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ORIGINAL ARTICLE

Long-term effectiveness of eye movement desensitization and reprocessing in children and adolescents with medically related subthreshold post-traumatic stress disorder: a randomized controlled trial

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Aims Medical procedures and hospitalizations can be experienced as traumatic and can lead to post-traumatic stress reactions. Eye movement desensitization and reprocessing (EMDR) shows promising results but very few long-term studies have been published. Therefore, our aim was to test the long-term (8 months post-treatment) effectiveness of EMDR in children and adolescents with medically related subthreshold post-traumatic stress disorder (PTSD).

Methods and results Seventy-four children (including 39 with congenital or acquired heart disease) aged 4–15 ($M = 9.6$ years) with subthreshold PTSD after previous hospitalization were included into a parallel group randomized controlled trial. Participants were randomized to EMDR ($n = 37$) or care-as-usual (CAU) ($n = 37$; medical care only). The primary outcome was PTSD symptoms of the child. Secondary outcomes were symptoms of depression and blood–injection–injury (BII) phobia, sleep problems, and health-related quality of life (HrQoL) of the child. Assessments of all outcomes were planned at baseline and 8 weeks and 8 months after the start of EMDR/CAU. We hypothesized that the EMDR group would show significantly more improvements on all outcomes over time. Both groups showed improvements over time on child's symptoms of PTSD (only parent report), depression, BII phobia, sleep problems, and most HrQoL subscales. GEE analyses showed no significant differences between the EMDR group (n_{T2} = 33, n_{T3} = 30) and the CAU group (n_{T2} = 35, n_{T3} = 32) on the primary outcome. One superior effect of EMDR over time was found for reducing parent-reported BII phobia of the child.

Conclusion EMDR did not perform better than CAU in reducing subthreshold PTSD up to 8 months post-treatment in previously hospitalized children. Possible explanations and clinical implications are discussed.

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Keywords EMDR • Congenital heart disease • Post-traumatic stress • Medical setting • Treatment outcome • Randomized controlled trial

Implications for practice

- This study provides preliminary evidence for the use of eye movement desensitization and reprocessing (EMDR) for blood–injection–injury phobia symptoms in children and adolescents after hospitalization.
- EMDR may be more effective for post-traumatic stress disorder (PTSD) symptoms when symptom severity is high.
- The effectiveness of EMDR for children and adolescents with full diagnostic PTSD after various medically related potentially traumatic events should be studied in the future.

Introduction

Exposure to medical care is common during childhood and adolescence, especially for children and adolescents with congenital heart disease (ConHD).[1] Medical care involves a variety of potentially traumatic events, such as painful diagnostics or medical treatments, surgical interventions, hospitalizations, life-threatening diagnoses, and separation of children from their caregivers. Subsequently, some children develop impairing emotional and behavioural difficulties, including post-traumatic stress.[2] The long-term prevalence of post-traumatic stress disorder (PTSD) in children with ConHD is approximately 29% and roughly 11% after injury.[3,4] Even more children (up to 38%) develop impairing symptoms of PTSD without meeting all criteria for a diagnostic disorder, called subthreshold PTSD.[5] Subthreshold PTSD is associated with long-lasting impairment comparable to full diagnostic PTSD and accounts for a substantial future PTSD burden.[6–8] Next to PTSD symptoms, 9–18% of adolescence with ConHD and 7–13% of critical ill children develop clinically relevant depressive symptoms.[9–11] Furthermore, it has been found that 31% of children with ConHD show significant medical fears.[12] Children with acquired heart disease also show more depressive and anxiety problems than children from the general population.[13] Decreased health-related quality of life (HrQoL) is experienced in 25–60% of children with a ConHD and in up to 43% of children after paediatric intensive care unit admission.[14,15] Sleep problems are also frequent, reported in up to 86% of children with common medical conditions and 79% of children with ConHD.[16,17]

Attuned psychosocial interventions should be offered to reduce the wide diversity of symptoms. Meta-analyses show that eye movement desensitization and reprocessing (EMDR) is an effective psychotherapy to reduce PTSD symptoms in adults.[18,19] EMDR has also been found to be effective in reducing depression, anxiety, and sleep problems, and in improving quality of life in adults.[20,21] During EMDR, the vividness and emotional intensity of a distressing memory is reduced by concentrating on that memory while simultaneously engaging in bilateral stimulation (typically horizontal eye movements). See the recent review of Landin-Romero *et al.*[22] for more information on possible underlying mechanisms of action. While there has been a great deal of research interest in EMDR, studies into its effectiveness for children are underrepresented. Furthermore, only few studies have documented long-term benefits of EMDR for children. Of the 11 available controlled studies into EMDR for children only three documented ≥6 months post-treatment follow-ups. All three studies found positive improvements to be maintained at 6–12 months follow-up.[23–25] To the best of our knowledge, only one other randomized controlled trial (RCT) studied EMDR in a sample of children (aged 6–12 years) with medically related trauma.[25] All participants in this study ($n = 27$) had experienced a motor vehicle accident and initially met two or more PTSD criteria. They were randomly assigned to either EMDR or a wait-list control group. Again, the study found that improvements of PTSD symptoms were maintained at 12-month follow-up.

