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To cite this article: Maya G. Meentken, Ingrid M. van Beynum, Elisabeth W. C. Aendekerk, Jeroen S. Legerstee, Hanan El Marroun, Jan van der Ende, Ramón J. L. Lindauer, Manon H. J. Hillegers, Henriette A. Moll, Wim A. Helbing & Elisabeth M. W. J. Utens (2018) Eye movement desensitization and reprocessing (EMDR) in children and adolescents with subthreshold PTSD after medically related trauma: design of a randomized controlled trial, *European Journal of Psychotraumatology*, 9:1, 1536287, DOI: [10.1080/20008198.2018.1536287](https://doi.org/10.1080/20008198.2018.1536287)

To link to this article: <https://doi.org/10.1080/20008198.2018.1536287>



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Published online: 22 Nov 2018.



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STUDY PROTOCOL



# Eye movement desensitization and reprocessing (EMDR) in children and adolescents with subthreshold PTSD after medically related trauma: design of a randomized controlled trial

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## ABSTRACT

**Background:** Three in every 10 children and adolescents admitted to a hospital or undergoing medical treatment develop subthreshold symptoms of posttraumatic stress disorder (PTSD). When untreated, subthreshold PTSD can have a serious impact on psychosocial functioning, quality of life and long-term psychopathology. However, research investigating subthreshold PTSD and its treatment following paediatric medical interventions and/or hospitalization is scarce. Eye Movement Desensitization and Reprocessing (EMDR) is a fast and non-invasive psychosocial treatment for posttraumatic stress complaints. However, the effectiveness of EMDR in paediatric patients with subthreshold PTSD has not previously been systematically investigated.

**Objective:** Describing the design of a randomized controlled trial (RCT) set up to evaluate the effectiveness of EMDR in children with subthreshold PTSD after hospitalization.

**Method:** Children aged 4–15 years who have undergone a one-time (trauma type I) or repeated (trauma type II) hospitalization up to five years ago will be included. Participating children will be first screened with a standardized questionnaire for PTSD-symptoms. Subsequently, children with subthreshold PTSD will be randomly assigned to (1) approximately six sessions of standardized EMDR or (2) care as usual (CAU). Children with full diagnostic PTSD do not participate in the RCT, but are referred for direct treatment. Follow-up measurements will take place after eight weeks and eight months.

**Discussion:** Considering the scarce evidence for the effectiveness of EMDR in children with medically related trauma, clinicians, researchers and children treated in hospitals can benefit from this study. Potential strengths and limitations of this study are discussed.

**Trial Registration:** Netherlands Trial Register NTR5801

## Desensibilización y reprocesamiento por movimientos oculares (EMDR) en niños y adolescentes con TEPT subumbral después de un trauma médico: diseño de un ensayo controlado aleatorizado

**Antecedentes:** Alrededor de 3 de cada 10 niños y adolescentes ingresados en un hospital o sometidos a tratamiento médico desarrollan síntomas subumbrales de trastorno de estrés postraumático (TEPT). Cuando no se trata, el TEPT subumbral puede tener un impacto grave en el funcionamiento psicosocial, la calidad de vida, y la psicopatología a largo plazo. Sin embargo, la investigación sobre el TEPT subumbral y su tratamiento después de las intervenciones médicas pediátricas y/o la hospitalización es escasa. La desensibilización y reprocesamiento por movimientos oculares (EMDR) es un tratamiento psicosocial rápido y no invasivo para las quejas de estrés postraumático. Sin embargo, la efectividad del EMDR en pacientes pediátricos con TEPT subumbral no ha sido previamente investigada de manera sistemática.

**Objetivo:** Describir el diseño de un ensayo controlado aleatorizado (RCT, en sus siglas en inglés) establecido para evaluar la efectividad de EMDR en niños con TEPT subumbral después de una hospitalización.

