

EMDR for children with medically related subthreshold PTSD: short-term effects on PTSD, blood-injection-injury phobia, depression and sleep

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ABSTRACT

Background: Paediatric illness, injury and medical procedures are potentially traumatic experiences with a range of possible negative psychosocial consequences. To prevent psychosocial impairment and improve medical adherence, evidence-based psychotherapy should be offered if indicated. Eye movement desensitization and reprocessing (EMDR) has been found to reduce symptoms of posttraumatic stress disorder (PTSD) in adults. The evidence for the use with children is promising. Furthermore, recent studies indicate its effectiveness for the treatment of other psychological symptomatology. However, the effectiveness of EMDR in children with subthreshold PTSD after medically related trauma has not yet been investigated.

Objective: Investigating the short-term effectiveness of EMDR on posttraumatic stress, anxiety, depression and sleep problems in children with subthreshold PTSD after hospitalization through a randomized controlled trial (RCT).

Method: Following baseline screening of 420 children from various Dutch hospitals, 74 children (4–15 years old) with medically related subthreshold PTSD were randomized to EMDR ($n = 37$) or care-as-usual (CAU; $n = 37$). Follow-up assessment took place after $M = 9.7$ weeks. Generalized Estimating Equation (GEE) analyses were performed to examine the effectiveness of EMDR compared to CAU.

Results: Children in both groups improved significantly over time on all outcomes. However, the EMDR group improved significantly more as to child-reported symptoms of blood-injection-injury (BII) phobia and depression, and child-, and parent-reported sleep problems of the child. There was no superior effect of EMDR compared to CAU on subthreshold PTSD symptom reduction.

Conclusions: EMDR did not perform better than CAU in reducing PTSD symptoms in a paediatric sample of children with subthreshold PTSD after hospitalization. However, the study results indicate that EMDR might be superior in reducing symptoms of blood-injection-injury phobia, depression and sleep problems.

EMDR para niños con TEPT subumbral médicamente relacionado: efectos a corto plazo en TEPT, belonefobia, depresión y sueño

Antecedentes: La enfermedad pediátrica, injuria y procedimientos médicos son experiencias potencialmente traumáticas con un rango de posibles consecuencias psicosociales negativas. Para prevenir el deterioro psicosocial y mejorar la adherencia médica, se debe ofrecer psicoterapia basada en evidencia si está indicada. Se ha observado que la Desensibilización y Reprocesamiento por Movimientos Oculares (EMDR) reduce los síntomas del Trastorno de Estrés Postraumático (TEPT) en adultos. La evidencia para su uso en niños es promisorio. Asimismo, estudios recientes indican su efectividad para el tratamiento de otra sintomatología psicológica. No obstante, la efectividad de la EMDR en niños con TEPT subumbral posterior a trauma médicamente relacionado aún no ha sido estudiada.

Objetivo: Investigar la efectividad a corto plazo de la EMDR en estrés postraumático, ansiedad, depresión y alteraciones del sueño en niños con TEPT subumbral posterior a hospitalización, a través de un ensayo controlado aleatorizado (ECA).

Método: Seguimiento de una muestra de 420 niños provenientes de varios hospitales holandeses, 74 niños (4–15 años de edad) con TEPT subumbral médicamente relacionado fueron aleatorizados a EMDR ($n=37$) o tratamiento habitual (TH, $n=37$). La evaluación

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PALABRAS CLAVE

TEPT; TEPT subumbral; EMDR; trauma psicológico; niño; adolescente; pediatría; cardiología; departamento de emergencias; ensayo controlado aleatorizado

关键词

PTSD; 阈下PTSD; EMDR; 心理创伤; 儿童; 青少年; 儿科; 心脏科; 急诊科; 随机对照试验

HIGHLIGHTS

- First RCT evaluating the effectiveness of EMDR in children with medically related subthreshold PTSD.
- EMDR was equally effective as CAU in reducing PTSD symptoms.
- EMDR was more effective than CAU in reducing symptoms of BII phobia, depression and sleep problems.

posterior tuvo lugar tras $M=9,7$ semanas. Se realizó un análisis de ecuaciones de estimación generalizadas (EEG) para examinar la efectividad de EMDR comparado con TH.

Resultados: Los niños en ambos grupos mejoraron significativamente a lo largo del tiempo en todas las variables. No obstante, el grupo EMDR mejoró significativamente más en los síntomas reportados por los niños respecto a belonefobia y depresión, y en alteraciones del sueño de los niños reportadas tanto por ellos como por sus padres. No hubo efecto superior de EMDR comparado con TH en la reducción de síntomas de TEPT subumbral.

Conclusiones: EMDR no actuó mejor que TH en la reducción de síntomas de TEPT en niños en una muestra pediátrica de niños con TEPT subumbral posterior a hospitalización. Sin embargo, los resultados del estudio indican que EMDR podría ser superior en la reducción de síntomas de belonefobia, depresión y alteraciones del sueño.