However, there are still gaps in the scientific literature on EMDR for children. The effectiveness of EMDR for children with cardiovascular disease has not been studied before. Furthermore, no other previous study has focused on children with subthreshold PTSD when evaluating the effectiveness of EMDR, even though it has been reported that children with subthreshold PTSD responded better to psychological treatment than those with PTSD.[26] Considering secondary prevention, investigating treatments for the use of subthreshold levels of mental disorders is very important. The current RCT is the first to evaluate the effectiveness of EMDR focusing on children with subthreshold PTSD after hospitalization at a paediatric cardiology department or following emergency department (ED) admission. This article specifically aims to investigate the long-term (8 months post-treatment) effectiveness of EMDR on reducing subthreshold PTSD (primary outcome), depression, BII phobia, and sleep problems, and improving HrQOL following hospitalization. The short-term results of our RCT were published recently and showed superior effects of EMDR on symptoms of BII phobia, depression and sleep problems of the child.[27] The aim of the present article was to investigate whether the positive effects of EMDR would maintain over time.

Methods

The present study was a single-blinded RCT with two parallel groups comparing EMDR and care-as-usual (CAU). After written informed consent (from parents/guardians and children ≥12 years) and a positive screening for subthreshold PTSD, participating children were randomized using a 1:1 allocation ratio. A detailed version of the study protocol has previously been published.[28] 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 designed conform

the CONSORT guidelines (Supplementary Information).[29] The investigation conforms with the principles outlined in the Declaration of Helsinki.[30]

Participants

Participants were continuously recruited from July 2016 until May 2018. Participants were recruited mainly at the Erasmus MC Sophia children's hospital (paediatrics division and paediatric cardiology division) and the Maasstad hospital (paediatrics division) in Rotterdam, the Netherlands. Additional participants were recruited at the paediatric cardiology division of the Radboud UMC Nijmegen (RUMC), and nationally through the Dutch Association for patients with a congenital heart defect (*Patiëntenvereniging Aangeboren Hartafwijkingen, PAH*) and the Dutch non-profit organization Heartchild Foundation (*Stichting Hartekind*). We expected medium effects on PTSD symptoms based on a meta-analysis.[31] A sample size of 78 participants was aimed to reach sufficient power.[28]

Participating children were 4–15 years old and had been hospitalized at least 4 weeks but no more than 5 years ago for at least one night. The amount of psychological reactions in children might differ after acute versus chronic medical events.[5,32] To encompass both groups we included children who had been hospitalized (i) at a paediatric cardiology department due to a congenital or acquired heart defect or (ii) after consultation at an ED due to acute injury or illness. Information on hospitalizations (number, data, length, and reason) was retrieved from the medical record by the research psychologist after possible participants were selected by the participating departments. For children included by the RUMC, PAH and Heartchild foundation, parent-report was used. We included children who experienced single and multiple hospitalizations with possible additional medical procedures.

Exclusion criteria were: (i) intellectual disability (IQ < 70) as assessed by previous standardized test or evaluated by a clinician; (ii) parental inability to read or write Dutch; (iii) diagnosis of a chronic illness for the ED subgroup; (iv) previous successful treatment for medically related PTSD; and (v) current psychological treatment.

Procedure

After having provided written informed consent, children and their parents completed a baseline measurement. The main goal of this measurement was to screen children for present post-traumatic stress symptoms using the Children's Responses to Trauma Inventory (CRTI).[33] Children who (i) fulfilled at least two of the three DSM-IV (Diagnostic and Statistical Manual of Mental Disorder, 4th edition) PTSD symptom criteria (i.e. re-experience, avoidance or hyperarousal) measured by the CRTI and/or (ii) had an above average score (i.e. >60th percentile) on the CRTI were invited for a semi-structured interview using the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA).[34] For children aged 4–7 we used the PTSD module of the Diagnostic Infant and Preschool Assessment (DIPA).[35] The interview was scheduled as soon as possible after the baseline assessment was completed. The purpose of the interview was to divide children into having subthreshold or full diagnostic PTSD. Children were defined as having subthreshold PTSD when they met at least one CRTI criterion (by child and/or parent report) but did not meet all criteria for a full diagnostic PTSD during the interview. Only children with subthreshold PTSD were enrolled in the randomization. Children with full diagnostic PTSD were excluded from the study and were referred for psychosocial care.

