ORIGINAL CONTRIBUTION

Trauma-focused cognitive behavioral therapy or eye movement desensitization and reprocessing: what works in children with posttraumatic stress symptoms? A randomized controlled trial

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Received: 23 November 2013 / Accepted: 4 June 2014 © Springer-Verlag Berlin Heidelberg 2014

Abstract To prevent adverse long-term effects, children who suffer from posttraumatic stress symptoms (PTSS) need treatment. Trauma-focused cognitive behavioral therapy (TF-CBT) is an established treatment for children with PTSS. However, alternatives are important for nonresponders or if TF-CBT trained therapists are unavailable. Eye movement desensitization and reprocessing (EMDR) is a promising treatment for which sound comparative evidence is lacking. The current randomized controlled trial investigates the effectiveness and efficiency of both treatments. Forty-eight children (8-18 years) were randomly assigned to eight sessions of TF-CBT or EMDR. The primary outcome was PTSS as measured with the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA). Secondary outcomes included parental report of child PTSD diagnosis status and questionnaires on comorbid problems. The Children's Revised Impact of Event Scale was administered during the course of treatment. TF-CBT and EMDR showed large reductions

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Department of Psychiatry, Four Algheny Center, Drexel University College of Medicine, Pittsburgh, PA 15212, USA from pre- to post-treatment on the CAPS-CA (-20.2; 95 % CI -12.2 to -28.1 and -20.9; 95 % CI -32.7 to -9.1). The difference in reduction was small and not statistically significant (mean difference of 0.69, 95 % CI -13.4 to 14.8). Treatment duration was not significantly shorter for EMDR (p = 0.09). Mixed model analysis of monitored PTSS during treatment showed a significant effect for time (p < 0.001) but not for treatment (p = 0.74). Parents of children treated with TF-CBT reported a significant reduction of comorbid depressive and hyperactive symptoms. TF-CBT and EMDR are effective and efficient in reducing PTSS in children.

Introduction

American and European studies report that 14–67 % of the studied children experienced at least one traumatic event before they have reached adulthood [1–3]. The majority of these children do not suffer from negative long-term effects. However, about 0.5–3 % develops full posttraumatic stress disorder (PTSD) and 13.4 % suffers from some posttraumatic stress symptoms (PTSS) [2, 3]. All of these children need attention since children with full and partial PTSD may experience impairment and distress to the same degree [4]. Impairment in educational and social functioning can also have negative long-term consequences for adult life. Furthermore, untreated PTSD can lead to the development of other anxiety, mood or substance use disorders [5]. To prevent these adverse long-term effects, treatment of PTSD is essential.

International guidelines for the treatment of PTSD advise trauma-focused cognitive behavioral therapy (TF-CBT) for the treatment of children with PTSD [6, 7]. Several reviews have confirmed these guidelines with findings indicating that TF-CBT leads to more reduction of PTSD than control conditions [8–10]. TF-CBT is the most researched therapy for children with PTSD. The protocol developed by Cohen et al. [11] has been applied in numerous randomized controlled trials (RCTs; see [8] for an overview). In these RCTs, children were included who experienced multiple types of trauma. Other TF-CBT protocols have mainly been studied in more homogeneous groups like children who were exposed to a motor vehicle accident or to violence (e.g., [12, 13]). Although well researched, TF-CBT has been subject to criticism: About 16-40 % of the treated children continue to fulfill diagnostic criteria for PTSD after treatment [14].

An alternative treatment option for these children may be eye movement desensitization and reprocessing (EMDR [15]). EMDR has been put into practice for the treatment of children with PTSD during the past 10 years. The guidelines for PTSD by the National Institute for Health and Care Excellence (NICE [6]) judged this treatment to show promising results. However, EMDR does not yet have the categorization of "evidence-based" like TF-CBT since it is less well researched in children with PTSD.

So far, EMDR and protocols similar to TF-CBT have been compared in two RCTs in children with PTSD. On the basis of these RCTs, it has been argued that EMDR is as effective as CBT and more efficient than CBT. In the study by Jaberghaderi, Greenwald, Rubin, Zand and Dolatabadi [16], 14 sexually abused girls received up to 12 sessions of either therapy. The authors found significant reductions of PTSS from pre- to post-treatment in both conditions. The between treatment comparison for PTSS was nonsignificant, but treatment length was significantly shorter in the EMDR group. However, this study suffered from a very small sample size and the lack of involvement of any expert TF-CBT consultants.

