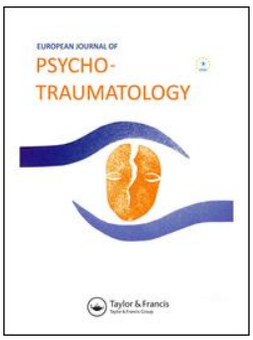

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STUDY PROTOCOL

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BEST FOR CAN – bringing empirically supported treatments to children and adolescents after child abuse and neglect: study protocol

Rita Rosner [a], Antonia Barke [a], Björn Albrecht [b], Hanna Christiansen [b], David Daniel Ebert [c,d], Franziska Lechner-Meichsner [e], Rainer Muche[f], Anna-Carlotta Zarski [c] and Regina Steil [e]

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ABSTRACT

Background: Despite a large body of evidence demonstrating the effectiveness of psychotherapy for posttraumatic stress for children and adolescents, the adoption of empirically supported treatments (ESTs) in routine care is low.

Objective: This implementation study aims to evaluate the dissemination of Trauma-Focused Cognitive Behavioural Therapy (TF-CBT) for children and adolescents with posttraumatic stress symptoms (PTSS) after child abuse and neglect (CAN) with a focus on supervision.

Method: In a cluster-randomized controlled trial, the study will evaluate the implementation of TF-CBT focussing on the training of therapists including the provision of supervision. The effectiveness of specialized trauma-focused supervision will be compared to supervision as usual with respect to the successful implementation of TF-CBT for youths with PTSS administered by psychotherapists with different levels of professional experience. The primary outcome is whether the patient receives a treatment with sufficient adherence to the TF-CBT manual. The unit of randomization will be the therapists. The main outcome will be analysed using multilevel logistic regressions. Secondary outcomes will concern further patient-related (reduction of PTSS and depressive symptoms) and therapist-related (professional quality of life) variables. Additional exploratory analyses are planned.

Discussion: Since the trial is designed as an implementation study, it permits naturalistic referrals to the participating therapists by patients, caregivers, child and youth welfare agencies and paediatricians. The strict primary outcome will help evaluating the role of model-based supervision in the implementation process. The explorative outcomes will evaluate whether implementation success translates into better patient outcomes. We expect that the dissemination measures will lead to a successful implementation of TF-CBT and promote sustainable structures in routine care that will remain in place after study completion and offer access to ESTs for future children and youths with a history of CAN.

Brindando tratamiento basado en evidencias a niños y adolescentes luego del abuso y la negligencia infantiles ('best for can', por sus siglas en inglés): un protocolo de investigación

Antecedentes: A pesar de que existe un robusto cuerpo de evidencia que demuestra la efectividad de la psicoterapia para el trastorno de estrés postraumático en niños y adolescentes, la adherencia a tratamientos basados en evidencia (TBEs) es baja en la atención de rutina.

Objetivo: El objetivo de este estudio de implementación es el de evaluar la difusión de la terapia cognitiva conductual enfocada en trauma (TCC-ET) para niños y adolescentes con síntomas de estrés postraumático (SEPT) secundarios al abuso y la negligencia infantiles con un enfoque en la supervisión.

Método: Dentro de un estudio por racimos controlado y aleatorizado, el estudio evaluará la implementación de la TCC-ET enfocándose en el entrenamiento de terapeutas e incluyendo el brindar supervisión a este entrenamiento. La efectividad de la supervisión especializada enfocada en trauma se comparará con la supervisión habitual ya realizada en la implementación exitosa de la TCC-ET para jóvenes con SEPT brindada por psicoterapeutas con diferentes niveles de experiencia profesional. El objetivo primario es evaluar si el paciente recibe un tratamiento con adecuada adherencia al manual de la TCC-ET. La unidad de aleatorización serán los terapeutas. El objetivo principal será analizado empleando regresiones logísticas multinivel. Los objetivos secundarios serán variables relacionadas con preocupaciones asociadas a los pacientes (reducción de SEPT y de síntomas depresivos)

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Implementation; Children; adolescents; supervision; abuse; neglect; trauma-focused cognitive behavioural therapy

PALABRAS CLAVE
Implementación; niños; adolescentes; supervisión; abuso; negligencia; terapia cognitivo conductual enfocada en trauma

关键词
实施; 儿童; 青少年; 督导; 虐待; 忽视; 聚焦创伤认知行为疗法

HIGHLIGHTS

- Protocol for astudy that investigates the implementation oftrauma-focused cognitive behavioural therapy for children and adolescents with posttraumatic stress symptoms following abuse.
- The study examines the role of trauma-focused supervision in providing adherent therapy and reducing patients' symptoms.

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Trial registration: German Clinical Trial Registry (GCTR), DRKS00020516, Registered 12 February 2020, https://www.drks.de/DRKS00020516.
Supplemental data for this article can be accessed here.

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y asociadas a los terapeutas (calidad de vida profesional). Se planea realizar análisis exploratorios adicionales.
Discusión: Debido a que el ensayo clínico está diseñado como un estudio de implementación, este permite generar derivaciones naturalísticas a los terapeutas participantes por parte de los pacientes, cuidadores, organismos de bienestar de niños y adolescentes y por pediatras. El riguroso objetivo primario ayudará a evaluar el papel de la supervisión basada en modelos durante el proceso de implementación. Los resultados exploratorios evaluarán si el éxito de la implementación se traduce en mejores resultados para los pacientes. Se espera que las medidas adoptadas para la difusión de la TCC-ET conlleven a su implementación exitosa y promuevan estructuras sostenibles en el cuidado rutinario que continúen luego de terminado el estudio. Además, se espera que estas medidas permitan que en un futuro los niños y jóvenes con antecedentes de abuso y negligencia infantiles cuenten con acceso a TBEs.

最适合的方式–为遭受儿童虐待和忽视后的儿童和青少年提供实证支持的治疗:研究方案

背景: 尽管有大量证据表明心理治疗对儿童和青少年创伤后应激的有效性，在常规护理中采用实证支持治疗 (EST) 的情况仍然很少。
目的: 本实施研究旨在评估针对遭受儿童虐待和忽视 (CAN) 后患上创伤后应激障碍症状 (PTSS) 的儿童和青少年的, 注重督导的聚焦创伤认知行为疗法 (TF-CBT) 的传播。
方法: 在一项整群随机对照试验中, 本研究将评估注重提供督导的治疗师培训的TF-CBT的实施情况。将聚焦创伤特定督导的有效性与对不同专业经验水平的心理治疗师管理下患有PTSS的年轻人成功实施TF-CBT的常规督导进行比较。主要结果是患者是否接受到足够遵守TF-CBT手册的治疗。随机化单位将是治疗师。主要结果将使用多层逻辑回归进行分析。次要结果将关注进一步与患者相关 (PTSS和抑郁症状的减少) 和与治疗师相关 (职业生活质量) 的变量。计划进行其他探索性分析。
讨论: 由于本试验是作为一项实施研究而设计的, 因此允许患者, 护理人员, 儿童和青年福利机构自然转介至预期的治疗师。严格的主要结果将有助于评估基于模型的督导在实施过程中的作用。探索性结果将评估实施成功是否可以转化为患者更好的结果。我们希望这些传播措施将带来TF-CBT的成功实施，并促进研究完成后仍有一席之地的常规护理中的可持续结构, 并为未来CAN历史中的儿童和青少年提供获得EST的机会。