Blinding and randomization

Stratified block randomization was performed by an independent research psychologist with four randomizations per block using opaque envelopes. The number of blocks was only known by the independent research psychologist. We stratified by trauma type (i.e. children who experienced a one-time hospitalization vs. children who experienced ≥2 hospitalizations or an additional medical procedure next to an one-time hospitalization[28]) and age. Four fixed blocks (trauma type 1/age 4–11; trauma type 1/age 12–15; trauma type 2/age 4–11; trauma type 2/age 12–15) were used. Participants and therapists could not be blinded due to the nature of EMDR. However, the research psychologist and research assistants performing all measurements and the treating physician were blinded of group allocation (they had no access to files containing this information, nor were they informed). Participants were instructed to not share their group allocation with the research team nor treating physician. To plan post-treatment measurements, the independent research psychologist provided a start date for both groups falling within 2 weeks after the interview (for the EMDR group this was the date of the intake and for the CAU group a random date was picked).

Measures

Parents and children (≥6 years of age) were asked to fill out online questionnaires (while thinking about a medical event the child experienced). Children aged 6–15 years filled out the same questionnaires. All questionnaires have adequate psychometric properties and Dutch normative data. Questionnaires were filled out at home at baseline and during two follow-up measurements that were planned 8 weeks and 8 months after the start of EMDR/CAU. Study data were collected and managed using GemsTracker.[36]

Post-traumatic stress symptoms (primary outcome)

The Dutch version of the Children's Responses to Trauma Inventory (CRTI)[33] provides a reliable and valid self-report (for ages 8–18) and parent-report (for ages 4–18) measure of the DSM-IV-TR PTSD symptoms. It contains 24 PTSD items divided into three symptom clusters of PTSD (intrusion, avoidance, and hyperarousal). The PTSD total score can range from 17 to 85, with a higher score indicating more problems. Internal consistency was .75, .90, and .88 for self-report and 0.87, 0.92, and 0.90 for parent-report at T1, T2 and T3, respectively (Cronbach's α).

Additionally, semi-structured interviews were administered (only to participants meeting at least one of the two CRTI criteria mentioned before) to exclude children with a full diagnostic PTSD. The interview scores were not used for statistical analyses. We used the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA) [34] for all participants aged 8–15 and the PTSD module of the DIPA[35] for all parents of participants aged 4–7. The interviews were administered by the research psychologist (trained in both instruments) at the Erasmus MC Sophia Children's Hospital.

Symptoms of depression (secondary outcome)

The Dutch Children's Depression Inventory 2 (CDI-2; 8–21 years)[37] has a parent version with 17 items on a 4-point Likert scale and a child version with 28 items on a 3-point Likert scale. The range of the total score of all items is 0 to 51 for parent report and 0 to 56 for child report. A higher score indicates more problems. Internal consistency was 0.81, 0.86, and 0.85 for self-report and 0.82, 0.84, and 0.86 for parent-report at T1, T2, and T3, respectively (Cronbach's α).

Symptoms of blood–injection–injury phobia (secondary outcome)

The BII subscale of the Screen for Child Anxiety Related Emotional Disorders (SCARED-NL; 7–19 years)[38] was used to measure child-report and parent-report of symptoms of BII phobia of the child. The BII subscale consists of 7 items and its total score ranges from 0 to 14 with a

higher score indicating more problems. Internal consistency was 0.74, 0.69, and 0.73 for child-report and 0.71, 0.76, and 0.74 for parent-report at T1, T2, and T3, respectively (Cronbach's α).

Sleep problems (secondary outcome)

Children filled out the Dutch Sleep Self Report (SSR; 23 items; 7–12 years)[39] and parents filled out the parallel parent version called Child Sleep Habits Questionnaire (CSHQ; 35 items; 4–10 years).[40] Maximum total scores are 69 for the SSR and 99 for the CSHQ. Again, a higher score indicates more sleep problems. Internal consistency was 0.73, 0.80, and 0.81 for the SSR and 0.81, 0.83, and 0.82 for the CSHQ at T1, T2, and T3, respectively (Cronbach's α).

Health-related quality of life (secondary outcome)

The TNO-AZL Questionnaires for Children's Health-Related Quality of Life (TACQOL; 8–15 years) provides a reliable and valid description of health-related quality of life.[41] Based on the 63 items, seven subscales can be computed, namely: body, motor, autonomy, cognition, social, positive emotions, and negative emotions. In contrast to the other questionnaires used, a higher score on the TACQOL subscales indicates better HrQoL. Cronbach's α on most subscales ranged from 0.66–.81, 0.62–0.82, and 0.66–0.83 for self-report and from 0.62–0.88, 0.66–0.90, and 0.74–0.92 for parent report at T1, T2, and T3, respectively. The only poor to inadequate internal consistencies were found for the subscale autonomy: Cronbach's α was 0.66, 0.62, and 0.32 for self-report and 0.59, 0.52, and 0.44 for parent report at T1, T2, and T3, respectively.

