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Effectiveness of Trauma-Focused Cognitive Behavioral Therapy for Children and Adolescents: A Randomized Controlled Trial in Eight German Mental Health Clinics

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Key Words
Children and adolescents · Effectiveness · Posttraumatic stress disorder · Randomized controlled trial · Trauma-focused cognitive behavioral therapy

Abstract
Background: Trauma-focused cognitive behavioral therapy (Tf-CBT) is efficacious for children and adolescents with posttraumatic stress symptoms (PTSS). Its effectiveness in clinical practice has still to be investigated. ***Aims:*** To determine whether Tf-CBT is superior to waiting list (WL), and to investigate the predictors of treatment response. ***Method:*** We conducted a single-blind parallel-group randomized controlled trial in eight German outpatient clinics with the main inclusion criteria of age 7–17 years, symptom score ≥35 on the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA), and caregiver participation. Patients were randomly assigned to 12 sessions of Tf-CBT (n = 76) or a WL (n = 83). The primary outcome was the CAPS-CA symptom score assessed at 4 months by blinded evaluators. The secondary measures were diagnostic status, the Children's Global Assessment Scale (CGAS), self-reported and caregiver-reported PTSS (UCLA-PTSD Reaction Index), the Child Posttraumatic Cognitions Inventory (CPTCI), the Children's Depression Inventory (CDI), the Screen for Child Anxiety-Related Emotional Disorders (SCARED), the Child Behavior Checklist (CBCL/4–18), and the Quality of Life Inventory for Children. ***Results:*** Intention-to-treat analyses showed that Tf-CBT was significantly superior to WL on the CAPS-CA (Tf-CBT: baseline = 58.51 ± 17.41; 4 months = 32.16 ± 26.02; WL: baseline = 57.39 ± 16.05; 4 months = 43.29 ± 25.2; $F_{1, 157} = 12.3$; $p = 0.001$; $d = 0.50$), in terms of secondary measures of the CGAS, UCLA-PTSD-RI, CPTCI, CDI, SCARED, and CBCL/4–18, but not in terms of quality of life. Age and comorbidity significantly predicted treatment response. ***Conclusions:*** Tf-CBT is effective for children and adolescents with heterogeneous trauma types in German service settings. Younger patients with fewer comorbid disorders show most improvement.

Introduction

There is a high prevalence of posttraumatic stress disorder (PTSD) among children and adolescents, with an estimated rate of 15.9% among those exposed to any traumatic events and even higher rates among girls exposed to interpersonal trauma [1]. Although evidence-based trauma-

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focused treatments are available [2], many children and adolescents with PTSD or other trauma-related disorders do not receive appropriate care. This was recently demonstrated when survivors of child sexual abuse reported on their experiences to the Independent Commissioner mandated by the German Federal Government to develop a societal agenda to improve prevention and intervention programs [3]. This example highlights the need to deliver effective treatments to the most vulnerable populations.

In comparison with no treatment or nonspecific psychotherapies, efficacy studies utilizing a randomized controlled trial (RCT) design demonstrated the superiority of trauma-focused interventions. They include cognitive therapy [4], narrative exposure therapy [5], prolonged exposure for adolescents [6], and trauma-focused cognitive behavioral therapy (Tf-CBT) [7]. Tf-CBT is the most frequently investigated treatment, with a total of 11 RCTs up to 2014 [7, 8]. The methodical limitations of previous studies of psychological therapies for PTSD comprise unclear risks of selection, detection and attrition biases, missing or incomplete information on blinding the assessors of the primary outcomes, small sample sizes, and heterogeneity both in the assessment and analysis of outcomes [2]. RCTs were rarely performed by researchers independent of the developers of the respective treatments. There are very few studies on especially vulnerable children and adolescents, for instance children and adolescents in out-of-home care, with multiple traumatic experiences, or with comorbid psychological disorders, and gender-specific outcome analyses. Most of the previous studies of psychological interventions for pediatric PTSD have been performed in specialized clinics affiliated to universities. Effectiveness studies are recommended to build on evidence from efficacy studies in specialized academic centers in community settings [9]. In this regard, the generalization of evidence for treatment has to consider factors such as the different structure of services delivering the treatment, the varying levels of the therapists' clinical experience and training, and different patient characteristics in community clinics.

Tf-CBT was developed in the USA [10]. Beyond that it has been investigated in low-resource countries using trained lay counsellors [11–13], in one Dutch academic mental health center [8], and in eight Norwegian community mental health outpatient clinics [14]. Jensen et al. [14] found that children and adolescents aged 10–18 years receiving Tf-CBT in Norwegian community mental health services reported significantly lower levels of posttraumatic stress symptoms (PTSS), depression, and general mental health symptoms, and significantly more improvement of psychosocial functioning compared to patients receiving therapy as usual. It is important to investigate the effectiveness of Tf-CBT in the context of the child and adolescent mental health services in Germany, too. These services are more diverse than in the Norwegian public mental health care system. Short-term trauma-focused treatments such as Tf-CBT would be a valuable extension to current clinical practice in Germany, which has been characterized, up to now, by the limited availability of trauma-focused psychotherapy and long delays until psychotherapy starts [15].

This study, therefore, aimed to fill the current gaps in the literature and investigated the effectiveness of Tf-CBT in a range of different German child and adolescent mental health services compared to a waiting-list (WL) group. Potential predictors of treatment response such as the patients' age, gender and trauma type, the presence of comorbid mental disorders, an academic versus community treatment setting, and the therapists' level of experience were explored.

Subjects and Methods

Design

This was a single-blind stratified (by severity of PTSS) parallel-group RCT conducted in eight German child and adolescent mental health clinics. The allocation ratio was 1:1. There were no changes to the trial design after its commencement, except for a raise in the upper age limit for the recruitment of patients from 14 to 17 years. This is because many of the patients at the participating centers identified with PTSD turned out to be 15–17 years old and urgently needed treatment. All the legal guardians of the study participants gave their informed written consent and the young patients themselves gave their written informed assent. The study received ethics approval from the IRB at the University of Ulm (12/08 and 192/13) and was registered under ClinicalTrials.gov (NCT01516827).

