



Effectiveness in routine care: trauma-focused treatment for PTSD

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ABSTRACT

Objective: The efficacy of trauma-focused cognitive behaviour therapy (tf-CBT) has been well established in randomized controlled trials (RCTs). More research is needed to demonstrate the effectiveness of tf-CBT in routine clinical care settings.

Method: Eighty-five patients (68 female) with a primary diagnosis of PTSD received tf-CBT at two German outpatient centres (Münster and Mannheim) between 2014 and 2016. Treatment was delivered mainly by therapists in training and treatment duration was based on symptom course. The treatment consisted of a preparation phase, a trauma-focused phase (comprising imaginal exposure, discrimination training, changing dysfunctional appraisals) and a phase of reclaiming-your-life assignments, and relapse prevention. In an intent-to-treat-analysis (ITT), linear mixed effects models were fitted for self-assessments of traumatic symptom severity using the PTSD Checklist for DSM-5 (PCL-5) and the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). Potential moderators for treatment outcome, e.g. number of suicide attempts, were investigated.

Results: The observed treatment effect was large for both the CAPS-5 (ITT: Cohen's $d = 2.07$, CI [1.62, 2.51]; completers $d = 2.34$, CI [1.84, 2.83]) and PCL-5 respectively (ITT: $d = 2.02$, CI [1.56, 2.48]; completers $d = 2.15$, CI [1.66, 2.64]), and remained stable six months and one-year post-treatment. $N = 27$ patients (31.48%) were defined as study dropout and of these, $n = 12$ (14.12%) dropped out of the study but completed treatment. None of the fixed-effect estimates for treatment predictors interacted significantly with the effect of time.

Conclusions: Tf-CBT is well-tolerated and it can be effectively delivered in routine clinical care. Its large treatment effects underline the practicability and benefits of the approach. This trial demonstrates its broad applicability among individuals with diverse patterns of clinical characteristics and comorbidities.

Eficacia en el cuidado rutinario: tratamiento centrado en el trauma para el TEPT

Objetivo: La eficacia de la terapia cognitivo-conductual centrada en el trauma (tf-CBT, por sus siglas en inglés) ha sido bien establecida en ensayos controlados aleatorizados (RCT). Se necesita más investigación para demostrar la efectividad de la tf-CBT en entornos de atención clínica rutinaria.

Método: Ochenta y cinco pacientes (68 mujeres) con un diagnóstico primario de TEPT recibieron tf-CBT en dos centros ambulatorios alemanes (Münster y Mannheim) entre el 2014 y el 2016. El tratamiento fue realizado principalmente por terapeutas en formación y la duración del tratamiento se basó en el curso de los síntomas. El tratamiento consistió en una fase de preparación, una fase centrada en el trauma (que incluía exposición imaginada, entrenamiento por discriminación, cambio de evaluaciones disfuncionales) y una fase de tareas de recuperación de la vida y prevención de recaídas. En un análisis por intención-de-tratar (ITT), se ajustaron modelos de efectos mixtos lineales para las autoevaluaciones de la severidad de los síntomas traumáticos utilizando la Lista de Chequeo del DSM-5 para TEPT (PCL-5) y la Escala TEPT Administrada-por-Clinicos (CAPS-5). Se investigaron los posibles moderadores del resultado del tratamiento, por ejemplo, el número de intentos de suicidio.

Resultados: Hubo un gran efecto observado del tratamiento tanto para el CAPS-5 (ITT: d de Cohen = 2.07, IC [1.62, 2.51]; pacientes completos $d = 2.34$, IC [1.84, 2.83]) como para el PCL-5 (ITT: $d = 2.02$, IC [1.56, 2.48]; pacientes completos $d = 2.15$, IC [1.66, 2.64]), y se mantuvo estable a los seis meses y un año después del tratamiento. Un total de 27 pacientes (31.48%) fueron definidos como abandonadores del estudio, de los cuales 12 (14.12%) abandonaron el estudio pero completaron el tratamiento. Ninguna de las estimaciones de efectos fijos para los predictores del tratamiento interactuó significativamente con el efecto del tiempo.

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HIGHLIGHTS

- In our phase-IV trial we tested the effectiveness of trauma-focused CBT in routine clinical care.
- The results demonstrate high effect sizes.
- No adverse events like suicide attempts were observed.
- Predictor analysis revealed no significant interaction with the effect of time.

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Conclusiones: La tf-CBT es bien tolerada y puede ser aplicada efectivamente en la atención clínica rutinaria. Sus grandes efectos terapéuticos destacan la viabilidad y los beneficios de este enfoque. Este ensayo demuestra su amplia aplicabilidad entre individuos con diversos patrones de características clínicas y comorbilidades.

1. Introduction

Posttraumatic stress disorder (PTSD) is a major mental health problem (Kessler et al., 2005; Koenen et al., 2017) associated with high comorbidity (particularly with depression, substance use and anxiety disorders; Galatzer-Levy et al., 2013), low quality of life (Pagotto et al., 2015) and a high risk of chronicity (Santiago et al., 2013; Zlotnick et al., 2004). Controlled treatment studies for PTSD show a generally high efficacy for psychological treatments with the strongest support for trauma-focused cognitive behaviour therapy (tf-CBT) (Lewis, Roberts, Andrew, et al., 2020; Watts et al., 2013), and stable long-term effects (Weber et al., 2021). Specifically, Coventry et al. (2020) found a generally high efficacy of tf-CBT for various subgroups including veterans, refugees, childhood sexual abuse. Treatments that include the components cognitive restructuring and imaginal exposure were the most effective in reducing PTSD symptoms. Guidelines on PTSD treatment usually recommend tf-CBT (including variations such as prolonged exposure or cognitive processing therapy) and/ or eye movement and desensitization and reprocessing (EMDR) as the most effective treatment approaches for PTSD (Martin et al., 2021).