**Método:** Se incluirán niños de 4 a 15 años que hayan sido sometidos a una hospitalización única (trauma tipo I) o repetida (trauma tipo II) hasta en los 5 años previos. Los niños participantes serán evaluados inicialmente con un cuestionario estandarizado para síntomas de TEPT. Posteriormente, los niños con TEPT subumbral serán asignados aleatoriamente a (1)

## ARTICLE HISTORY

Received 11 June 2018  
Revised 18 September 2018  
Accepted 25 September 2018

## KEYWORDS

PTSD; subthreshold PTSD; trauma; EMDR; children; adolescents; paediatric; RCT; cardiology; emergency department

## PALABRAS CLAVE

TEPT; TEPT subumbral; trauma; EMDR; niños; adolescentes; pediátrico; RCT; cardiología; servicio de urgencias

## 关键词

PTSD; 阈下PTSD; 创伤; EMDR; 儿童; 青少年; 儿科; RCT; 心髒病; 急诊科

## HIGHLIGHTS

- This RCT specifically focusses on the effectiveness of EMDR in children and adolescents (4–15 years) with subthreshold PTSD after medically related trauma.
- Short- and long-term effectiveness of EMDR on PTSD symptoms will be measured.
- Data about the prevalence of subthreshold PTSD and possible predictors of the treatment effect is also obtained.
- If EMDR proves to be evidence-based, it can be structurally implemented in the (psychosocial) care of children with subthreshold PTSD in Dutch hospitals.

seis sesiones de EMDR estandarizado o (2) cuidados usuales (CAU, por sus siglas en inglés). Los niños con diagnóstico completo de TEPT no participan en el RCT, pero serán derivados para tratamiento directo. Las mediciones de seguimiento se llevarán a cabo después de ocho semanas y ocho meses.

**Discusión:** Teniendo en cuenta la escasa evidencia de la efectividad de EMDR en niños con trauma médico, los clínicos, los investigadores y los niños tratados en hospitales pueden beneficiarse de este estudio. Se discuten las fortalezas y limitaciones potenciales de este estudio.

### 经历医学相关创伤后出现阈下PTSD的儿童和青少年眼动脱敏和再处理 (EMDR) : 随机对照试验设计

**背景:** 每10名儿童和青少年中约有3名住院或正在接受治疗, 由此出现创伤后应激障碍 (PTSD) 的阈下症状。如果不加以治疗, 阈下 PTSD可能对心理社会功能、生活质量和长期精神病理产生严重影响。然而, 对阈下 PTSD及其在儿科医疗干预和/或入院后对其治疗的研究很少。眼动运动脱敏和再处理 (EMDR) 是一种快速且无创的针对创伤后应激问题的心理社会疗法。然而, EMDR在患有亚阈值PTSD的儿科病人中的有效性过去没有被系统地研究过。

**目的:** 本论文描述了一项随机对照试验 (RCT) 的设计, 该试验旨在评估EMDR对住院后出现阈下PTSD的患儿的有效性。

**方法:** 研究包括4—15岁的儿童, 他们在5年内接受过一次性 (I型创伤) 或重复 (II型创伤) 住院治疗。参与的儿童将被首先接受PTSD症状的标准化问卷调查。随后, 具有阈下PTSD的儿童将被随机分配到: 1) 大约6次标准化EMDR ; 或者2) 照常照顾 (CAU)。完全符合创伤后应激障碍诊断的儿童不参加RCT, 但可转诊接受直接治疗。追踪测量将在8周和8个月后进行。

**讨论:** 考虑到关于EMDR对患有医学相关创伤的儿童的有效性的证据还很少, 临床医生、研究人员和患儿都可以从这项研究中受益。本研究的潜在优势和局限性也在文中进行了讨论。

**试验注册:** 荷兰试验注册号 NTR5801

## 1. Background

Children and adolescents admitted to hospitals often undergo invasive, painful and potentially traumatic medical procedures. Apart from possible physical health consequences, such as reduced exercise capacity, scars or chronic pain, medical events can impact mental health and lead to posttraumatic stress symptoms (PTSS) including flashbacks, avoidance or numbing of memories of the event and hyperarousal. If symptoms are disturbing and persistent, children may even develop a posttraumatic stress disorder (PTSD). About one in every 10 children develops PTSD due to hospital admission and medical procedures (Bronner, Knoester, Bos, Last, & Grootenhuis, 2008). Some children fail to meet all criteria for a PTSD diagnosis, but still suffer from similar impairments (Carrion, Weems, Ray, & Reiss, 2002; Price, Kassam-Adams, Alderfer, Christofferson, & Kazak, 2016; Zhang, Ross, & Davidson, 2004). In general, the presence of impairing posttraumatic stress symptoms that do not meet the full diagnostic criteria for PTSD is referred to as subthreshold PTSD (McLaughlin et al., 2015). About 25–38% of children develop subthreshold PTSD after illness or injury (Kahana, Feeny, Youngstrom, & Drotar, 2006). Despite growing evidence for the negative impact of medically related trauma on child development, it has received less scientific attention than other forms of childhood trauma, such as physical or sexual abuse (Daviss et al., 2000; Pinquart, 2018). Furthermore,

research has mainly focused on multiple-incident trauma and only a few studies have examined the impact of multiple versus single trauma (Adler-Nevo & Manassis, 2005).