Demographics

Demographic information was gathered with the general scale of the Rotterdam's Quality of Life Interview.[42] Furthermore, we checked for the experience of non-medical stressful life events using the life events scale of the Cognitive Emotion Regulation Questionnaire.[43]

Intervention

The intervention was provided using the Dutch version of the standard EMDR protocol for children.[44] Young children or children with preverbal memories were treated with the modified protocol by Lovett.[45,46] In accordance to the standard protocol, children could make a drawing of their distressing medical experiences during therapy to facilitate a mental representation of the memory. All EMDR sessions took place at the Erasmus MC Sophia Children's Hospital in Rotterdam, the Netherlands and were provided by five licensed and experienced clinical psychologists. Sessions were planned once a week and lasted approximately 50 min. Parents were allowed to be present during the sessions when the child agreed on this with the therapist but were instructed not to interfere with the session. EMDR treatment was completed when Subjective Units of Distress of all selected memories regarding the medical trauma were zero. Only when this was impossible, EMDR treatment was ended when positive cognitions were established (rated by the child) and child, parents and therapist agreed that PTSD symptoms had sufficiently decreased. Therapists reported all details and dates to the independent researcher who documented this in protected files.

Children in the CAU (care-as-usual control) group also received standard medical care and standard study-related procedures (psychological screening and interview). They did not receive EMDR or any other form of psychotherapy.

Treatment integrity

Treatment integrity was ensured by providing regular supervision by an EMDR Europe consultant (licensed EMDR supervisor) and by rating all videotaped or documented sessions of 10 randomly chosen children (27%) as to adherence to the protocol. Rating was done by a research psychologist trained in the EMDR protocol and by two trained Master students in psychology (supervised by the aforementioned research psychologist) using an EMDR-specific treatment integrity checklist (16 items). A total score ranging from 0 to 16 can be computed from the checklist with a higher score indicating higher protocol adherence. All total scores given independently by all three raters were ranging between 13 and 16, indicating high agreement between the raters and high treatment integrity.

Statistical analyses

We used *t*-tests and χ^2 tests where appropriate to test differences in baseline characteristics between the EMDR and CAU groups.

We conducted Generalized Estimating Equations (GEE) with an unstructured correlation matrix to examine the effect of the intervention on all outcomes. The GEE analysis accounted for all assessments and were performed using intention-to-treat principles. Every outcome was analysed separately. We included time of the assessments in every GEE analyses and added the interaction between group (EMDR vs. CAU) to test for the effects of the intervention. *Wald* χ^2 tests indicated whether the interactions were significant. If interactions were significant, we conducted subsequent analyses in which we included age, gender and whether the child had experienced ≥1 other non-medical stressful life event as covariates. For explorative analyses, we ran the same GEE analyses again separated by group (cardio vs. ED).

P-values of <0.05 were considered significant. Cohen's *d* effect sizes were computed as the interaction effect of group by time multiplied by the number of weeks at the endpoint divided by the pooled standard deviations of the outcomes at T1.[47] GEE accommodates missing data. SPSS version 24.0 was used for all statistical analyses.[48]

Results

General characteristics

We randomized 74 children to the EMDR ($n = 37$) and CAU ($n = 37$) group (see *Figure 1*). There were no significant differences between both groups on demographic baseline variables (see *Table 1*). The average number of EMDR sessions received was $M = 3.53$ ($SD = 1.90$; range 1–9). Every child in the EMDR group was treated for at least one medically related distressing memory. The follow-up assessments took place $M_{T2} = 9.75$ ($SD = 2.28$) weeks and $M_{T3} = 8.15$ ($SD = 0.57$) months after the start of EMDR/CAU. The time between baseline and follow-up assessments was not different for both groups. Two participants of the CAU group reported the start of mental health care after the 8 weeks follow-up. No study-related adverse events were communicated.

Long-term effectiveness of EMDR

Primary outcome

Child report: The interaction of group by time was not significant for PTSD symptoms reported by the child (see *Table 2*). The improvement over time was also not significant for child-reported PTSD symptoms ($b = -0.02$, $P = 0.641$).

Parent report: The interaction of group by time was not significant for parent-reported PTSD symptoms of the child neither (see *Table 2*). However, the improvement of child PTSD symptoms over time reported by parents was significant ($b = -0.20$, $P = 0.000$).