Yet, despite an excellent evidence-based support for tf-CBT, this approach is under-used in clinical practice due to several concerns (e.g. Feeny et al., 2003; Murray et al., 2022). Therapists treating patients with high levels of psychopathology often fear (a) symptom worsening with regard to PTSD symptoms as well as comorbid symptoms (e.g. further emotional dysregulation including self-harming behaviour and increase in dissociative symptoms) if they primarily focus on trauma processing, and (b) high dropout rates when focusing on trauma exposure (Feeny et al., 2003). This clinical concern is in correspondence with the finding that general emotion dysregulation is highly associated with PTSD symptoms (Christ et al., 2021; Seligowski et al., 2015). A multi-component approach (Coventry et al., 2020) that includes some sort of emotion regulation training and interventions that address dissociative symptoms might increase clinical utility, yet empirical evidence reveals heterogeneous results whether this preparation phase is needed for an effective PTSD treatment. Phase-based approaches like STAIR (Cloitre et al., 2010) or DBT-PTSD (Bohus et al., 2013, 2020) support the utility of a preparation phase that includes improvement of emotion regulation skills and anti-dissociative skills,

whereas other studies support the idea that emotion regulation improves as a by-product of exposure treatment (Voorendonk et al., 2020). In sum, only few studies investigated emotion regulation as an additional outcome variable in PTSD treatments. With regard to the concern of dropouts, evidence shows dropout rates that range between 16% (Lewis, Roberts, Gibson, et al., 2020) and 21% (Varker et al., 2021). Since in routine care the inclusion criteria for treatment are less rigid than in RCT's, it can be assumed that dropout rates might be higher compared to RCTs. In sum, phase-based interventions have been found to be efficacious in phase-III-research; however, it has not systematically been shown that they are superior to pure trauma-focused interventions. Nevertheless, using a phase-based approach in clinical practice appears sensible as this may address some of the concerns held by therapists and therefore help disseminating trauma-focused interventions.

Phase-IV-trials can deliver more insights into the effectiveness of evidence-based interventions in clinical routine. To date, there are only few published effectiveness studies in the context of PTSD (Duffy et al., 2007; Ehlers et al., 2013; Gillespie et al., 2002). Results from this line of research suggests a high effectiveness and high tolerability of empirically well-evaluated PTSD treatment protocols in routine care. However, none of these three studies reported outcome effects on emotion regulation or dissociative symptoms. Reported dropout rates in these studies range between 13.9% (Ehlers et al., 2013) and 20.9% (Duffy et al., 2007), whereas Gillespie et al. (2002) do not report on dropouts.

To further improve treatment effectiveness and reduce dropouts as well as the proportion of non-responders, it is important to gain knowledge on moderators of treatment effects, thus understanding for whom treatment works and what conditions are important for treatment efficacy (Kraemer et al., 2002). Some studies have identified the trauma types combat trauma and sexual assault (Zandberg et al., 2016), comorbid anxiety and depression (Tarrier et al., 2000), and psychotropic medication pre-treatment (Taylor et al., 2001) as moderators of treatment outcome, whereas other studies could not replicate these findings and suggested only PTSD severity pre-treatment as a moderator (van Minnen et al., 2002). In their effectiveness study, Ehlers (2013) found a moderating effects for the following predictors: PTSD not being the primary complaint, treatment

needed for multiple traumas, social problems, relationship status, comorbid mood disorder, history of suicide attempts, history of substance dependence, longer time since the main trauma. The authors also investigated therapist effects and found that therapist experience was associated with somewhat better outcome and less dropouts. Similarly, Duffy et al. (2007) found that rather inexperienced therapists did not address patients' concerns adequately before reliving their trauma which was associated with more dropouts.

Given the currently limited literature on phase-IV trials for PTSD treatment, we aimed to investigate the effectiveness of tf-CBT for patients with PTSD in routine clinical care. Treatment was carried out mainly by therapists in CBT training who received regular supervision from senior therapists. The study had the following research aims: (1) assessing the effectiveness of a phase-based tf-CBT approach under routine clinical care conditions with mainly rather unexperienced therapists; (2) investigating possible moderators for treatment response.

2. Method

2.1. Participants

This naturalistic study took place at two university-based outpatient clinics (Münster and Mannheim, Germany) between February 2014 and April 2016. The study was approved by the ethics committees of both universities. $N = 85$ participants took part in the study and received treatment. Inclusion criteria were the age of at least 18 and a PTSD diagnosis. Exclusion criteria comprised current substance dependence, psychotic disorders, BMI lower than 17.5 and acute suicidality.

Of the 85 participants, $n = 27$ (31.48%) were defined as dropouts: $n = 12$ (14.12%) dropped out from study assessments but continued treatment, $n = 5$ (6%) dropped out from treatment, $n = 8$ both (9%), $n = 2$ (2%) unknown reason. All dropouts were included in the analyses as part of the intent-to-treat [ITT] sample. Participants were on average 35.8 years old ($SD = 12.85$), mostly female (80%) and 48.2% were employed. Most of the participants (63.53%) reported interpersonal violence as the most distressing traumatic event. 70.59% of all participants reported a history of childhood abuse in the Childhood Trauma Questionnaire (CTQ; Bernstein et al., 1994), with emotional neglect ($M = 16.05$, $SD = 6.63$) and emotional abuse ($M = 13.86$, $SD = 6.53$) being the most frequently reported types of maltreatment, followed by sexual abuse ($M = 11.21$, $SD = 7.26$), physical neglect ($M = 10.32$, $SD = 5.07$), and physical abuse ($M = 9.61$, $SD = 5.65$).

Participants fulfilled on average two axis-1 diagnoses. There were no significant differences in age,

gender, comorbid disorders, trauma characteristics or suicidality between completers and dropouts (all p 's $< .05$). However, study completers reported significantly more time since major trauma than study dropouts ($t(75) = 2.08$, $p = .04$). Further characteristics of the sample can be found in Table 1.