Objectives

The study investigated the primary hypothesis that Tf-CBT is superior in terms of reducing PTSS assessed by independent assessors at 4 months compared to a WL control group. Secondary exploratory analyses compared the effectiveness of Tf-CBT to WL with regard to the following outcomes: remission of PTSD diagnosis, remission of comorbid mental disorders, improvement of psychosocial functioning, reduction of self-reported and caregiver-reported PTSS, posttraumatic cognitions, general behavioral and emotional symptoms, symptoms of anxiety and depression, and improvement of quality of life. Additionally, this study examined whether Tf-CBT was equally effective: (1) independent of the patient's age, (2) in male and female patients, (3) in patients with experience of interpersonal or accidental traumatic events, (4) in patients with or without comorbid disorders, (5) whether delivered in community or university clinics or (6) whether delivered by therapists with versus without previous experience in Tf-CBT.

Participants

Participants qualified for the study according to the following inclusion criteria:

1 Age 7–17 years, as Tf-CBT was developed for this age group
2 Exposure to one or more traumatic event(s) after age 2 and dating back at least 3 months, with regard to the ability of the patients to remember the event(s) and to the high spontaneous remissions of PTSS in the first weeks and months after a traumatic event
3 At least medium severity of PTSS as indicated by a total symptom score of ≥35 and at least one symptom per DSM-IV clusters B, C, and D assessed with the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA); some children do not meet the full DSM-IV criteria, although they manifest clinically significant PTSS and need treatment [16], and hence, patients with only one symptom of avoidance/numbing and one symptom of hyperarousal were included in the study if they were significantly impaired due to their PTSS
4 PTSD was the main disorder based on clinical estimation, if comorbid disorders were present
5 Availability of a nonoffending adult caregiver for the treatment, as the inclusion of a caregiver is part of the treatment model
6 Willingness and ability of the patient and the caregiver to attend weekly treatment sessions
7 Safe living circumstances to minimize the risk of retraumatization during the study
8 Sufficient cognitive ability to respond to cognitive interventions, as indicated by a raw score of ≥14 on the block design and vocabulary subtests of the Wechsler Intelligence Scale for Children (WISC IV)
9 Patients' and caregivers' sufficient command of the German language to participate in the treatment

Exclusion Criteria:

1 Acute suicidal behavior or suicidal ideations requiring immediate hospitalization
2 Severe head trauma indicated by a score <9 on the Glasgow Coma Scale [17] as known from the patient's medical history, to avoid brain dysfunction or retrograde amnesia of the traumatic event due to head injury
3 A current or lifetime diagnosis of a pervasive developmental disorder or psychosis, to assure sufficient response to cognitive interventions
4 Psychopharmacological treatment started <6 weeks before recruitment or change of psychotropic medication during the course of the study; the latter was continuously monitored throughout the study
5 Concurrent psychotherapy during the study
6 Current severe mental disorder of the patient's main caregiver as evaluated by the responsible clinician, such as psychosis, severe episode of depression, or severe substance abuse, to assure the ability of the caregiver to participate in the treatment
7 A sibling of the patient already participating in the study (to avoid the transference of treatment effects if siblings are randomized in different conditions)

Intervention

Tf-CBT is a short-term, component-based intervention [10]. The format was 12 weekly 90-min parallel or conjoint sessions with patients and caregivers spread over a period of 4 months. The nine components (psychoeducation and parent training, relaxation and affective modulation, learning cognitive coping skills, trauma narrative, cognitive processing of the trauma, in vivo mastery of trauma reminders, enhancing safety, and future development) constituted the three treatment phases: stabilization and skill building (sessions 1–4), exposure and cognitive processing of the trauma (sessions 5–8), and fostering safety and future development (sessions 9–12).

The 26 study therapists (mean age: 37.4 years) had completed or advanced clinical training and had on average 8.3 years (range: 1–31) of clinical experience. Five study therapists were MDs specializing in child and adolescent psychiatry/psychotherapy. Ten therapists had a diploma or master's degree in psychology and had subsequently trained as psychological psychotherapists (n = 7) or family therapists (n = 3), and 11 study therapists were either psychologists or social workers with a diploma or master's degree and had subsequently trained as child and adolescent psychotherapists. All therapists read the treatment manual in German [18], completed a certified web-based training program (www.musc.edu/tfcbt), and attended a 2-day personal training course in Tf-CBT run by trainers approved by the developers of the treatment. All therapists were supervised by the senior therapists at their center and were invited to clinical consultation conference calls with either one of the developers of the intervention (Anthony Mannarino, PhD) or an approved Tf-CBT trainer (Laura Murray, PhD).

Control Group

A WL of 4 months was chosen to monitor spontaneous changes in the outcomes of this study. Due to the limited availability of trauma-focused therapy, waiting for therapy is the typical situation of traumatized children and adolescents in Germany once they have been identified as having PTSD. During the waiting period, reassessments of outcomes after 2 and 4 months were performed by trained assessors. All patients in the WL group had access to clinical management as needed; however, neither formal psychotherapy nor trauma-focused interventions were applied during the waiting period. The safety of the patients was monitored by the responsible clinicians at the study centers. Most of the patients in the control group were not given any clinical appointments beyond the 2 regular reassessments. Seven participants in the control group had between 1 and 6 (mean 2.57) clinical visits beyond the 2 regular reassessments. There were no hospitalizations during the waiting period. All patients and caregivers randomized to the control group were told that they would be offered trauma-focused treatment after 4 months.

Evaluation of Therapy

Once randomized to the intervention group, 73 patients (96%) started with Tf-CBT, 65 (86%) completed at least 8 sessions of Tf-CBT including the trauma narrative, and 58 (76%) completed the full 12 sessions. For further details of the progress of participants through the study, see the CONSORT diagram (fig. 1). The actual mean duration of treatment was 15.9 ± 5.9 weeks.