Currently, trauma-focused cognitive behavioural therapy (TF-CBT) is the most acknowledged, evidence-based treatment for PTSD in children (de Arellano et al., 2014). A drawback of this treatment is that reliving and replaying feared thoughts and memories are psychologically very intensive. Another treatment for PTSD is eye movement desensitization and reprocessing (EMDR; Shapiro, 1996). EMDR is a standardized treatment method based on bilateral stimulation to help process traumatic memories. Compared to TF-CBT, 'EMDR does not involve (a) detailed descriptions of the event, (b) direct challenging of beliefs, (c) extended exposure, or (d) homework' (World Health Organization, 2013, p. 1). Furthermore, EMDR seems to work faster (often < 8 sessions at 45–60 min; Beer and De Roos, 2017) than traditional TF-CBT (8–12 sessions at 90 min; van Balkom et al., 2013) and is thus cheaper and more efficient (De Roos et al., 2011, 2017).

The effectiveness of EMDR on PTSD in adults has been demonstrated in various reviews and in a meta-analysis (Bisson, Roberts, Andrew, Cooper, & Lewis, 2013; Chen et al., 2014; Shapiro, 2014). Together with TF-CBT, EMDR is recommended as a first-choice treatment for PTSD in various international practice guidelines (National Institute for Health and Clinical Excellence, 2005; Ursano et al., 2004; van Balkom

et al., 2013; World Health Organization, 2013). However, research examining the benefit of EMDR in children is scarce. Two recent meta-analysis of small studies (mostly RCTs) demonstrated that EMDR had positive results in children with PTSS and PTSD (Moreno-Alcázar et al., 2017; Rodenburg, Benjamin, De Roos, Meijer, & Stams, 2009). However, the studies in these meta-analyses had mostly small sample sizes ( $N = 14\text{--}67$ ) and covered diverse traumas varying from natural disasters to interpersonal trauma. Even though some studies examining the effectiveness of EMDR included children with subthreshold PTSD in their sample (De Roos et al., 2017; Diehle, Opmeer, Boer, Mannarino, & Lindauer, 2014; Kemp, Drummond, & McDermott, 2010; Wilson, Becker, & Tinker, 1997), no research has yet specifically focused on the effect of EMDR to reduce distress in children with medically related subthreshold PTSD, nor on predictors of EMDR treatment effect in this population. It is very important to identify and reduce subthreshold PTSD in children with medically related trauma to prevent these children developing full diagnostic PTSD and growing up with unresolved trauma and anxieties regarding medical treatment, since this may harm their medical adherence and their (mental) health later in life.

With regard to predictors of treatment effect of EMDR in children, the literature is scarce. Hensel (2009) found that increasing age, higher pre-treatment severity of PTSS and longer time since the traumatic event positively influenced the treatment effect of EMDR for children and adolescents with diverse single-incident trauma. Moreno-Alcázar et al. (2017) suggested that gender might play a role in predicting treatment effect, stating that the effect size for EMDR was nearly zero in studies that included mostly boys. Predictors of EMDR treatment effect in a medical setting are still unknown.

The hypotheses of this study are (1) EMDR will lead to significant improvements of psychosocial functioning, quality of life, school functioning and sleep in children with subthreshold PTSD and (2) older age, female gender and higher initial PTSS of the child will be associated with better outcomes in the EMDR group. Other potential medical, parental and child predictors of the EMDR treatment effect will be analysed.

## 2. Objectives

The main aim of this randomized controlled trial (RCT) is to study the effectiveness of standardized EMDR on reducing PTSS in children with subthreshold PTSD following hospitalization in The Netherlands. Further, we aim to identify factors

predicting treatment success of EMDR in children with medically related trauma.