2.2. Study protocol

The treatment took place under routine clinical care conditions. In total, $N = 41$ therapists were involved in the study, $n = 24$ and $n = 17$ at each site respectively. All therapists had a master's degree in psychology. One therapist was a senior therapist with PTSD treatment expertise and has treated $n = 4$ participants. All other therapists were in their postgraduate CBT training without specialized PTSD treatment expertise. All therapists received qualified supervision from experienced therapists at least every fourth session.

We announced the study at the homepage of the outpatient clinics and invited patients to establish contact. In a general first appointment for all patients regardless of their symptoms, senior therapists assessed the patients against our inclusion criteria. Eligible patients were informed about the study. $N = 85$ patients fulfilled the inclusion criteria and signed the informed consent to participate in the study received the next available study treatment. Patients who did not sign informed consent were offered the same treatment without any disadvantages.

All participants were interviewed with structured, clinician-led interviews (SCID-I, SCID-II and CAPS-5) to assess diagnostic criteria and they all completed self-report instruments. The structured and clinician-led interview for PTSD, CAPS-5 was conducted by independent interviewers. Diagnostic instruments were conducted at pre-treatment, post-treatment and at three, six and 12 months follow up. After completing the diagnostic instruments, participants received a modularized tf-CBT that included DBT-based interventions for improving emotion regulation when needed and cognitive therapy for PTSD of Ehlers (2013).

First, the treatment focused on preparation for the trauma-focused treatment module. This first module aimed at gaining commitment and good crisis management skills. All participants received individualized psychoeducation on the development and maintenance of PTSD. If participants engaged in treatment-interfering escape mechanisms like self-injury or had a high proneness to dissociation they learned specific skills and emotion regulation strategies to better control their impulses. The main goal of this module was to establish skills for a better behavioural control (crisis management skills). As soon as possible, therapists started with the trauma-focused treatment module including imaginal reliving of the most distressing

Table 1. Demographic and clinical characteristics and of the intent-to-treat sample (ITT), the completer sample and subjects who dropped out of the study.

Variable	N (%) / M (SD)		
	ITT (N = 85)	Completers (n = 58)	Dropouts (n = 27)
Age in years	35.84 (12.85)	35.88 (13.06)	35.74 (12.65)
Gender			
Female	68 (80%)	49 (84.48%)	19 (70.37%)
Male	17 (20%)	9 (15.52%)	8 (29.63%)
Relationship status			
Not married, without partner	22 (25.88%)	18 (31.03%)	4 (14.81%)
Not married with partner	28 (32.94%)	19 (32.76%)	9 (33.33%)
Married living together	23 (27.06%)	13 (22.41%)	10 (37.03%)
Married not living together	3 (3.53%)	1 (1.72%)	2 (7.41%)
Divorced	5 (5.88%)	4 (6.90%)	1 (3.70%)
Widowed	1 (1.18%)	1 (1.72%)	4 (14.81%)
Education level			
University degree	9 (10.59%)	5 (8.62%)	4 (14.81%)
High school ^a	12 (14.11%)	4 (6.9%)	8 (29.63%)
Secondary school ^b	52 (61.18%)	38 (65.51%)	14 (51.85%)
Primary school	3 (3.5%)	3 (5.17%)	0 (0%)
No degree	4 (4.71%)	3 (5.17%)	1 (3.7%)
Other	5 (5.89%)	5 (8.62%)	0 (0%)
Work status			
Full-time job	30 (35.29%)	18 (31.03%)	3 (11.11%)
Part-time job	11 (12.94%)	8 (13.79%)	5 (18.52%)
Not working	12 (14.12%)	7 (12.07%)	2 (7.41%)
Unemployed	10 (11.76%)	8 (13.79%)	2 (7.41%)
Pensioner	5 (5.88%)	5 (8.62%)	12 (44.44%)
Other	11 (12.94%)	9 (15.52%)	3 (11.11%)
Type of trauma			
Interpersonal	54 (63.53%)	35 (60.34%)	19 (70.37%)
Other	15 (17.65%)	12 (20.69%)	3 (11.11%)
Years since main trauma	10.49 (11.69)	12.01 (13.30)	7.33 (6.45)
Childhood abuse present	60 (70.59%)	40 (68.97%)	20 (74.07%)
CTQ subscales			
Emotional abuse	13.86 (6.53)	13.69 (6.45)	14.24 (6.83)
Emotional neglect	16.05 (6.63)	16.11 (6.77)	15.92 (6.45)
Physical abuse	9.61 (5.65)	9.96 (6.05)	8.84 (4.69)
Physical neglect	10.32 (5.07)	10.63 (5.51)	9.64 (3.98)
Sexual abuse	11.21 (7.26)	11.47 (7.33)	10.62 (7.23)
Number of axis-1 diagnoses (ICD-10) in total	2.04 (1.11)	2.07 (1.14)	1.96 (1.06)
Comorbid axis-1 disorder	42 (49.41%)	28 (48.28%)	14 (51.85%)
Comorbid anxiety disorder	18 (21.18%)	9 (15.52%)	9 (33.33%)
Comorbid mood disorder	40 (47.09%)	30 (51.72%)	10 (37.04%)
Comorbid personality disorder	13 (15.29%)	12 (20.69%)	1 (3.70%)
Borderline Personality Disorder	9 (9.85%)	9 (15.5%)	0 (0%)
History of substance dependence	7 (8.24%)	6 (10.34%)	1 (3.70%)
Current suicidal ideation	37 (43.53%)	24 (41.38%)	13 (48.15%)
Subjects with past suicide attempts	23 (27.06%)	17 (29.31%)	6 (22.22%)
Number of suicide attempts	0.55 (0.97)	0.48 (0.99)	0.58 (0.96)
Pre-treatment BDI-sum-score	28.49 (12.96)	28.04 (13.26)	29.46 (12.48)
Pre-treatment CAPS-5-sum-score	37.81 (10.52)	35.79 (10.12)	42.54 (10.09)
Number of treatment sessions	37.42 (19.76)	40.74 (17.90)	28.16 (22.18)

Note. CTQ = Childhood trauma questionnaire; BDI = Beck's Depression Inventory; CAPS-5 = Clinician-administered PTSD scale for DSM-5.