患有医疗相关阈下PTSD儿童的EMDR:对PTSD, 血液-注射-损伤型恐惧, 抑郁和睡眠的短期效果

背景: 儿科疾病, 损伤和医疗程序是潜在的创伤经历, 可能产生一系列负面的社会心理后果。为防止社会心理损伤并提高医疗依从性, 必要时提供循证心理治疗。已经发现, 眼动脱敏与再加工 (EMDR) 可以减轻成年人的创伤后应激障碍 (PTSD) 症状, 用于儿童的证据很有前景。此外, 最近的研究表明其可用于治疗其他心理症状。然而, 尚未研究过EMDR对经历医疗创伤后患有阈下PTSD儿童的的疗效。

目标: 通过随机对照试验 (RCT) 考查EMDR对住院后患有阈下PTSD儿童的创伤后应激, 焦虑, 抑郁和睡眠问题的短期疗效。

方法: 在对来自荷兰各家医院的420名儿童进行基线筛查之后, 将74名患有医疗相关阈下PTSD的儿童 (4-15岁) 随机分为EMDR组 ($n = 37$) 或日常护理组 (CAU; $n= 37$)。平均9.7周左右进行随访评估。进行了广义估计方程 (GEE) 分析, 以考查EMDR相比CAU的疗效。

结果: 随着时间的推移, 两组儿童的所有结果均有显著改善。但是, EMDR组在儿童报告的血液-注射-损伤型 (BI) 恐惧和抑郁以及儿童和父母报告的儿童睡眠问题方面有更明显的改善。相较于CAU, EMDR对阈下PTSD症状的减轻没有更好的效果。

结论: 在住院后患有阈下PTSD儿童的儿科样本中, EMDR在减轻PTSD症状方面没有表现出比CAU更好的疗效。但是, 研究结果表明, EMDR可能在减轻血液-注射-损伤型恐惧, 抑郁和睡眠问题方面具有更大的优势。

1. Background

A growing number of studies have confirmed posttraumatic stress reactions and other psychopathological symptoms in children and adolescents after hospitalization and medical procedures (Kahana, Feeny, Youngstrom, & Drotar, 2006; Price, Kassam-Adams, Alderfer, Christofferson, & Kazak, 2015). Although many children are resilient and show a reduction in symptoms in the weeks after the medical event, some experience long-term impairing symptomatology or even develop a mental disorder. Common symptoms after medical events are posttraumatic stress, anxiety (especially blood-injection-injury phobia), mood and sleep problems (Lewandowski, Ward, & Palermo, 2011; Pinquart & Shen, 2010, 2011; Price et al., 2015). Prevalence rates of posttraumatic stress disorder (PTSD) in children after chronic illness (e.g. heart disease) or acute injury (e.g. after traffic accidents) vary from 12 to 31% (Meentken, van Beynum, Legerstee, Helbing, & Utens, 2017; Olofsson, Bunketorp, & Andersson, 2009). PTSD is a serious mental disorder which is associated with substantial impairment in cognitive, academic, social and emotional functioning (De Bellis, Hooper, Woolley, & Shen, 2009; Leskin & White, 2007; Moradi, Taghavi, Neshat-Doost, Yule, & Dalgleish, 2000; Trickett, Noll, & Putnam, 2011). Similar impairment is seen in children with subthreshold PTSD (i.e. not meeting all criteria for a full diagnostic PTSD), which is even more common than full diagnostic PTSD, namely

25–38% (Carrion, Weems, Ray, & Reiss, 2002; Kahana et al., 2006; Price et al., 2015; Zhang, Ross, & Davidson, 2004). These findings underscore the clinical significance of subthreshold PTSD and suggest a need for appropriate treatment options. However, subthreshold PTSD is often overlooked and stays untreated which can lead to worsening of the symptoms and full diagnostic PTSD (Cukor, Wyka, Jayasinghe, & Difede, 2010). While treatment possibilities for full diagnostic PTSD are widely studied, evaluations of treatment options for subthreshold PTSD are very scarce (Dickstein, Walter, Schumm, & Chard, 2013; Gutermann et al., 2016).

Eye movement desensitization and reprocessing (EMDR) is one of the most studied evidence-based psychotherapies for PTSD treatment in adults (Bisson, Roberts, Andrew, Cooper, & Lewis, 2013; Chen et al., 2014; Seidler & Wagner, 2006). Like many psychotherapies, EMDR was developed for adults and was later adapted for children. Consequently, scientific studies into the effectiveness of EMDR for children are under-represented (Herschell, McNeil, & McNeil, 2004; Khan et al., 2018). Two meta-analyses and one review including only a few studies show promising results regarding EMDR for children (Greyber, Dulmus, & Cristalli, 2012; Moreno-Alcázar et al., 2017; Rodenburg, Benjamin, De Roos, Meijer, & Stams, 2009). Interestingly, a recent meta-analysis comparing the effectiveness of EMDR and cognitive behavioural therapy (CBT) showed that children with subthreshold PTSD exhibited significantly greater reductions in PTSD symptoms following

treatment than those who were reported to have full diagnostic PTSD (Lewey et al., 2018). However, the effectiveness of EMDR for children has not yet been investigated focusing solely on children with subthreshold PTSD.

EMDR has originally been developed as PTSD treatment, but it has also been shown to be useful for the treatment of other mental health issues (Valiente-Gómez et al., 2017). Evidence suggests that EMDR reduces symptoms of anxiety and depression in children (Bae, Kim, & Park, 2008; De Roos et al., 2011; Moreno-Alcázar et al., 2017; Oras, Ezpeleta, & Ahmad, 2004) and sleep problems in adults (Raboni, Alonso, Tufik, & Suchecki, 2014). However, these EMDR treatment outcomes have not yet been studied in paediatric medical settings.