Abbreviations: BayDSG: Bayerisches Datenschutzgesetz [Bavarian Data Protection Act]; BMBF: Bundesministerium für Bildung und Forschung [Federal Ministry of Education and Research]; CAN: Child abuse and neglect; CATS: Child and Adolescent Trauma Screen; CATS-2: Child and Adolescent Trauma Screen, (expanded version with additional items for complex PTSD); CC: Case consultation; CGI: Clinical Global Impression Scale; CME: Continuing medical education; CONSORT: Consolidated Standards of Reporting Trials; CTQ: Child Trauma Questionnaire; CYWA: Child and youth welfare agency; DISYPS-III: Diagnostik-System für psychische Störungen nach ICD-10 und DSM-5 für Kinder und Jugendliche – III [Diagnostic System for Mental Disorders According to ICD-10 and DSM-5 for Children and Adolescents]; DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition; DSMB: Data safety and monitoring board; EBPAS: Evidence-Based Practice Attitude Scale; EST: Empirically supported treatment; FBB: Fragebogen zur Beurteilung der Behandlung [Questionnaire for Treatment Satisfaction]; GCP: Good clinical practice; IC: Informed consent; ICC: Intraclass correlation coefficient; ICD-10: International Classification of Diseases, 10th edition; ICD-11: International Classification of Diseases, 11th edition; ICS: Implementation Climate Scale; IQ: Intelligence quotient; ITT: Intent-to-treat; LPT: Licenced psychotherapist; MFQ: Mood and Feelings Questionnaire; PIT: Psychotherapist in training; ProQol: Professional Quality of Life Scale; PTS: Posttraumatic stress; PTSD: Posttraumatic stress disorder; PTSS: Posttraumatic stress symptoms; RCT: Randomized controlled trial; SAE: Serious adverse event; SAPPTI: State-accredited postgradual psychotherapy training institute; SATT: Sufficiently adherent TF-CBT therapy; SAU: Supervision as usual; SDQ: Strengths and Difficulties Questionnaire; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; SR: Standardized session records; TF-CBT: Trauma-Focused Cognitive Behavioural Therapy; TFS: Trauma-focused supervision; TSC: Trial steering committee; VAS: Visual analogue scale; WMA: World Medical Association

1. Background

Children and adolescents exposed to abuse and neglect (CAN) have an elevated risk of developing mental disorders, developmental impairments (such as educational failure), and physical health problems that often persist into adulthood. Effective trauma-focused treatments for child survivors of CAN have been developed. However, the availability of these empirically supported treatments (ESTs) is limited

in Germany (Fegert et al., 2011). Especially in German child welfare populations, a large service gap exists (Fegert et al., 2013; Ganser, Münzer, Plener, Witt, & Goldbeck, 2016; Münzer, Fegert, & Goldbeck, 2015). Consequently, the majority of traumatized youths in need receives no, or unspecific non-evidence-based services, resulting in significant impairment (Chen et al., 2010; Irish, Kobayashi, & Delahanty, 2010) despite evidence that survivors receiving ESTs benefit significantly more than those receiving unspecific interventions (Gutermann et al., 2016; Gutermann, Schwartzkopff, & Steil, 2017).

An EST with strong empirical support is trauma-focused cognitive behavioural therapy (TF-CBT) with medium to large effect sizes (Cohen et al., 2016; de Arellano et al., 2014; Gillies, Taylor, Gray, O'Brien, & D'Abrew, 2012; Goldbeck, Muche, Sachser, Tutus, & Rosner, 2016). Besides posttraumatic stress symptoms (PTSS), TF-CBT also improved depression, anxiety and externalizing symptoms (Goldbeck et al., 2016).

Multiple barriers impede the implementation of TF-CBT for survivors of CAN: Service-providing clinicians may have limited knowledge and skills, negative attitudes towards research results, and fears that patients experience distress through trauma-focused assessments or interventions (Ruzek & Rosen, 2009). On the referrers' and the patients' side, lack of knowledge, insufficient support by caregivers and the non-availability of suitable treatment places may act as barriers. Considering the health system, the implementation of TF-CBT may be hindered by the organization of services and a lack of training and supervision for therapists (Frueh, Grubaugh, Cusack, & Elhai, 2009). Clinical guidelines are designed to improve service provision (e.g. (Schäfer, Gast, & Hofmann, 2019)). However, in isolation they have limited effects on clinical practice (Fixsen & Blase, 1993; Girlanda, Fiedler, Becker, Barbui, & Koesters, 2017; Ruzek & Rosen, 2009).

Therefore, an active approach to disseminating effective mental health treatments is needed (Chorpita & Regan, 2009). Previous studies demonstrated that interdisciplinary collaboration in the communities can foster closer relationships between institutions and practitioners and thereby improve outcomes of trauma-exposed youths (Bai, Wells, & Hillemeier, 2009). Systematic assessments of trauma and PTSS (Frueh et al., 2009; Ruzek & Rosen, 2009) increase trauma awareness among child welfare workers and clinicians. In this study, we will thus combine training therapists to provide TF-CBT with training child and youth welfare agency (CYWA) staff and paediatricians in appropriate screening procedures. By connecting the therapists with CYWA staff and paediatricians through shared training sessions, we will establish a sustainable network of referral structures.

The current gold standard for improving the adoption of an EST by psychotherapists is a combination of training in a manualized EST, and clinical consultation/supervision (Chorpita & Daleiden, 2014; Sholomskas et al., 2005). Supervision in particular is regarded as a promising part of optimizing training (Rakovshik & McManus, 2010). Research on supervision is sparse (Weck, 2013), but since trauma-focused treatments often encounter the specific barrier of therapists' fear of 'retraumatizing' the patient when using exposure-based interventions, supervision may be of great importance. Supervision has also been reported to improve therapist fidelity and, in turn, enhance the retention of patients and their outcomes (Beidas, Edmunds, Marcus, & Kendall, 2012; Dorsey et al., 2013; Schoenwald, Sheidow, & Chapman, 2009).

1.1. Objectives of the current trial

Aiming to close the service gap for survivors of CAN, our study will disseminate the implementation of TF-CBT in the German mental healthcare system by training psychotherapists to deliver TF-CBT and child and youth welfare agency staff and paediatricians to recognize PTSS and apply appropriate screening and referral procedures.

Because the provision of supervision requires additional resources, we will evaluate whether model-specific trauma-focused supervision (TFS) leads to improved implementation outcomes compared to supervision as usual (SAU). We expect TFS to be superior to current supervision practice in Germany regarding the delivery of treatments adhering to the TF-CBT manual and symptomatic improvement for the treated children. Investigating the usefulness of TFS as a means of implementing TF-CBT and simultaneously examining whether such implementation translates into improved outcomes for the patients, classifies our design as a Hybrid Type III implementation study. (Bauer, Damschroder, Hagedorn, Smith, & Kilbourne, 2015)

Further research questions are related to both stakeholder groups: those receiving care (patients and their caregivers) and those providing it (therapists, CYWA staff, paediatricians and supervisors).