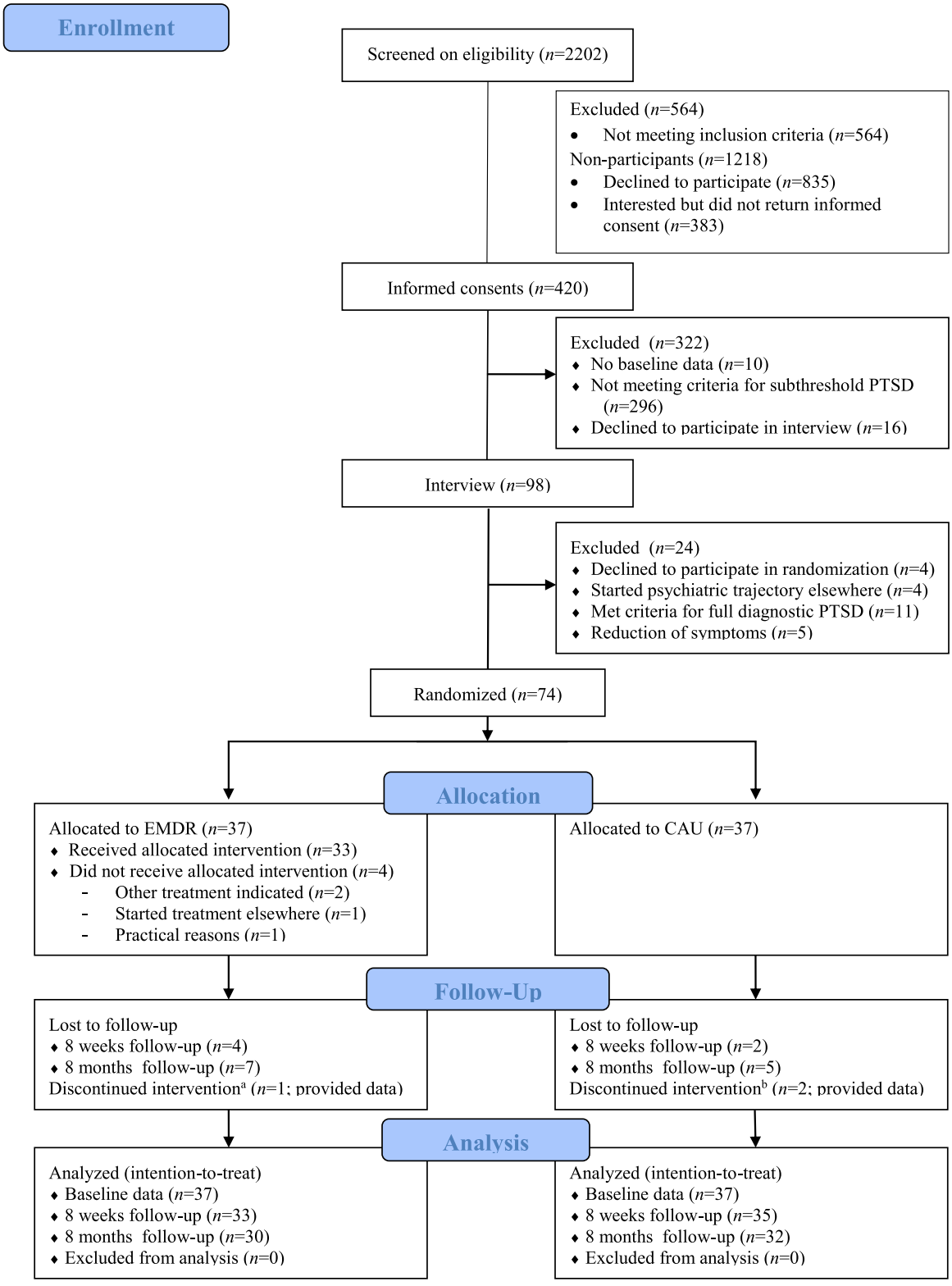

Figure 1 CONSORT flow chart.
[a]Did not show up for last sessions and did not answer to calls nor e-mails. [b]Two participants of the CAU group started mental health services after T2. Participation rate: 100/(total non-participants + informed consents) *informedconsent

Table I Baseline demographics

	N	Total	EMDR group (n = 37)	CAU group (n = 37)	χ^2 or t value	P-value
Child						
Age in years, M ± SD	74	9.6 ± 2.9	9.8 ± 2.7	9.4 ± 3.1	-0.52	0.60
Gender—male, *n* (%)	74	49 (66.2)	25 (67.6)	24 (64.9)	0.06	0.81
Ethnicity, *n* (%)	72				3.20	0.20
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)		
Prior non-medical stressful life event, *n* (%)	67				0.03	0.86
Yes		55 (82.1)	29 (82.9)	26 (81.3)		
No		12 (17.9)	6 (17.1)	6 (18.8)		
Parental						
Education, *n* (%)	74				0.36	0.84
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						
Department, *n* (%)	74				0.05	0.82
Cardiology		39 (52.7)	19 (51.4)	20 (54.1)		
Emergency department		35 (47.3)	18 (48.6)	17 (45.9)		
Trauma type, *n* (%)	74				0.32	0.57
I—Single PTME		16 (21.6)	9 (24.3)	7 (18.9)		
II—Multiple PTMEs		58 (78.4)	28 (75.7)	30 (81.1)		
No. of hospitalizations, M ± SD	71	4.01 ± 4.00	4.5 ± 4.4	3.6 ± 3.5	-0.98	0.33
Length of hospitalization(s) in days, M ± SD	59	28.14 ± 47.23	31.7 ± 54.9	24.2 ± 37.6	-0.61	0.55
Time since last medical event in years, M ± SD	71	1.76 ± 1.42	1.7 ± 1.5	1.8 ± 1.4	0.27	0.79
Type of medical event, *n* (%)	74				0.45	0.93
Heart disease		39 (52.7)	19 (51.4)	20 (54.1)		
Accident (motor-vehicle)		7 (9.5)	3 (8.1)	4 (10.8)		
Accident (other)		14 (18.9)	7 (18.9)	7 (18.9)		
Acute illness		14 (18.9)	8 (21.6)	6 (16.2)		