The use of EMDR in medical settings was recently recommended by the developer of EMDR herself (Shapiro, 2014). However, studies into the effectiveness of EMDR in a paediatric medical setting are scarce. Kemp, Drummond, and McDermott (2010) found significant PTSD symptom reduction after four EMDR sessions in children (6–12 years) who were injured in motor vehicle accidents and initially met two or more PTSD criteria. However, this study had a very small sample size (controls $n = 14$, EMDR $n = 13$). Another small study with children who experienced a road traffic accident ($n = 11$) found significant reductions of PTSD, general anxiety, and depression after an average of 2.4 EMDR sessions (Ribchester, Yule, & Duncan, 2010). However, this study did not use a control group. A very small quasi-experimental study in Iranian children who survived serious traffic accidents also claims to show positive results of EMDR, but no firm conclusions can be drawn from the article due to methodological reasons (HassanzadehMoghaddam & Khalatbari, 2016). Furthermore, a study in children who had experienced different kinds of traumas, including a small subsample of children with medically related trauma (23% accidents, 7% serious illness), also found promising results for EMDR in reducing PTSD symptoms (Diehle, Opmeer, Boer, Mannarino, & Lindauer, 2014). Again, the sample size was small (CBT $n = 23$, EMDR $n = 25$).

Overviewing this rather unexplored field, systematic research in larger samples remains urgently needed. Our study represents the first randomized controlled trial that specifically aims to investigate the effectiveness of EMDR in reducing medically related subthreshold PTSD after hospitalization for paediatric illness or injury. Secondary aims were to test the effectiveness of EMDR in reducing children's anxiety (especially blood-injection-injury phobia), depression and sleep problems. The outcome variables investigated in this article (subthreshold PTSD, symptoms of anxiety and depression, and sleep

problems) were selected a priori. The choice for anxiety, depression and sleep problems next to subthreshold PTSD was based on their close association with each other (Chorney, Detweiler, Morris, & Kuhn, 2007). Anxiety and depression appear to be strongly correlated and highly comorbid with PTSD (Garber & Weersing, 2010; Kahana et al., 2006). Furthermore, there is also a significant symptom overlap with sleep (Chorney et al., 2007).

2. Methods

2.1. Design

This randomized controlled trial (RCT) represents a single-centre study. All therapy sessions took place in the Erasmus MC – Sophia children's hospital in Rotterdam, the Netherlands. Participants were recruited via the Sophia children's hospital (divisions of paediatrics and paediatric cardiology), the paediatrics division of the Maastad hospital in Rotterdam, the paediatric cardiology division of the Radboud UMC Nijmegen, and nationally through the Dutch Association for patients with a congenital heart defect, and the Dutch non-profit organization Heartchild Foundation (*Stichting Hartekind*). A detailed article about the study protocol has been published previously (Meentken et al., 2018). The study was approved by the Medical Ethics Committee of the Erasmus Medical Centre in the Netherlands, registered in the Dutch Trial Register (NTR5801), and performed conform the Declaration of Helsinki (World Medical Association, 2001).

2.2. Participants

The target group was 4–15-year-old children with medically related subthreshold PTSD after ≥ 1 hospitalization(s) of at least one night. The presence of subthreshold PTSD was first investigated with the Children's Responses to Trauma Inventory (CRTI; Alisic, Eland, Huijbregts, & Kleber, 2012). Subthreshold PTSD was defined as either (1) fulfilling at least two of the three DSM-IV PTSD symptom criteria (re-experience, avoidance or hyperarousal) and/or (2) having an above average score ($>60^{\text{th}}$ percentile) on the CRTI; without a full diagnostic PTSD score on a semi-structured interview afterwards. The last hospitalization or additional medical procedure(s) should have occurred at least 4 weeks and at most 5 years ago. The inclusion period was from July 2016 until May 2018.

The screening for subthreshold PTSD took place during a baseline assessment (T1). For this assessment, we included children who had been hospitalized (1) after consultation at an emergency department due to acute injury or illness, or (2) at a paediatric cardiology department due to a congenital or acquired heart defect. Both groups encompassed children who experienced

single (type I trauma) or multiple (type II trauma) medical events. In this study, we defined type I trauma as a first hospitalization of previously healthy children. Type II trauma was defined as ≥ 2 hospitalizations or an additional medical procedure (e.g. surgery) next to an one-time hospitalization.

Exclusion criteria were: (1) intellectual disability ($IQ < 70$); (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.

2.3. Procedure

After informed consent was obtained, 420 participants were asked to fill out questionnaires to screen for PTSD symptoms (primary outcome) and other related psychosocial symptoms (secondary outcomes) during a baseline assessment (Meentken et al., [submitted for publication](#)). Subsequently, children (aged 8–15 years) with baseline scores indicating at least subthreshold levels of PTSD were invited for a semi-structured interview (Clinician-Administered PTSD Scale for Children and Adolescents, CAPS-CA; Lindauer (2014)). For children aged 4–7 years with at least subthreshold levels of PTSD, one parent was interviewed using the PTSD module of the Diagnostic Infant and Preschool Assessment (DIPA; Gigengack, van Meijel, and Lindauer ([unpublished internal document](#))). Since our study focused on children with subthreshold PTSD, children with a full diagnostic PTSD score on the interview were excluded and referred for treatment. Seventy-four children with subthreshold PTSD were randomized on a 1:1 ratio into the EMDR ($n = 37$) or care-as-usual group (CAU; $n = 37$). Randomization was stratified by trauma type (i.e. type I vs. type II trauma) and age (i.e. 4–11 vs. 12–15) using blocks. Randomization was performed by an independent researcher (using opaque envelopes) and concealed from the researcher enrolling and assessing participants. Questionnaires were filled out at baseline (T1) and during a follow-up assessment $M = 9.7$ ($SD = 2.5$) weeks after the first EMDR session (T2). Of the 74 randomized children, three (EMDR $n = 2$; CAU $n = 1$) were erroneously randomized due to misinterpretation of their score (two children scored only one point below the cut-off). Within the EMDR group, four children did not start with EMDR at all after randomization. See [Figure 1](#) for an overview.