^aHigh school: 12–13 years of school education in the German school system.

^bSecondary school: 9–10 years of school education in the German school system.

memories. Imaginal reliving was conducted with the goal of updating trauma memory (Ehlers, 2013) and included discrimination training or anti-dissociative skills if necessary. Cognitive restructuring techniques were used to modify dysfunctional, maladaptive cognitions about the trauma or its consequences. Trigger analyses and in vivo exposure were conducted to further reduce avoidance behaviour. The last treatment module aimed at reclaiming one's life and improving quality of life. This could also include the treatment of another axis-one diagnosis if necessary. In general, therapists were allowed to switch between modules if this seemed appropriate to the therapist and the supervisor.

The trauma-focused treatment module was introduced between session 1 and 39 ($M = 11.52$, $SD = 8.78$, median = 10). Sessions had a duration of 50 minutes. Participants received on average $M = 37.22$ ($SD = 20.15$; range: 1–80, median = 38) sessions over a period of $M = 56.04$ ($SD = 26.92$; median = 51.3) weeks with $n = 4$ in the ITT sample receiving 80 sessions (4.7%). In total, $n = 16$ (18.8%) received more than 45 sessions and $n = 69$ (81.2%) received not more than 45 sessions. Although the number of sessions is higher than in most RCTs evaluating trauma-focused interventions for PTSD, the overall treatment dose was similar as 50 min sessions were used in the current study, whereas most RCTs

evaluating PTSD treatment have typically used 90–100 min sessions. During the exposure phase, we used 100 min per appointment and that counts two sessions. Thus, the average of 37 sessions in the current study would be equivalent to 19 sessions in a typical PTSD RCT. In addition, the number of sessions provided in this study is representative in the German health care system, where the number of sessions is very flexible and go up to a total of 80 sessions for CBT. Therapy completers received on average 40.74 ($SD = 17.90$) sessions, while treatment dropouts ended treatment on average after $M = 28.16$ sessions ($SD = 22.18$). The study design aimed at delivering 1–2 weekly sessions during the trauma-focused module with longer between-session intervals to the end of treatment to allow for booster sessions relapse prevention. However, as noted in Gillespie et al. (2002), PTSD patients tend to miss sessions due to several reasons. Given this and due to the study design in clinical routine, the aim of regular weekly sessions was not strictly fulfilled.

Before each session, the patients completed weekly questionnaires (as part of the process measures). At the end of therapy and after the post-measurements, patients were invited to take part in follow-up surveys at 3, 6, 12 and 24 months. If a patient did not wish to participate in the study, they were offered the same treatment under the same conditions.

2.3. Measures

Diagnoses were assessed using the Structured Clinical Interview for DSM-IV (SCID-I & SCID-II) (First, 2002). SCID-I and SCID-II both have satisfactory psychometric properties (Lobbstaël et al., 2011).

The Childhood Trauma Questionnaire (CTQ; Bernstein et al., 1994) assesses childhood maltreatment experiences as self-report on a 5-point-scale with a range from 1 = *not at all* to 5 = *very often*. Test-retest reliability ($ICC = .88$) and internal validity ($\alpha = .79$ to $\alpha = .94$) for CTQ were found to be satisfactory (Bernstein et al., 1994), for the current sample, α was .64.

Traumatic events were assessed using the German version of the Life Events Checklist (LEC; Weathers et al., 2013). This self-report instrument assesses 16 traumatic events with an additional item for any other traumatic event.

The Clinician-Administered PTSD Scale for DSM-5, CAPS-5 (Müller-Engelmann et al., 2020) and the self-rating scale Posttraumatic Stress Disorder Checklist for DSM-5, PCL-5 (Krüger-Gottschalk et al., 2017) are the primary outcome measures. The CAPS-5 was administered to determine the diagnostic criteria for PTSD according to DSM-5 and to assess the severity of each symptom over the past month on a 5-point-scale ranging from 0 = *absent* to 4 = *extreme/ incapacitating*. The *PTSD Checklist for DSM-5* is a self-report measure

with 20 items that correspond to the DSM-5 criteria for PTSD. Participants report the intensity of their PTSD symptoms over the past month on a 5-point-scale ranging from 0 = *not at all* to 4 = *extremely*. The internal consistency in the current sample was $\alpha = .89$.

To assess for comorbid depressive symptoms, the *Beck Depression Inventory-II* (BDI-II; Kühner et al., 2007) was used. The BDI-II is widely used and a well-validated measure of depressive symptom severity. The internal consistency in the current sample was $\alpha = .91$.

The Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004) is a self-report assessment to measure emotion regulation strategies on a 5-point-scale from 1 = *almost never* to 5 = *almost always*. In an initial validation, internal consistency ($\alpha = .93$) and test-retest reliability ($r = .88$) were satisfactory (Gratz & Roemer, 2004). The internal consistency in the current sample was $\alpha = .84$.

To measure dissociative symptoms, the short version of the questionnaire Dissociative Experiences Scale (DES; German version FDS-20) was administered. Test-retest reliability ($r = .70$ to $r = .82$) and internal validity ($\alpha = .93$) for the FDS-20 were satisfactory (Spitzer et al., 2004). The internal consistency in the current sample was $\alpha = .95$.

2.4. Statistical analysis

The statistical analysis was conducted with RStudio (RStudio Team, 2020) using R Version 4.2.1 (R Core Team, 2020). Linear mixed models (LMM) with random and fixed effects were computed with the R Package lme (Bates et al., 2015) for pre and post treatment values of the intent-to-treat (ITT) sample. A maximum-likelihood estimator was employed and a significance criterion of $\alpha = .05$ was set for all analyses. The LMMs used all available data points and missing data was assumed to be missing at random (MAR), with analyses conducted under a maximum-likelihood framework. This approach assumes that the probability of missingness is related to observed but not unobserved data, which is accounted for within the linear mixed model computations. This method ensures that missing values do not bias the results, allowing robust inference under the MAR assumption. In order to preserve the observed data structure and provide unbiased estimates, no imputation method was applied.