The second RCT of CBT versus EMDR has been conducted by de Roos et al. [17]. They randomly assigned 52 children who had experienced a firework disaster to four sessions EMDR or CBT with a possible extension of the treatment duration. Both treatments were effective in reducing PTSS. The treatment duration was significantly shorter for EMDR. However, EMDR was compared to a more general CBT treatment in this study, not TF-CBT.

There are three major problems with the design of these two RCTs that could account for the difference in treatment duration: First, in the study by Jaberghaderi et al. [16], the duration of the CBT treatment was set to a minimum of ten sessions, whereas the EMDR treatment was not. Therefore, treatment duration was biased from the start. Second, in both RCTs, early termination of the treatment was determined on the basis of subjective outcomes rather than standardized instruments. Application of standardized instruments is necessary to produce a valid result. Thirdly, symptoms were not measured at the same point of time (i.e., after a standard number of sessions or a standard duration in time). Therefore, it is impossible to say whether one treatment is indeed more efficient than the other since outcomes for different points in time cannot be compared.

The current study compared TF-CBT and EMDR in children with PTSS in an RCT conducted in a Dutch outpatient facility. Specifically, we addressed the following research questions: What are the effects of TF-CBT and EMDR in the outpatient setting? Which of the two treatments is more effective? And which of the two treatments is more efficient in terms of the number of treatment sessions?

Methods

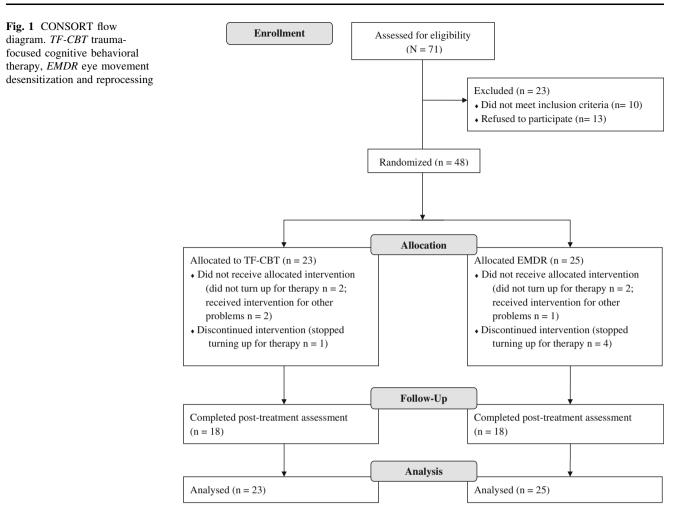
Study design

The present study was a prospective randomized openlabel blinded endpoint (PROBE) trial with two parallel groups comparing TF-CBT and EMDR. After informed consent, participants were individually randomized to one of the two conditions. Randomization was performed with an allocation ration 1:1 using block randomization stratified by age. A methodologist prepared the randomization list which was managed by a researcher who was not further involved in the current project. The researcher managing the randomization list directly communicated the assigned condition to the therapist.

Participants

Children were recruited at the trauma center of the department of child and adolescent psychiatry, de Bascule, of the Academic Medical Centre in Amsterdam. Recruitment took place from May 2009 to June 2012. Since published research on this topic is lacking, we estimated a feasible sample size and calculated the effects that could be demonstrated with this sample size: With 75 children per treatment group, we could demonstrate a mean delta difference of 3 points considering a standard deviation of 6.5 points with a power of 80 % and a significance level of 5 % (two sided).

Eligible were children meeting the following inclusion criteria: age between 8 and 18 years; command of the Dutch language; exposure to at least one single traumatic event; the last traumatic event occurred at least 4 weeks prior to the first measurement; and partial or full PTSD as reported by the child (interviewed with the CAPS-CA) or



the caretaker (interviewed with the ADIS-P PTSD module). Partial PTSD was defined as either fulfilling two of the three symptom clusters or one symptom present in each of the three symptom clusters [18, 19]. Children showing clinical signs of psychotic disorder, substance use disorder, pervasive developmental disorder (e.g., autism) or acute suicidality were excluded. After 12 months of slow recruitment, we adjusted the inclusion criteria in order to also include children who had experienced multiple-event trauma. Figure 1 describes the flow of participants in a CONSORT flowchart.