2.4. Measures

Children ≥ 6 years of age were asked to fill out questionnaires. Parent-report was asked for children of all included ages. Participants were asked to fill out the

questionnaires with regard to a medical event. All questionnaires have adequate psychometric properties.

2.4.1. Primary outcome

PTSD symptoms were measured using the Dutch version of the Children's Responses to Trauma Inventory (CRTI; Alisic et al., 2012). The CRTI contains 24 PTSD items which can be divided into three subscales related to the DSM-IV-TR symptom clusters of PTSD (intrusion, avoidance, and hyperarousal). The total PTSD score can range from 17 to 85, with a higher score indicating more problems. The scores on the subscales intrusion and hyperarousal can range from 5–25 and on avoidance from 7–35.

2.4.2. Secondary outcomes

Symptoms of depression were measured through the total score of the Dutch Children's Depression Inventory 2 (CDI-2; Bodden, Braet, & Stikkelbroek, 2016). The parent version contains 17 items with a 4-point Likert scale and the child version contains 28 items with a 3-point Likert scale. Scores can range from 0 to 51 (parent-version) or 56 (child-version). A higher score indicates more problems.

Symptoms of blood-injection-injury (BII) phobia and anxiety in general were measured through the BII subscale (7 items) and the total score (69 items) of the Dutch Screen for Child Anxiety Related Emotional Disorders (SCARED-NL; Muris, Bodden, Hale, Birmaher, & Mayer, 2011). Responses are scored on a 3-point Likert scale (0–2) with a maximum score of 14 (BII subscale) and 138 (total score). A higher score indicates more problems.

Sleep problems were measured using the total score of the Dutch Sleep Self Report (SSR, 23 items; Steur et al., 2019) and the Dutch parallel parent version called Child Sleep Habits Questionnaire (CSHQ, 35 items; J. A. Owens, Spirito, & McGuinn, 2000). Responses are rated on a 3-point Likert scale (1–3) with maximum total scores of 69 (SSR) and 99 (CSHQ). Again, a higher score indicates more sleep problems.

Social validity questions were added to investigate parents' and children's subjective evaluation of the EMDR treatment. Three aspects of social validity (satisfaction with EMDR, usefulness of EMDR and recommendation of EMDR) were assessed in the EMDR group at T2. A 10-point Likert scale (0–10) was used with a higher score indicating more satisfaction, perceived usefulness and willingness to recommend EMDR.

2.5. Intervention

EMDR is based on the assumption that traumatic memories are stored inadequately. During therapy, the child is asked to think about a currently disturbing memory while simultaneously focusing on a bilateral stimulation (i.e. eye movements). This