Treatment outcome and effect sizes. Effect sizes were computed from means and standard deviations of the CAPS-5 and PCL-5 scores using the Cohen's d statistic (Cohen, 1988). The analysis for predictors and moderators of the treatment effect was conducted by applying hierarchical linear modelling. First, an intercept only model (Model 1) was fit, which included fixed effects for time (pre to post treatment) on the severity of PTSD-symptoms (in sum scores of the CAPS-5 and PCL-5 respectively). Secondly,

random intercepts were added for participants (Model 2). Then, to investigate their influence on the treatment effect, individual candidate predictors (e. g. clinical characteristics) were added as fixed effects at level two in separate models. The numerical predictors were centred (following Kraemer et al., 2002a) and for the number of traumatic situations a median split was conducted. Predictors showing a significant interaction effect with time were then added to Model 2 to receive a full model (Model 3). All steps were conducted separately for the CAPS-5 and PCL-5, firstly for the intent-to-treat sample and then repeated for all subjects who completed the study. The completer analyses included only subjects who successfully conducted the complete study, while the ITT-analyses also included subjects who dropped out of treatment while providing enough data for the analyses. Reliable changes pre to post treatment were evaluated with the reliable change index (as proposed by Jacobson & Truax, 1991) and changes in the CAPS-5 sum scores greater than 11.71 are considered as reliable symptom improvement (or exacerbation).

3. Results

3.1. Treatment effectiveness

The observed treatment effect from pre- to post-treatment was large for both the CAPS-5 (ITT: $d = 2.07$, CI [1.62, 2.51]; study completers $d = 2.34$, CI [1.84, 2.83]) and PCL-5 respectively (ITT: $d = 2.02$, CI [1.56, 2.48]; completers $d = 2.15$, CI [1.66, 2.64]). A total of 38 out of 85 (44.71%) participants showed remission from PTSD and 54 out of 85 (63.53%) showed a treatment response, defined as pre-post changes greater than the reliable change index (as proposed by Jacobson

& Truax, 1991). There were no subjects with a reliable symptom worsening in PTSD symptoms.

Figures 1 and 2 pictures the treatment effects for the main outcome variables in the ITT sample.

Both completers and dropouts benefited from treatment and had significant symptom improvements from pre- to post-assessments on the CAPS-5, $t(53) = 17.29$, $p < .001$ for completers, $t(6) = 7.31$, $p < .001$ for dropouts, and on the PCL-5, $t(51) = 14.08$, $p < .001$ for completers, $t(3) = 2.36$, $p = .05$ for dropouts. There were no significant differences in symptom severity between post-treatment and follow-up on either the CAPS-5 ($t(21.18) = 1.47$, $p = .155$) or the PCL-5 scale ($t(74.61) = 0.74$, $p = .460$), i.e. the effect of treatment remained stable between post-treatment and follow-up (for statistics and descriptive data at the different time points see Table 2).

Depressive symptoms measured with the BDI-II were also significantly reduced from pre to post treatment (see Table 2).

Patients showed reductions in dissociative symptoms measured on the DES (German version FDS-20) from $M = 21.04$ ($SD = 20.32$) at pre to $M = 7.76$ ($SD = 11.24$) at post, $t(54) = 6.16$, $p < .001$. This effect as large ($d = 0.81$) and appeared to be stable at the follow-up measurements (follow-up 1: $M = 6.83$, $SD = 9.86$; follow-up 2: $M = 5.99$, $SD = 8.89$).

Besides, patients showed reductions in emotion regulation difficulties measured with the DERS from $M = 107.10$ ($SD = 26.45$) at pre to $M = 79.53$ ($SD = 30.29$) at post treatment, $t(53) = 7.40$, $p < .001$. This effect was also large ($d = 0.97$) and appeared to be stable at the follow-up measurements (follow-up 1: $M = 79.11$, $SD = 29.85$; follow-up 2: $M = 75.12$, $SD = 27.51$).

Effect sizes for all measures at follow-up 1 can be seen in Table 3.

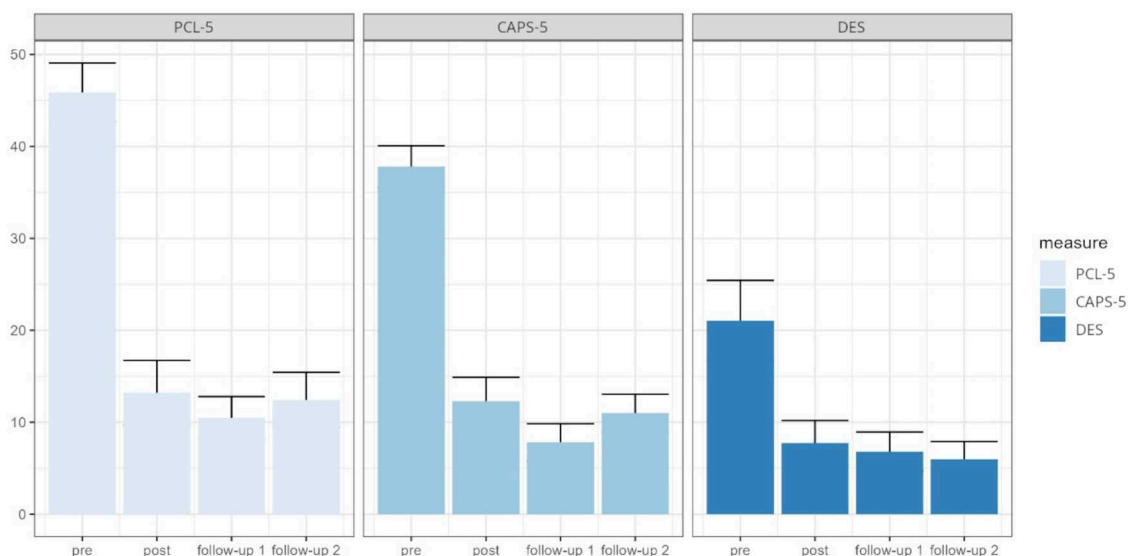


Figure 1. Means of symptom-scores for the ITT sample at the investigated time points.