1.1.1. Recipients of care

Previous RCTs of TF-CBT reported large improvements for PTSS and depression (Goldbeck et al., 2016). Since supervision may play a role in transferring the improvements found in RCTs into routine care, we expect patient outcomes that improved in RCTs (PTSS, depressive symptoms) to be superior in the TFS condition compared to SAU.

1.1.2. Health and care providers

Measuring personal and institutional factors on the health providers' side, such as their personal attitude towards evidence-based practices and the implementation climate of the institutions where they work allows addressing questions of implementation strategy.

Working with children who have suffered CAN may impact the professional quality of life of the health care workers in various ways. We will investigate the influence of the implementation process on their professional quality of life.

Supervision provides the therapist with feedback and encouragement from an expert offering an outside perspective and allows for reflection on the therapy process. In TFS, it also affords an opportunity to discuss the manual and its application to the individual case. We therefore expect TFS to improve adherence to the manual.

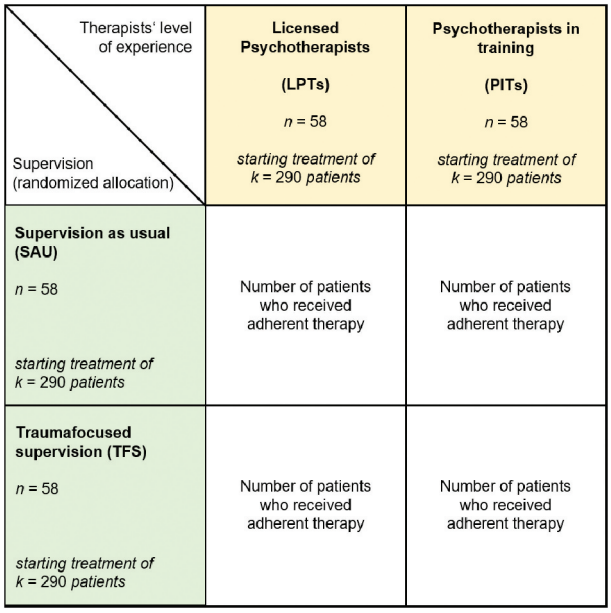

Figure 1. Study design.

2. Methods

2.1. Trial design

The BESTFORCAN study is designed as a Hybrid Type III implementation study, with an overall 2 × 2 design (Bauer et al., 2015). One factor is the therapists' level of professional experience (Licensed psychotherapists vs. Psychotherapists in training), the other factor is the type of supervision (TFS vs. SAU) the therapists receive (Figure 1). We use a cluster-randomization design: The unit of randomization are the therapists, with individual patients nested in therapists.

2.2. Study setting

The study is funded by the BMBF (grant number 01KR1804), will be coordinated from four research sites (Universities of Marburg, Frankfurt/Main, Eichstätt-Ingolstadt, Erlangen-Nürnberg) and carried out at numerous study sites all across Germany. It will last four years. During this period, 58 licenced psychotherapists (LPTs) in five German regions (Köln/Bonn, Bremen, Leipzig/Halle/Erfurt, Berlin/Potsdam and Hannover/Hamburg) and 58 psychotherapists in training (PITs) from a minimum five state approved postgradual psychotherapy training institutes (SAPPTIs) in Berlin, Bielefeld, Bochum, Landau, Mannheim and Marburg will be invited to participate in our TF-CBT training programme. The trained LPTs will treat patients in their own private practices, the PITs in the outpatient clinics attached to the SAPPTIs. The patient treatments will be individual psychotherapy sessions with the patient and the caregiver and be part of routine care with the therapists reimbursed by the health insurers in the standard manner in accordance with German regulations. The referral process will proceed naturalistically. According to the randomization outcome, the therapists will engage in SAU or be allocated to TFS. The TFS will be delivered as telephone-based case conferences (CCs) with expert TF-CBT practitioners.

2.3. Participants

2.3.1. Inclusion and exclusion criteria

For the different groups of study participants, different sets of inclusion and exclusion criteria apply (see Figure 2 for participant flow).

Child and adolescent LPTs and PITs are eligible to participate in the TF-CBT training programme if they work as a PIT in one of the collaborating SAPPTIs or as an LPT in one of the selected regions and by providing informed consent (IC). They will be excluded if the time left to the end of their postgradual training or their retirement is insufficient for the TF-CBT training and the subsequent treatment of patients. Study information will be provided and the IC collected by the study centres in Frankfurt (for the LPTs) and in Marburg (for the PITs).

Patients are eligible to participate if they are between 5–20 years old, have experienced CAN according to the event criteria proposed for ICD-11 (Sierau, 2019; Slep, Heyman, & Foran, 2015), have a diagnosis of maltreatment-related PTSD according to the diagnostic criteria of ICD-10, or any mental disorder and at least 21 points in the Child and Adolescent Trauma Screen (CATS-2) (Sachser et al., 2017). At least one caregiver must be prepared to attend regular treatment sessions. Patients will be excluded in case of an intelligence quotient (IQ)

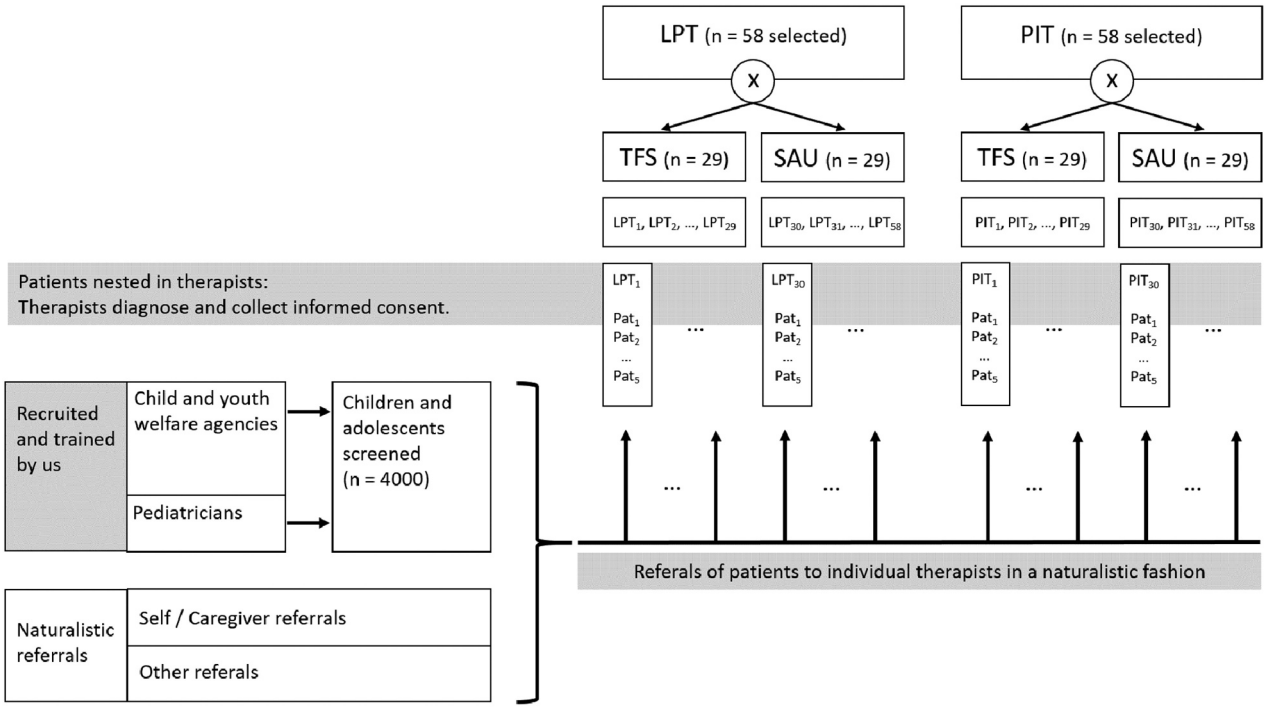

Figure 2. Participant referral and allocation.