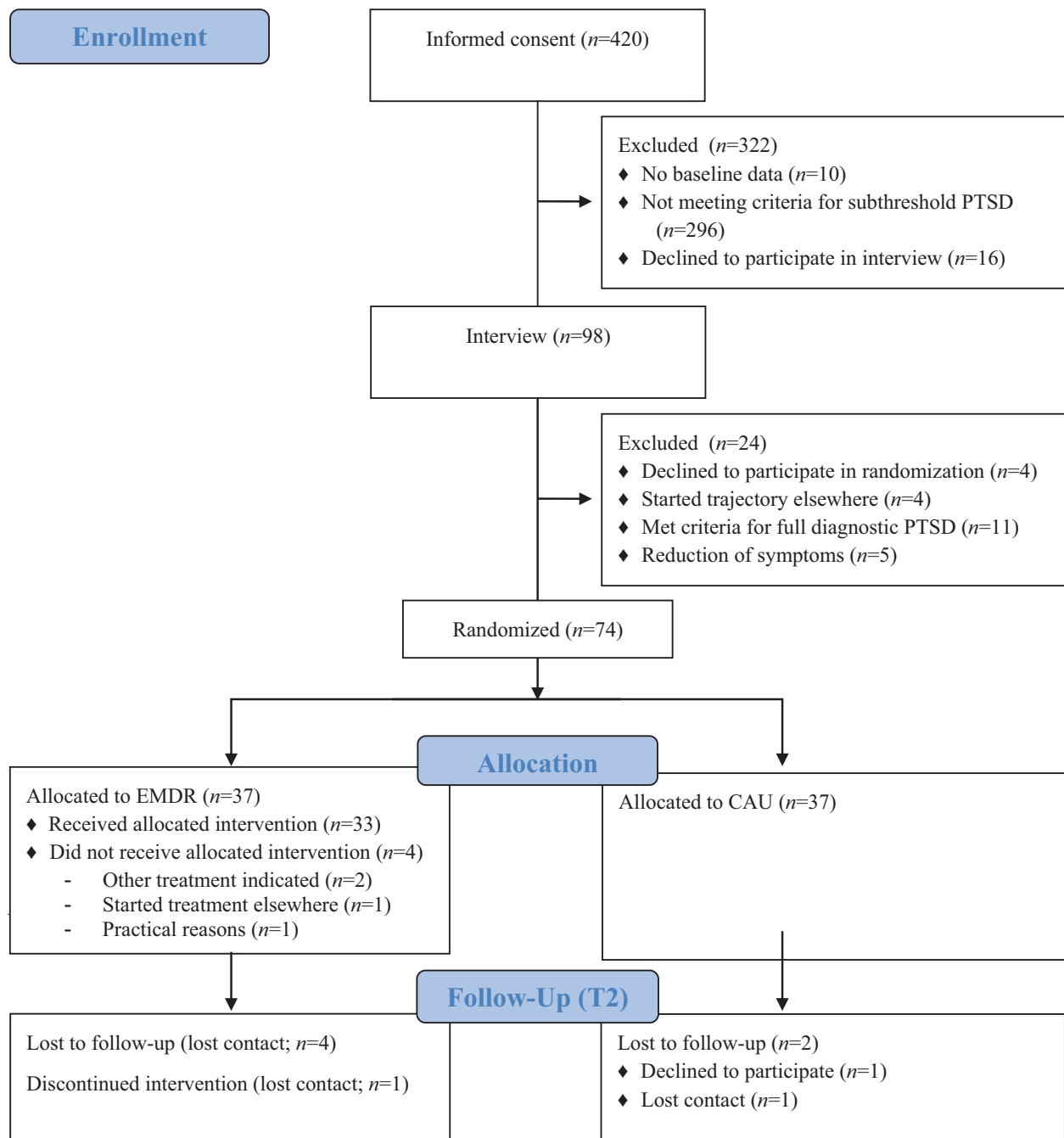


Figure 1. Flow chart.

initiates processing of the memory. The working mechanism of EMDR is still unclear. The hypothesis with most support is that engaging in two simultaneous tasks (i.e. eye movements and thinking about a disturbing memory) draws on the limited capacity of the working memory and therefore decreases the vividness of the image (Landin-Romero, Moreno-Alcazar, Pagani, & Amann, 2018).

Children in the EMDR group received $M = 3.5$ ($SD = 1.9$) EMDR sessions (intake included) of approximately 50 minutes. Parents were allowed to be present during the sessions when the child agreed on this with the therapist. EMDR therapy was provided by five licenced and experienced clinical psychologists following 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). EMDR treatment was completed when (1) Subjective Units of Distress (SUDs) of all selected memories regarding the medical trauma were zero and/or (2) positive cognitions were established (rated by the child) and/or (3) child, parents and therapist agreed that PTSD symptoms had sufficiently decreased.

Children in the CAU group only received standard medical care.

2.6. Treatment integrity

All five EMDR-therapists participated in regular supervision sessions provided by a EMDR Europe

consultant (licensed supervisor). All EMDR sessions were video-taped. If no consent for videotaping was obtained, the therapists provided detailed written records. All sessions of 10 randomly chosen children (27%) were rated on protocol adherence by a trained research psychologist and two trained Master students in psychology, supervised by the aforementioned research psychologist. Rating was done with an EMDR-specific treatment integrity checklist with a total score ranging from 0–16. There was good agreement between all three independent raters: all total scores given ranged between 13–16. Treatment integrity was high with 95%.

2.7. Statistical analyses

We conducted *t*-tests and χ^2 -tests to test differences between the EMDR and CAU group baseline characteristics. Correlations between child and parent report were analysed using Pearson's *r* and differences were tested using paired sample *t*-test. To test for differences in outcome scores between both groups in the total sample, Generalized Estimating Equations (GEE) with an unstructured correlation matrix were performed following the intention-to-treat principle. We conducted a GEE analysis for each outcome separately. In each analysis, we first added time (T1 vs. T2) and group (EMDR vs. CAU) as factors. Interactions between time and group were tested for significance with Wald χ^2 tests. Second, if the interaction was significant, we ran the GEE analyses again adding age, gender and whether the child had experienced ≥ 1 other non-medical stressful life

events as covariates. Third, for all significant interactions, we also added trauma type, hospital department, and time since last medical event as covariates and, for explorative analyses, their interaction with time and group.

In addition, we ran the analyses of the first step again (1) following the per-protocol principle and (2) without the three erroneously randomized children. Effect sizes were measured with Cohen's *d* by dividing the difference between the estimated means of both groups at T2 by the pooled standard deviation at T1 (Feingold, 2009). SPSS version 24.0 was used for all statistical analyses.

3. Results

3.1. Baseline characteristics

At baseline, no differences were found between the EMDR and CAU group with regard to baseline demographics. See Table 1 for more information. However, the EMDR group had a significantly higher mean score at baseline on the child-reported total sleep problem score than the CAU group [$t(65) = -2.3, p < .05$].

3.2. Parent-child agreement

3.2.1. PTSD symptoms

The correlation between child and parent report on the primary outcome (CRTI) was moderate ($r = .31$) at T1 and high ($r = .56$) at T2. Differences between

Table 1. Baseline demographics.

