

Feasibility of a Parent-led Stepped Care Trauma-focused Cognitive Behavioural Therapy for Children: a Mixed Methods Pilot Trial Protocol

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Study Protocol

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Abstract

Background: Traumatizing events put children at risk of developing severe mental health problems. There is a large gap between the need for and access to evidence-based treatments for traumatized children and youth. To bridge this gap, the treatment model stepped care trauma-focused cognitive behavioural therapy (stepped care TF-CBT) has been developed. The model consists of a parent-led therapist assisted component (step one), with an option to step up non-responders to standard therapist-led TF-CBT treatment (step two). We will investigate the feasibility, acceptability, outcomes and predictors of an adapted stepped care TF-CBT model, where step one is placed in the first-line municipal health services and step two in the second-line specialist health services. We will include the perspectives of children, caregivers, therapists and service leaders.

Methods: This is a multicentre feasibility study, with a mixed methods longitudinal research design. We recruited 45 therapists across 19 municipalities in Norway and provided training in the stepped care TF-CBT model. Through the therapists, an estimated 78-83 child-caregiver dyads will be recruited. The main criteria for inclusion are age 7-12 years, at least moderate post-traumatic stress symptoms following exposure to trauma, and that receiving parent-led treatment is safe for the child. Interviews to explore experiences with the model will be conducted with children, caregivers, therapists and municipal service leaders. Further data from children, caregivers and therapists will be collected throughout treatment and at 3-month follow-up to assess post-traumatic stress symptoms and mental health, daily functioning, quality of life and therapeutic alliance.

Discussion: The results will help inform clinicians and policymakers of the potential benefits and barriers of providing step one of stepped care TF-CBT in a first-line setting. The study will increase knowledge of factors that characterize children and families that benefit from the parent-led step one, and families that may need modifications in the model, or different interventions.

Trial registration: *ClinicalTrials.gov*, NCT04073862. Retrospectively registered 03 June 2019 (first patient recruited May 2019), <https://clinicaltrials.gov/ct2/show/NCT04073862>

Background

Every year, a substantial number of children are exposed to violence or other potentially traumatizing events (1, 2). Although many children recover without need for treatment, childhood trauma and adverse events can lead to long-term consequences into adulthood and is a significant contributor to public health issues (2–4). This includes serious health problems such as post-traumatic stress disorder (PTSD), anxiety, depression, behavioural difficulties and substance dependence (4–6). Trauma-exposed children and youth also have an increased risk for dropping out of school and education, and are more often unemployed (7, 8).

There are evidence-based treatment options for children with post-traumatic stress symptoms, including trauma-focused cognitive behavioural therapy (TF-CBT) and eye movement desensitisation and

reprocessing treatment (EMDR) (9–11). Still, there is a large gap between the need for treatment and access to these treatments (12–14). Delays in treatment can result in initially mild or moderate symptoms developing into more severe mental health issues over time. Thus, there is a need for continued efforts to ensure that evidence-based treatments, with appropriate levels of care, are easily accessible and cost-efficient.

Limited treatment resources can be a barrier for treatment that result in long waitlists or declined referrals if the child's symptoms are not considered severe enough. Further, barriers that can stop families from seeking help for their child can be related to lack of resources to follow-up long-term treatment, stigma or wanting to be able to help the child themselves (13, 15–17). In addition, dropout from treatment represents a substantial challenge (18), and insufficient involvement of parents in the treatment has been reported as an important barrier for treatment adherence (15).

The stepped care TF-CBT model is an adaptation of standard TF-CBT and was developed to provide an easily accessible and convenient first-line intervention, by addressing both barriers related to treatment resources and barriers to seeking treatment (19, 20). Step one consists of a parent-led intervention assisted and supervised by the therapist. For children where the first step does not result in sufficient improvement in post-traumatic symptoms, the child receives step two, which consists of standard, therapist-led TF-CBT.

This two-step treatment approach has several potential advantages. First, as there are large differences in the developmental paths following trauma (21, 22), a stepped care approach to trauma-treatment has been recommended (23). Stepped care implies that the interventions should be given at the lowest effective level of care, which can be stepped up to a higher intensity intervention when needed. Second, parent-led interventions also have the potential to strengthen parenting skills, and let children heal at home in their natural environment (24).

In two randomized trial ($n=53$ and $n=183$), the stepped care TF-CBT treatment was found to be equally effective in reducing post traumatic symptoms compared to standard TF-CBT (25, 26). In these trials, step one of the treatment model was sufficient for 7 out of 10 children and costs were 51% and 54% lower for the stepped care model compared to standard TF-CBT.

Caregivers have reported overall satisfaction with the treatment (16) and were equally satisfied with receiving stepped care TF-CBT and standard TF-CBT (27). However, about 1 out of 5 caregivers felt uncertain in their roles when leading meetings with the child (16) and about 15% found the parent-led approach to be the least helpful aspect of the stepped care treatment (27). This illustrates that caregivers and families differed in how suitable this parent-led model was, and more knowledge of enablers and barriers for parent-led treatment is necessary to better select and tailor appropriate treatment for individual families.

In addition to caregivers' perceptions, it is crucial to understand how the children feel about receiving trauma treatment from their caregivers, and whether they find the treatment helpful. This has been

explored to some extent in the US pilot study of stepped care TF-CBT (age 8-12 years, n=16). When asked what was most helpful, only one child named the parent-involvement, however when asked what they liked, nearly half mentioned the at-home parent-child meetings, and when asked what they disliked, none brought up the parent-led approach (16).

Parent-led treatment is also a novel approach for many therapists. The therapist must take on the role of a supervisor and follow the child and the treatment from more of a distance. This can be challenging in exposure-based trauma treatment, where finding a suitable level of gradual exposure is central (9). The therapists' experiences with enablers and barriers, and their engagement with the model, are important for the feasibility of implementation (28), both because they are not likely to use a model they do not believe in or are uncomfortable with, and because therapist factors such as competence and treatment alliance have been linked to child outcomes (29–32).

In summary, stepped care TF-CBT shows promising results for reducing symptoms in trauma-exposed children and appears to be liked by children and caregivers. This study will contribute to the field of trauma treatment by providing more in-depth knowledge about how participants perceive working with a parent-led and stepped care model and which families seem to profit the most from the treatment. This may increase our understanding of potential barriers that may impede the implementation of the model and inform training and dissemination practices for the future. In addition, this pilot study is the first outside of the US and the first conducted by a research group that was not part of developing the model.