Informed consent was obtained from parents/caretakers of all participants and from children older than 11 years. The current study was approved by the Medical Ethics Committee of the Academic Medical Centre in Amsterdam and is registered in the Dutch trial register, trial id: NTR1814.

Outcome measures

For all children, assessments took place prior to and posttreatment with at least 8 weeks in between. All instruments were administered by trained psychologists. Assessors were blinded to the allocated treatment condition of the children. The CRIES-13 was besides pre-and post-treatment also administered after sessions two, four and six.

Primary outcome measure

Children were interviewed with the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA [20]). The CAPS-CA has widely become known as gold standard for the assessment of PTSD in children. It is a standardized clinical interview developed to assess the 17 PTSSs that complies with the DSM-IV-TR standards. The interviewer can rate the frequency and the intensity for each symptom on a five-point Likert scale. The overall severity score can vary between minimal (<20) and extreme (>79–136). Besides this continuous score, each symptom can be rated as present or absent. For this, we chose the most frequently used scoring rule "frequency at least 1 and intensity at least 2" as proposed by Weathers, Ruscio and Keane [21] to score a symptom as being present. The Dutch version of the CAPS-CA has shown

good psychometric properties (Cronbach's α 's: 0.62–0.83; ICC for interrater reliability: 0.97–0.99, [22]).

Secondary outcome measures

We interviewed parents with the Anxiety Disorder Interview Schedule for DSM-IV: Child and Parent interview schedule (ADIS C/P [23]) to inquire about PTSD diagnosis status of their child. In this structured clinical interview, symptoms can be rated as either present or absent. The Children's Revised Impact of Event Scale (CRIES-13 [24, 25]) is a screening tool for PTSS. This self-report questionnaire consists of 13 items which can be scored as never (0), rarely (1), sometimes (3) or often (5). The items are clustered in three subscales: avoidance, re-experiencing and arousal. In our sample, we found Cronbach's $\alpha = 0.83$ for the total scale and 0.79, 0.64 and 0.70 for the three subscales intrusion, avoidance and arousal, respectively. Children and parents filled out the Revised Child Anxiety and Depression Scale (RCADS [26]). Forty-seven items inquire about symptoms of anxiety and depression. Items are scored one a four-point Likert scale ranging from 0 (never) to 3 (always). In our study, Cronbach's α for the subscales of the child version was as follows: 0.87 for social phobia (SP); 0.87 for panic disorder (PD); 0.83 for generalized anxiety disorder (GAD); 0.93 for major depressive disorder (MDD); 0.78 for separation anxiety disorder (SAD); and 0.70 for obsessive compulsive disorder (OCD). Cronbach's α for the parent version was as follows: 0.89 for SP; 0.88 for PD; 0.86 for GAD; 0.90 for MDD; 0.77 for SAD; and 0.85 for OCD. The Strength and Difficulties Questionnaire (SDQ [27]), is a brief behavioral screening questionnaire with five subscales. The 25 items can be scored as 0 = not true, 1 = somewhat true, or 2 = certainly true. We administered the parent version in the current study. In our sample, Cronbach's α for the subscales was as follows: 0.81 for emotional problem; 0.51 for conduct problems; 0.74 for hyperactivity/inattention; 0.58 for peer problems; and 0.65 for prosocial scale.

Interventions

Both conditions consisted of a maximum of eight sessions with 60-min duration, which were given on a weekly basis. Eight experienced CBT therapists delivered the treatment in this study. They were trained in both TF-CBT and EMDR before they became involved in the study. Half of the therapists were EMDR practitioners and two had just completed the basic and advanced EMDR training. For the TF-CBT protocol, therapists completed a training by either Laura Murray or Anthony Mannarino. Supervision was provided weekly by an expert on EMDR for children (Renée Beer) and experts on TF-CBT (Renée Beer and Ramón Lindauer, both TF-CBT trainers). To ensure treatment fidelity, therapists filled out protocol-specific checklists and recorded each session on video. A random selection of 25 % of all videos was evaluated for treatment integrity. Treatment integrity as scored by the therapists was for both conditions larger than 70 % (75 % for EMDR and 73 % for TF-CBT). The rating of the video records by two independent raters resulted in an interrater reliability with the therapist of $\kappa = 0.66$, indicating good reliability of the therapists' scores.