of < 50, current psychosis, severe substance disorder, acute suicidality, or other current psychotherapy. Stable psychotropic medication will be allowed. Study information will be provided and the IC collected by the participating therapists via a standardized procedure overseen by the study centres in Frankfurt (LPTs) and in Marburg (PITs).

2.3.2. Sample size

Due to the hierarchical data structure, sample size calculation is based on a two-step procedure and resulted in a group size of 116 therapists (equally in SAU and TFS) treating 580 patients. (For details see supplementary digital content 1).

2.3.3. Recruitment

Recruitment strategies include standard public relations work, a homepage (www.bestforcan.de) and reports about the project in professional journals (Rosner, Fornaro, & Unterhitzenberger, 2019), cooperation with professional organizations and directly contacting LPTs and PITs (through their programme directors). For therapists, additional costs caused by project participation will be covered.

Once the first therapists and referrers will have been trained, we will begin recruiting the patients and their caregivers. Given the prevalence data (Ganser et al., 2016), we will screen a total of >4,000 children and adolescents with a history of CAN. CYWAs in the relevant regions will be invited to the training and to implement screening and referral processes, thus increasing the number of identified cases (Münzer et al., 2015). Patients will receive tokens for completed reassessment/monitoring of their symptoms. Collected tokens can be exchanged for small incentives, aiming to reduce dropouts from the study. CYWAs will be reimbursed for the additional time investment of their social workers. Paediatricians will be recruited via their own professional association and reimbursed for the additional time invested in screening patients (Figure 2).

2.4. Randomization procedure

The unit of randomization will be the therapists. The randomization will stratify for therapist experience (PIT or LPT) and in case of the PITs for the SAPPTI to balance for the effect of different SAPPTIs. An independent statistician (Rainer Muche, University Ulm) will perform the randomization as stratified block randomization with permuted block length using the randomization software ROM (Rohlmann, Muche, & Goldschmidt, 2004). The therapists will be randomized after the live training workshop.

2.5. Timeline and points of assessment

The points of assessment are structured according to the person the data refers to, regardless of who supplies it: i.e. patient-related data are all data that refer to the individual patient, regardless whether they are

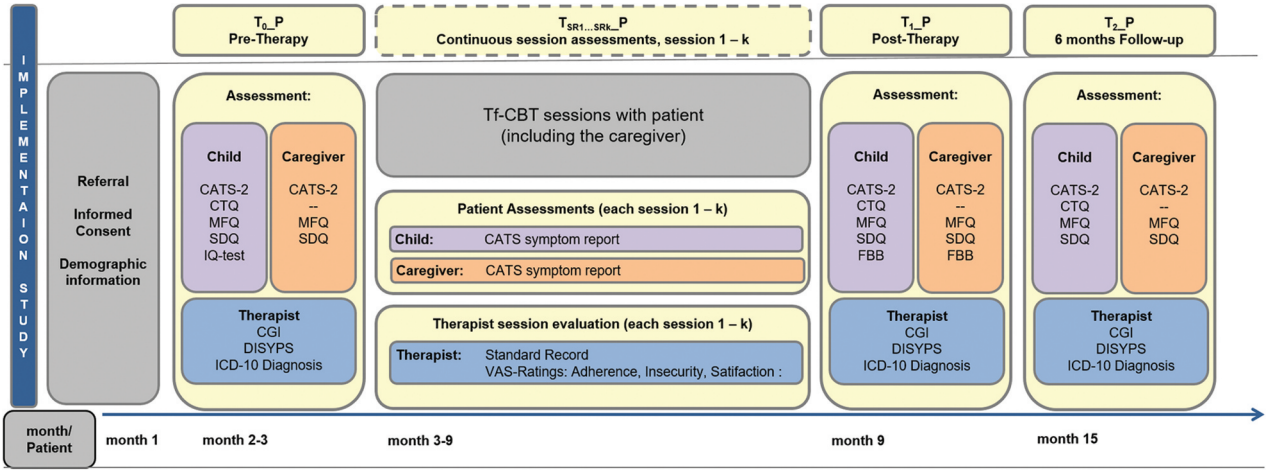

Figure 3. Therapists' points of assessment.

self-report measures, caregiver measures or therapist assessments.

2.5.1. Therapists

After the therapist's IC, assessment points are: baseline (T_0_Th_Therapist), after the web-based training (T_1_Th_Therapist), after the live workshop (T_2_Th_Therapist) and during the treatment phase after 6 (T_3_Th_Therapist) and 18 months (T_4_Th_Therapist) after randomization. We will also carry out an isolated assessment (T_{RR}_Th_Therapist) how receiving the randomization result affects the readiness to use TF-CBT (Figure 3).

2.5.2. Patients

After their IC and collection of demographic data, the children and adolescents will be assessed at three main time points by the therapists: at baseline T_0_P before TF-CBT, at T_1_P post TF-CBT and at T_2_P at the 6 months follow-up. Patient data consist of self-report measures, and caregiver and therapist ratings. In addition, at T_0_P the patient's IQ and whether they experienced CAN will be assessed. These assessments will be carried out by the therapists in the first session(s) using the standard procedures of their normal clinical routine. At the end, at T_1_P, treatment satisfaction will be measured (Figure 4). Beside the main assessment points, in continuous assessments at each session, the patient and the caregiver will fill in a brief symptom report to monitor the PTSS throughout the therapy. The therapists will record for each session, which TF-CBT element they worked on, how much time they spent with the child, the caregiver or both, whether the therapist had supervision regarding the case in the interim and how they rate their own adherence and self-efficacy in the session (Figure 4).

