMDR intervention on PTSD has been shown in adults, and is advised in the multidisciplinary directive of the Trimbos institute. However, EMDR is not routinely offered to children. A previous meta-analysis demonstrated that EMDR can have positive results in children with PTSD symptoms, also compared to the classic cognitive behavioral therapy. However, the cause of PTSD symptoms in these children varied: firework disaster, sexual abuse, hurricane and different events.
Remarkably, no previous study investigated PTSD symptoms due to medically-related trauma. Our hypothesis is that EMDR is an effective treatment for children with medically-related trauma.

Our hypotheses are: 1) EMDR will lead to significant improvement of psychosocial functioning, quality of life and somatic complaints in children with elevated PTSD symptoms (subclinical/partial PTSD). 2) Children with unfavourable predictors (low socioeconomic status, less adequate coping) will benefit more from EMDR as compared to children with favourable predictors.

Study objective

The objective of the study is to

I. study the effectiveness of a standardized EMDR protocol for children with elevated PTSD symptoms (so-called subclinical/partial PTSD) with medically related trauma, and

II. To identify factors predicting treatment success of EMDR in children with medically related trauma.

Study design

(please see also MECT protocl Par. 3 and Figure 1)

The study is a randomized controlled trial (RCT) stratified by Trauma type (I/II) and age, patients with PTSD symptoms are allocated to: a) a EMDR or b) care-as-usual CAU. All patients will receive adequate medical care (CAU). In case of a clinical PTSD, patients will not be randomized but referred directly for psychosocial care.
At baseline (T0), self-reported and parent-reported PTSS symptoms are assessed in children aged 4-16 year (n= 78). At the first follow-up (T1), two

weeks after the end of the EMDR intervention or CAU, self-reported and parent-reported PTSS symptoms are assessed in children aged 4-16 year. At the second follow-up (T2), 6 months after the end of the EMDR intervention or CAU, the same assessment will be carried out,

Intervention

EMDR is a standardized treatment method for trauma, consisting of a structured nine-phase approach to address the past, present, and future aspects of a traumatic or distressing memory (a detailed description is given below).
The difference between EMDR and traditional cognitive behavioural therapy (CBT) is that with EMDR the child does not have to relive the traumatic event, which may be very burdensome and extensive (this is done in CBT). Rather, in EMDR a child is asked to select a memory of the trauma that is currently emotionally painful. This memory will be discussed (why it is painful, what emotions it evokes) Then, the desensitization is initiated. Painful thoughts are neutralized by making simultaneously controlled rhythmic eye movements. The exact working mechanisms behind EMDR are not precisely known; the rationale is that the working memory in the brain cannot handle competing tasks and thus the traumatic memory is neutralized. Finally, pleasant and positive thoughts are installed.

Intervention (EMDR):
The EMDR treatment will focus on reducing PTSD symptoms and will consist of six weekly sessions of 1 hour. The EMDR session consists of nine phases. Phases 3 to 8 regular are repeated in accordance with a standardized age-appropriate protocol.

Phase 1: includes assessing the patients medical, psychological and trauma history, as is done in any psychotherapeutic treatment
Phase 2: the preparatory stage, is intended to build the therapeutic relationship. Parents and child receive psychoeducation about how EMDR is done. The psychologist facilitates that realistic expectations are established and the child/parents are taught about PTSD symptoms.
Phase 3: Assessment phase of traumatic event. The psychologist explores the sensory, cognitive and affective components of the traumatic memory. The child is describing the visual image that is most lively and repulsive. Then it is explored which negative image of the child is evoked by that image (such as "I'm a failure ') and the child learns to formulate desired positive image in the opposite direction formulation (such as: "I can succeed).
Phase 4: the desensitization starts. The child is asked to take the image in mind as well as the tension in feels in parts of the body, and at the same time

the child has to simultaneously follow the hand of the therapist, thus making horizontal eye movements. After each set of eye movements, a chain of free associations can arise. It is important that children notice what they think / hear / smell / feel. This reprocessing continues until the image does not evoke tension any more.
Phase 5: Installation phase. The positive cognition, that was obtained in phase 3, is reinforced.
Phase 6: the child examines if it feels unpleasant feelings in the body ('body scan*)
Phase 7: the psychologists checks if there is avoidance behavior. If so, the child is taught the cognition that it can cope with this situation in future ((future template).
Phase 8: the phase of closing, followed by phase 9: the re-evaluation phase, in which potential additional goals and progress are discussed and evaluated

The EMDR will be performed by licensed, and experienced health-psychologists (GZ-psychologen) of the ErasmusMC-Sophia, who followed specific, EMDR training (training by the Vereniging EMDR Nederland).
To ensure protocol adherence, these EMDR psychologists will receive regular supervisions (1 supervision hour per 3 EDMR sessions) by a licensed psychologist-supervisor.