Therapists had to work through all modules. However, they were free in shortening the time they spend on each module and could therefore terminate treatments early, meaning in less than eight sessions if: (1) all modules had been administered; (2) the child's total score on the CRIES-13 was lower than 10 points; and (3) child and parent agreed with early termination.

TF-CBT

For the TF-CBT condition, we followed the protocol as developed by Cohen et al. [11]. In consultation with Anthony Mannarino, we adapted the original 12 sessions version of the protocol and fitted the modules into eight sessions. Components that are included in this program are as follows: psycho-education; relaxation; affective expression and regulation; cognitive coping; gradual exposure by creating the child's trauma narrative; parent management skills; conjoint child-parent session; and enhancing future safety and development. Children worked on their trauma narrative in sessions four, five and six and shared the narrative with their parents in session seven. Parents were invited to also join sessions one, two, three and eight or spent 15 min of a session alone with the therapist.

EMDR

In the current study, the Dutch EMDR protocol for children and adolescents was used [28]. This protocol is based on Shapiro's EMDR protocol that was originally developed for adults [15]. The main components of this protocol include the following: psycho-education about the trauma and the therapy; preparation of the target memory, desensitization of the memory; identification and processing of body sensations; and re-evaluation of the target. Desensitization of the memory started in session three and was pursued till session seven. Children were asked to keep the target image in mind while simultaneously concentrating on the distracting stimulus (typically following the finger of the therapist). After episodes of 30s, the child is asked to report what he/she had just experienced. This is repeatedly done until the target does not induce any more distress in the child. Parents were invited to join 15 min of each session or to spend this time alone with the therapist.

Statistical analysis

All analyses were performed in SPSS 19. Pre-treatment group differences with respect to age, sex, ethnicity and type of traumatic event were assessed using independent samples *t* tests for continuous and χ^2 tests for categorical data.

For the primary outcome, the CAPS-CA, data for all participants were analyzed according to intention to treat principles. Missing values at post-treatment were considered missing at random and were completed using multiple imputation [29]. We imputed five datasets and combined the analyses based on each imputed datasets using Rubin's Rule [29]. We calculated delta scores for pre- to posttreatment and used the independent samples t test to compare TF-CBT and EMDR. For the calculation of effect sizes (Cohen's d) for within group effects, we divided the difference in means between pre- and post-treatment by the standard deviation of the difference in means. For betweengroup differences, the effect size was calculated by subtracting the mean difference of the EMDR group from the mean difference of the TF-CBT group and dividing this difference by the pooled standard deviation of both groups. In addition, we calculated the Reliable Change Index (RCI) to determine whether the magnitude of change on the CAPS-CA was statistically reliable on the individual patient level [30]. An RCI >1.96 indicates that a participant has recovered, while an RCI < -1.96 indicates that a participant has deteriorated.

We analyzed for the ADIS-P interview only those cases that were complete at pre- and post-treatment. Changes in diagnosis status from pre- to post-treatment were analyzed with Fisher's exact test statistic for both treatment conditions separately. For the RCADS and SDQ, we allowed 20 % missing values per subscale. Values were replaced by the individual mean of the valid items of the subscale. We calculated delta scores for pre- to post-treatment and used the independent samples *t* test to compare TF-CBT and EMDR.

For the evaluation of difference in efficiency between the two treatments, we examined the time (number of sessions) until participants finished treatment and used a Kaplan–Meier survival analysis with a log-rank test to compare intervention groups. For the investigation of PTSD symptom change on the CRIES-13, we analyzed the data for all five time points (pre-treatment, after session two, after session four, after session six and post-treatment) in a linear mixed model. Time, treatment condition, the interaction term time \times treatment condition and sex were entered as fixed factors and age as covariate to the model. We chose a compound symmetry matrix as covariance structure since this model showed the smallest AIC value and therefore was judged to have the best fit.