2.5.3. CYWA staff, programme directors, paediatricians

After their IC, paediatricians and the staff and programme directors of the CYWAs will complete a questionnaire regarding their professional quality

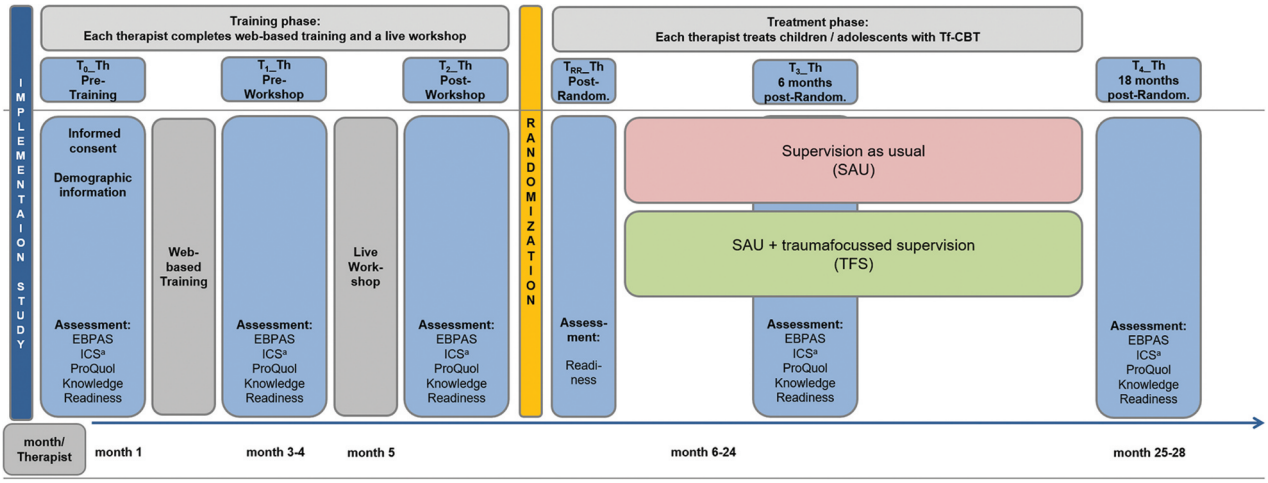

Figure 4. Patients' points of assessment.

of life. Paediatricians will also answer questions about their attitude towards evidence-based treatments. These assessments will be repeated after the conclusion of the study.

2.5.4. Supervisors

At the end of the programme, the supervisors will be interviewed with a qualitative interview and asked about their views of possible barriers and facilitating factors regarding the implementation of TF-CBT.

2.6. Interventions

All patients will receive TF-CBT. All therapists who will deliver TF-CBT will receive the same training: they will complete a web-based training course (https://tfkvt.ku.de/) comprising 12 chapters. Each chapter takes 45–60 minutes to complete and includes textual instructions, videos and self-test multiple choice questions. A final exam of 48 questions concludes the web-training. Subsequently the therapist will participate in a 2-day (18 hours) live workshop with an expert TF-CBT practitioner as a trainer and with a study coordinator training them in how to perform the diagnostic procedures related to child and caregiver. While COVID-19 measures preclude physical meetings, the live workshops will be held as live web meetings. The therapist will then be randomized to TFS or SAU.

2.6.1. TF-CBT

TF-CBT is a brief manualized psychotherapy (12–15 sessions) for the treatment of PTSS in children and adolescents aged 5–21 years (Cohen, Mannarino, & Deblinger, 2017). It is designed to involve a trusted caregiver in the treatment sessions.

Treatment is usually delivered in double sessions of 100 mins; one half with the child and one with the caregiver. Therapists in our study may adapt it to single sessions if double sessions are not feasible in routine care. The manual follows a step-by step approach covering nine modules: (1) Psychoeducation, (2) Parenting skills, (3) Relaxation, (4) Affect modulation, (5) Cognitive coping, (6) Trauma narrative, (7) In vivo exposure, (8) Conjoint parent and child session on problem solving, (9) Enhancing safety and development.

The central component is the trauma narrative. In the trauma narrative, the youths tell their story of the traumatic experience in a stepwise process and, depending on age, write it down in a 'story' or 'book', create a picture or another symbolization of the traumatic experience. In these sessions, the child and the therapist are involved. Once the narrative is completed, it is shared in a joint session with the caregiver. The sessions preceding the trauma narrative are designed to prepare the way by psychoeducation and providing the children and caregivers with a variety of coping skills. The sessions after the sharing of the narrative focus on cognitive restructuring and problems that may persist after the exposition and promoting future development.

2.6.2. SAU

SAU will not be provided or regulated by the study at all. Instead, the therapists will engage in any supervision they choose for themselves (LPTs) or are required to complete within their training (PITs). For LPTs, this could mean as little as no supervision at all, more or less intervision (informal case discussions with colleagues) or self-sought supervision of any frequency (Ochs et al., 2012). PITs, during their training, are required to complete one hour supervision per four hours of therapy. For them, SAU will therefore contain a considerable amount of high quality supervision. The study will monitor the amount and nature of the supervision by therapist self-report.

2.6.3. TFS

In TFS, supervision will be added to SAU. The additional TFS will be delivered by six expert practitioners and trainers in TF-CBT. They are qualified, licenced psychotherapists, working in their own private practice or in university hospitals. All of them have completed the 'train the trainer' programme by Tony Mannarino (or are currently in the process of doing so) and have been involved as supervisors or research psychologists on earlier RCTs on TF-CBT. Each supervisor will supervise 1–3 groups of six therapists (i.e. 6–18 therapists in total).

Therapists in this condition receive fortnightly CCs by telephone. These consultations will monitor patients' symptoms, provide the therapist with feedback and offer behavioural rehearsal of specific TF-CBT skills (Cohen et al., 2017). TFS will be delivered in a group of up to six therapists, with each CC lasting 50 mins. The TFS consists of model-specific case consultations (CC) that closely follow and advocate the principles of TF-CBT (e.g. trauma-focused, component-based). The sessions are highly structured. Each session will begin with patient symptom reports and updates of the therapy module worked at and proceed to individual cases regarding which the therapist has encountered any problems or questions. These will then be discussed and rehearsed, ensuring that important topics are covered in each session. The other participants will take part in the rehearsal, be asked to make suggestions of their own, and also have the opportunity to learn from the model.

Therapists will begin to call in from randomization onwards and for a minimum of 12 months,

continuing as long as they have active patients. The fidelity of supervisors will be ensured by quarterly telephone consultations on supervisory tasks and ratings of supervision calls by trained raters. The raters are advanced students who have completed the web-based TF-CBT training and received a two-day live workshop on TF-CBT. They are part of every supervision session and fill in the rating immediately after its conclusion. In addition, the first author (RR) will participate in a subsample of supervisions and complete identical ratings, thus allowing the calculation of interrater reliabilities.

2.7. Outcomes (endpoints)

Whether the patients receive a sufficiently adherent TF-CBT therapy (SATT) is the primary outcome of the implementation trial. In order to qualify as a SATT, the therapist must complete at least eight double (or 16 single) sessions implementing TF-CBT modules (1–5); begin the trauma narrative in double sessions 7–11 (or 14–22 single), and complete the therapy within 18 double (36 single) sessions. The TF-CBT modules implemented will be recorded on a standardized form by the therapists at the end of each session. Whether the sessions conform to the SATT conditions will be judged from these records by two independent raters blind to the supervision condition. It is intended that all therapists take on five patients who meet the inclusion criteria. The analysis of the outcome will be based on an intent-to-treat (ITT) analysis.

Secondary outcomes for patients are: the reduction of PTSS (measured with CATS-2, caregiver and self-rating, see below) from T_0_P to T_1_P; and T_2_P and the reduction of depression (measured with MFQ, caregiver and self-rating, see below) from T_0_P to T_1_P and T_2_P.