Care-as-usual: after randomization, half of the patients will receive the EMDR treatment, the other half receives their regular medical care, if applicable, called care-as-usual (thus no additional psychosocial intervention).

Study burden and risks

Most questionnaires will need to be filled in online, taking approximately 1.5 hour per assessment for patients and approximately 1 hour per assessment for parents. Only the CBSK/CBSA will be filled in on paper when the patient comes to the hospital (or it will be sent home).
At T1 also a diagnostic psychiatric interview will be executed by a research psychologist at the hospital (1 hour), to identify whether patients scoring above the clinical cut-off, suffer from a clinical, psychopathological PTSD disorder. In case of a clinical PTSD disorder (or if patients/parents at any time-point express a need for acute psychosocial care), adequate referral for psychosocial care will be arranged; it would be unethical to randomize these patients.
The same research psychologist will conduct a shortend version of the same diagnostic psychiatric interview at T2 and T3 (30 minutes each) if necessary. That is only when the child meets another symptom criteria (that he/she did not meet at T1) or when the PTSD-total score falls within a higher normative category (e.g. from above average at T1 to high at T2).
For patients in the EMDR group, 6 outpatient sessions will take place in the ErasmusMC-Sophia. These will be combined as much as possible with regular checkup visits.

Considering research findings that ca. 35% of children with medical related trauma suffer from partial PTSD, we think it most likely that these patients will benefit from the EMDR intervention.
For each assessment and EMDR visit, parents/patients will receive 20 Euros for travel costs.
All parents/children who refuse to participate in the whole screeningmeasure, will be asked if they are willing to fill in only the SVLK once.

The risks associated with participation can be considered negligible and the burden minimal. Compared to traditional CGT, EMDR is less painful and stressful for patients, because exposure to traumatic memories is very short during EMDR sessions.
There is a slight, potential, but not serious risk that children/adolescents during the EMDR process temporarily may be more tense, irritable and have more trouble falling asleep. From extensive clinical practice, it is a well-known fact that these phenomena usually quickly disappear within a few days. Patients and parents/guardians will be advised to keep a diary about these phenomena and to discuss them with their EMDR-psychotherapist during their next appointment. All patients can also stay in contact with their psychotherapist by e-mail or telephone. Furthermore, patients will be taught to imagine a safe place so they can calm down and reassure themselves in the case of too much arousal. In this way, the EMDR procedure encompasses a lot of different *safety strategies*, which patients and/or parents can use to help themselves. It is a comfortable procedure with a fast reduction of anxiety, which leads to feelings of hope and relief and is known to be experienced as supporting rather than distressing

In the unlikely event a worsening of PTSD symptoms occurs, resulting in psychiatric problems, direct referral to our clinic Child and Adolescent Psychiatry/Psychology takes place. We do not expect this to happen; moreover, experienced GZ-psychologists therapists will perform the EMDR under supervision.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Inclusion criteria: eligible are all consecutive patients who 1) underwent one or more admissions to a hospital between July 2011 and April 2018 (time between the baseline screening for this study and the prior admission is at least 4 weeks up to maximally 5 years ago) and 2) are 4-16 years old during the inclusion period (July 2016 * May 2018), encompassing:
1) previously healthy children (with no underlying chronic illness/handicap) admitted to the hospital for the first time via the emergency department and children who had a one-time hospitalization at the department of child cardiology (trauma type I); and
2) patients with recurrent admissions via the emergency department or at the department of child cardiology or children who had a medical procedure (e.g. surgery) apart from a one-time admission (trauma type II).

Exclusion criteria

Exclusion criteria: Mental retardation, inability to read or write Dutch, previous psychological treatment for PTSD symptoms, epilepsy.
For exclusion in the RCT: children with a score below the 60th percentile on the SVLK and/or meeting less than 2 of the 3 SVLK PTSD subscales, and children with a clinical, psychiatric posttraumatic sress disorder (measured by the CAPS-CA/DIPA)

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:	Recruitment stopped
Start date (anticipated):	21-07-2016
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	08-04-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-08-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2017

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-06-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-06-2018
Application type:	Amendment
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

ID: 29358
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56156.078.16
OMON	NL-OMON29358