In previous studies, step one and two of the model was provided by the same therapist, in this Norwegian pilot we will place step one in municipal mental health care and step two in the second line services (the child and adolescent mental health services; CAMHS). This division is an adaptation of the model, and fits with the already defined responsibilities of the two service levels in Norway (33). The municipal mental health care aims to provide preventive short-term interventions, and requires no referral (33), and standard TF-CBT has already been successfully implemented in the majority of the CAMHS (34). The division over service levels and across therapists may have the added benefit of increasing collaboration across service levels (33) and to make step one more accessible. With this adaptation, it will be important to explore whether there are potential negative effects for families that need to be stepped up and hence will be transferred to a new therapist and service provider.

Research questions

The overarching aim of this study is to investigate the feasibility of the adapted version of the stepped care TF-CBT model in Norway. Specifically, we will explore 1) the suitability and acceptability of the parent-led step one in the first-line municipal health services, from child, caregiver and service level perspectives, 2) whether the division of step one and step two across first- and second-line mental health services is suitable and acceptable from child, caregiver and service level perspectives, and 3) whether the treatment is associated with improvement in the child's mental health and quality of life. Secondary aims will be to investigate 4) which factors predict or are part of mechanisms for treatment-response and

non-response to step one, and 5) whether there are relationships between the parent's mental health and the child's outcomes.

Although the study is largely explorative, we have registered some hypothesis related to research question 3- 5, based on findings in previous studies:

- i. Children will report lower symptom levels and better functioning and quality of life after the completion of step one.
- ii. Parents will report lower symptom levels, reduced parental stress, and increase in positive aspects of being a parent after the completion of step one.
- iii. Children exposed to several traumatic events will be at higher risk of non-response compared to children exposed to fewer traumatic events.
- iv. Children exposed to interpersonal trauma will be at higher risk of non-response compared to children exposed to non-interpersonal trauma.
- v. Higher levels of child post-traumatic stress symptoms, depression, and posttraumatic cognitions pre-treatment predicts non-response.
- vi. Higher levels of parents' post-traumatic stress symptoms, anxiety, depression, and negative emotional reactions related to the child's trauma pre-treatment will predict dropout and non-response.
- vii. Lower levels of parents' perceived social support and less perceived positive aspects of being a parent pre-treatment will predict dropout and non-response.
- viii. More barriers and lower expectations to the treatment by parents will predict dropout and non-response.
- ix. Changes in parents' mental health (post-traumatic stress symptoms, anxiety, depression), emotional reactions and perceived positive aspects of being a parent will predict subsequent change in the child's general functioning, depressive symptoms, and quality of life, but will not predict changes in child's level of post-traumatic stress symptoms.

Method

Study design and setting

This is a multicentre, feasibility study, with an exploratory mixed methods longitudinal research design. We will investigate a stepped care TF-CBT intervention for a single group of trauma-exposed children, recruited naturalistically from municipal mental health services in Norway. All relevant elements of the Standard Protocol Items: Recommendations for International Trials (SPIRIT) checklist (35) are reported in this study protocol.

In Norway, all health care for children younger than 18 years is publicly funded, and available at no cost. Mental health services for children are organized into the first- and second-line levels of care. The first-line municipal health services aim to be low-threshold, with a focus on promoting public health and

preventing negative health outcomes. Children and caregivers can contact these services directly or be put in contact with them through other health services. The second-line specialist health services, CAMHS, are part of the state-funded hospitals. Children can be referred to the specialist health services by medical practitioners, licensed psychologists or the child protective services.

Participants and sample size

The study includes participants on three levels: 1) The municipalities in the project, including participating therapists and leaders, 2) Child-caregiver dyads that are enrolled in the treatment, and 3) Therapists in CAMHS that have assumed treatment responsibility for children that have been stepped up to receive standard TF-CBT (step two).

Municipalities and therapists in municipal health care

Municipality eligibility criteria for participation

As municipalities in Norway differ widely in size, geography, and organization, we recruited 19 municipalities to ensure representability across different settings, and to ensure a large enough pool for recruitment of patients. The municipalities were opportunistically approached, with an effort to select municipalities that included urban, suburban, and rural areas, as well as large and small populations. Criteria were that the municipality 1) belonged to the catchment area of a CAMHS where standard TF-CBT was implemented, 2) to ensure collegial support during the training the municipalities had to have at least two employed therapists in mental health services for children and young people, eligible for receiving training in stepped care TF-CBT.

Therapist eligibility criteria for participation and training

For therapists, participation was self-selected and voluntary, given that the following eligibility criteria were met:

1. Employment in municipal health services.
2. See children aged 7-12 years in their practice.
3. Licensed clinical psychologist or psychiatrist. Other professions (for example clinical social worker) will be considered if the clinician is a certified TF-CBT therapist *or* has other relevant training within CBT, has clinical experience with therapy or parent guidance, and works in a team with a clinical psychologist/psychiatrist.

From the 19 participating municipalities, 45 therapists received training. A list of participating municipalities can be obtained from the research group upon request.

Children and caregivers

Sample size

We will need 58 children and caregivers that have completed the treatment and have valid pre and post treatment assessments. This number is based on power calculations for a model with an expected R² of 0.15 of the predictor variables 80% power, conducted with the MBESS R Package. With an estimated dropout rate of 25-30% (36) we expect that we need to recruit approximately 78-83 dyads of children and caregivers.

Child eligibility criteria for participation

Inclusion criteria for receiving stepped care TF-CBT are:

1. The child is aged 7-12 years.
2. The child has been exposed to a potentially traumatizing event according to the DSM-5 A-criterion (37).
3. The child has a minimum of 5 symptoms of post-traumatic stress (1 symptom must be re-experiencing and 1 must be avoidance) with an intensity score of at least 2 on the Child and Adolescent Trauma Screen (CATS 2.0) (38).
4. The child was 3 years or older at the time of the traumatic event to ensure they have an explicit memory of the event.
5. There has been at least 1 month since the child experienced the traumatic event. This is according to the diagnostic criteria for PTSD (37).
6. The child must confirm, in a conversation alone with the therapist, that they feel safe at home and together with the caregiver.

Child exclusion criteria for participation

1. Suspicions of suicidality, psychosis, intellectual disability, autism spectrum disorder or any other condition that could limit the child's ability to complete the workbook.
2. The child is on a psychotropic medication regime that has not been stable for at least 4 weeks (2 weeks for stimulants or benzodiazepines).
3. The child is currently receiving other trauma treatment.