## 3. Method

### 3.1. Design

This study represents a prospective single-blind RCT. Prior to randomization, all participants completed a screening measurement (see Assessments). After screening, only participants with subthreshold PTSD are randomized on a 1:1 basis to either EMDR or care-as-usual (CAU; medical care only if necessary). Randomization is stratified by trauma type (I/II) and age (4–11/12–15). This study represents a single-centre study, as all therapy sessions take place in the Erasmus MC Sophia Children's Hospital. However, patients are not only recruited at the paediatrics and paediatric cardiology division of the Erasmus MC, but also by the Dutch Association for patients with a congenital heart defect (PAH), the Dutch non-profit organization *Stichting Hartekind*, the paediatric division of the Maastad Ziekenhuis Rotterdam and the paediatric cardiology division of the Radboud UMC. The study protocol has been approved by the Medical Ethics Review Committee of the Erasmus MC in The Netherlands. The study is registered in the Dutch Trial Register as NTR5801.

### 3.2. Participants

The target group of this study consists of children and adolescents (4–15 years old) suffering from subthreshold PTSD after one or more hospitalization(s) or additional medical treatment that occurred at least four weeks up to maximally five years before recruitment. Inclusion period is from July 2016 until May 2018, and follow-up assessments will be complete in September 2018 (T2) and March 2019 (T3).

In this study, subthreshold PTSD is defined as either fulfilling two of the three DSM-IV PTSD symptom criteria (re-experience, avoidance or hyperarousal) and/or having a score above the cut-off on the primary outcome measuring PTSS (without a full diagnostic PTSD score on a semi-structured interview afterwards; see Assessments). The group will consist of children with trauma type I and trauma type II. In this study, we defined trauma type I as a *first hospitalization* of previously healthy children after consultation at the emergency department (due to injury or *acute* illness) or the paediatric cardiology department (due to a heart disease). Trauma type II is defined as *recurrent hospitalizations* (after consultation at the emergency department or the paediatric cardiology department) or an additional medical procedure (e.g. surgery) next to a one-time hospitalization.



Exclusion criteria are: (1) intellectual disability; (2) parental inability to read or write Dutch; (3) diagnosis of a chronic illness for the Emergency Department subgroup; (4) previous successful treatment for medically related PTSD; and (5) current psychological treatment. Additionally, exclusion criteria for participation in the randomization are: (6) not meeting the study criteria for subthreshold PTSD; and (7) a full diagnostic PTSD score on the semi-structured interview.

### 3.3. Procedure

All eligible patients receive an information letter and are invited to participate in the study. Additionally, flyers about the study are distributed in the waiting areas of the participating departments. Interested patients are asked to give informed consent. For patients younger than 12 years, informed consent is obtained from their parents/guardians. For patients between 12–15 years, informed consent is obtained from both the patient and his/her parents/guardians.

After informed consent, all participants (6–15 years), their parents/guardians and teachers are asked to complete an age-appropriate screening measurement. The questionnaires are valid for two weeks so that every participant has enough time to fill out the questionnaires. For the 4–5-year-olds only parents (and teachers) are asked to complete questionnaires. If parents and/or the child report subthreshold PTSD (or higher) at the screening assessment, the child (8–15 years) or one parent (4–7 years) is invited for a semi-structured clinical interview. If patients meet all criteria for a full diagnostic PTSD diagnose during the semi-structured interview, they are not randomized but referred directly for psychosocial care. Only children with subthreshold PTSD are asked to participate in the RCT, since this is the focus of the study. Moreover, it would be unethical to randomize children with full diagnostic PTSD to the control group. Children without subthreshold PTSD symptoms only perform the baseline assessment. An independent researcher allocates the participants with subthreshold PTSD in either the EMDR or CAU group. Considering the nature of EMDR, it is not possible to blind the participants nor the therapists providing EMDR. However, the research psychologist and research assistants performing all outcome measurements and completing the interviews with participants are blinded. Participants are instructed not to discuss their allocation with the interviewer. All participants receive a voucher and all travel costs are compensated.

Follow-up assessments will take place eight weeks and eight months after the start of EMDR/CAU. Figure 1 shows the flowchart of the study.