Treatment adherence was monitored by trained Tf-CBT clinicians based on video files of treatment sessions using a content checklist for the evaluation of the 12-session format treatment. The therapists' affiliations to study sites were known to the adherence monitors. The complete first case of each therapist as well as a random sample of 25% of the sessions of further cases were evaluated. Adherence to the manual was confirmed in 96% of the evaluated sessions.

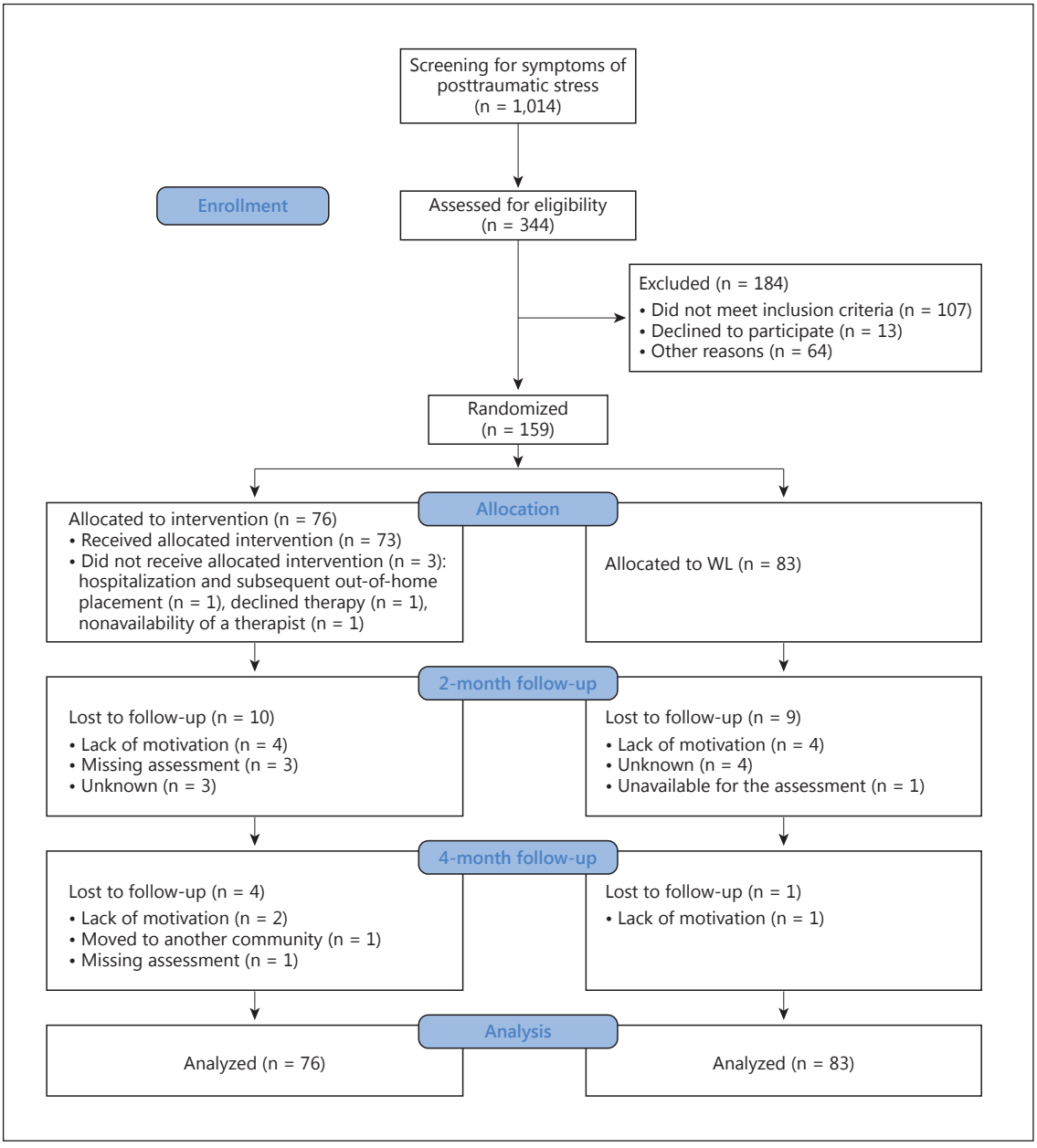

Fig. 1. CONSORT flowchart of the study.

Outcomes and Instruments

The primary outcome was the total frequency and intensity score of PTSS as assessed by the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA) [19]. The CAPS-CA was also used to establish the diagnostic status with regard to the DSM-IV criteria for PTSD. The German version of the CAPS-CA has an interrater reliability of $\kappa = 0.68$ and the internal consistency of the total symptom score is $\alpha = 0.91$ [20]. In the current study, the internal consistency of the symptom score was $\alpha = 0.79$. The following secondary outcomes were assessed. The presence of comorbid mental disorders according to DSM-IV criteria was determined using the Schedule of Affective Disorders and Schizophrenia for School-Age Children Revised for DSM IV (K-SADS) [21] administered to the child and the caregiver. Interrater agreement in scoring screens and diagnoses for this interview have been shown to be high, within a range of $\kappa = 0.63$ and $\kappa = 1.00$ depending on the diagnosis [22].

The level of psychosocial functioning was assessed using the Children's Global Assessment Scale (CGAS) [23] with scores between 0 and 100, with higher values indicating good functioning in different life domains.

PTSS were reported on the child and adolescent and caregiver versions of the UCLA-PTSD Reaction Index. Several reports found Cronbach's α to be 0.90 [24]. In the current study Cronbach's α was 0.85 for the caregiver version and 0.78 for the self-report version.

The patients' cognitive distortions related to the trauma were assessed by self-reports on the Child Posttraumatic Cognitions Inventory (CPTCI) [25]. The German version of the CPTCI [26] has good reliability (α = 0.94) and convergent validity with standard measures of PTSS and depression. In the current study Cronbach's α was 0.92.