Caregiver/family exclusion criteria for participation

1. A caregiver that is the cause of the trauma exposure cannot be the caregiver that leads the treatment or live in the same household as the child at the time of treatment.
2. The caregiver has had a substance use disorder within the past 3 months, suspected suicidality or any other condition that could limit the caregiver's ability to complete the workbook.

3. There is a need for an interpreter, as the caregiver has insufficient Norwegian language skills to follow the workbook and complete the treatment according to the instructions.
4. If siblings are eligible for participating at the same time, only the youngest will be included.

Recruitment of child-caregiver dyads

The children and their caregivers will be recruited by the therapists in the municipalities. Therapists are instructed to screen all children between 7-12 years of age for potentially traumatizing events (with CATS 2.0) and assess further for eligibility if the child reports exposure to at least one event. Both children and caregivers will receive written and oral information about the study, voluntary participation and that declining to participate will not affect access to therapy.

Intervention

Training of therapists

The therapists received a two-day training on basic trauma understanding and the basic principles of TF-CBT treatment from certified TF-CBT consultants at the Norwegian Centre for Violence and Traumatic Stress Studies (NKVTS). Subsequently, the therapists received a two-day training in stepped care TF-CBT, led by Dr. Alison Salloum, who is a developer of the model. The therapists were also required to complete a TF-CBT webcourse through the Medical University of South Carolina (estimated at 10 hours; <https://tfcbt2.musc.edu>), and to participate in monthly video consultations with Dr. Salloum throughout the project period. In addition, therapists receive weekly telephone/video supervision by psychologists trained in the model at NKVTS.

Stepped care TF-CBT model

The stepped care TF-CBT model builds on the treatment principles of standard TF-CBT (9). The parent-led step one consists of psychoeducation, parenting skills, relaxation skills, affective expression and modulation, safety, trauma narrative, and imaginal and in vivo exposures. The model is scheduled to consist of 11 parent-child at-home meetings, and three therapist-led sessions at the therapists' office. Two additional therapy sessions are provided as needed. During the home-meetings the caregiver and child work together to complete the tasks in a Norwegian translation of the workbook, *Stepping Together* (39), which is based on the therapist-led Preschool PTSD Treatment (40, 41). The tasks in the workbook focus on building coping skills and having the child complete trauma-focused exposures. Normally, step one lasts for 6-9 weeks, and after completion the child's symptoms are assessed (T2). Children who meet responder-criteria continue to a 6-week maintenance phase followed by another assessment (T3). If the child still meets the responder-criteria at T3, the treatment is considered complete. For those who do not meet responder-criteria, standard TF-CBT, a more intensive, therapist-led treatment is provided as step

two. In the Norwegian context, in contrast to the US (20), stepping up will imply that responsibility for the treatment is transferred from the municipal service level to the corresponding CAMHS.

Treatment fidelity

Psychologists in the research group will use audio recordings from treatment sessions to determine fidelity, according to a 22-item fidelity check-list. For a case to count towards completed training, the therapist would have to achieve at least 90% fidelity within each case (a minimum of 20 out of 22 items on the checklist). The research group will listen to each therapists' first two cases in their entirety (or listen to all cases until the therapist has achieved fidelity in two subsequent cases), and then listen to one session from each case according to a randomization procedure. To check for effect of treatment fidelity, analyses will be done both with and without cases where the therapist did not reach treatment fidelity.

Responder-criteria

The child is considered a responder to step one if the child reports fewer than 5 traumatic stress symptoms according to CATS 2.0, and the therapist rates the child's clinical global impressions improvement (CGI-I) to be improved, much improved or very much improved/symptom free. As the CGI-I is a subjective assessment made by the therapist, we provided a specific training in scoring the CGI-I using case vignettes to calibrate the therapists' interpretation of the CGI-I response-categories. These responder-criteria must be met both after the 6-9 weeks of at-home treatment (T2), and after the 6-week maintenance phase (T3).

Data collection

Qualitative interview procedure

Children, caregivers, therapists, and municipal leaders will be interviewed about their perspectives on experiences with stepped care TF-CBT. Based on previous literature on important themes and the project research questions, we developed semi-structured interview guides to explore the suitability and acceptability of the model and perceived treatment outcomes (research questions 1-3).

All interviews will be recorded and transcribed intelligent verbatim. Due to restrictions during the covid-19 pandemic most interviews will be conducted by telephone or encrypted video calls.

Children and caregivers

The caregivers and children will be contacted consecutively after they finish treatment and asked to participate in the qualitative interviews (Figure 1). We expect to include around 15 caregivers and 20 children, but recruitment will continue until saturation has been met. We might also select participants

more strategically to include enough participants with interrupted treatment if this is necessary. Families that are stepped up to treatment in CAMHS will be contacted a second time 6 weeks after starting treatment, in order to explore their experiences with the transition.

Therapists and municipal leaders

The therapists that receive training will be invited to an interview, either at the time when they have completed their two first stepped care TF-CBT cases, or – in the case of therapist dropout - at the time when they withdraw from participation in the project.

Interviews with municipal leaders will be conducted before project start in their municipality, and after the municipality has experience with at least two completed stepped care TF-CBT cases, or the time point where the municipality withdraws from the project.

Quantitative data collection

Children and caregivers participating in the study will be assessed through questionnaires completed on iPads at the therapist's office (use of paper versions, or access through computers or smartphones is possible if necessary). The data is encrypted and sent to safe storage. During the treatment period, the therapist is responsible for collecting the assessments from the children and caregivers, as well as contributing their own. After treatment has ended, the research group will contact the families for the follow-up assessment (T4). As T4 data will be collected 3 months after completed treatment, the child-caregiver dyad will be offered a 500NOK (~57 USD) gift card as compensation for completing the assessment. An overview of the seven time points for assessments can be found in Table 1 and are visualised in Figure 1.

Screening, eligibility, and non-participation

As part of assessing the suitability and acceptability of the treatment model in the municipal setting (research question 1), the therapists will log the number of children screened for participation, the main reason for non-eligibility (did not meet symptom criteria; need for interpreter; other inclusion/exclusion criteria; therapist lacked capacity), whether the families offered participation *want* to start the treatment (yes; yes, but second caregiver with parental responsibility did not consent; yes, but non-participation for other reason; no) and whether they want other treatment instead (at a different treatment service; in the municipal health service; wanted no treatment).