The following secondary outcomes for therapists will be analysed:

Their session-wise ($T_{SR0\text{-}k}$) self-ratings of insecurity in implementing TF-CBT. As an overall therapist outcome their attitude towards ESTs will be analysed across T_1_Th, T_2_Th, T_3_Th and T_4_Th.

As exploratory outcomes that allow additional in-depth analyses, several additional variables will be assessed regarding patients, therapists, CYWA staff and paediatricians (e.g. treatment satisfaction, professional quality of life).

2.8. Measures

2.8.1. Patient-related measures

Patient-related information, including the assessed construct, and the person carrying out the assessment by time points is listed in Table 1.

2.8.1.1. Demographic information. A questionnaire assesses standard demographic information about the child and the caregiver, and information about the child's residency (e.g. in care), occupation or school.

2.8.1.2. PTS symptoms and PTSD diagnosis. The *Child and Adolescent Trauma Screen* (CATS-2) will be used to assess PTSS. It is based on the CATS (Sachser et al., 2017) and has three sections. The first section consists of an event list asking in a dichotomous format whether the child has experienced the said event. The following 20 items correspond to PTSD criteria B-E in the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition (DSM-5) (American Psychiatric Association, 2013)

Table 1. Patient-related instruments, person carrying out the assessment and points of assessment.

Construct	Instrument (Abbrev.)	Assessing person	Baseline	Therapy end	Follow-up (6 months)	Every session
			T_0_P_x	T_1_P_x	T_2_P_x	$T_{SR1\text{-}k}$_P_x
Socio-demographic information in general		P, CG	X			
Demographic information re life situation child		P, CG	X	X	X	
Medication		P, CG	X	X	X	
Diagnosis	ICD-10 with DISYPS-III	T	X	X	X	
Intelligence	Therapist's routine test	T	X			
Mental Health, global	CGI	T	X	X	X	
Posttraumatic stress (PTS) symptoms	CATS-2	P, CG	X	X	X	
Main PTS symptoms	CATS-symptom scale	P, CG				X
Type of traumatic experience	CTQ	P, CG	X	X	X	
Depressive symptoms	MFQ	P, CG	X	X	X	
Emotional/behavioural problems	SDQ	P, CG	X	X	X	
Treatment satisfaction	FBB	P, CG		X	X	
Appropriate treatment element received	Standardized Record	T				X

P: patient; CG: care giver; T: therapist; ICD-10: International Classification of Diseases, 10th edition; DISYPS-III: Diagnostik-System für psychische Störungen nach ICD-10 und DSM-5 für Kinder und Jugendliche – III [Diagnostic System for Mental Disorders According to ICD-10 and DSM-5 for Children and Adolescents]; CGI: Clinical Global Impression Scale; CATS-2: Child and Adolescent Trauma Screen, 2nd edition; CTQ: Child Trauma Questionnaire; MFQ: Mood and Feelings Questionnaire; SDQ: Strengths and Difficulties Questionnaire; FBB: Fragebogen zur Beurteilung der Behandlung [Questionnaire for Treatment Satisfaction].

and measure the severity of PTSS. The child or adolescent rate the symptom frequency for the total of traumatic events experienced on a 4-point scale ranging from 0 (*never*) to 3 (*almost always*). In the concluding section, the CATS evaluates with five dichotomous items whether the PTSS interferes with important areas of functioning. The German version of the CATS has good to excellent psychometric properties for the self-report (α =.90) and the caregiver report (α = .88) (Sachser et al., 2017). For the current study, a slightly adapted version (CATS-2) will be used to cover ICD-11 PTSD and complex PTSD criteria besides DSM-5. The CATS-symptom report, consists of a subset of 7-items assessing the main PTSS.

2.8.1.3. Comorbid diagnoses. Comorbid ICD-10 diagnoses will be assessed with the *Diagnostik-System für psychische Störungen nach ICD-10 und DSM-5 für Kinder und Jugendliche-III* (DISYPS-III) (Döpfner & Görtz-Dorten, 2017) used as a standardized Checklist.

2.8.1.4. General mental health. A global assessment of the child's or adolescent's mental health will be made by the therapist according to the *Clinical Global Impression scale* (CGI) (Guy, 1976) consisting of one general rating of the child's health from 1 = 'patient's health cannot be assessed', 2 = 'completely healthy' to 8 = 'extremely ill'.

2.8.1.5. Intelligence. Measuring the intelligence is part of German standard diagnostic procedures in child and adolescent psychotherapy. Since the current study is an implementation study, intelligence testing will be left to the therapists' routine procedures as long as the tests are normed and age-appropriate. The therapists will record the IQ score and the test used.

2.8.1.6. Experiences of emotional, physical or sexual abuse, maltreatment and neglect. The *Child Trauma Questionnaire* (CTQ) retrospectively assesses childhood experiences of emotional, physical and sexual abuse, maltreatment and neglect (Bernstein et al., 2003; Klinitzke, Romppel, Hauser, Brahler, & Glaesmer, 2012). Its 28 items are rated on a 5-point scale from 1 = 'not at all' to 5 = 'very often' and allow determining the type of abuse experienced. Patients aged 12 years and older are asked to complete the CTQ.

2.8.1.7. Depressive symptoms. The short version of the *Mood and Feelings Questionnaire* (MFQ) (Angold et al., 1995; Messer et al., 1995) will be used to assess symptoms of depression in children and adolescents. It includes 13 statements about typical depressive symptoms. The participants rate on a 3-point scale whether the statement has been true in the last two weeks from 0 = 'Not true', 1 = 'Sometimes' and 2 = 'True'. There is a self-report version for the child or adolescent and one for caregiver ratings of the patient's symptoms.

2.8.1.8. Conduct and peer problems, hyperactivity and attention problems. The *Strengths and Difficulties Questionnaire* (SDQ) (Goodman, Meltzer, & Bailey, 1998; Lohbeck, Schultheiß, Petermann, & Petermann, 2015; Petermann, Petermann, & Schreyer, 2010) assesses a range of emotional and behavioural problems in four areas: hyperactivity and attention problems, emotional problems, conduct problems and peer problems. In addition, it contains a scale regarding prosocial behaviour. The SDQ's 25 items describe instances of feelings and behaviours and the child or adolescent has to rate on a 3-point scale from 0 = 'this statement does not apply', 1 = 'partially applies' and 2 = 'completely applies'. There is also a caregiver version. The German version has favourable psychometric properties (α = .82). (Woerner, Rothenberger, & Becker, 2004)

2.8.1.9. Treatment satisfaction. Treatment satisfaction will be assessed after the therapy and at the follow-up by *Fragebogen zur Beurteilung der Behandlung* [FBB; Questionnaire for Treatment Satisfaction] (Mattejat & Remschmidt, 1998). The FBB consists of 21 items that retrospectively appraise the treatment process and its result. The items are rated from 0 = 'not at all' to 4 = 'always'. The questionnaire will be completed by the child or adolescent and the caregiver.

2.8.1.10. TF-CBT components implemented in each session. The therapist will use a standardized session record (SR), which contains the nine different components of TF-CBT, to record after each session what TF-CBT element he or she had focussed on and how much time he or she spent working with the child and the caregiver. As a patient-related variable, the SRs will be used to determine the treatment dose regarding TF-CBT and whether the patient received a SATT. As a therapist-related variable, it will be used to assess therapist adherence.