Symptoms of anxiety were assessed by self-reports and caregiver reports on the Screen for Child Anxiety-Related Emotional Disorders (SCARED) with repeatedly reported excellent psychometric properties [27]. Internal consistency for the self-report and the caregiver version in the current study was α = 0.92.

Symptoms of depression were assessed by patients' self-reports on the Children's Depression Inventory (CDI) [28], a questionnaire with good reliability (α between 0.82 and 0.85) and high convergent validity with other measures of depression [29]. The internal consistency in the current study was α = 0.89.

The Child Behavior Checklist 4–18 (CBCL/4–18) [30] was applied to the patients' caregivers. The CBCL/4–18 covers a wide range of 120 symptoms and has excellent psychometric properties with α >0.85 for the total symptom scale and for the internalizing and externalizing symptom scales [31]. In the current study, internal consistency was very good with α between 0.86 and 0.94.

The patients' quality of life was assessed by self-reports and caregiver-reports on the Inventory of Quality of Life for Children (ILK) [32], a measure of functioning and well-being on 5-point rating scales in seven domains of life. Good internal consistency (α between 0.53 and 0.76), retest reliability, and discriminant validity with the CDI (r = –0.64) were reported [33]. Satisfactory internal consistency was demonstrated by α = 0.68 in this study.

CAPS-CA, K-SADS, and CGAS were administered at baseline and after treatment or waiting period by independent assessors. Their blinding for the participant's group was assured by careful selection of assessors not previously involved with the same patient and by cross-check before and after each interview. Before each reassessment, patients and caregivers were instructed to refrain from reporting to the assessor whether they received treatment or not. All assessors were carefully trained in the clinical interviews and in the scoring procedures, and the assessors' adherence to the interview manuals was continuously monitored by an experienced clinician based on videotapes of the interviews. There were no individual biases among the assessors, as indicated by the absence of significant differences between the mean total symptom scores of a random selection of 5 CAPS-CA interviews per assessor and the mean total symptom scores of all other clinical interviews. Independence and blinding of assessors was ensured by using separate facilities for treatment and assessment, and by carefully training assessors not to ask patients about their treatment. Successful blinding of the assessors was checked before and after each outcome interview. All questionnaires were repeatedly used at baseline and after 2 and 4 months of treatment or waiting time.

Sample Size

In accordance with previous studies of psychotherapy with children and adolescents [34] and with our own pilot study [35], we calculated the sample size based on the following assumptions regarding the primary outcome of our study. We expected a pre-post effect size of at least d = 1.40 for the Tf-CBT group and a maximum pre-post effect size of d = 0.80 caused by spontaneous remissions of PTSS or by treatment expectancy in the WL group. To test the primary hypotheses of superiority of Tf-CBT compared to WL by a t-test for independent samples, at least 60 patients per group were needed to detect a significant difference in means in the primary outcome measure at a level of 0.05 (2-tailed) with a statistical power of 0.90. To compensate for an unknown clustering effect, we added 10% to the estimated sample size, resulting in at least 132 patients equally distributed across both groups for analysis according to intention-to-treat (ITT) principles. To increase the power for the secondary analysis of predictors of treatment response and given the need to compensate for an expected dropout rate, we added 18 patients, resulting in a targeted sample size of at least 150 patients.

Randomization

Randomization was performed independently of the study group by a biostatistician at the Institute of Epidemiology and Medical Biometry of the University of Ulm. We used block randomization with permuted blocks to allocate patients in a 1:1 ratio to either Tf-CBT or WL, with study sites and severity of PTSS (cut-off score ≥55 on the CAPS-CA total symptom score) treated as strata. No departures from random assignment were permitted. The random allocation sequence was generated by the ROM software program. The study participants were assigned to the groups centrally by the consulting biostatistician, and the random sequence was hidden from the study site coordinators, therapists, and assessors.

Recruitment and Informed Consent/Assent

Recruitment was carried out between February 2012 and January 2015 at eight German child and adolescent mental health clinics. Three clinics were located at academic mental health care centers, whereas the other five sites were community clinics without any academic infrastructure. Institutions could become study sites once they had agreed to comply with the implementation of the study protocol at their clinic and if the heads of the clinics agreed to clinicians and assessors attending training and participating in regular conference calls with the coordinating study center. All participating clinics screened their patients for eligibility. Referrals by other local clinicians and child welfare institutions as well as self-referrals of patients were encouraged by announcing the study in locally distributed flyers and on the websites of the project and participating clinics. The patients who were initially deemed eligible for the study were invited for a comprehensive clinical assessment. Patients who fulfilled all inclusion criteria were invited to participate and enrolled in the study.

Statistical Methods

Raw data were extracted from the database and imported into the Statistical Package for the Social Sciences, version 21 for Windows. Single missing values in questionnaire raw item scores were replaced by the respondent's mean value for the other items of the respective scale if fewer than 25% of the values were missing. All primary and secondary outcome analyses were based on the assessment at 4 months and performed as an ITT analysis using the last-observation-carried-forward (LOCF) procedure to replace missing values due to participants dropping out of the study.