	N	Total	EMDR group n = 37	CAU group n = 37	<i>p</i> -value
Child					
Age in years, M \pm SD	74	9.6 \pm 2.9	9.8 \pm 2.7	9.4 \pm 3.1	.604
Gender, n (%)	74				.806
Girls		25 (33.8)	12 (32.4)	13 (35.1)	
Boys		49 (66.2)	25 (67.6)	24 (64.9)	
Ethnicity, n (%)	72				.202
Dutch		59 (81.9)	32 (88.9)	27 (75.0)	
Other Western		4 (5.6)	2 (5.6)	2 (5.6)	
Non-Western		9 (12.5)	2 (5.6)	7 (19.4)	
Other stressful life events, n (%)	67				.864
Yes		55 (82.1)	29 (82.9)	26 (81.3)	
No		12 (17.9)	6 (17.1)	6 (18.8)	
Parental					
Education, n (%)	74				.836
High		41 (55.4)	21 (56.8)	20 (54.1)	
Medium		30 (40.5)	15 (40.5)	15 (40.5)	
Low		3 (4.1)	1 (2.7)	2 (5.4)	
Medical					.816
Department, n (%);	74				
Cardiology		39 (52.7)	19 (51.4)	20 (54.1)	
Emergency unit		35 (47.3)	18 (48.6)	17 (45.9)	
Trauma Type, n (%)	74				.572
I		16 (21.6)	9 (24.3)	7 (18.9)	
II		58 (78.4)	28 (75.7)	30 (81.1)	
No. of hospitalizations, M \pm SD	71	4.01 \pm 4.00	4.5 \pm 4.4	3.6 \pm 3.5	.331
Length of hospitalization(s) in days, M \pm SD	59	28.14 \pm 47.23	31.7 \pm 54.9	24.2 \pm 37.6	.545
Time since last medical event in years, M \pm SD	71	1.76 \pm 1.42	1.7 \pm 1.5	1.8 \pm 1.4	.789

M, mean; SD, standard deviation; no., number. χ^2 tests were used for categorical variables. *T*-tests were used for continuous variables.

child and parent report at the two time points were not significant.

3.2.2. Symptoms of depression

The correlation between parent and child report on depression was high at T1 ($r = .58$) and T2 ($r = .76$). Differences between child and parent report could not be tested due to incomparable questionnaires.

3.2.3. Symptoms of BII phobia and anxiety in general

Parent and child report for BII phobia was high at T1 ($r = .71$) and T2 ($r = .75$). There were significant differences in the T1 scores for parent report ($M = 5.06$, $SD = 3.16$) and child report ($M = 5.76$, $SD = 3.21$); $t(66) = -2.35$, $p = .02$. The correlation between parent and child report on the SCARED-NL total score was also high at T1 ($r = .53$) and T2 ($r = .75$). There were no significant differences between child and parent report.

3.2.4. Sleep problems

The correlation between child and parent report on sleep problems were high at T1 ($r = .53$) and T2 ($r = .79$). To test for differences between child and parent reported sleep problems, CSHQ total scores were divided by 35 (number of CSHQ items) and then multiplied by 23 (number of SSR items). At both assessment points, children ($M_{T1} = 37.09$, $SD_{T1} = 5.97$; $M_{T2} = 34.18$, $SD_{T2} = 6.36$) reported significantly more sleep problems than parents ($M_{T1} = 32.70$, $SD_{T1} = 5.47$; $M_{T2} = 30.23$, $SD_{T2} = 5.50$); $t_{T1}(66) = -6.47$, $p = .00$ and $t_{T2}(56) = -7.56$, $p = .00$.

3.3. Primary outcome

Outcomes of the EMDR and CAU group are shown in Table 2. Children in both groups showed a similar reduction in PTSD symptoms from baseline to follow-up. EMDR was not significantly superior compared to CAU in reducing child-reported ($b = -0.5$, $p = .853$) and parent-reported ($b = -3.5$, $p = .275$) PTSD symptoms of the child. The same was true for all three PTSD subscales.

3.4. Secondary outcomes

From baseline to follow-up, child-reported symptoms of blood-injection-injury phobia decreased significantly more in the EMDR group than in the CAU group ($b = -1.5$, $p = .034$). This effect remained significant in a secondary GEE analysis controlling for age, gender and other stressful life events ($b = -1.5$, $p = .034$, Cohen's $d = -.46$). In contrast, parent-reported BII phobia symptom reduction in the child did not differ significantly between the EMDR group and the CAU group ($b = -0.5$, $p = .364$).

As to child-reported anxiety symptoms, EMDR was not superior in reducing child-reported total anxiety symptoms compared to CAU ($b = -6.8$, $p = .101$). The same was true for parent-reported total child anxiety symptoms ($b = -3.8$, $p = .288$).

Child-reported symptoms of depression declined significantly more in the EMDR group than in the CAU group ($b = -2.5$, $p = .037$). This effect remained significant after controlling for age, gender and other stressful life events ($b = -2.5$, $p = .037$, Cohen's $d = -.40$). As to parent-reported symptoms of

Table 2. Outcome measures for EMDR vs. CAU.