Table 1

Primary and secondary quantitative outcome measures for child, caregiver and therapist

Timepoint for measure	T0	T1/P1	P2	P3	T2/P4	T3	T4
Weeks from treatment start	Screen	0	2	4	6-9	12-15	24-30
Main outcomes/responder criteria: child, caregiver and therapist reports							
Potentially traumatic events (CATS 2.0)	X				X	X	X
Post-traumatic symptoms (CATS 2.0)	X				X	X	X
Global severity (CGI-S)	X				X ^t	X ^t	
Global improvement (CGI-I)		X	X	X	X	X	X
Children	T0	T1/P1	P2	P3	T2/P4	T3	T4
Negative cognitions (CPTCI-S)		X			X	X	X
Caregiver support (CASSS 2000, PT module)		X			X	X	X
Depression (SMFQ)		X			X	X	X
Somatic symptoms (CSSI-8)		X			X	X	X
Health-related quality of life (17D)		X			X	X	X
School-related quality of life (Kidscreen-52)		X			X	X	X
Subjective quality of life (QoL-1)							X
Treatment satisfaction		(X)	(X)	(X)		X	
Post-treatment use of treatment components							X
Change in child-caregiver relationship							X
Caregivers	T0	T1/P1	P2	P3	T2/P4	T3	T4
Demographics/background	X						X ¹
Child's psychosocial functioning (PSC-17)	X				X	X	X
Emotional reactions (PERQ)	X				X	X	X
Parental stress (PSS)	X				X	X	X
Depression/anxiety (SCL-10)	X				X	X	X
Perceived social support (MSPSS)	X				X	X	X
Potentially traumatic events (SLESQ)	X				X	X	X
Post-traumatic symptoms (PCL-5)	X				X	X	X

Timepoint for measure	T0	T1/P1	P2	P3	T2/P4	T3	T4
Subjective quality of life (QoL-1)							X
Credibility of treatment (CEQ-P)		X					
Barriers for treatment completion		X					
Trajectory from trauma event to treatment		X					
Satisfaction with treatment (CSQ-8)		(X)	(X)	(X)		X	
Child's treatment needs after ended treatment							X
Post-treatment use of treatment components							X
Change in child-caregiver relationship							X
Therapist	T0	T1/P1	P2	P3	T2/P4	T3	T4
Acceptability, appropriateness, and feasibility (AIM/IAM/FIM) of stepped care TF-CBT		Before first patient ²					
Implementation leadership (ILS)		Before first patient ²					
Child/caregiver fidelity and caregiver effort		X	X	X			
Working and therapeutic alliance - child, caregiver and therapist							
Therapeutic alliance to therapist (TASCP)	X	X	X	X			
Working alliance with caregiver (TASCC)	X	X	X				

T: Time of main assessments, P: Time of process assessments (alliance). (X): If treatment is ended at this time-point. **T0:** Baseline assessment for inclusion (up to 4 weeks before treatment start). **T1/P1:** First session (0 weeks), **P2:** Second session (2 weeks), **P3:** Third session (4 weeks), **T2/P4:** Completion of step one (6-9 weeks), **T3:** Completion of maintenance phase (12-15 weeks), **T4:** Follow-up (24-30 weeks). ¹ Only background information that could change will be reassessed, such as medication regime. ² After training, before the municipality started recruitment efforts.

Primary Outcomes

Child and Adolescent Trauma Screen 2.0 (CATS 2.0) screens for potentially stressful or traumatizing events, post-traumatic stress symptoms and interference of symptoms in psychosocial functioning. It is filled out by both child and caregiver. CATS 2.0 is an update of CATS (38) and accommodates for the adjustments in DSM-5 and ICD-11. The list of 15 potentially stressful or frightening experiences (yes/no) addresses life-time experiences at T1, and experiences that have occurred since the last assessment at T2, T3 and T4. Post-traumatic stress symptoms in the last 4 weeks are assessed with 20 items that reflect intrusions/re-experiencing, avoidance, negative changes in cognition/mood and hyperarousal, and are scored from 0 (never) to 3 (almost always). The symptom scale is summed, giving a sum score

ranging from 0 to 60. Finally, 5 items assess interference of symptoms on psychosocial functioning in the last 4 weeks (yes/no).

Clinical Global Impression Severity (CGI-S) and Improvement (CGI-I) were developed to give clinicians a global, 1-item tool for assessment of status and function (CGI-S) and subsequent change in function (CGI-I). It is much used with several adaptations to suit different patient groups. In this study, the measures are rated by child, caregiver and therapist, and the therapist's rating is part of the criteria for treatment response. The CGI-S ("assess the degree of symptoms the child is experiencing, and how it affects daily functioning") is scored on a 7-point scale from 0 (no symptoms) to 6 (extremely ill) (42, 43), and the CGI-I ("assess the global improvement seen against your first severity assessment of the child") is scored on an 8-point scale from 1 (no symptoms) to 8 (very much worse). The original CGI-I has a 7-point scale, in this study the option "no symptoms" was added in line with the version used in previous studies of stepped care TF-CBT (44).

Secondary outcomes

Child measures

Children's Post-Traumatic Cognitions Inventory Short (CPTCI-S) is a validated measure of negative thoughts after trauma (45), with a Norwegian translation done by NKVTS in collaboration with the developers. CPTCI-S consists of two subscales: "permanent and disturbing change" (6 items) and "fragile person in a scary world" (4 items). Each item is scored on a scale from 1 (do not agree at all) to 4 (agree a lot) and summed giving a sum score ranging from 10 to 40.

The Parent support module of the Child and Adolescent Social Support Scale (CASSS 2000) developed for ages 8-17 years (46), will be used to assess the children's self-reported experience of parent support. We did not include the importance rating section of the scale, which is intended for clinical use and not research. The research group has translated the scale in collaboration with the developers, with two independent forward translations and an independent back translation to ensure the quality of the translation. For this study, the wording was changed so the responses reflect support from only the parent/caregiver that has led the treatment of the child, and not "the parents" in general. The 12 items are scored from 1 (never) to 6 (always) and summed, giving a sum score ranging from 12 to 72.

The Short Moods and Feeling Questionnaire (SMFQ) child version consists of 13 statements where children self-report symptoms of depression in the last two weeks. The scale has been validated internationally among children aged 7-11 years (47). The 13 items are scored 0 (not correct) to 2 (correct) and summed giving a sum score from 0 to 26.