Note: PCL-5 = PTSD Checklist for DSM-5; CAPS-5 = Clinician-Administered PTSD Scale for DSM-5; DES = Dissociative Experiences Scale. Error bars represent 95% confidence intervals.

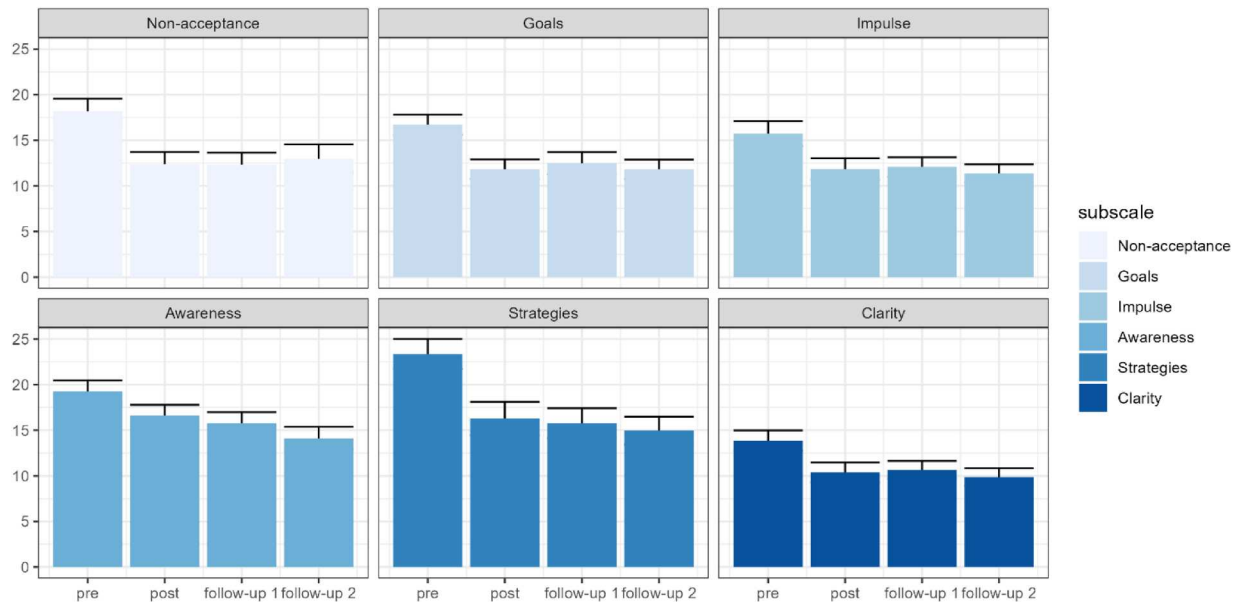


Figure 2. Means scores on the DERS-subscales by time point for the ITT-sample. Note: Error bars represent 95% confidence intervals.

Table 2. Mean (SD) of PTSD symptom severity before and after treatment on the CAPS-5 and PCL-5.

	Pre	Post	Follow-up 1	Follow-up 2	Cohen's <i>d</i> [CI] (pre – post)
CAPS-5					
ITT	37.81 (10.52)	12.29 (12.09)	7.85 (9.37)	11.00 (9.55)	2.07 [1.62; 2.51]
Completers	35.79 (10.12)	10.67 (10.94)	5.36 (4.39)	9.86 (8.49)	2.34 [1.84; 2.83]
Dropouts	42.54 (10.09)	23.38 (14.52)	21.50 (20.51)	16.33 (13.08)	1.10 [-0.15; 2.35]
PCL-5					
ITT	45.87 (14.75)	13.20 (16.33)	10.46 (10.86)	12.44 (13.93)	2.02 [1.56; 2.48]
Completers	45.15 (14.36)	11.82 (15.62)	10.20 (11.03)	10.61 (11.40)	2.15 [1.66; 2.64]
Dropouts	47.44 (15.74)	28.40 (18.05)	12.67 (11.15)	23.80 (23.17)	1.07 [-0.78; 2.91]
BDI					
ITT	28.49 (12.96)	14 (12.34)			1.16 [0.63; 1.69]
Completers	28.04 (13.26)	13.16 (12.26)			1.26 [0.69; 1.82]
Dropouts	29.46 (12.48)	22.67 (11.68)			0.34 [-1.94; 2.63]
DERS					
ITT	107.1 (26.45)	79.53 (30.29)	79.11 (29.85)	75.12 (27.51)	0.93 [0.53; 1.34]
Completers	106.7 (26.03)	77.30 (29.31)	77.96 (31.25)	71.74 (24.16)	1.04 [0.62; 1.47]
Dropouts	107.8 (27.86)	101.8 (34.39)	101.75 (22.25)	93.4 (39.67)	0.12 [-1.34; 1.58]
DES					
ITT	21.04 (20.32)	7.76 (11.24)	6.83 (9.86)	5.99 (8.9)	0.79 [0.40; 1.19]
Completers	21.26 (19.51)	6.48 (9.33)	9.25 (9.55)	4.98 (8.06)	0.90 [0.48; 1.31]
Dropouts	20.52 (22.58)	21.1 (20.35)	9.5 (13.06)	14.67 (13)	0.13 [-1.33; 1.59]

3.2. Adverse events

No serious adverse events (e.g. suicide attempts) occurred during therapy. In patients with self-harming behaviour pre-treatment, self-harming behaviour without the need for medical intervention occurred in 37.65% of the patients (*n* = 32) during treatment.