Table 1. Sample description at baseline and group comparisons

	Total (n = 159)	Tf-CBT (n = 76)	WL (n = 83)	Statistics
Age, years	13.03±2.80	12.66±2.92	13.36±2.64	$t_{157} = 1.59$, p = 0.113
Gender				$\chi^2(1) = 0.276$, p = 0.599
Male	45 (28.3)	23 (30.3)	22 (26.6)	
Female	114 (71.7)	53 (69.7)	61 (73.5)	
Country of birth				$\chi^2(1) = 0.035$, p = 0.853
German native	143 (89.9)	68 (89.5)	75 (90.4)	
Non-German native	11 (6.9)	5 (6.6)	6 (7.2)	
Missing information	5 (3.1)	3 (3.9)	2 (2.4)	
Living situation				
With one parent	80 (50.3)	44 (57.9)	36 (43.4)	z = 1.83, p = 0.068
With both parents	37 (23.3)	17 (22.4)	20 (24.1)	z = –0.26, p = 0.795
In a group home	25 (15.7)	9 (11.8)	16 (19.3)	z = –1.29, p = 0.197
With foster parents	9 (5.7)	2 (2.6)	7 (8.4)	
With other relatives	4 (2.5)	2 (2.6)	2 (2.4)	
Missing information	4 (2.5)	2 (2.6)	2 (2.4)	
Parental education				
<9 years' schooling	4 (2.5)	2 (2.6)	2 (2.4)	
9–11 years' schooling	82 (51.6)	37 (48.7)	45 (54.2)	z = –0.70, p = 0.484
≥12 years' schooling	39 (24.5)	24 (31.6)	15 (18.1)	z = 2.68, p = 0.004
Missing information	34 (21.4)	13 (17.1)	21 (25.3)	
Type of clinic				$\chi^2(1) = 0.004$, p = 0.951
Academic clinic	77 (48.4)	37 (48.7)	40 (48.2)	
Community clinic	82 (51.6)	39 (51.3)	43 (51.8)	
Number of traumatic events	6.35±3.70	6.26±3.45	6.45±3.94	$t_{157} = 0.31$, p = 0.757
Type of index event				$\chi^2(1) = 1.98$, p = 0.048
Interpersonal	122 (76.7)	61 (80.3)	61 (73.5)	
Accidental	37 (23.3)	15 (19.7)	22 (26.6)	
PTSD diagnosis DSM-IV	120 (75.5)	57 (75.0)	63 (75.9)	z = –0.13, p = 0.897
Comorbid disorder DSM-IV				
>1 comorbid disorder	54 (34.0)	24 (31.6)	30 (36.1)	z = –0.61, p = 0.542
Depressive disorders	31 (19.5)	11 (14.5)	20 (24.1)	z = –1.53, p = 0.126
Anxiety disorders	16 (10.1)	7 (9.2)	9 (10.8)	
ADHD	10 (6.3)	5 (6.6)	5 (6.0)	
Disruptive behavior disorders	7 (4.4)	2 (2.6)	5 (6.0)	
Psychotropic medication				
Any	24 (15.1)	8 (10.5)	16 (19.3)	z = –1.54, p = 0.124
Antidepressant	11 (6.9)	3 (3.9)	8 (9.6)	
Psychostimulant	10 (6.3)	4 (5.3)	6 (7.2)	
Antipsychotic	8 (5.0)	2 (2.6)	6 (7.2)	
Other	1 (0.6)	1 (1.3)	0 (0)	
Treatment expectancy				
Patient	1.80±0.84	1.82±0.91	1.78±0.82	$t_{148} = –0.663$, p = 0.509
Caregiver	1.65±0.75	1.61±0.66	1.69±0.82	$t_{151} = 0.270$, p = 0.787

Values are means ± SD or n (%), as appropriate.

The primary hypothesis was tested by a repeated-measures analysis of variance (ANOVA), with measurement time point as a repeated-measures independent variable and group (Tf-CBT, WL) as a between-group independent variable and with the CAPS-CA total symptom score as the dependent variable. The interaction term of time and group indicated whether the treatment was superior to the control group. All secondary outcomes were investigated in an exploratory manner. Analyses of secondary dimensional outcomes were also performed by ANOVAs with either two or three measurement time points, depending on the number of reassessments. Dichotomous secondary outcomes (presence of a PTSD diagnosis, presence of at least one comorbid disorder) were

analyzed by z tests at 4 months. The significance level for all analyses was set to 0.05 (2-tailed). Given the exploratory nature of the secondary analyses, the significance level was not adjusted. Cohen's effect size d was calculated for within-group pre-post comparisons and to estimate the between-group effect size at 4 months adjusted for the baseline values [36, 37].

In addition, completer analyses of all outcomes were performed with the same statistical methods as in the ITT analyses. They were based on the patients undergoing at least 8 sessions of Tf-CBT in the treatment group and on all study participants with results for the follow-up assessment at 4 months. Individual percentage changes in all dimensional outcomes between the baseline assessment and the 4-month follow-up assessment were calculated, and completers in both groups were compared by t tests for independent samples.

To predict the treatment response of the Tf-CBT completers, the change between pre- and post-treatment scores in the primary outcome (CAPS-CA total symptom score) served as the dependent variable. In a stepwise hierarchical regression we entered age, number of comorbid disorders, gender, trauma type (interpersonal vs. accidental), type of clinic (academic vs. community mental health center), and therapist experience (first or second study case of the respective therapist vs. higher number) as possible predictor variables. A significant increment of R^2 was chosen as the criterion for the inclusion of independent variables in the final regression model.

Results

A total of 159 patients were randomized either to Tf-CBT (n = 76) or WL (n = 83). At the reassessment of the primary and secondary outcomes at 4 months, 24 patients (15%) were lost to follow-up. Hence, the primary outcome was assessed in 135 participants.

Sample Description and Baseline Group Comparisons

Patients were on average 13 years old, 71% were female, and their most frequent living situation was with one biological parent (50%). Eighteen patients (11%) lived out of home at the time of the study, either in foster families or in group homes. The most frequently reported traumatic index events were experiences of sexual abuse, sexual assaults, physical violence, or witnessing domestic violence. For further details of the sample description, see table 1. There were no significant differences between the groups in most sociodemographic or outcome variables at baseline or in treatment expectancy. However, in the intervention group the patients reported significantly more interpersonal index events, and the proportion of better-educated parents was slightly higher compared to the control group (table 1).

Analyses of the Primary Outcome

The repeated-measures ANOVA of the CAPS-CA total symptom score as assessed by blinded evaluators and calculated based on the ITT sample (n = 159) with LOCF demonstrated a significant interaction of group and time ($F_{1, 157} = 12.3$; $p = 0.001$), indicating superiority of the intervention compared to the control group (table 2). A significant main effect of time ($F_1 = 133.98$; $p < 0.001$) and no main effect of group ($F_1 = 2.87$; $p = 0.092$) were found. Pre-post effect sizes were d = 1.51 for the Tf-CBT group and d = 0.88 for the control group. The posttreatment between-group effect size was d = 0.50. There were no significant site effects in the primary outcome.