Children's somatic symptoms inventory short form (CSSI-8) assesses how much the children are bothered by somatic symptoms in the last two weeks. The CSSI-8 is a short form of the validated Child Somatization Inventory (CSI-24) (48) and has previously been used in Norway (49). The items are scored from 0 (not at all) to 4 (a whole lot) and summed giving a sum score ranged from 0 to 32.

Health related quality of life in pre-adolescence: a 17-dimensional health-related measure (17D) is a validated health-related quality of life survey for children aged 8-11 years (50). It includes one question each about 17 dimensions of physical and mental health, with 5 response options tailored for each question. Quality of life is determined by calculating a single index (17D score) on a 0-1 scale, where 1 is the better outcome, however, it is also possible to investigate the dimensions of health-related quality of life separately.

KIDSCREEN School environment module includes 6 items from the KIDSCREEN-52 (51, 52), which measures health-related quality of life in relation to the school environment in the last week. The scale has been validated across Europe (53) and in Norway (54). Items are scored from 1 (not at all) to 5 (extremely), the responses are summed and translated into Rasch person parameter estimates and T-values, this will give T-value scale means of about 50, with higher scores indicating better school-related quality of life, and standard deviations of about 10 (53).

Subjective quality of life (QoL-1) assesses quality of life using one item (All in all, how satisfied are you with your life right now) and is much used in national surveys (55, 56). Both child and caregiver will be asked about their QoL, with responses given on a numeric rating scale from 0 (not at all satisfied) to 10 (very satisfied). As QoL-1 will only be assessed at T4, we included an additional modified question where they will be asked to think back to before treatment start and rate change in QoL (Is your satisfaction higher, lower or not changed now, compared to before you started treatment), where responses are given on a 7-point scale (much more satisfied; more satisfied; a little more satisfied; no change, a little less satisfied, less satisfied, much less satisfied).

Treatment satisfaction is assessed through 3 questions focusing on the therapy experience (57): I liked coming to the therapist; Going to the clinic helped me with my problems; If I were ever having problems again, I would want to come back to this clinic. The three items are scored from 1 (all the time) to 4 (not at all).

Post-treatment use of treatment components will be assessed at T4 with a self-made question (In the last month, have you used any of the skills you learned while working through the workbook Stepping Together) with a list of the treatment components/exercises (safe place; slow breathing; muscle relaxation; used scary feeling score to talk about how you feel; safety plan; practised doing things you are scared of; no, I have not needed to use any of these; no, it might have helped me, but I have not used them; other - describe). They will be asked whether they had done these things alone or together with the caregiver (alone; with the caregiver; both) and whether doing things from the list had made them feel better, worse, or not changed anything (assessed on a scale from 1 to 7: Very much improved; improved; a little improved; no change; a little worse; worse; much worse; don't know).

Change in the child-caregiver relationship will be assessed at T4 through two self-made questions: "Think back to the time before you started working with the workbook and compare to **now**. Do you and your caregiver spend less or more time together, just the two of you, or is there no change?" and "When you are together with your caregiver, do you feel worse, better or is there no change?", with responses given on a

scale from 1 to 7 (much more/better; more/better; a little more/better; no change; a little less/worse; less/worse; much less/worse; other; don't know).

Caregiver measures

Background information and demographics

At T1, the caregivers will be asked to provide varied background information about the child, themselves, biological parents and the household/family the child lives in.

About the child: Who the child lives with (both parents in one household; mostly father; mostly mother; equally shared between mother and father; foster care; other); region of birth (Nordic country; Western Europe; Eastern Europe; Asia including Turkey; North America/Oceania; South- and Middle-America; Africa) and if applicable, years in Norway; medications (assessed at T1 and T4: none; asthma/allergies; for concentration, impulsivity, ADHD; for sleep; mood stabilizers; other).

About the participating caregiver (often one of the biological parents): Age, who they are in relation to the child (father; mother; foster father; foster mother; other family; other); marital status (single; married; separated; widower; co-habitant; other); region of birth (response categories as above), level of completed education (none; mandatory primary/middle school; high school/upper secondary school; vocational school; minimum 4 years of university; more than 4 years of university); work (full-time; part-time; looking for work; student; receiving benefits/other); whether they had access to as much babysitting and child care help as they needed (not at all; rarely; sometimes; usually; almost always).

About the other biological parent: Region of birth; level of completed education (response categories as above, including an "unknown" option).

About the family/household: Number of members in the household; number of other children in the household and their ages; total household income; support from municipal and specialist services in the last two months (assessed at T1 and T4: CAMHS; educational psychology service; child protective services; school health services; social services; general practitioner; other services).

Pediatric Symptom Checklist (PSC-17) is a parent-report of three areas of the child's behaviour: attention (e.g. ability to concentrate), externalizing behaviour (e.g. fighting, teasing) and internalizing behaviour (e.g. anxiety). The PSC-17 is a short form of the P-34, and is considered a good alternative to longer scales (58). The Norwegian translation has been done by the research group, with two independent translations into Norwegian, and a back translation to English to ensure the quality of the translation. The 17 items are scored from 0 (never) to 2 (often) and summed to give a sum score ranging from 0 to 34.

The Parental Emotional Response Questionnaire (PERQ) is a validated scale concerning parents' feelings and reactions to what the child has experienced (59). The scale measures three underlying factors related

to distress, shame and guilt (60). The 15 items are scored from 1 (never) to 5 (always) and summed giving a total sum score ranging from 15 to 75.

The Parental Stress Scale (PSS) is a validated measure of both the positive aspects of being a parent and experienced stress in parenting during the last two weeks (61). Both two- and four-factor structures for the scale have been suggested; in a recent Norwegian study factor analysis found support for two factors; parental stressors and lack of rewards (62). The items are scored from 1 (strongly disagree) to 5 (strongly agree) and when summing the full 18-item scale it gives a total sum score ranging from 18 to 90.

The Symptom Check-list-10 (SCL-10S) is one of three 10-item short-versions of SCL-25 or HSCL-90. The SCL-10S consists of 10 questions that measure anxiety and depression symptoms in the last week (63). SCL-10S is derived from the SCL-25, which again is a short version of the Hopkins SCL-90 (64) and is a widely used and validated scale in Norwegian context (65). The 10 items are scored 1 (not at all) to 4 (extremely), and the summed total is divided by 10 to create a mean item score ranging from 1 to 4.