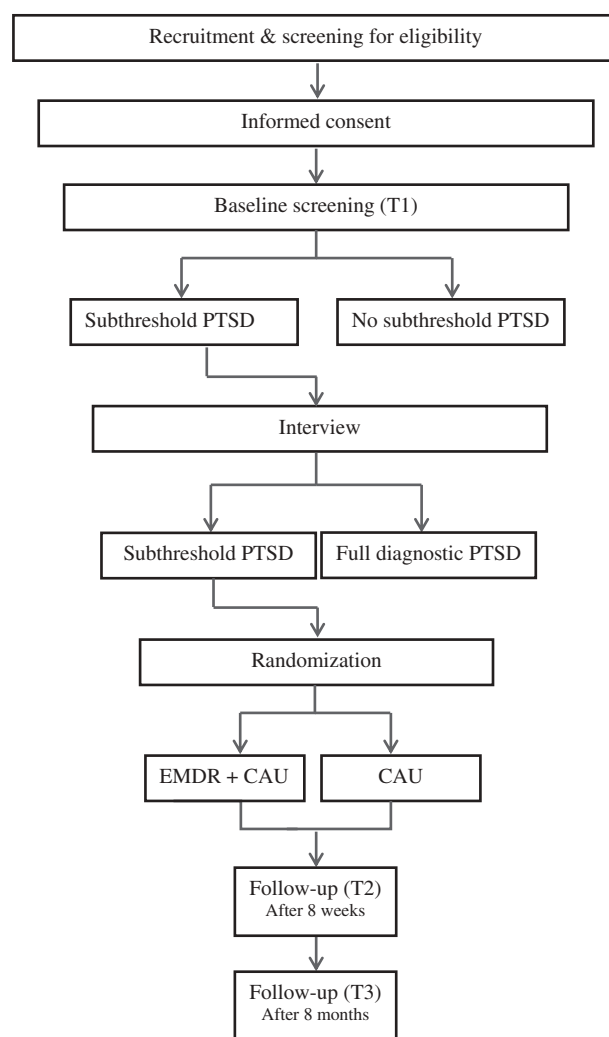


Figure 1. Study design.

### 3.4. Assessments

Almost all questionnaires are completed online by parents, children (6–15 years) and teachers. Only one questionnaire is filled out on paper. All questionnaires have adequate psychometric properties. In Table 1, all instruments and measurement time-points are listed.

**PTSD symptoms (primary outcome).** The Children's Responses to Trauma Inventory (CRTI; in Dutch: Schokverwerkingslijst, SVLK) is used to measure PTSD-symptoms (Alisic & Kleber, 2010; Alisic, Eland, Huijbregts, & Kleber, 2012). The CRTI consists of 24 PTSD-items plus 10 non-specific items. In this study, only the 24 PTSD-items are administered. The PTSD-items can be divided into three subscales related to the DSM-IV-TR symptom clusters of PTSD: intrusion, avoidance and hyperarousal (American Psychiatric Association, 2013). The PTSD-total score is computed and used as a primary outcome. Both the parent and the child version are administered. Normative data is available from 4–18 years for the parent version and 8–18 years for the child version.

**Table 1.** Instruments used in the RCT into effectiveness of EMDR in children/adolescents with subthreshold PTSD after medically related trauma.

Variable	Instrument	Format	Informant	T1	T2	T3
<b>Key outcome</b>						
PTSD symptoms	Dutch Children's Responses to Trauma Inventory (CRTI)	Online questionnaire	Parent, child <sup>a</sup>	x	x	x
<b>Exclusion criteria RCT</b>						
PTSD	Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA)	Child interview	Child <sup>b</sup>	x	x*	x*
PTSD	Diagnostic Infant and Preschool Assessment (DIPA)	Parent interview	Parent <sup>c</sup>	x	x*	x*
<b>Secondary outcomes</b>						
Anxiety	Screen for Child Anxiety Related Emotional Disorders (SCARED-NL)	Online questionnaire	Parent, child <sup>a</sup>	x	x	x
Depression	Child Depression Inventory 2 (CDI-2)	Online questionnaire	Parent, child <sup>a</sup>	x	x	x
Quality of life	Child Health-Related Quality Of Life (TACQOL)	Online questionnaire	Parent, child <sup>a</sup>	x	x	x
Sleep	Sleep Self-Report (SSR)/Child Sleep Habits Questionnaire (CSHQ)	Online questionnaire	Parent, child <sup>a</sup>	x	x	x
Self-perception	Self-Perception Profile for Children (SPP-C)/Self-Perception Profile for Adolescents (SPP-A)	Paper questionnaire	Child <sup>a</sup>	x	x	x
Attention (Problems) and school functioning	Child Behavior Checklist (CBCL)/Teacher Report Form (TRF)	Online questionnaire	Parent, teacher	x	x	x
Social validity	n.a.	Conceptualized questions	Parent, child <sup>a</sup>	x	x	x
Impact CRTI questions	n.a.	Conceptualized question	Child <sup>a</sup>	x		
<b>Predictors</b>						
Demographic factors	Rotterdam Quality of Life Interview	Online questionnaire	Parent	x		
Cognitive coping styles	Cognitive Emotion Regulation Questionnaire for Children (CERQ-C)	Online questionnaire	Child <sup>a</sup>	x		
Stressful life events	Life events scale of CERQ	Online questionnaire	Child <sup>a</sup>	x		
Parental stress	Distress thermometer (LTO)	Online questionnaire	Parent	x		
Somatic complaints	Questionnaire Somatic Complaints in children	Online questionnaire	Parent, child <sup>a</sup>	x		
Family functioning	Family Assessment Device (FAD)	Online questionnaire	Parent	x		
Information about hospitalizations and medical interventions	n.a.	Medical records	Clinician/researcher/parent	x		