Results

Baseline characteristics

Forty-eight children were randomized to EMDR (n = 25) or TF-CBT (n = 23). Eighteen were male (38 %). On average, children were 13 years old (SD 3.5; range 8-18 years). The large majority was Dutch, 77 % with 46 % having Dutch mothers and 33 % having Dutch fathers. Table 1 reports more detailed information about baseline characteristics of the sample. No major differences were observed in baseline characteristics for children in the two treatment conditions. Children had experienced different kinds of single-event traumas: accidents (23 %), sexual assault (17 %); threat (with weapon) (13 %); kidnapping (10 %); serious illness (7 %); or other (30 %). Exposure to domestic violence (44 %) and sexual assault (39 %) and other (17 %) was reported for multiple-event traumas. Children who experienced a single-event trauma did not differ from children who experienced multipleevent trauma in terms of CAPS-CA severity scores [t(46) = 1.15, p = 0.26].

Dropouts

Twelve children were lost to follow-up before the end of the study: Seven children did not attend any EMDR or TF-CBT session. One child dropped out after the first EMDR session and two children after the second session. One child did not show up for treatment after three TF-CBT sessions and one child after five sessions of EMDR. Treatment non-completers did not differ from treatment completers with respect to demographic variables or scores on the CAPS-CA and ADIS-P. On the questionnaires, treatment non-completers differed only by significantly higher scores on the OCD subscale of the RCADS child version from treatment completers.

Intervention outcome

Primary outcome measure

CAPS-CA scores in both TF-CBT and EMDR groups improved by approximately 20 points, with a difference in improvement of 0.69 (95 % CI -13.4 to 14.8) in favor of EMDR (Table 2). We found a large effect size for TF-CBT of 1.1 and a medium effect size for EMDR of 0.72. For six children in each treatment condition, the RCI was larger **Table 1** Demographics andsample characteristics

Characteristics at baseline	$\begin{array}{l} \text{TF-CBT} \\ (n = 23) \end{array}$	EMDR $(n = 25)$	Total $(n = 48)$	χ^2/t value
Boys (%)	9 (39)	9 (36)	18 (38)	0.05
Child age mean (SD)	12.8 ± 3.2	13.0 ± 3.7	12.9 ± 3.5	-0.21
Child ethnicity, Dutch (%)	17 (74)	20 (80)	73 (77)	0.70
Mother ethnicity, Dutch (%) $(n = 45)$	10 (44)	12 (48)	22 (46)	0.20
Father ethnicity, Dutch (%) $(n = 44)$	7 (30)	9 (36)	16 (33)	0.16
Single-event trauma	17 (74)	13 (52)	30 (63)	2.5
Different kinds of experienced trauma types	6.7	6.3	6.5	0.43

than 1.96. One child showed a clearly deviating pattern in CAPS-CA scores over time, which appeared to be associated with several comorbid problems so this participant could be classified as an outlier. To investigate the impact of this outlier on the overall results, we repeated the primary analysis without this participant, resulting in a similar small and nonsignificant difference in improvement (between-group difference of 3.7; 95 % CI -7.3 to 14.6; p = 0.51).

Secondary outcome measures

Prior to treatment, seven children in the TF-CBT condition were diagnosed with PTSD on the ADIS-P, six fulfilled a partial diagnosis, and four had no PTSD. After treatment, these were one, three and 13. In the EMDR condition, nine children fulfilled a PTSD diagnosis, five fulfilled a partial diagnosis, and one had no diagnosis at pre-treatment. After treatment, this changed to one, seven and seven subsequently. The difference in diagnosis status between preand post-treatment was neither significant for TF-CBT (Fisher's exact test p = 0.45) nor for EMDR (Fisher's exact test p = 0.56).

With respect to child reported comorbid problems, we found in the TF-CBT and the EMDR condition improvements from pre- to post-treatment on all subscales of the RCADS (See for more information Table 2). Parents in the TF-CBT condition also reported improvements on all RCADS subscales and on all but the prosocial subscale of the SDQ. Improvements were significant for the RCADS subscale "major depressive disorder" (p < 0.05) and the SDQ subscale "hyperactivity" (p < 0.05). In the EMDR condition, parents reported improvements on all RCADS subscales but for the "separation anxiety disorder" and the "social phobia" subscales. Parents also reported worse results at post-treatment on the SDQ subscales "conduct problems" and "hyperactivity." On the three other subscales, parents reported small improvements from preto post-treatment. None of the differences from pre- to post- treatment were significant in the EMDR condition. Neither were any between-group differences (See for more information Table 3).