Outcome measure	EMDR group (n=37)		CAU group (n=37)		B^a	P -value ^b	Effect size ^c
	T1	T2	T1	T2			
Posttraumatic stress symptoms							
Child-report							
Total PTSD score	45.00 ± 9.17	32.00 ± 11.80	44.37 ± 8.32	31.54 ± 11.76	-0.509	0.853	-.06
Intrusion	12.20 ± 4.19	8.29 ± 3.60	11.53 ± 3.08	7.50 ± 2.93	-0.044	0.966	-.01
Avoidance	18.77 ± 3.85	13.10 ± 5.32	18.69 ± 4.27	13.50 ± 5.06	-0.601	0.658	-.15
Hyperarousal	14.03 ± 4.11	10.61 ± 4.82	14.16 ± 4.30	10.54 ± 5.37	0.293	0.790	0.07
Parent-report							
Total PTSD score	44.51 ± 10.80	32.94 ± 10.44	43.46 ± 9.78	35.43 ± 12.58	-3.468	0.275	-.34
Intrusion	11.86 ± 4.18	8.42 ± 3.64	11.14 ± 3.56	9.14 ± 3.80	-1.420	0.214	-.37
Avoidance	17.97 ± 5.12	13.58 ± 5.26	17.76 ± 4.91	14.37 ± 5.55	-1.038	0.482	-.21
Hyperarousal	14.68 ± 4.14	10.94 ± 3.42	14.57 ± 3.84	11.91 ± 4.81	-0.990	0.355	-.25
Symptoms of depression							
Child-report	11.23 ± 6.04	6.17 ± 5.27	9.03 ± 6.38	7.07 ± 6.55	-2.473	0.037*	-.40
Parent-report	17.59 ± 6.42	12.06 ± 6.03	14.65 ± 6.63	12.14 ± 7.20	-2.551	0.050	-.39
Symptoms of blood-injection-injury phobia							
Child-report	6.31 ± 3.23	4.30 ± 2.83	5.16 ± 3.12	4.37 ± 3.20	-1.463	0.034*	-.46
Parent-report	5.38 ± 3.06	4.52 ± 3.05	4.49 ± 3.05	4.17 ± 3.48	-0.541	0.364	-.18
Symptoms of anxiety							
Child-report	46.09 ± 22.87	28.73 ± 17.39	39.91 ± 16.86	29.63 ± 21.13	-6.834	0.101	-.34
Parent-report	38.97 ± 16.76	27.39 ± 13.87	37.49 ± 20.43	30.43 ± 20.84	-3.833	0.288	-.20
Sleep problems							
Child-report	38.63 ± 6.48	33.80 ± 6.04	35.41 ± 4.92	34.59 ± 6.80	-3.614	0.003*	-.63
Parent-report	51.14 ± 8.61	46.12 ± 8.20	48.76 ± 7.96	47.35 ± 8.15	-2.751	0.032*	-.33

Mean ± Standard deviation. * $p < .05$.

^aGEE analyses. Uncorrected interaction of time × group.

^bGEE analyses. P-values indicates level of significance of the uncorrected time × group interaction.

^cCohen's d .

depression of the child, a trend towards significance in favour of the EMDR group was found ($b = -2.6$, $p = .05$).

With regard to child-reported sleep problems we found a significant larger reduction from baseline to follow-up for the EMDR group compared with the CAU group ($b = -3.6$, $p = .003$). This effect remained significant after controlling for age, gender and other stressful life events ($b = -3.6$, $p = .003$, Cohen's $d = -.63$). Children's sleep problems reported by the parents also reduced significantly more in the EMDR group than the CAU group ($b = -2.8$, $p = .032$). However, this effect was not significant anymore after controlling for age, gender and other stressful life events ($b = -2.6$, $p = .059$, Cohen's $d = -.31$).

3.5. Explorative analyses

No significant differences in treatment effect were found for trauma type and hospital department. However, the effect of EMDR in reducing child-reported symptoms of depression and sleep problems were larger the longer ago the last medical event happened.

3.6. Additional analyses

Per-protocol analyses revealed some minor deviations regarding the secondary outcomes compared to intention-to-treat analyses. In addition to the findings that EMDR was superior to CAU in treating BII phobia (child-report), depression (child-report) and sleep problems (child-report and parent-report), per-protocol analyses showed that EMDR was also superior in treating parent-reported symptoms of depression of the child and child-reported total anxiety score.

Furthermore, we did another analyses without the children who were erroneously randomized. In contrast to the previous analyses, improvements between baseline and follow-up regarding child-reported depressive symptoms and parent-reported sleep problems of the child were not significantly larger for the EMDR group anymore. However, the superior effects of EMDR on child-reported BII phobia symptoms and child-reported sleep problems remained significant.

3.7. Social validity

On a scale of 1 to 10, mean child ($n = 29$) and parent ($n = 31$) ratings of satisfaction with EMDR treatment were 8.2 ($SD = 1.6$) and 8.0 ($SD = 1.1$), respectively. The mean level of perceived usefulness of EMDR rated by children was 7.8 ($SD = 1.9$) and by parents 6.8 ($SD = 2.3$). On average, the willingness to recommend EMDR to others was rated with a 7.9

($SD = 2.3$) by children and with a 7.7 ($SD = 1.7$) by parents.

4. Discussion

This study presents outcomes of the first randomized controlled trial investigating the effectiveness of EMDR compared with CAU for children with medically related subthreshold PTSD after hospitalization for illness or injury. Children of both groups improved over time, but EMDR was superior in reducing symptoms of depression and BII phobia, and sleep problems.

We found significant improvements for both the EMDR and the CAU group over time on all outcomes. This could be due to the fact that children in the CAU group participated in a baseline psychological screening and an interview with a psychologist and, thereby, received additional attention from a professional. Participating in a structured assessment and hearing that PTSD symptoms were of subthreshold nature might be therapeutic in itself by acknowledging and normalizing the child's symptoms. Furthermore, research suggests that participating in a psychological study can decrease psychosocial symptomatology (Arrindell, 2001; McCambridge, 2015).

With regard to PTSD symptom reduction, EMDR was as effective as CAU. This is in contrast to two meta analyses reporting on smaller studies (Moreno-Alcázar et al., 2017; Rodenburg et al., 2009). However, these studies did not specifically focus on medically related trauma and subthreshold PTSD. It is possible that with medically related subthreshold levels of PTSD, receiving attention from a mental health professional is enough to reduce symptoms and that EMDR, therefore, had no superior effect compared to CAU in our sample. Bearing in mind the limited resources of psychotherapists, a stepped-care model might be most efficient and cost-effective for monitoring and treating symptoms. This model proposes that mental health care is provided in steps and based on the needs of the child, with only those with persistent severe symptoms progressing to psychotherapy (Marsac, Hildenbrand, & Kassam-Adams, 2017). Additionally, natural remission from PTSD symptoms can also occur (Cukor et al., 2010; Smith et al., 2007). Exact remission rates, however, of children with medically related subthreshold PTSD are unknown. Future research should provide more insights into predictors of the EMDR treatment effect. It is important to note that we did not find any harmful effect of EMDR and that parents and children evaluated EMDR as very satisfactory.