<sup>a</sup>Only for children aged  $\geq 6$  years; <sup>b</sup>only for children aged  $\geq 8$  years; <sup>c</sup>only for children aged  $\leq 7$  years; \*only if necessary.

Note. T1 = before intervention; T2 = eight weeks after start of intervention; T3 = eight months after start of intervention.

Additionally, a diagnostic psychiatric semi-structured interview is administered to every participant that reports PTSD (full or subthreshold) on the CRTI. This is done only to differentiate between participants with subthreshold PTSD and those with full diagnostic PTSD. The scores are not used for statistical analysis. The semi-structured interviews used in this study are the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA; Lindauer, 2014; Nader et al., 1996) and the PTSD module of the Diagnostic Infant and Preschool Assessment (DIPA). The CAPS-CA is administered to children aged 8–15. The CAPS-CA is the international gold standard for determining the presence of PTSD. For children aged 4–7, one parent is interviewed with the PTSD module of the Diagnostic Infant and Preschool Assessment (DIPA; Gigengack, van Meijel, & Lindauer, 2009). This module consists of 55 items, assessing the presence of PTSD according to the DSM-V criteria.

*Anxiety* is assessed with the Dutch version of the Screen for Child Anxiety Related Emotional Disorders (SCARED-NL; Muris, Bodden, Hale, Birmaher, & Mayer, 2011). This is a 69-item screening instrument for anxiety symptoms in children aged 7–19 years. The child and parent version are administered.

*Depression* is measured using the Child Depression Inventory 2 (CDI-2; Kovacs, 2011; Bodden, Braet, & Stikkelbroek, 2016). The CDI-2 is designed for children aged 8–21 years, with a child (containing 28 items) and parent (containing 17 items) form. Both are administered.

The *Quality of Life* of the participants is assessed with the TNO-AZL Questionnaire for Children's Health-Related Quality of Life (TACQOL; 63 items) for children aged 6–15 years (Vogels et al., 1999; Vogels, Bruil, Koopman, Fekkes, & Verrips, 2004). The child, as well as the parent form, are administered.

*Sleep* quality and disturbances are measured with the Sleep Self-Report (SSR; 26 items, 7–12 years; Owens, Spirito, McGuinn, & Nobile, 2000) and the parallel parent version which is called Child Sleep Habits Questionnaire (CSHQ; 35 items, 4–10 years; Owens, Spirito, & McGuinn, 2000).

*Self-perception* is evaluated using the Dutch versions of Harter's Self-Perception Profile for Children (SPP-C; in Dutch CBSK, 8–12 years) and Adolescents (SPP-A, in Dutch CBSA, 12–18 years; Treffers, Goedhart, & Veerman et al., 2002; Veerman, Straathof, Treffers, Bergh, & Brink, 1997, 2004). The questionnaires consist of 36 (SPP-C) and 35 (SPP-A) items. The same subscales can be computed for both questionnaires. These questionnaires are filled out on paper by children because of licence reasons. There is no parent version of this questionnaire.

*Attention problems and school functioning* are measured with the Child Behavior Checklist (CBCL 6–18; Achenbach & Rescorla, 2001, 2003). Only its subscale attention problems (10 items) and the items about school (4 items) are administered to parents. We also used the complete Teacher Report Form (TRF 6–18), which is a parallel version of the CBCL, to obtain standardized reports from teachers. The original CBCL and TRF recall-period is six months. Because of the treatment period, the instruction will be changed into six weeks for the T2-assessment only.