The Multidimensional Scale of Perceived Social Support (MSPSS) reflects experienced support from family, friends and significant others (66). The scale is validated in several languages (67–69), and has previously been used in a Norwegian context (70). The 12 items are scored from 1 (strongly disagree) to 7 (strongly agree) and a mean item score is used, ranging from 1 to 7.

The Stressful Life-Events Screening Questionnaire (SLESQ) is a validated measure of exposure to stressful events, such as serious illness, sudden or violent loss of a family member, rape and violence (71, 72). The measure has been adapted and validated for Norwegian conditions (73). Responses on the list of 15 potential events are given as yes or no. At T1, caregivers are asked about any events that have occurred in their life-time, at T2, T3 and T4 they are asked about events that have occurred since they last filled out the questionnaire.

The PTSD Checklist for DSM-5 (PCL-5) assesses post-traumatic symptoms in the last four weeks. It is based on the criteria for PTSD diagnosis in DSM-5 (74) and measures four aspects of post-traumatic symptoms: intrusions/re-experiencing, avoidance, negative changes in cognition/mood and hyperarousal. PCL-5 has been validated in Norway (75). The 20 items are scored from 0 (not at all) to 4 (extremely) and summed giving a total score ranging from 0 to 80.

Subjective quality of life (QoL-1) will be assessed at T4 with the same question described under child measures. In addition, the caregivers will be asked to assess their child's QoL and change in QoL.

Credibility expectancy questionnaire – Parent Version (CEQ-P) is a validated assessment of how parents perceive a treatments credibility and the effect the treatment will have on their child's health (76). It is based on the validated CEQ (77). In this study, the three items that assesses treatment credibility will be included, and one of the three items that assesses expected change. The three credibility-items (How logical does this treatment seem to you; How confident are you that this treatment will be successful in

removing your child's PTSD symptoms; How confident would you be in recommending this treatment to a friend who has a child with a similar problem) are scored on a numeric rating scale from 1 to 10, where 1 is labelled not at all logical/confident/successful and 10 is labelled very logical/confident/successful, respectively. The scores are summed, giving a total score ranging from 3 to 30. The expectancy-item that is included (By the end of this treatment, how much improvement in your child's symptoms do you think will occur), is scored on an 11-point scale from 0–100% expected improvement. In addition, one question assesses credibility of the treatment to decrease other types of problems (How successful do you think this treatment will be in decreasing other (non-trauma) problems your child) (26, 78), which is scored from 1 not at all successful to 10 very successful. Translation was done by the project group, with two independent forward translations to Norwegian and one independent back translation to English to verify the wording.

Barriers for treatment completion

A checklist of potential barriers for completing treatment was created, based on the external demands subscale (79) of the barriers to treatment participation scale (80) and adapted to the conditions of the study (for instance items related to the cost of treatment were irrelevant as all treatment for children in municipal and specialist health care is free of charge). The adapted list consists of nine potential barriers and responses will be given as yes/no: Challenges in the family, such as illness, crisis or economic difficulties; Currently moving houses or making other large changes; Travel to the therapists office is long or difficult; Challenges with obtaining care/babysitter for other children in the household; The caregivers work situation/schedule; The child's school or leisure activities; The family experiences a lot of stress and it is difficult to find time; There are disagreements about what treatment the child should receive, or if the child needs treatment at all; Other.

Trajectory from trauma event to treatment will be assessed through 5 self-made questions, including 3 questions related to the time-line: Total time since the traumatic event occurred; Time from the event occurred until the trauma was uncovered; Time from the trauma was uncovered to first help (<1 month; <3 months; <6 months; < 12 months; 12-24 months; >24 months), and 2 questions related to persons/services involved: Who the child first told/who first uncovered the trauma; Who contacted the municipal services on behalf of the child (the child; caregiver; schoolteacher; school health services; general practitioner; CAMSH; emergency room; dentist; social services; child protective services; police; a friend of the child; others).

The Client Satisfaction Questionnaire (CSQ-8, parent rated version) is a short-version of CSQ-18, and is the most used and validated assessment of caregivers satisfaction with a child's treatment (81, 82). It has been used to evaluate the parents' satisfaction with stepped care TF-CBT in previous studies (26). The 8 items are scored from 1 (poor) to 4 (excellent) and summed giving a total score ranging from 8 to 32.

Treatment needs after ended treatment will be assessed at end of treatment and for responders, again at T4. At end of treatment, the therapists log the reason for ending treatment (completed step one with no

need for further contact; completed step one with need for further contact; interrupted step one, including reason for interruption). When the therapist's assessment is that there is need for further contact or the treatment is interrupted, the plan for the child's further treatment will be logged (step two at CAMHS; referred to CAMHS for non-trauma focused treatment; non-trauma focused treatment in the municipal health service; does not want further treatment anywhere; other).

At T4, the caregiver will report on whether the child receives any treatment for trauma at follow-up (for the same trauma; for new traumatic experiences; both of the above; other - describe), and if yes, where the treatment was provided (CAMHS; municipal health services; other – describe). The caregiver will also be asked whether they believe their child needs more treatment than they are already receiving (no; yes – describe what the child needs treatment for).

Post-treatment use of treatment components

The caregivers will be asked to assess the child's use of different treatment components through the same questions asked of the child (see description under child measures).

Change in the child-caregiver relationship

Caregivers will be asked the same questions as the child about the amount of time and quality of time spent with their child (see description under child measures). In addition, they will be asked "Do you find it easier or more difficult to talk to and help your child now, or is there no change?" (much easier; easier: a little easier; no change; a little more difficult; more difficult; much more difficult; other), and they will be asked an open-ended question to describe what has changed (or not changed). Finally, caregivers will be asked an open-ended question about any thoughts or experiences about the treatment that they wanted to share with the research group.

Therapist measures

Acceptability of Intervention Measure (AIM), **Intervention Appropriateness Measure (IAM)** and **Feasibility of Intervention Measure (FIM)** are three related instruments recently developed to assess to which extent someone believes an intervention is acceptable, appropriate and feasible (83) and has shown good validity (84). The scale was translated to Norwegian by NKVTS in collaboration with the developer of the scale. Each measure has 4-items that are scored from 1 (completely disagree) to 5 (completely agree). Average scores are calculated for each measure separately (AIM, IAM and FIM), giving a score ranging from 1 to 5.

The Implementation Leadership Scale (ILS) consists of four subscales that assess the degree to which the therapist's leader is proactive, knowledgeable, supportive, and perseverant about implementation (85). The scale has been validated in Norwegian context (86). Each scale consists of 4 items each, and responses are given from 0 (not at all) to 4 (a very great extent). An average score is calculated, giving a sum score ranging from 0 to 4.