Efficiency of treatments

In the TF-CBT condition, three children terminated their treatment earlier than eight sessions: two finished treatment after seven sessions, and one finished after six sessions. In the EMDR condition, seven children received less than eight sessions: four children received six sessions, two received seven sessions, and one finished treatment after only four sessions. The log-rank test of the Kaplan–Meier survival analysis for the difference in treatment length between groups was not significant, $\chi^2 = 2.84$, p = 0.09.

Another way to investigate differences in efficiency between treatment groups is to use mixed model analysis, where all available measurements over time are included. The parameter of interest is the interaction effect of time by treatment, which reflects whether the treatments differ in average improvement over time. Mixed model analysis of the CRIES-13 results revealed no effect for treatment condition, p = 0.44 or the interaction of treatment by time, p = 0.74. The only significant result we found was for time, p < 0.001.

Discussion

Our RCT of TF-CBT and EMDR suggests that both treatments are effective in children with PTSS in an outpatient setting. Results on both child and parent measures support this conclusion. We found no significant differences between TF-CBT and EMDR on the CAPS-CA. Our effect size for TF-CBT is comparable to the effect size for

	TF-(TF-CBT				EMDR	R				Between	
	и	T1 M (SD)	T2 M (SD)	T1–T2 (95 % CI)	р	и	T1 M (SD)	T2 M (SD)	T1–T2 (95 % CI)	р	$\Delta_{\rm TF-CBT} - \Delta_{\rm EMDR}$ (95 % CI)	<i>p</i> (
CAPS-CA	23	42.3 (15.2)	22.1 (23.3)	-20.2 (-28.1, -12.2)	1.1	25	44.5 (19.4)	23.6 (30.0)	-20.9 (-32.7, -9.1)	0.72	0.69 (-13.4, 14.8)	0.14
RCADS												
sad	13	4.3 (3.7)	3.1 (2.7)	1.2 (-0.49, 2.9)	0.43	8	4.1 (3.5)	3.1 (3.7)	0.98 (-2.6, 4.6)	0.23	0.24 (-3.0, 3.5)	0.06
sp	12	8.2 (4.9)	7.3 (5.7)	0.83(-1.8, 3.5)	0.20	8	5.0(5.0)	3.8 (2.9)	1.3 (-1.7, 4.2)	0.35	-0.42(-4.2, 3.4)	-0.13
gad	13	5.7 (4.7)	5.6 (3.5)	0.08 (-2.7, 2.9)	0.02	8	3.4 (2.2)	1.6 (1.3)	1.8 (0.35, 3.2)	1.0	-1.7 (-5.3, 1.9)	-0.50
pd	13	5.1 (3.6)	3.5 (3.6)	1.5 (-1.2, 4.2)	0.35	8	3.6 (3.7)	2.8 (2.9)	0.88(-0.94, 2.7)	0.40	0.66(-2.9, 4.2)	0.18
ocd	13	4.7 (2.8)	3.00 (2.5)	1.7 (-0.20, 3.7)	0.54	8	3.8 (2.4)	2.1 (1.6)	1.6 (-0.37, 3.6)	0.68	0.11(-2.6, 2.9)	0.04
ppm	13	9.1 (5.2)	7.1 (6.0)	2.0(-1.1, 5.0)	0.39	8	4.7 (4.9)	3.1 (2.0)	1.6(-2.5, 5.6)	0.32	$0.42 \ (-4.3, 5.1)$	0.13
	TF-CBT	3T				EMDR	R				Between	
	и	T1 M (SD)	T2 M (SD)	T1–T2 (95 % CI)	q	и	T1 M (SD)	T2 M (SD)	T1–T2 (95 % CI)	d	d _{TF-CBT} – d _{EMDR} (95 % CI)	р
RCADS												
sad	11	5.8 (2.9)	3.6 (2.8)	2.2 (-0.16, 4.5)	0.63	6	4.3 (3.0)	5.1 (3.1)	-0.74(-3.1, 1.7)	-0.24	2.9 (-0.22, 6.0)	0.89
sp	10	9.3 (3.1)	6.6(4.4)	2.7 (-1.2, 6.5)	0.50	6	6.7 (2.7)	7.4 (2.9)	-0.78(-3.9, 2.3)	-0.20	3.4 (-1.2, 8.0)	0.74
gad	10	5.7 (2.7)	4.8 (2.7)	0.94 (-1.4, 3.2)	0.29	6	4.4 (2.2)	3.4 (2.0)	1.0 (-0.76, 2.8)	0.43	-0.06(-2.8, 2.7)	-0.02
pd	10	3.7 (2.7)	3.2 (2.7)	0.51 (-2.7, 3.7)	0.11	6	3.9 (4.0)	2.5 (2.4)	0.89 (-1.5, 3.2)	0.29	-0.38 (-4.2, 3.4)	-0.10
ocd	11	2.7 (2.3)	1.7 (1.5)	0.99(-0.68, 2.7)	0.40	6	1.9 (2.0)	1.8 (2.2)	0.11 (-2.4, 2.6)	0.03	0.88 (-1.8, 3.6)	0.30
ppm	11	9.3 (4.2)	5.8 (2.9)	3.5 (0.89, 6.2)	06.0	6	6.1 (6.3)	4.8 (3.2)	1.3 (-2.5, 5.2)	0.27	2.2 (-2.0, 6.4)	0.50
SDQ												
emo	11	4.8 (2.9)	2.6 (1.8)	2.1 (-0.18, 4.5)	0.62	6	2.9 (2.2)	2.7 (1.3)	0.22 (-2.0, 2.4)	0.08	1.9(-1.1, 4.9)	0.58
cond	11	2.4 (1.6)	2.1 (1.2)	0.27 (-0.81, 1.4)	0.17	6	1.2 (1.1)	2.3 (1.5)	-1.0(-2.5, 0.40)	-0.55	1.3 (-0.33, 2.9)	0.68
hyper	11	5.8 (2.0)	4.8 (1.7)	1.0 (0.15, 1.9)	0.79	6	5.2 (2.6)	5.7 (2.4)	-0.50(-2.0, 1.0)	-0.25	1.5 (-0.03, 3.0)	0.89
	•	6				(