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

Secondary outcomes

Child report: There were no significant interactions of group by time for any of the secondary child-report outcomes (see *Table 2*). Both groups showed improvements on the secondary outcomes over time: depressive symptoms (b = -0.06, P = 0.000), symptoms of BII phobia (b = -0.05, P = .000), sleep problems (b = -0.04, P = 0.020), HrQoL-body (b = 0.07, P = 0.000), HrQoL-Motor (b = 0.03, P = 0.022), HrQoL-Autonomy (b = 0.02, P = 0.034), HrQoL-Cognitive (b = 0.04, P = 0.004), HrQoL-Positive Emotions (b = 0.03, P = 0.000), and HrQoL-Negative Emotions (b = 0.02, P = 0.004). The improvement over time was not significant for child-reported HrQoL-Social (b = 0.03, P = 0.053).

Parent-report: One interaction of group by time was significant for parent-report (see *Table 2*). That is, EMDR was more effective than CAU in reducing parent-reported BII-phobia of the child. This interaction was still significant when controlling for age, gender, and other non-medical stressful life events (b = -0.03, P = 0.033). Furthermore, both groups showed improvements on the following secondary outcomes over time: depressive symptoms (b = -0.04, P = 0.009), symptoms of BII phobia (b=-0.03, P = 0.000), sleep problems (b = -0.07, p = 0.000), HrQoL-body (b = 0.03, P = 0.037), HrQoL-Cognitive (b = 0.03, P = 0.045), HrQoL-Social (b = 0.03, P = 0.001), and HrQoL-Negative Emotions (b = 0.03, P = 0.000). The improvement over time was not significant for parent-reported HrQoL-Motor (b = 0.02, P = 0.083), HrQoL-Autonomy (b = 0.01, P = 0.108), and HrQoL-Positive Emotions (b = 0.00, P = 0.543).

Explorative analyses

One interaction of group by time was significant when running the GEE analyses by group. For the cardiology group, EMDR was more effective than CAU in reducing parent-reported BII-phobia of the child (b = -0.06, P = 0.000). The same interaction was not significant

Table 2 Means and standard deviations for child- and parent-reported outcomes at T1, T2 and T3, and interaction effects of group by time