Analyses of Secondary Outcomes

After treatment, 34 of the 57 patients who had fulfilled the diagnostic criteria of PTSD at baseline (44.7%) were no longer diagnosed as having PTSD, as was the case in 24 of the 63 patients (28.9%) with a previous full PTSD diagnosis after 4 months of waiting. This difference was significant (z = –2.16; p = 0.031). No participant without a PTSD diagnosis at baseline was diagnosed as having PTSD diagnosis after treatment. Among the patients in the treatment group, 7 (29.2%) no longer fulfilled the criteria for any comorbid mental disorder after 4 months, whereas 6 patients (20%) in the control group no longer had their comorbid disorder(s) at that time point (z = 0.46; p = 0.646).

Table 2 provides means, standard deviations, interaction effects between group and time, and effect sizes for all dimensional outcome measures. Significant interaction effects indicated superiority of the Tf-CBT group compared to the control group in 9 of the 12 secondary outcomes. Controlled effect sizes indicated by Cohen's d ranged from small to medium. Only for quality of life was there no interaction effect.

Completer Analyses

There were no significant differences between treatment and follow-up assessment completers and patients dropping out from the study in any of the sociodemographic and outcome variables at baseline. Analyses of completers confirmed all previously significant findings of the ITT analyses. They also provided slightly higher estimates of effect sizes in all dimensional outcomes of treatment completers compared to WL controls. Controlled effect sizes in the completer analyses ranged from d = 0.36 to d = 0.73, with the latter coefficient indicating the effect size of the primary outcome (online suppl. table 2a; see www.karger.com/doi/10.1159/000442824 for all online suppl. material). Additional completer analyses with percentage changes are presented in table 3.

Table 2. Primary and secondary outcomes based on ITT analyses with LOCF: means ± SD by group and assessment time point, within-group effect sizes, results of repeated-measures ANOVAs (time × group interaction), and controlled effect sizes

Outcome	TF-CBT					WL					Interaction time × group	Controlled effect size d
	n	baseline	2 months	4 months	pre-post effect size d	n	baseline	2 months	4 months	pre-post effect size d		
Primary												
CAPS-CA total	76	58.51±17.41	–	32.16±26.02	1.51	83	57.39±16.05	–	43.29±25.20	0.88	$F_{1, 157} = 12.31$, p = 0.001	0.50
Reexperiencing	76	21.43±7.00	–	11.64±9.41	1.40	83	20.76±7.38	–	15.17±9.69	0.76	$F_{1, 157} = 7.82$, p = 0.006	0.46
Avoidance	76	19.72±8.67	–	11.03±10.51	1.00	83	19.80±7.51	–	15.75±10.68	0.54	$F_{1, 157} = 9.99$, p = 0.002	0.44
Hyperarousal	76	17.36±7.51	–	9.49±9.15	1.05	83	16.83±6.84	–	12.37±8.82	0.65	$F_{1, 157} = 6.64$, p = 0.011	0.40
Secondary												
UCLA-Self	74	36.24±11.14	31.14±13.64	22.85±14.56	1.20	82	36.63±9.56	33.09±11.92	29.11±13.82	0.79	$F_{2, 308} = 5.02$, p = 0.010	0.40
UCLA-Care	68	34.65±11.80	33.49±11.43	25.51±11.69	0.77	81	33.80±10.91	33.00±10.69	30.73±10.91	0.28	$F_{2, 294} = 7.93$, p = 0.001	0.54
CPTCI	75	57.36±16.32	52.29±17.86	44.63±16.68	0.78	82	57.93±15.29	56.57±16.74	53.28±17.00	0.30	$F_{2, 310} = 8.56$, p < 0.001	0.48
CGAS	70	56.01±11.71	–	65.14±16.07	–0.78	80	58.74±10.84	–	60.34±14.79	–0.15	$F_{1, 148} = 10.50$, p = 0.001	–0.55
CDI	74	59.88±12.79	57.14±13.11	52.00±13.10	0.62	83	63.11±11.86	61.82±12.82	59.90±13.87	0.27	$F_{2, 310} = 5.23$, p = 0.007	0.32
SCARED-Self	74	30.72±15.88	28.89±16.75	22.55±15.56	0.51	83	33.59±14.80	31.34±15.71	28.92±17.44	0.32	$F_{2, 310} = 2.39$, p = 0.10	0.20
SCARED-Care	70	27.11±15.06	24.84±13.81	19.46±13.63	0.51	80	22.79±13.02	21.51±13.93	19.53±12.56	0.25	$F_{2, 296} = 4.27$, p = 0.016	0.31
CBCL total	73	69.16±9.09	67.01±9.07	62.75±11.71	0.71	81	68.38±7.78	67.81±9.75	66.42±10.52	0.25	$F_{2, 304} = 8.48$, p = 0.001	0.42
Externalizing	73	63.08±11.59	61.36±10.52	58.85±11.91	0.36	81	63.07±10.71	63.22±11.74	62.36±12.16	0.07	$F_{2, 304} = 5.99$, p = 0.004	0.29
Internalizing	73	71.29±8.45	68.51±9.40	63.25±10.74	0.95	81	68.89±7.97	68.51±9.40	66.05±10.63	0.36	$F_{2, 304} = 9.82$, p < 0.001	0.56
ILK-Self	76	64.47±16.30	66.74±16.08	71.54±16.07	–0.43	83	59.17±15.78	60.57±16.97	63.08±17.22	–0.25	$F_{2, 314} = 0.67$, p = 0.480	–0.18
ILK-Care	73	59.34±12.54	64.01±12.05	67.90±14.04	–0.64	81	58.99±13.62	59.95±15.61	63.02±14.89	–0.28	$F_{2, 304} = 1.74$, p = 0.181	–0.36

CAPS-CA = Clinician-Administered PTSD Scale for Children and Adolescents; UCLA = The University of California at Los Angeles post-traumatic stress disorder reaction index for children and adolescents (Self = self-report; Care = caregiver report); CPTCI = Child Post-Traumatic Cognitions Inventory; CGAS = Children's Global Assessment Scale; CDI = Children's Depression Inventory; SCARED = Screen for Anxiety-Related Emotional Disorders; CBCL = Child Behavior Checklist 4–18; ILK = Quality of Life Inventory for Children and Adolescents. CDI and CBCL Scores are T-Scores. Greenhouse-Geisser corrected p values are reported above.