2.8.2. Therapist-related measures

A number of therapist-related measures is assessed (Table 2).

2.8.2.1. Demographic information. Standard demographic information about the therapists, their professional education and experience regarding disorders related to CAN will be collected.

Table 2. Therapist-related instruments and points of assessment.

Construct	Instrument (Abbreviation)	Assessing person	Baseline T_0_Th	After online training T_1_Th	After workshop T_2_Th	After Random-ization T_{RR}_Th	After 6 months T_3_Th	After 18 months T_4_Th	After each session $T_{SR1\text{-}k}$_Th
Socio-demographic information		T	X						
Basis information re supervisor		T	X						
TF-CBT Knowledge and Skills	TF-CBT Knowledge Test	T	X	X	X		X	X	
Readiness to implement TF-CBT	VAS Rating	T	X	X	X	X	X	X	
Competence with regard to TF-CBT	VAS Rating	T	X	X	X	X	X	X	
Fears with regard to implementing TF-CBT	VAS Rating	T	X	X	X	X	X	X	
Likelihood of implementing TF-CBT	VAS Rating	T	X	X	X	X	X	X	
Adherence in the individual therapy session	VAS Rating	T							X
Insecurity in implement-ting TF-CBT in individual therapy session	VAS Rating	T							X
Satisfaction with individual therapy session	VAS Rating	T							X
Adherence overall (TFS only)	VAS-Rating	S							X[a]
Professional Quality of Life	ProQol	T	X	X	X		X	X	
Attitude towards evidence based treatments	EPBAS	T	X	X	X		X	X	
Implementation Climate[b]	ICS	T	X	X	X		X	X	

[a]The session is the supervision session in the trauma-focussed supervision condition (TFS); TF-CBT: Trauma-focussed cognitive behavioural therapy; ProQol: Professional Quality of Life Scale; EBPAS: Evidence-Based Practice Attitude Scale; ICS: Implementation Climate Scale; T: therapist; S: supervisor; VAS: visual analogue scale. [b]for psychotherapists in training (PITs) only.

2.8.2.2. TF-CBT knowledge and skills. For the assessment of TF-CBT knowledge, a typical CME test (partially modelled after the TF-CBT Knowledge test (Heck, Saunders, & Smith, 2015)) with 14 multiple choice questions will be employed. To assess skills, two case vignettes of therapy situations will be presented, with an open question inviting a brief reflection on the situation and three multiple choice items pertaining to TF-CBT skills relevant in the situation. The open questions will be qualitatively evaluated. To prevent practice effects, parallel versions will be used at the assessment points.

2.8.2.3. Readiness, competence, fears and likelihood of implementation. The readiness to implement TF-CBT and the related variables will be assessed with custom-made visual analogue scales (VASs) on which the therapists rate the factors: 'At this moment, … ' (A) … how competent do you feel regarding the use of TF-CBT? (B) … how ready are you to use TF-CBT? (C) … do you feel worried to use TF-CBT? and (D) … how likely do you rate that you will use TF-CBT? The anchors for A, B, and D are 0 = 'not at all' and 100 = 'completely', the anchors for C are 0 = 'none' and 100 = 'extremely'.

2.8.2.4. Therapists' adherence to TF-CBT. The therapists' adherence to the TF-CBT manual will be assessed with two different measures. The therapists will rate their own adherence to the manual after each session using a VAS from 0 = 'none' to 100 = 'complete'. In addition, their session-wise SRs (see 2.8.1.10) will be rated for adherence to the manual by independent raters blinded to the condition TFS/SAU.

2.8.2.5. Therapeutic competence and satisfaction. After each session, the therapists record with VASs how competent they felt regarding the TF-CBT elements, whether they encountered barriers in implementing them, and how satisfied they felt with themselves as TF-CBT therapists. The anchors are 0 = 'not at all' and 100 = 'completely'.

2.8.2.6. Professional quality of life. The therapists' professional quality of life will be assessed with the *Professional Quality of Life Scale* (ProQol) (Stamm 2009). It contains 30 items expressing negative and positive aspects of working with patients experiencing suffering. The respondents rate on a 5-point scale the frequency from 1 = 'never' to 5 = 'very often' with which they had the respective experience in the last month. The items form three subscales corresponding to compassion satisfaction, compassion fatigue and secondary traumatic stress.

2.8.2.7. Attitude towards evidence-based treatments. The therapists' attitude towards evidence-based treatments will be assessed with the *Evidence-Based Practice Attitude Scale-36* (EPBAS-36) (Aarons, 2004; Rye, Torres, Friborg, Skre, & Aarons, 2017). The EBPAS-36 consists of 36 items measuring 12 domains pertaining to provider attitudes towards adopting new evidence-based practices.

2.8.2.8. Implementation climate. The perceived implementation climate will be measured by the *Implementation Climate Scale* (ICS) (Ehrhart,

Aarons, & Farahnak, 2014). The ICS captures six dimensions of the organizational context that indicate to employees the extent to which their organization values the implementation of ESTs. The respondents rate their agreement with 18 statements on a 5-point scale from 0 = 'not at all' to 4 = 'very great extent'.

2.8.3. CYWA and paediatrician-related measures

The CYWA staff, directors and paediatricians will answer the ProQoL (Stamm 2009). In addition, the paediatricians will also complete the EBPAS-36 (Aarons, 2004; Rye et al., 2017).

2.8.4. Supervisor-related measures

Regarding the supervisors, qualitative measures will be used and their retrospective reflections regarding barriers and facilitating factors and the supervision process assessed by qualitative interviews and expert statements.

2.9. Data management and storage

All assessments will be completed online via LimeSurvey and data entered will be transmitted directly and in pseudonymized form to the central, independent data-handling centre at the University of Erlangen and stored on an internal server. In the therapy setting, a tablet with a navigation app is used for the assessments, which does not save any data but forwards them to LimeSurvey. For each individual data assessment, an individualized link including the study ID of the participant is used. The data handling centre will monitor the quality and completeness of the data and the compliance of the measurements with the assessment schedule determined by the study protocol.

2.10. Statistical analysis

We will analyse the primary outcome, whether a patient receives a SATT, by a multilevel mixed logistic regression model to account for cases being nested within therapists. The supervision condition will be a fixed factor and, in case of PITs, site a random factor for both follow-ups. The analysis will be based on the intent-to-treat basis: a significance level of alpha = 0.05 will be used.

The additional hypotheses will be assessed analogously with multilevel mixed models. Depending upon the nature of the outcome (dichotomous or continuous), logistic or linear models will be used. The analyses for secondary outcomes will be interpreted as exploratory, so no adjustment for multiple testing will be applied.

We will also use exploratory logistic models to examine the influence of other therapist variables (gender, age, experience level, case consultation attendance, supervision attendance) on our primary outcome. With respect to patient safety, we will compare the number of serious adverse events (SAEs) between the conditions, using Chi-square tests at the end of the trial.