	EMDR			CAU			GEE analyses		
	T1 ($n = 37$)	T2 ($n = 33$)	T3 ($n = 30$)	T1 ($n = 37$)	T2 ($n = 35$)	T3 ($n = 32$)	B^a	P^b	Effect size[c] (95% CI)
Child report									
CRTI PTSD score	45.00 ± 9.17	32.00 ± 11.80	29.97 ± 10.93	44.37 ± 8.32	31.54 ± 11.76	30.77 ± 10.75	-0.10	0.26	-0.37 (-0.85, 0.12)
CDI-2 total score	11.23 ± 6.04	6.17 ± 5.27	6.18 ± 5.22	9.03 ± 6.38	7.07 ± 6.55	6.58 ± 6.21	-0.05	0.06	-0.25 (-0.73, 0.23)
SCARED BII	6.31 ± 3.23	4.30 ± 2.83	3.75 ± 2.40	5.16 ± 3.12	4.37 ± 3.20	3.15 ± 3.43	-0.00	0.85	-0.03 (-0.51, 0.45)
SSR	38.63 ± 6.48	33.80 ± 6.04	33.57 ± 7.24	35.41 ± 4.92	34.59 ± 6.80	33.04 ± 5.71	0.05	0.21	0.30 (-0.19, 0.78)
TACQOL Body	22.54 ± 5.13	25.80 ± 4.06	25.07 ± 5.19	22.44 ± 6.04	23.56 ± 5.89	26.96 ± 5.71	-0.06	0.06	-0.36 (-0.84, 0.13)
TACQOL Motor	27.14 ± 5.74	29.83 ± 3.71	27.86 ± 4.63	28.00 ± 4.23	28.78 ± 3.75	30.42 ± 2.16	-0.05	0.09	-0.31 (-0.79, 0.18)
TACQOL Auto	30.26 ± 2.59	30.97 ± 2.28	30.75 ± 1.67	30.59 ± 2.86	30.85 ± 2.43	31.62 ± 0.75	-0.02	0.28	-0.19 (-0.67, 0.30)
TACQOL Cognit	25.63 ± 6.01	27.00 ± 4.91	28.46 ± 4.16	24.78 ± 6.03	25.63 ± 6.45	26.27 ± 5.70	0.01	0.76	0.05 (-0.43, 0.53)
TACQOL Social	27.11 ± 5.37	29.17 ± 3.33	28.43 ± 3.48	28.63 ± 4.32	28.52 ± 3.94	29.69 ± 3.51	0.00	0.86	0.03 (-0.45, 0.51)
TACQOL EmPos	12.26 ± 2.66	14.17 ± 2.17	13.57 ± 3.00	12.56 ± 3.02	13.04 ± 2.93	14.35 ± 2.04	-0.01	0.66	-0.08 (-0.56, 0.40)
TACQOL EmNeg	11.54 ± 2.85	13.20 ± 2.16	13.25 ± 2.65	11.53 ± 3.13	11.78 ± 3.07	12.38 ± 3.06	0.02	0.31	0.18 (-0.30, 0.66)
Parent report									
CRTI PTSD score	44.51 ± 10.80	32.94 ± 10.44	29.37 ± 9.04	43.46 ± 9.78	35.43 ± 12.58	32.19 ± 10.77	-0.03	0.56	-0.11 (-0.57, 0.34)
CDI-2 total score	17.59 ± 6.42	12.06 ± 6.03	12.17 ± 6.75	14.65 ± 6.63	12.14 ± 7.20	11.63 ± 6.92	-0.00	0.95	-0.01 (-0.47, 0.45)
SCARED BII	5.38 ± 3.06	4.52 ± 3.05	2.97 ± 2.08	4.49 ± 3.05	4.17 ± 3.48	4.16 ± 3.38	-0.03	0.01*	-0.36 (-0.82, 0.11)
CSHQ	51.14 ± 8.61	46.12 ± 8.20	44.48 ± 7.13	48.76 ± 7.96	47.35 ± 8.15	46.56 ± 8.50	-0.05	0.15	-0.20 (-0.66, 0.26)
TACQOL Body	24.16 ± 4.46	25.50 ± 4.05	26.62 ± 4.19	24.46 ± 4.72	25.73 ± 4.43	25.78 ± 4.99	0.03	0.30	0.19 (-0.27, 0.64)
TACQOL Motor	27.51 ± 4.26	29.47 ± 3.15	29.45 ± 2.44	28.76 ± 3.83	29.48 ± 3.62	28.75 ± 4.25	0.04	0.06	0.34 (-0.12, 0.80)
TACQOL Auto	29.57 ± 2.74	30.34 ± 2.16	30.07 ± 2.20	30.08 ± 2.55	30.24 ± 2.36	30.59 ± 2.15	0.00	0.93	0.01 (-0.44, 0.47)
TACQOL Cognit	25.22 ± 4.80	26.06 ± 5.51	28.69 ± 4.38	25.65 ± 5.49	26.67 ± 6.17	25.97 ± 5.92	0.06	0.06	0.36 (-0.10, 0.82)
TACQOL Social	26.76 ± 3.52	28.88 ± 3.37	29.38 ± 2.88	28.41 ± 3.63	28.36 ± 4.60	29.13 ± 3.83	0.02	0.21	0.19 (-0.27, 0.65)
TACQOL EmPos	13.24 ± 3.03	14.66 ± 2.16	14.07 ± 3.06	13.70 ± 2.73	13.85 ± 2.95	14.22 ± 2.57	-0.00	0.78	-0.04 (-0.49, 0.42)
TACQOL EmNeg	9.92 ± 3.30	12.06 ± 2.85	12.52 ± 2.08	10.54 ± 3.01	11.42 ± 2.84	11.59 ± 3.04	0.02	0.10	0.26 (-0.20, 0.72)

Data are represented as mean ± standard deviation.

CAU, care-as-usual; CDI-2, Children's Depression Inventory 2; CI, confidence interval; CRTI, Children's Responses to Trauma Inventory; CSHQ, Child Sleep Habits Questionnaire; PTSD, post-traumatic stress disorder; SCARED BII, BII subscale of the Screen for Child Anxiety Related Emotional Disorders; SSR, Sleep Self Report; TACQOL, TNO-AZL Questionnaires for Children's Health-Related Quality of Life.

[a]GEE analyses. Interaction of group by time.

[b]GEE analyses. *P*-values indicates level of significance of the group by time interaction. *Significant.

[c]Cohen's *d*.

for the ED group (b = -0.00, P = 0.854).

Discussion

The present RCT examined the long-term effectiveness of EMDR on PTSD symptoms and other psychological complaints in children with medically related subthreshold PTSD. The results show that most outcomes improved over time with one significant difference between the EMDR and CAU group.