Alliance measures – child, caregiver and therapist

The Therapeutic Alliance Scale for Caregivers and Parents (TASCP) assesses the alliance between the therapist and the caregiver through two parallel forms to be filled out by the caregiver and the therapist (87, 88). The scales have been translated to Norwegian by NKVTS (30) and the 12 items measures two factors: Bond between caregiver and therapist (6 items) and level of task collaboration (6 items). A third, trauma-specific factor has been added in this study following advice from the developer of the scale (2 items: "The therapist tries to help me with the difficult thoughts and feelings I have after what happened" and "The therapist and I have found a way to work together that helps me with the difficult thoughts and feelings I have after what happened"). The 14 items are scored from 1 (not true at all) to 4 (very true) and summed giving a total sum score ranging from 14 to 56 (12 to 48 when using only the 12 original items).

The Therapeutic Alliance Scale for Children and Caregivers (TASCC) is a 7-item measure that was developed by the project group to assesses the alliance between the child and the caregiver using parallel forms to be filled out by the child and caregiver. It is an adaptation of the 12-item revised Therapeutic Alliance for Children (TASC-r) scale (87, 89), which measures two factors: bond between child and therapist and level of task collaboration (89). Wording was changed to reflect the alliance between child and caregiver. To devise a shorter scale, the 3 items with the highest loadings on each factor (57) was included, in addition 1 new item was added to assess a third, trauma-specific factor. The included items for bond between child and caregiver were "When I have the special meetings with my caregiver, I want the meetings to end quickly"; "I look forward to the special meetings with my caregiver"; "I'd rather do other things than have special meetings with my caregiver". The included items for task collaboration were "I work with my caregiver to solve my problems"; "I use the special meetings with my caregiver to make changes in my life"; "I think my caregiver and I work well together to solve my problems". The trauma-specific item that was added was "My caregiver tries to help me with the difficult thoughts and feelings I have after what happened". The items were rephrased for the caregiver form, e.g. "The child works with me to solve their problems" and "My child would rather do other things than have special meetings with me". Responses will be given on a scale from 1 (not true at all) to 4 (very true), and summed, giving a sum score ranging from 7 to 28 (6 to 24 when using only the 6 items from the original scale).

Assessment of study materials and effort ratings

The therapists will log whether the caregivers use and complete the 9 "just for you"-sections of the workbook, which of the 42 components from the 11 parent-child meetings ("special meetings") that are completed and the amount of time the child and caregiver spend on each of the 11 parent-child meetings.

Parent effort in completing the components of step one will be rated by the therapists on a 5-point scale from 0 (no effort) to 5 (maximum effort) (90).

Data analysis plan

Qualitative: The interviews will be analysed with methods suitable for the research questions. To explore the experiences of the participants and the implications of these experiences, we will use narrative analyses, such as thematic analyses, and interpretative phenomenological analysis (IPA) (91).

Quantitative: All analyses will be 2-sided with a set level for significance at 5%, or 95% confidence intervals. Comparisons will be made using paired t-tests, chi-square tests and ANOVA tests. When looking at predictors, we will use adjusted regression analyses and mediator analyses. Due to the nested nature of the data (clients within therapists), multilevel analyses will be the preferred strategy for analyses. Additional analyses will be considered, as this is largely an exploratory study.

Possible harm

Several measures will be taken to ensure that the potential harm of participation in the study is as low as possible. Consultants from the project group follow each therapist closely, and the suitability of the model for families are discussed with the consultants before treatment start. The first two cases are listened to in their entirety, and one session from each subsequent case. In addition, there are specific symptom-criteria to guide the necessity of stepping up treatment to standard TF-CBT at T2 and T3, and additional assessments of clinical global impressions at each therapist session and phone call to reveal red flags related to the child's symptoms. When it comes to contribution of data through questionnaires and interviews, previous studies have found that children are generally not upset by participation in studies and assessments of trauma and symptoms (34).

Ethics approval and dissemination

The study has been approved by the Norwegian Regional Ethics Committee South-East (Reference: REK 2018/771). Results from the study will primarily be disseminated through peer-reviewed articles and a report to the Norwegian Health Directory. In addition, some results that are specific to the Norwegian context may be disseminated through reports and national or Scandinavian channels.

Discussion

Results for the effect and acceptability of stepped care TF-CBT are promising so far, and an important next step in the development and implementation of a new treatment is to investigate feasibility in different contexts (92). As training and implementation of new treatments is both costly and time-consuming (28), the models that are introduced should be proven effective, acceptable and suitable.

This study protocol describes how the current feasibility study will investigate the suitability and acceptability of stepped care TF-CBT treatment in the Norwegian health care system. As an adaptation to

the Norwegian context the parent-led, therapist assisted step one, is offered as a low-threshold treatment in the first-line municipal health services, while non-responders to step one are referred to standard TF-CBT (step two) in the second-line specialist health services, CAMHS. The overall aims are to gain knowledge of whether this is a suitable treatment model in the first-line municipal mental health services, investigate the characteristics of children and caregivers that do or do not benefit from the treatment, and learn more about the mechanisms of change during treatment. We expect that most children, caregivers, therapists, and municipality leaders will find the model suitable and acceptable, however, we also expect that some aspects will be perceived as challenging, and that there may be need for adjustments in both the material and strategy for future implementation.

Through the qualitative interviews, we will explore the perspectives of the children, caregivers, therapists and municipal leaders, and have a unique opportunity to learn more about potential overlaps or discrepancies in their experiences and views of stepped care TF-CBT. Interviews of therapists and municipal leaders that withdrew from the project will provide important information about individual and contextual circumstances that might hinder or facilitate therapists' use of new treatment models in general, and stepped care TF-CBT in particular.

We know that several factors can influence treatment outcomes. In addition to exploring the impact of socio-economic status and practical barriers for treatment in the context of stepped care TF-CBT, we will investigate several relevant factors that could predict outcomes or contribute to knowledge of mechanisms of change. Symptoms of depression, negative cognitions, somatic symptoms, and health related quality of life have all been associated with post-traumatic stress symptoms and treatment outcomes (93). Factors that have been found to predict outcomes include caregiver-therapist therapeutic alliance (32), child-perceived caregiver-support (94), the caregivers' mental health status and changes in caregivers' symptoms (95), and caregivers' social support (96). In addition, the quality of the child – caregiver working alliance is a factor that can be assumed to influence outcome (27).