Sleep problems are part of the DSM-V criteria for PTSD. However, sleep problems are rarely investigated as treatment outcome of EMDR. The present

study presents support for the use of EMDR to reduce sleep problems in children after hospitalization. This is in line with Raboni et al. (2014), who showed that EMDR treatment of PTSD improved sleep quality in adults.

Furthermore, PTSD tends to be closely related to specific phobias as these often have a traumatic origin too (McNally & Saigh, 1993). Interestingly, we found a superior effect of EMDR in reducing child-reported symptoms of blood-injection-injury phobia. This is in line with previous research indicating a positive effect of EMDR on dental phobia (De Jongh, Van den Oord, & Ten Broeke, 2002; Doering, Ohlmeier, de Jongh, Hofmann, & Bisping, 2013). Our finding that EMDR can reduce BII is clinically very relevant: it may be beneficial for future medical adherence as phobic patients tend to avoid the source of their fear.

Level of medical adherence has also been found to be smaller in patients who suffer from depression (DiMatteo, Lepper, & Croghan, 2000). In line with previous findings, our results indicate that child-reported symptoms of depression decreased significantly more in the EMDR group than in the CAU group (Bae et al., 2008; De Roos et al., 2017) and thereby possibly improved medical adherence.

As to our multi-informant approach, correlations between child and parent report were moderate to high. Still, children reported significantly higher mean scores on BII phobia at T1 and sleep problems at T1 and T2 compared to parent-report. Earlier research has also found that child report tends to be higher than parent report on both outcomes (Owens, Spirito, McGuinn, & Nobile, 2000; Wren, Bridge, & Birmaher, 2004). It has been argued that some aspects of internalizing problems and sleep may manifest beyond parent's awareness and therefore child-report might be more reliable (Becker, 2014; Cosi, Canals, Hernández-Martinez, & Vigil-Colet, 2010). However this might not be true for young children.

The additional analyses revealed that per-protocol analyses showed additional superior effects of EMDR on reducing child-reported anxiety and parent-reported symptoms of depression of the child. However, per-protocol analyses represents the best-case scenario and may therefore show an exaggerated effect (Ranganathan, Pramesh, & Aggarwal, 2016). Furthermore, we also tested whether the benefits of EMDR remained when the three erroneously randomized children were eliminated from the statistical analyses. The superior effects of EMDR on child-reported BII phobia and sleep problems remained significant. Since results were changing during the additional analyses, results of this study should be interpreted with caution.

Finally, we also explored whether trauma type (I vs. II), type of department (emergency vs. cardiology) or time since last medical event (0–5 years) influence the

found treatment effects. In accordance to Diehle et al. (2014), treatment effect was not related to trauma type. The same was true for hospital department. However, the time elapsed since the last medical event did influence the treatment effect. The longer ago the last medical event happened, the more effective was EMDR in reducing child-reported symptoms of depression and sleep problems. This finding is explorative and should be tested in future studies.

4.1. Strengths and limitations

This study presents several strengths. First, our sample size was relatively large compared to earlier research into the effectiveness of EMDR in children. Second, we used parent and child report for all outcomes and included a broad age range. Third, we recruited participants throughout the Netherlands which increases generalizability. Fourth, all therapists received regular supervision and treatment integrity was assessed by multiple independent raters. Fifth, randomization was stratified and done by an independent researcher. Sixth, the researcher who was responsible for all assessments was blinded for randomization outcome. Finally, we specified the trauma type that children in our sample had experienced and explored the effects of trauma type during analyses.

Some limitations should also be noted. First, it should be noted that the CAU group did not represent real care-as-usual as this group received a psychological screening and interview in addition to regular medical care. No similar attention placebo control group was provided. Second, follow-up questionnaires were sent to participants 8 weeks after the first EMDR session regardless of whether EMDR was completed or not for methodological reasons. Therefore, the time between completion of EMDR and follow-up was different for every participant and six participants had not completed therapy when filling out the follow-up assessment. Third, EMDR might be more effective in children with more severe PTSD symptoms. However, it would have been unethical to randomize children with full diagnostic PTSD into a CAU group when other treatment options for PTSD are available. Fourth, due to the nature of EMDR it was not possible to blind participants to their group allocation. Finally, we did not assess parental mental health which is associated with parent report of the child's emotional wellbeing (Shemesh et al., 2005) and we did not provide any treatment for parents. The effectiveness of EMDR might improve when an active parental treatment component would be added (Cobham et al., 2012; De Roos et al., 2011).

Despite the mentioned possible limitations, this study represents the largest RCT up-to-date investigating the effectiveness of EMDR in children with

medically related subthreshold PTSD after hospitalization.

5. Conclusion

In children with medically related subthreshold PTSD, EMDR and CAU performed similarly well at reducing PTSD symptoms. However, the present study provides some indication for the effectiveness of EMDR in reducing BII phobia, depression and sleep problems. No firm conclusions can be drawn from these findings since results changed during additional analyses. Comparable studies should be done to support the implementation of EMDR as an evidence-based therapy for BII phobia, depression and sleep problems after paediatric hospitalization.

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