RCADS Revised Child Anxiety and Depression Scale, sad separation anxiety disorder, sp social phobia, pd panic disorder, mdd major depressive disorder, gad generalized anxiety disorder, ocd obsessive compulsive disorder, SDQ strength and difficulties questionnaire, emo emotional symptoms, cond conduct problems, hyper hyperactivity/inattention, peer peoplems, prosoc prosocial behavior

0.89 0.15 -0.24

1.5 (-0.03, 3.0) $0.25 \ (-1.4, \ 1.9)$ 0.67 (-1.8, 1.1)

0.08 -0.25

0

0.00 (-0.94, 0.94)

-0.50 (-2.0, 1.0)0.11 (-1.0, 1.2)

2.3 (2.0)

6 6 6

0.790.19 -0.21

> 0.36 (-0.92, 1.7) -0.36 (-1.5, 0.77)

8.5 (1.4) 1.6 (1.6) 4.8 (1.7)

8.1 (1.6)

prosoc

1.9 (1.8) 5.8 (2.0)

11 ΞΞ

hyper peer

8.0 (2.0)

8.0 (2.1) 2.4 (2.3) 5.2 (2.6)

CBT that was found by de Roos and colleagues [17] but was smaller than effect sizes that have been found in previous TF-CBT studies (e.g., [31, 32]). Explanations for this relatively small effect size could be differences in protocol length since we used an eight sessions protocol while others used 12 or 16 sessions protocols or differences in study population. With the adaptation of our inclusion criteria, our sample population was not restricted to children who experienced a single traumatic event. However, an explorative analysis showed that the effect sizes for children who experienced single- or multiple-event trauma were about the same, suggesting that treatment effect was not related to trauma type. In contrast to the strong effect size for TF-CBT, we found only for six children in the TF-CBT condition a significant reliable change from pre- to post-treatment. An explanation for this could be that while some children showed very large symptom reductions, others showed only moderate symptom reductions. Since we included besides children with full PTSD also children with partial PTSD, change scores on the CAPS-CA for the latter group might have been low due to a floor effect.

The same concern about reliable change from pre- to post-treatment was found for the results in the EMDR condition. Here were also only six children with a significant reliable change from pre-to post-treatment. One child deteriorated which explains the relatively low effect size for the EMDR condition. Examination of pre-treatment data for this participant showed that this girl scored particularly high on all subscales of the RCADS, indicating high comorbid problems. Results from adult studies suggest that comorbid depression and generalized anxiety are negatively associated with PTSD treatment outcome [33, 34]. Our findings indicate that the same might be true for children. The current sample did not offer a comparable case in the TF-CBT condition so we cannot tell if it is a treatment-specific finding.