Table 3. Percentage change among study participants in the treatment condition versus WL condition in dimensional primary and secondary outcomes with 95% CI and group comparisons (completer analyses; n = 133)

Variable	Tf-CBT (n = 60)		WL (n = 73)		Statistics
	% change	95% CI	% change	95% CI	
Primary					
CAPS-CA total	56.5	47.9, 65.1	28.6	19.5, 37.6	$t_{131} = -4.41$, p < 0.001
Reexperiencing	51.5	40.0, 63.0	26.4	15.1, 37.8	$t_{131} = -3.07$, p = 0.003
Avoidance	54.6	41.3, 68.0	19.8	5.5, 34.0	$t_{131} = -3.51$, p = 0.001
Hyperarousal	56.2	45.1, 67.3	26.2	11.0, 41.4	$t_{131} = -3.06$, p = 0.003
Secondary					
UCLA-Self	41.9	30.6, 53.2	19.1	10.5, 27.7	$t_{126} = -3.26$, p < 0.001
UCLA-Care	23.6	11.8, 35.4	6.9	–1.7, 15.5	$t_{120} = -2.35$, p = 0.020
CPTCI	25.2	18.9, 31.5	9.0	3.7, 14.4	$t_{122} = -3.93$, p < 0.001
CGAS	–23.9	–32.2, –15.5	–4.7	–11.2, 1.8	$t_{120} = 3.68$, p < 0.001
CDI	13.7	8.4, 19.0	6.0	2.4, 9.5	$t_{129} = -2.49$, p = 0.014
SCARED-Self	16.0	–18.6, 50.6	11.5	–1.9, 24.9	$t_{126} = -0.26$, p = 0.794
SCARED-Care	26.8	11.3, 42.3	–2.1	–25.5, 21.9	$t_{119} = -1.93$, p = 0.056
CBCL total	11.9	8.2, 15.6	3.3	0.5, 6.0	$t_{124} = -3.87$, p < 0.001
Externalizing	8.0	4.9, 11.2	0.9	–1.9, 3.8	$t_{124} = -3.35$, p < 0.001
Internalizing	14.1	10.7, 17.4	4.6	1.6, 7.7	$t_{124} = -4.18$, p < 0.001
ILK-Self	–21.5	–33.5, –9.6	–13.6	–24.7, –2.5	$t_{123} = -0.97$, p = 0.334
ILK-Care	–22.8	–32.3, –13.3	–14.1	–25.4, –2.8	$t_{119} = -1.14$, p = 0.256

For legend see table 2.

Table 4. Summary of hierarchical regression analysis for variables predicting treatment response (percentage change in the primary outcome CAPS-CA total symptoms) among treatment completers (n = 60)

Variable	Model 1			*Model 2*			Model 3			Model 4			Model 5			Model 6		
	B	SE B	β	*B*	*SE B*	*β*	B	SE B	β	B	SE B	β	B	SE B	β	B	SE B	β
Age	–3.27	1.48	–0.28**	*–3.23*	*1.45*	*–0.28***	–3.23	1.44	–0.28**	–3.19	1.44	–0.27**	–3.14	1.45	–0.27**	–3.09	1.46	–0.26**
Comorbid disorder				*–11.44*	*5.94*	*–0.24**	–11.45	5.91	–0.24*	–11.02	5.91	–0.23*	–11.19	5.95	–0.23*	–11.45	6.00	–0.24*
Gender							–10.94	8.67	–0.16	–11.38	8.65	–0.16	–11.80	8.74	–0.17	–12.21	8.82	–0.17
Trauma type										11.91	10.43	0.14	12.66	10.58	0.15	13.51	10.73	0.16
Type of clinic													4.70	8.33	0.07	6.56	8.94	0.10
Therapist experience																–5.22	8.78	–0.08
R^2		0.078			*0.134*			0.158			0.178			0.182			0.188	
F for change in R^2		4.89**			*3.71**			1.59			1.30			0.32			0.35	

* p < 0.1; ** p < 0.05.

Predictor Analyses

In a stepwise hierarchical regression we entered age, number of comorbid disorders, gender, trauma type, treatment setting, and therapist experience as possible predictor variables for percentage changes in the CAPS-CA total score in the Tf-CBT group (table 4). A significant increment of R^2 was demonstrated for the inclusion of age and comorbid disorders. Younger patients and patients with fewer comorbid disorders benefitted more from treatment. Neither gender, trauma type, type of clinic nor Tf-CBT-specific therapist experience made significant contributions to R^2. A model containing age and comorbid disorders was, therefore, chosen. Together, they explained 13.4% of the variance in treatment response.

Adverse Events

Adverse events during treatment were monitored throughout the study. No adverse events were reported. The analyses of reports on cases who prematurely dropped out of the study showed reasons unlinked to the treatment, such as unexpected out-of-home placement, unavailability of the patient or the caregiver for further treatment sessions, or lack of motivation for treatment.

Discussion

This is the first study of the effectiveness of Tf-CBT in German child and adolescent outpatient mental health clinics compared to a WL condition. Unfortunately, the latter represents the typical situation up to now of the underserved population of traumatized children and adolescents in current German mental health care. Our multicenter study builds on prior findings of the efficacy of Tf-CBT [38]. In accordance with observations among patients referred to German child and adolescent mental health services, our study sample comprised a wide range of different trauma types and symptom manifestations, as well as a significant proportion of patients with comorbid mental disorders and of patients living with only one biological parent or out of home. Although 25% of the study participants did not fulfil all the diagnostic criteria of PTSD according to DSM-IV, the required minimum symptom severity ensured a clinically relevant level of PTSS in our study sample.