2.11. Monitoring safety and ethics

The study was planned and is conducted in accordance with the declaration of Helsinki (World Medical Association, 2013), the Guideline for Good Clinical Practice, and the European and German data protection legislation. It has been reviewed and approved by the Institutional Review Boards of the Friedrich-Alexander University Erlangen (approval18/12/2019; #266_19 B), the Goethe University Frankfurt (approval 06/01/2020; #19-510), the Catholic University Eichstätt-Ingolstadt (approval 15/01/2020; #010-20) and the Philipps University Marburg (14/01/2020; #2020-2). The trial has been approved by the data protection officer according to BayDSG of the Friedrich-Alexander-University Erlangen-Nürnberg.

The study will be steered by a Trial Steering Committee (TSC). The study centres will monitor the processes involving screening of patients through CYWA staff and paediatricians, patient allocation to therapists according to a manual of standard procedures. An external statistician will allocate the therapists to the conditions. The data centre at the University of Erlangen will monitor and ensure the quality and completeness of all data. An independent committee consisting of three experts of the fields of Clinical Psychology and Psychiatry (DSMB Board) will oversee study safety. They will be regularly informed on all safety aspects, especially the occurrence of any serious adverse events (SAEs) and may make recommendations to the TSC concerning changes to the study protocol or termination of the study. SAEs are defined in line with the GCP guidelines as including events with deadly outcomes or life-threatening characteristics; events that require unforeseen or prolonged hospitalization; events with a permanent or severe disability as a consequence or with a potential for other serious medical or psychological consequences (e.g. attempted suicide, development of serious addiction). The occurrence of SAEs will be documented during the interventions and follow-up-assessments and will be treated according to a procedural manual.

3. Discussion

In this study, we investigate the dissemination and implementation of TF-CBT for children and adolescents with PTSS after CAN with a particular focus on the provision of supervision. We train LPTs and PITs

and compare therapists who receive TFS to therapists who receive SAU. It is hypothesized that patients of therapists in the TFS-condition will be more likely to receive a SATT. As additional outcomes we will analyse whether TFS improves the therapists' treatment fidelity and the patients' PTSS outcomes as well as therapists' professional quality of life. Disseminating TF-CBT will serve to counter the scarcity of empirically supported treatments (ESTs) offered in routine care for children and adolescents suffering from PTSS.

In order to counteract bias, we will recruit a diverse sample of therapists. They will be randomized after the completion of the live workshop. The blinding to the condition up to this point in time will ensure that there is no interaction of the expected condition and participant at the workshops. In order to assess both supervision conditions, we will collect information about the dosage and type of supervision received by therapists in each condition. Patients, caregivers and CYWA staff will be blind to the supervision condition. To rule out financial barriers, therapists will receive case lump sums to account for additional time for diagnostics and documentation. The most problematic type of bias is the possibility that therapists drop out after learning about their randomization result because they did not receive the preferred option of supervision or because they were only interested in the free training offered. Since participants, including therapists, are free to end study participation at any time, this cannot be precluded.

Patients will be recruited in a naturalistic manner. We will allow all paths of referral and will make the offer of a therapy place widely known through CYWAs, paediatricians, our project website etc. This will ensure that children and youths with varied ages and backgrounds are recruited and offered treatment. In addition, the CYWAs will implement a systematic screening for PTSS. The variety of naturalistic ways in which patients are able to enter the study will reduce patient selection biases and assure a high external validity.

The training (therapists, CYWA staff and paediatricians) will be highly standardized, including e-learning, and training workshops with identical presentation slides. The staff of the collaborating CYWAs will be trained for half a day together with the PITs and LPTs. Training therapists and referrers together will promote collaboration between the groups through personal contact and improve referral pathways for affected children and adolescents.

In order to reduce drop-out rates for therapists, CYWA staff and paediatricians, they will receive reimbursements. For patients, the strategies focus on incentives so that they provide data for all assessment points. In order to encourage adherence to the assessments, personalized reminders will be sent by email.

Primary and secondary outcomes are determined in the study protocol to avoid selective reporting (reporting bias/publication bias). The primary outcome, whether a patient receives a SATT, is a 'hard' criterion, which is easy and unambiguous to assess. The secondary outcomes on patient level are all well-established measures and most can be considered as blinded assessments insofar as they are self-ratings or caregiver ratings and neither patients nor caregivers know the randomization outcome. The only non-blinded secondary outcomes are the therapists' ICD-10 diagnoses at therapy completion and his or her CGI rating. The secondary outcomes on the therapist level concern treatment fidelity. Since therapists are not blind to the condition, this important secondary outcome will be assessed by session-wise self-rating of adherence and through an independent evaluation of the SRs.

The results of this study will be published in accordance with this protocol irrespective of significant results to avoid publication bias. The SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials: http://www.spirit-statement.org) were considered in writing the study protocol, taking into account that the current trial is an implementation trial and its main target is not evaluating the effectiveness of the patient-level intervention. (Supplementary digital content 2) The publication of results will consider the CONSORT guidelines (Consolidated Standards of Reporting Trials; http://www.consort-statement.org/) where appropriate for such trials. The study was registered with the German Clinical Trial Register (ID: DRKS00020516).

The strategic goal of the study is the implementation and dissemination of TF-CBT for children and adolescents with PTSD among psychotherapists as well as in CYWAs and among paediatricians. It is hoped that the screening and referral procedures established, will stay in place after the study's completion and that LPTs will pass on their knowledge to their own supervisees and networks. On a broader level, it is expected that this implementation study could serve as a blueprint for the future implementation of other ESTs into the routine practice of psychotherapists, CYWAs and paediatricians.

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Authors' contributions

All authors have read and approved the final manuscript. RR, HC, DE and RS are principal investigators of the study. RM is the trial statistician. AB, BA, FLM, ACZ will coordinate the subprojects. AB, RR, RS drafted the manuscript.

Availability of data and material

Upon request from the authors.

Consent for publication

All authors have read the manuscript and approved its publication.

Data availability statement

Since this manuscript describes a study protocol, provision of a data set is not applicable.

Instead we provide guideline-based documentation (SPIRIT Statement, Supplementary Material 2) and a Trial registration:

Trial registration: German Clinical Trial Registry (GCTR), DRKS00020516, Registered 12 February 2020, https://www.drks.de/DRKS00020516.

Date of first enrolment

27 February 2020.

Disclosure statement

Dr. Albrecht, Dr. Barke, Dr. Christiansen, Dr. Lechner-Meichsner, Dr. Muche, Dr. Rosner, Dr. Steil, and Dr. Zarski have nothing to disclose. Dr. Ebert reports other from Get.On Institute, personal fees from Sanofi, personal fees from Novartis, personal fees from Minddistrict, personal fees from Lantern, personal fees from Schoen Kliniken, personal fees from Ideamed, grants from EU H2020 , grants from BMBF, outside the submitted work; and Dr. Ebert has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy. He is also stakeholder of the Institute for health training online (GET.ON), which aims to implement scientific findings related to digital health interventions into routine care.

Ethics approval and consent to participate

The Institutional Review Boards of all participating universities approved the research protocol: Friedrich Alexander University Erlangen (approval18/12/2019; #266_19 B, Goethe University Frankfurt (approval 06/01/2020; #19-510), Philipps University Marburg (approval 14/01/2020; #2020-2), Catholic University Eichstaett-Ingolstadt (approval 15/01/2020; #010-20). The consent to participate is available in German and was reviewed by the IRBs.

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