Our findings generally imply that EMDR did not reduce comorbid problems effectively: While outcomes on the children's self-report questionnaires indicated that children generally improved on comorbid problems, parents reported more problems for their children after treatment on the RCADS subscales "separation anxiety disorder" and "social phobia" and on the SDQ subscales "conduct problems" and "hyperactivity." These results do not agree with results from previous EMDR studies, which reported significant improvement on measures of anxiety and depression [17, 35]. However, in these studies, only the combined results of measures were reported, whereas results on subscale levels were not. Therefore, we cannot be sure whether our findings are truly different from earlier studies.

In the TF-CBT condition, children and parents reported improvement on comorbid problems. However, only the

improvements on the parent RCADS "major depressive disorder" subscale and the SDQ "hyperactivity" subscale were significant. With respect to depression, our results match previous findings [12]. We could not replicate the findings from studies by Cohen et al. [32] and Smith et al. [12] who found significant within-group difference from pre- to post-treatment on measures of anxiety. Overall, our results on comorbid problems suggest that parents of children in the TF-CBT condition report more positive treatment effects than parents of children in the EMDR condition. Parents in the TF-CBT condition were more involved in the modules of their child's therapy and also spent time on a parent-specific "parent management skills" module. It is possible that through this involvement, parents learned better to cope with the emotions and behavior of their children and developed more effective behavior management skills than parents in the EMDR condition.

Our findings on the ADIS-P PTSD status post-treatment are very encouraging for the application of TF-CBT and EMDR in clinical practice. In each condition, only one child remained with a full PTSD diagnosis.

With respect to treatment length, we observed slightly shorter treatment courses for EMDR, although this difference was not significant. In terms of clinical improvement rate, results on the CRIES-13 suggested that the major reduction in PTSS happened in both conditions in session three and four. This pattern does not indicate that EMDR is more efficient than TF-CBT like earlier studies have suggested. This pattern rather suggests that both treatments work in the same way. This is plausible given that both treatments start in session three and four with exposure and cognitive restructuring. Although there are differences in the practical execution of these modules, they seem to lead to the same result.

Limitations

Due to slow recruitment, we did not reach the planned sample size of 150 participants. In order to reach this sample size, we adjusted the inclusion criteria. A disadvantage of a broader spectrum of patients was that we included a more heterogeneous sample and observed considerable variability in the results. On the other hand, our RCT now better reflects the real-life setting of an outpatient facility. In most outpatient facilities, children with all kinds of trauma are treated, and by loosening the restrictions on trauma type, our study results apply to a wider range of traumatized children.

The consequence of a relatively small sample size is that our study has limited power to detect modest differences between the two treatments. However, in view of the observed results, the lack of power does not affect the strengths of our conclusions. A post hoc power analysis based on the current results showed that even with a sample size exceeding 10,000 participants, we would not have been able to demonstrate a statistically significant difference between the two treatments. Since we found only small overall differences between these treatments, we would rather suggest that future studies specifically target predictive factors of treatment effects to address the question who benefits most from which treatment protocol?

Since long-term follow-up data of our trial are missing, we cannot draw conclusions about the long-term effects of the treatments. Furthermore, due to ethical reasons, we did not include a non-treatment control group. However, past research on TF-CBT and EMDR has demonstrated that active treatments outperform non-treatment control conditions [8, 9].

Although it is an advantage of our study that all therapists were trained in both protocols, there were still differences between and within therapists' experience with the protocols. These might have influenced treatment results. Visual inspection of the results however did not suggest any relationship between a therapist's experience with a treatment protocol and treatment outcome.

Conclusion

We conclude that TF-CBT and EMDR are both effective and efficient in treating children with PTSS in the outpatient setting. RCT results are generally limited to an evaluation of overall effects between treatment groups, while effectiveness may be different across identifiable subgroups. In order to find out which therapy works best for which child, future studies should address predictive factors of treatment effects.

Acknowledgments The authors would like to thank all children and parents who took part in the current study. Furthermore, we would like to thank the Frijling Prins Fonds for financial support. We also want to acknowledge the work of all the therapists and research assistants who were involved in this project. Especially we want to thank Renée Beer for her contributions to the research project.

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

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