No difference in self-harming behaviour was found between completers and dropouts.

3.3. Moderator analysis

None of the candidate predictors showed significant interaction effects with time in the full ITT-models

Table 3. Cohen's *d* [CI] of symptom severity change between before treatment and follow-up 1.

	ITT	Completers	Dropouts
CAPS-5	2.57 [1.36; 3.77]	3.43 [1.96; 4.91]	NA
PCL-5	2.45 [1.70; 3.20]	2.51 [1.69; 3.32]	1.79 [-0.90; 4.47]
DEERS	0.87 [0.30; 1.44]	0.92 [0.29; 1.54]	0.53 [-1.23; 2.29]
DES	0.91 [0.37; 1.45]	1.00 [0.41; 1.60]	0.37 [-1.38; 2.11]

for the CAPS-5 (see Table 4) and the PCL-5 scores (see Table A3 appendix). In the univariate ITT-models (see Tables A1 and A2 appendix) several predictors showed significant main effects and interactions on the PCL-5 and CAPS-5 scores respectively. However, when added to the full models, only a main effect of the number of suicide attempts for the CAPS-5 scores remained significant (see Table 2; Table A3 appendix for PCL-5). This indicates that higher numbers of suicide attempts were related to higher levels of PTSD symptom severity across assessments (non-specific prediction).

In the full models of the completer analysis, the history of substance dependence showed a significant interaction with time for the CAPS-5 and a main effect of the number of diagnoses for the PCL-5 reached significance (see Table A6 appendix; for the univariate models of the completer analysis see Tables A4 and A5 appendix).

The number of therapy sessions differed significantly ($t(58.26) = 2.68, p = .01$) between the two treatment centres with patients in Münster ($M = 41.89, SD = 19.53$) receiving more sessions than in Mannheim ($M = 29.54, SD = 19.06$). To control for this difference, the number of therapy sessions was added to all individual linear mixed models for the candidate predictors (see Tables A1 and A2 appendix) and in all models there was no interaction with the effect of time (all p 's > 0.05).

A linear mixed model with time (pre vs. post), self-harming behaviour (no vs. yes) and an interaction of time* self-harming behaviour as independent variables for the CAPS-5 scores revealed a significant main effect of self-harming behaviour, indicating that patients with self-harming behaviour generally showed higher CAPS-5 scores across all time points ($F(1,80) = 4.73, p = .03$). However, the interaction term remained non-significant ($F(1,59) = 0.65, p$

= .42), i.e. self-harming behaviour did not moderate the treatment effect.

4. Discussion

We aimed at assessing the effectiveness of a tf-CBT treatment in routine clinical practice with therapists in training. The findings show a high applicability of the tf-CBT approach with very high ITT effect sizes of $d = 2.57$ (CAPS-5) and $d = 2.45$ (PCL-5) for the follow up assessment. These effect sizes are in line with or even compare favourably to recent meta-analytic findings (Coventry et al., 2020; Hoppen et al., 2023, 2024). Importantly, earlier studies typically included well-trained and experienced therapists, whereas our data demonstrate that tf-CBT can be effectively be delivered by less experienced practitioners. Hoppen et al. (2024) reported in their meta-analyses large effect sizes with Hedges $g = 1.03$ and 1.13 for the comparison between active and passive control groups. In recent RCTs, effect sizes of $d = 0.98/d = 1.35$ (Bohus et al., 2020), $d = 1.72$ (Boterhoven de Haan et al., 2020), $d = 1.52$ (Voorendonk et al., 2020) and $d = 1.95 / d = 2.45$ (Ehlers et al., 2014) were reported. In phase-IV trials, Ehlers et al. (2013) reported $d = 1.63$ from pre to posttreatment, Duffy et al. (2007) $d = 1.74$ and Gillespie et al. (2002) $d = 2.47$. The effect sizes of our phase-IV trial compare favourably with these recent results. In sum, the treatment was associated with a significant reduction in PTSD, depression, dissociation, and emotion regulation difficulties. Therefore, our results highlight that tf-CBT can be effectively delivered by less experienced practitioners.

The rather high effect sizes could possibly be due to the duration of treatment since patients were allowed to stay in treatment until therapist and patient agreed on treatment completion. The decision against a fixed amount of treatment sessions is in line with Schnurr and Lunney (2016) who argued that treatment should ideally be continued until remission from PTSD is reached which is relevant for an improvement of quality of life. On average, our participants reported a median of 5 traumatic events and they received $M = 37.22$ ($SD = 20.15$) sessions (duration of one session:

Table 4. Estimates of random effects (patient) and fixed effects (time, clinical characteristics) from linear mixed models on sum scores of the CAPS-5.

	Model 1 Intercept only	Model 2 Random intercepts for patients	Model 3 Full model
Constant	37.91(1.23)***	37.92 (1.15)***	37.58 (1.25)***
Time	-24.65 (1.31)***	-24.50 (1.33)***	-23.68 (1.6)***
Number of suicide attempts			3.39 (1.23)***
Time * number of suicide attempts			-2.829 (1.60) ^(*)
History of substance dependence			0.35 (3.96)
Time * history of substance dependence			-8.62 (4.68) ^(*)
<i>N</i>	145	145	118
Akaike Information Criterion	1,090.39	1,092.54	871.64
Bayesian Information Criterion	1,102.24	1,110.32	898.82

*** $p < .001$, ** $p < .01$, * $p < .05$, (^(*)) $p < .10$.

50 minutes), completers received $M = 40.74$ ($SD = 17.9$) sessions and dropouts $M = 28.16$ ($SD = 22.18$). Given the number of traumatic events and therefore the symptom severity, participants might have needed even more sessions. The amount of sessions is comparable to the study of Bohus et al. (2020) and suggest that patients with multiple traumas need a higher treatment dose (see Galovski et al., 2012; National Institute for Health and Care Excellence [NICE] guidelines, 2018).