Our study demonstrates the superiority of Tf-CBT to the WL in terms of remission of PTSS and dysfunctional trauma-related cognitions, PTSD diagnoses, and a broad range of comorbid symptoms, such as depression, anxiety, and other internalizing and externalizing symptoms. Tf-CBT was also superior to WL in improving the patients' psychosocial functioning. Improvement to quality of life was not greater in the intervention group; this may be due to ceiling effects and a limited sensitivity of the measure for changes. It could be demonstrated that Tf-CBT was effective independently of gender, trauma type, level of specialization of the service, and the therapist's individual experience with this treatment model. However, predictor analyses revealed that the patients' age and comorbidity were significantly associated with treatment response, indicating that younger patients and patients with fewer comorbid disorders benefitted most.

In accordance with a prior effectiveness study in Norway [14], our findings demonstrate that the successful implementation of Tf-CBT in different child and mental health outpatient clinics and the effective delivery by clinicians with a heterogeneous level of prior training in CBT or child psychotherapy in general are feasible once comprehensive therapist training is provided, which encompasses face-to-face training and an e-learning course

with ongoing case consultations. It is worth noting that the almost identical within-group effect sizes of the CAPS-CA symptom score in the Tf-CBT groups in the Norwegian study (d = 1.49) and in our study (d = 1.51) underline the effectiveness of this treatment model in community mental health care. Dropout rates from treatment both in the Norwegian study and in our study were low compared to dropout rates in other studies of child psychotherapy or in clinical practice.

Unexpectedly, we observed a major improvement in the WL control group, with a pre-post effect size of d = 0.88 in the primary outcome – exactly the same effect size as in the active control group (treatment as usual) of the Norwegian study [14]. The documented treatment of our study participants during the waiting period comprised ongoing medication for 19.3% of the patients and less than 1 clinical visit on average. A previous study of trauma-focused cognitive psychotherapy with children and adolescents with PTSD after a single trauma [4] demonstrated that the study participants improved significantly by simply monitoring their symptoms. Thus, beyond an unspecific 'placebo' effect of mere attention by including somebody in a study and providing careful and repeated clinical assessments, a more specific therapeutic effect of validating the diagnosis of a PTSD and offering treatment can be assumed. All study participants randomized to the control group received the information that they would be offered Tf-CBT after the waiting period if indicated. This information may have instilled a sense of relief and positive treatment expectancy. As access to trauma-focused treatment for children and adolescents in Germany has unfortunately been limited up to now, the prospect of help within a reasonable time frame may have had a disburdening effect on the patients and their families.

The fact that younger and less comorbid children benefitted more from treatment underlines the importance of early trauma-focused interventions. On the other hand, these results indicate the need to improve intervention, especially for adolescents and for patients with comorbid conditions. It is important to recognize that neither the type of the clinic nor the specific clinical experience of the therapists was associated with treatment response. Thus, community therapists with no previous experience in trauma-focused psychotherapy can be successfully trained in Tf-CBT. This observation opens the door to the future dissemination and implementation of the treatment model. Moreover, there was no difference in treatment response regarding type of trauma. Thus, this study backs previous results that Tf-CBT is as effective after single accidental traumatic events as in those surviving multiple interpersonal traumas.

Limitations

Besides the unavoidable limitations of any psychosocial intervention study, such as the impossibility of blinding of the patients and therapists for the treatment, the absence of an active control group did not allow us to compare Tf-CBT with a comparator comprising the same dosage of attention. However, there is considerable evidence of the superiority of Tf-CBT compared to nontrauma-focused psychotherapy from previous studies [7, 38]. The major improvement in our WL control group, on the same level as the treatment as usual in the Norwegian study, rather suggests the equivalence of waiting and nonspecific psychotherapy. Another limitation is the lack of blinding of treatment adherence monitors to the respective study center. Although the randomization worked well, as indicated by the group comparisons in most variables, significant differences did, however, emerge in terms of index events and parental education. It is unlikely that these marginal differences have substantially distorted the outcome results. Another limitation is that our results do not yet indicate the maintenance of improvement after the end of the treatment. Follow-up assessments at 6 and 12 months after treatment have to be completed to determine the sustainability of treatment effects. As the predictor analyses only explain 13.4% of the variance in the primary outcome, this leaves room for further research on other potential moderators and mediators of treatment outcome.

Further Directions

As in other intervention studies with pediatric PTSD, a significant proportion of patients in our study responded insufficiently to treatment. This is indicated by the fact that 30% of patients still met the diagnostic criteria of PTSD after treatment. To improve response rates and prevent chronic PTSD, modifications to Tf-CBT might be considered, such as better tailoring of the interventions to individual needs, prolonged treatment, or integrating treatment components that target comorbid conditions. On the other hand, the high rate of remissions in our WL group indicates that some patients might not require a full-blown, 12-session course of Tf-CBT, but rather fewer and shorter interventions or just watchful waiting. A stepped care approach [39] using continuous symptom monitoring and the stepwise application of different dosages of treatment might allow for improved tailoring of the intervention to the patients' varying needs. In a first step, low-dose interventions, such as validation and nor-

malization of the disorder and delivery of specific psychoeducation, might be sufficient for some patients. In a second step full, manualized treatment, such as the treatment manual used in our study, might be effective for the majority of patients. In a third step, an extended treatment format might better meet the needs of those patients with a high risk of chronic PTSD, as indicated by an insufficient response to step 2 and/or by complex symptom manifestations [40].

Systematic implementation and dissemination research [41] are required to identify the most effective strategies for integrating short and effective treatments such as Tf-CBT into regular child and mental health care. On the service system level, the investigation of strategies to motivate stakeholders in mental health care to sustainably incorporate evidence-based treatments into their service portfolio is recommended. The results of this study may encourage clinicians to use Tf-CBT and stimulate researchers to look at quality improvements to services for the benefit of traumatized children and adolescents.

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Disclosure Statement

The authors declare that they have no conflicts of interest.

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