We found preliminary evidence that EMDR was significantly superior than CAU in reducing parent-reported symptoms of children's BII-phobia. It is possible that this was a random finding. However, it is supported by earlier research that has found EMDR to be effective in reducing dental phobia.[49,50] This could have high clinical relevance as phobic people tend to avoid the source of their fear. Consequently, children with symptoms of BII-phobia might avoid medical treatment. This is especially concerning considering the necessity of continuous medical checkups for children affected by a heart disease. By reducing BII phobia symptoms, EMDR contributes to medically necessary adherence. Future research is needed before validated statements can be made. This is also true considering the fact that we only found a superior long-term effect for parent-reported BII-phobia of the child. On self-report, both the EMDR and the CAU group showed improvement. Nevertheless, it has been argued that parent report might identify recovery from anxiety symptoms better than child report.[51] Unfortunately, we could not control for parental psychopathology, which has been found to influence parent report of the child's mental health, as we did not measure parental psychopathology.[52] Our results regarding the effectiveness of EMDR in treating BII phobia symptoms warrants further research in this area. Especially as the effect of EMDR on BII phobia seemed to be present in the cardiology group only.

Our results that EMDR was not superior than CAU in reducing symptoms of PTSD, depression, and sleep problems and in improving HrQoL over time are not in line with earlier studies with ≥6 months post-treatment follow-ups.[23–25] In our view, there are five major possible explanations for this. *First*, CAU did not represent standard medical care in this study as all participants received detailed information about possible reactions to a potentially traumatic medical event (through an information letter), a psychological screening (i.e. questionnaires), an interview about PTSD symptoms with a psychologist and a conversation together with their parents about the nature of their PTSD symptoms after the interview. Trauma-related symptoms were thereby acknowledged, validated, and normalized. This is not part of standard medical care in the Netherlands. It has been found earlier that merely participating in a psychological study and/or receiving psychoeducation can improve mental health.[53–55] *Second*, the average PTSD symptom scores appear lower in our sample (age 4–15) compared to the sample of De Roos *et al.*[24] who also used the CRTI to measure PTSD symptoms in treatment-seeking youth (age 8–18) following single-incident trauma. It is possible that EMDR shows its superior effects only when symptom severity is high, whereas a brief trauma-focused psychoeducational intervention might be equally effective when symptom severity is moderate. This is in line with research into online interventions based on cognitive behavioural therapy that found improvements and usefulness primarily in children and adults with high initial PTSD symptom levels following medical events.[56–58] *Third*, it is likely that participants of both groups were more motivated than non-participants to address psychosocial needs and seek help, which might have washed out differences between the EMDR and CAU group on the long run. Furthermore, more than half of all participants had at least one parent with a high educational level. Together with professional psychological attention, motivation and cognitive skills might have led to improvements in the CAU group. *Fourth*, although our sample size of 74 children was close to the aimed 78 participants, perhaps we would have found significant group differences with a larger sample size. *Fifth*, most outcome variables improved over time regardless of the group. Therefore, it might be possible that our study showed natural improvements without any study-related effects. However, children were included into the study on average almost 2 years after their last medical event and still showed subthreshold levels of PTSD at baseline. Therefore, the chances seem small that the significant improvements are unrelated to the study.

Strengths and limitations

While this study is the first to evaluate the effectiveness of EMDR in a relatively large sample of children with medically related subthreshold PTSD recruited throughout the Netherlands, including a broad age range, multi-informant outcomes, high treatment integrity, and single-blind randomization, some limitations must be considered. *First*, it is possible that some participants in the CAU group might have arranged psychosocial treatment for themselves during the study period. However, participants were asked friendly to communicate any contact with a mental health specialist during the study period. Two children of the CAU group started EMDR elsewhere between both follow-up assessments. *Second*, we did not measure parental mental health nor did parents receive treatment. Research suggests that parental mental health is a strong predictor for child PTSD symptoms and that involving parents in the treatment of their child might be beneficial.[59–62] *Third*, it must be noted that the used self-report questionnaires were not validated for children aged 6 and 7 years old. However, our main aim was to compare changes between the EMDR and CAU group over time (and not to make comparisons to the normative data). It is still possible that their responses were biased because parents helped them to fill out the questionnaires. *Fourth*, families with a low educational level were underrepresented in this study which might limit generalizability of the findings. *Fifth*, participation rate was low in our sample (26%, see *Figure 1*) which may limit generalizability of our findings. *Sixth*, it was not the scope of the article to explore whether severity of the heart condition is related to treatment outcome. This could be relevant for future studies. *Finally*, this study is the first RCT investigating the effectiveness of EMDR specifically for children with medically related subthreshold PTSD. It is unclear to which extent our findings are generalizable to other kind of traumas or to children with full diagnostic PTSD.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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