Strengths and limitations

While acknowledging the potential implications of this study there are limitations that must be mentioned. Since this is an open trial with no control group, we cannot know for certain whether any changes in child and caregiver symptoms can be ascribed to the stepped care TF-CBT model. As therapists self-select for participation in the project, and participation is voluntary for families, we cannot exclude the risk of selection bias. However, despite the mentioned limitations, this is the first study to investigate the feasibility of the stepped care TF-CBT model outside the USA, and the results may provide important information for the future implementation of this, or other parent-led models, including the adaptability and transferability of the model.

Trial status

Recruitment began in May 2019, the recruitment, intervention and data collection are expected to conclude fall 2022. The first publications based on qualitative data from therapists, and a subsample of children and caregivers, will be submitted for publication in 2022. The main articles based on the quantitative data will be submitted in 2022 and 2023.

Abbreviations

17D: 17-dimensional health-related measure

AIM: Acceptability of Intervention Measure

ANOVA: Analysis of variance

CAMHS: Child and adolescent mental health services CASSS: Child and Adolescent Social Support Scale

CATS: Child and Adolescent Trauma Screen

CBT: Cognitive behavioural treatment

CEQ-P: Credibility expectancy questionnaire – Parent Version

CGI-S/CGI-I: Clinical global impressions Severity/ Clinical global impressions improvement

CPTCI-S: Children's Post-Traumatic Cognitions Inventory Short

CSQ-8: Client Satisfaction Questionnaire

CSSI-8: Children's somatic symptoms inventory

DSM-5: Diagnostic and statistical manual of mental disorders fifth edition

FIM: Feasibility of Intervention Measure

IAM: Intervention Appropriateness Measure

ICD-11: International Classification of Diseases 11th Revision

ILS: Implementation Leadership Scale

IPA: Interpretative phenomenological analysis

MSPSS: Multidimensional Scale of Perceived Social Support

NKVTS: Norwegian Centre for Violence and Traumatic Stress Studies

PCL-5: PTSD Checklist for DSM-5

PERQ: Parental Emotional Response Questionnaire

PSC-17: Pediatric Symptom Checklist

PSS: Parental Stress Scale

PTSD: Post-traumatic stress disorder

QI: Qualitative Interview

QoL: Quality of life

REK: Regional Ethics Committee

SCL: Symptom Check-list

SLESQ: Stressful Life-Events Screening Questionnaire

SMFQ: Short Moods and Feeling Questionnaire

TASCC: Therapeutic Alliance Scale for Children and Caregivers

TASCP: Therapeutic Alliance Scale for Caregivers and Parents

TASC-r: Therapeutic Alliance for Children revised

TF-CBT: Trauma focused cognitive behavioural treatment

Declarations

Ethics approval and consent to participate

Caregivers with parental responsibility have to consent in writing for the child to participate, and for data collection on behalf of the child and themselves. The child receives tailored written and oral information and gives oral consent without the caregiver present. The study has been approved by the regional ethics committee south-east (REK- 2018/771).

Consent for publication

Not applicable.

Availability of data and material

Not currently applicable. Participant level data will not be available due to the small and potentially identifiable dataset.

Competing interests

The authors declare no competing interests.

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Authors' contributions

SMO and TKJ have initiated the project. MM, SMO and IS have been involved in the management of the project. IS and SMO have written the first draft of the manuscript. All authors (IS, MM, AN, TKJ, EMF, CUS, GMD, MK, KM, RCN, SMO) have contributed to the development of the design of the project and study protocol, revising the manuscript and approved the final version.

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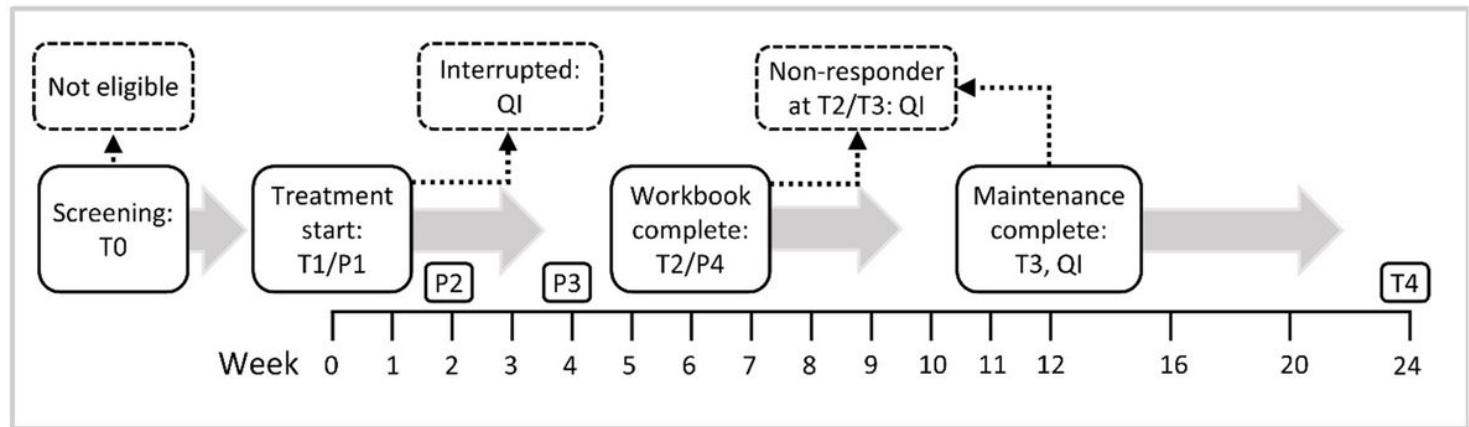
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Figures



Possible trajectories for screened children: 1) Not eligible due to inclusion/exclusion criteria, 2) Treatment is interrupted at some point before T2, 3) Does not meet responder criteria (symptom reduction) at T2 or T3 and is stepped up to treatment in CAMHS, and 4) Responds to step one without further need for trauma-treatment.

Quantitative data: Child, caregiver and therapist complete assessments at T0, T1/P1, P2, P3, T2/P4 and T3. In addition, child and caregiver complete assessment at T4.

Qualitative interviews (QI): Child and caregiver will be contacted for interviews in interrupted and non-responder cases, and a subsample of responder cases.

Figure 1

Flowchart for treatment and quantitative and qualitative (QI) data collection

Supplementary Files

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