To evaluate the *subjective satisfaction* (hereby referred to as *social validity*) regarding EMDR, questions specifically designed for this study are asked to patients and parents who were randomized to the EMDR group: (1) 'How satisfied are you with the EMDR treatment that you(r child) received as part of this study?', (2) 'How meaningful was EMDR?' and (3) 'Would you recommend EMDR to others?'. Scores are on a 10-point scale, with 0 representing a very negative score and 10 a very positive score.

To measure the *subjective impact of the trauma-related questions* of the CRTI, the specifically for this study designed question 'How did you experience it to be reminded of the unpleasant event through the herefore asked questions?' is asked to all participating children (6–15). The child has four different answer options, namely 'I did not feel upset at all because of the questions', 'I did feel a little upset because of the questions', 'I did feel quite upset because of the questions' or 'I did feel very upset because of the questions'.

*Demographic factors*, such as education and ethnicity, are assessed with the general scale of the Rotterdam's Quality of Life Interview (RKvL; Utens, van Rijen, Erdman, & Verhulst, 2000).

*Cognitive coping* (towards negative life events) is assessed with the Cognitive Emotion Regulation Questionnaire (CERQ). It has a child version for 9–11-year-olds (CERQ-K; Garnefski, Rieffe, Jellesma, Terwogt, & Kraaij, 2007) and a version for 12–18 year old adolescents (Garnefski, Kraaij, & Spinhoven, 2002); both have 36 items. The only difference between both version is the age-appropriate formulation of the questions. The additional life events scale is also administered.

*Parental stress*. The Distress Thermometer (DT; in Dutch Last Thermometer, LTO; Haverman et al., 2013) and its problem list is used to assess the parent-reported amount of impairment due to stress and the problems causing this stress (46 items). It was designed for parents with a child aged 0–18 years that needed treatment in a hospital.

*Somatic complaints* of the child are measured with the Questionnaire Somatic Complaints (in Dutch Vragenlijst Lichamelijke Klachten, VLK; Vanderfaellie, De Fever, & Vandenplas, 2004). The child version and

parent version (40 items) were designed for children aged 8–13 years.

*Family functioning* is evaluated with the ‘General Functioning subscale’ of the Dutch version of the Family Assessment Device (FAD-N; Wenniger, van Loon, Benoist, & Moleman, 1995). This subscale contains 12 items and will be completed by the parents.

### 3.5. Intervention

Participants allocated to the EMDR group will receive approximately six weekly sessions of 60 minutes, depending on how many sessions are needed. The intervention is terminated when (1) Subjective Units of Distress (SUDs) of all selected memories regarding the medical trauma are zero and/or (2) positive cognitions are established (rated by the child) and/or (3) child, parents and therapist agree that PTSD symptoms sufficiently decreased. EMDR is performed by EMDR-licensed and experienced health psychologists of the Erasmus MC Sophia Children’s Hospital. In this study, the standard Dutch EMDR protocol for children and adolescents (De Roos, Beer, de Jongh, & Ten Broeke, 2013) or the adapted version for young children (Lovett, 1999, 2015) are used. It consists of a structured eight-phase approach to address the past, present and future aspects of the traumatic memory. During the sessions, a child is asked to select a memory that is currently most distressing with regard to a previous hospitalization. The painful thoughts are then desensitized through controlled rhythmic eye movements, and pleasant and positive thoughts are programmed (van Den Hout, Eidhof, Verboom, Littel, & Engelhard, 2014). Visual stimulation is done with an official EMDR lightbar to enhance standardization of the treatment. When administration with the lightbar was not feasible, pads or self-tapping were used consistent with the official EMDR standards. There are different theoretical frameworks behind the mechanism of EMDR. The most prominent one is the working memory theory (e.g. Maxfield, Melnyk, & Hayman, 2008). The rationale is that humans have limited working memory capacity and engaging in dual-attention tasks therefore reduces the vividness and emotional intensity of memories. All sessions are videotaped and 20% will be randomly evaluated on treatment integrity using an EMDR-specific treatment integrity checklist. To ensure further protocol adherence, the trained EMDR therapists receive regular supervisions by a licensed EMDR supervisor.

The participants in the care-as-usual group receive standard medical care if that is necessary, as do all participants in the study.