Although the effect sizes in our trial are high, the remission rate was in the medium range but still in line with meta-analytic findings. Specifically, the remission rate from PTSD in our sample was 44.71%, which is somewhat higher than the recent meta-analytic findings reported by Cuijpers et al. (2024). An effectiveness study on DBT-PE (Harned et al., 2021) reported a remission rate of 31.3%, an RCT on DBT-PTSD (Bohus et al., 2020) reported a remission rate of 58%. Ehlers et al. (2013) and Duffy et al. (2007) did not report remission rates.

No adverse events such as suicide attempts or other severe self-harming behaviour were observed during treatment and no reliable clinical worsening of PTSD symptoms was observed. The dropout rates are comparable to other studies. A total of 31.48% of our sample did not provide complete data and was therefore excluded from data analyses. Of note, 17.65% of the sample ($n = 15$) dropped out of treatment, whereas an additional 14.12% withdrew from the study assessments but had completed the treatment. A treatment dropout rate of 17.65% is comparable to earlier effectiveness studies in routine care (e.g. Ehlers et al., 2013; Duffy et al., 2007). In addition, it compares favourably with average dropout rates for PTSD treatment estimated in recent meta-analyses, ranging from 20.9% (Varker et al., 2021) and 26.34% (Hoppen et al., 2023), to even 41.5% (Mitchell et al., 2023). To gain deeper knowledge about the reasons for dropout, future studies could assess participants' potential tendencies to dropout and their specific reasons at the beginning of each treatment sessions. This may help better understand the patient needs and adapt treatment processes to reduce dropout rates. Our data suggest that tf-CBT, particularly when employing a phase-based approach, is tolerable in a community sample.

However, it is important to acknowledge the limitation imposed by the absence of a control group in our study. However, it is important to acknowledge the limitation imposed by the absence of a control group in our study. Although this is typical and even recommendable for effectiveness studies, future research may include pragmatic randomized controlled trials that systematically compare the effects of different trauma-focused interventions (e.g. TF-CBT vs. EMDR) in routine care. Given the fact that the

therapists had a very low level of experience in PTSD treatment, the high effect sizes and low treatment dropout rates are especially promising and contradict the fear of high dropout rates.

Altogether, our data support the insights gathered in RCTs in academic settings that tf-CBT is effective in treating both PTSD following exposure to single as well as multiple traumatic events (Hoppen et al., 2024) by demonstrating that tf-CBT is also effective in routine care.

The second aim of the study was to identify relevant moderators of treatment outcome. Firstly, the univariate models showed a prediction of PTSD-symptoms for depressive (BDI) and dissociative symptoms (DES). Further, in these models, the number of suicide attempts and the history of substance dependence showed both a predictive and a moderating effect. However, and importantly, in the full model, the only marginally significant moderators were the number of suicide attempts and the history of substance dependence. These two variables were also found as moderator and predictors of the treatment effect in the univariate models conducted by Ehlers et al. (2013), but not in the full models. In contrast, Ehlers et al. (2013) revealed social problems and 'multiple traumas need treatment' as robust moderators of the treatment effect. Interestingly, we could not replicate findings from other studies who found type of trauma, time passed since trauma (Ehlers et al., 2013; Duffy et al., 2007), number of traumatic events (Ehlers et al., 2013), length of therapy, number of comorbid diagnoses, major depression/ current mood disorder (Ehlers et al., 2013; Duffy et al., 2007), current anxiety disorder, personality disorder (Ehlers et al., 2013), borderline personality disorder or childhood abuse as significant moderator variables or nonspecific predictors. As we had no restriction for treatment dose but chose a pragmatic approach of an individualized case formulation, treatment could be tailored for the needs of each participants. This can possibly explain why number of traumatic events, months since trauma and various comorbid symptoms and disorders did not moderate the treatment effect. Also, participants were rather homogeneous regarding the type of trauma experienced. A limited diversity of trauma type may have contributed to the somehow inconclusive results of the moderator analysis. Future trials may include patients with various types of trauma to better examine the moderating role of trauma type in treatment outcomes.

The study has several limitations. The missing control group can be seen as a first limitation. Second, we did not systematically assess the reasons for drop out. Third, therapists followed a modularized treatment approach where patients learned skills for emotions regulation if needed before approaching the trauma-focused module including imaginal exposure. Therefore, the treatment duration differed between the

participants depending on their need for emotion regulation skills. In contrast to the phase-based DBT approach for PTSD (Bohus et al., 2013, 2020; Harned et al., 2021), we did not deliver a formalized DBT treatment including skills training in groups. However, we individualized the first treatment phase according to patients needs in an individual case formulation and thus individualized skills training based on DBT principles was administered during therapy sessions. Overall, study participants showed improved emotion regulation competences and less dissociative symptoms at post treatment. It remains unclear if the modularized approach helped to gain more competencies in emotion regulation and to reduce dissociation or if this is mainly due to the trauma-focused approach in the second treatment module. This is to be tested in a controlled study design. We used a phase-based treatment approach that was applied in a very flexible way, leading to a high variability in treatment duration and number of sessions. Depending on the patient's needs, therapists could decide on the dose of each intervention individually. This implies that participants varied in their dose of emotion regulation skills and trauma exposure, respectively. Our data did not allow to test the effect of this flexibility on the treatment outcome. In future studies, it would be informative to directly compare the effectiveness of flexible vs. standardized treatment approaches as well as investigate the impact of treatment dose on outcome.

Future research using larger and more heterogeneous samples as well as comparison groups is needed to test the generalizability of findings as well as to more closely investigate potential moderators and the efficacy of specific intervention tools on treatment outcome. Additionally, exploring the integration of other therapeutic techniques (e.g. EMDR) in naturalistic settings could provide more comprehensive treatment frameworks. This may help to identify potential mechanism of change and help in finetuning specific interventions to further improve the treatment effect.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Data availability statement

Dataset and materials are available from the corresponding author.

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