### 3.6. Sample size

The effectiveness of EMDR in this study sample for treating PTSD symptoms is measured by the difference in CRTI-PTSD total score at T2 between the EMDR and the CAU group. A meta-analysis has shown that the effect size (Cohen’s *d*) of EMDR on PTSD symptoms in children is 0.67 versus a waiting list control group, 0.65 versus care-as-usual and 0.25 versus CBT (Rodenburg et al., 2009). This meta-analysis studied the efficacy of EMDR in children aged 4–18 years with PTSS after single and multiple heterogeneous trauma’s. With an effect size of 0.65, an alpha of 0.05 (two-tailed) and a power of 0.80, a sample size of 78 (39 per group) is needed to detect differences in the primary outcome between the EMDR and CAU group.

### 3.7. Data analysis

To evaluate differences in demographics, trauma-related and other baseline clinical characteristics between the two groups, descriptive statistics will be computed. The primary analysis will be conducted using an intention-to-treat analysis. There are two follow-up measurements (T2 and T3) to assess treatment results over time. Linear mixed models will be used to test the effectiveness of EMDR on the primary outcome (CRTI-PTSD total score) assessed at three time points. The first follow-up measurement (T2) will be considered the primary endpoint. T3 will be considered as a secondary endpoint. Trauma type, gender and age will be included as covariates. P-values of < 0.05 will be considered significant.

For the secondary outcomes (psychosocial functioning, quality of life, etc.) linear mixed models will be used as well.

To identify predictors (demographic factors, coping, parental stress, etc.) for treatment response to EMDR, we will first run univariate regression analyses with all potential predictor variables and the PTSD total score as outcome (separately for child and parent report) on T2 in the EMDR sub-group. Second, we will test for moderation by entering interaction terms between the significant predictor variables from the first step and treatment condition in the linear mixed model.

Multiple imputation methods will be used to deal with missing values. Separate analyses will be done for every informant (child, parent and teacher).

## 4. Discussion

This paper describes the study design and protocol of the first randomized controlled trial to test the



effectiveness of EMDR on reducing subthreshold PTSD in children and adolescents after medically related trauma. Given the scarcity of research in this area, this study will provide essential information for psychologists considering the use of EMDR in paediatric patients. Another strength of this study is that we include children with single and multiple trauma so we can explore differences in prevalence of subthreshold PTSD and EMDR effectiveness. Posttraumatic stress symptoms are measured not only by self-report but also through parent-report and a validated semi-structured interview. Short- and long-term outcomes and possible predictors of the treatment effect are also measured.

Currently, the majority of children and adolescents do not receive any psychosocial care after medical procedures or hospitalization. If EMDR proves to be an effective and evidence-based intervention in this population, then there is good evidence to structurally implement EMDR into the psychosocial care of Dutch hospitals. Screening for PTSS and other co-morbid mental health complaints is not currently part of standard paediatric medical care in many hospitals. This study introduces mental health screening for young patients after hospitalization at several hospitals throughout The Netherlands. This will provide new information about the prevalence of subthreshold PTSD and other psychiatric comorbid difficulties in children and adolescents with medically related trauma type I and II in The Netherlands.

Despite its strengths, this study might also face some limitations. This is a single-centre study as all EMDR sessions were provided in the Erasmus MC only. However, patients were recruited from all over The Netherlands, enhancing the generalizability of our findings. As we used a care-as-usual control group, statements about the unique treatment effect of EMDR will not be possible. Any treatment effect observed could also be due to general contact aspects of a psychosocial intervention. However, it has repeatedly been shown that EMDR is as effective as TF-CBT or even more effective (De Roos et al., 2011, 2017; Diehle et al., 2014; Rodenburg et al., 2009). It is also possible that some of the participants in the care-as-usual group will nonetheless search psychological treatment during the assessment period. The screening procedure may raise awareness about their posttraumatic stress symptoms and thus motivate them to seek help. Parents are asked to communicate it with us if they seek help on their own during the study.

Despite these possible limitations, this study represents the largest RCT up-to-date focusing on the effectiveness of EMDR in children with subthreshold PTSD after medically related trauma and will therefore contribute to the knowledge of clinicians and researchers and the well-being of children in hospitals.

## Acknowledgments

We acknowledge the Dutch Association for patients with a congenital heart defect (PAH), the paediatric division of the Maastad Ziekenhuis Rotterdam and the paediatric cardiology division of the Radboud UMC for their efforts in the recruitment of participants.

## Disclosure statement

No potential conflict of interest was reported by the authors.

## Funding

This work was supported by Innovatiefonds Zorgverzekeraars, Stichting Hartekind and Vereniging EMDR Nederland.

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