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Stepped Care Versus Standard Trauma-focused Cognitive Behavioral Therapy for Young Children

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Stepped care versus standard trauma-focused cognitive behavioral therapy for young children

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Abstract

Background—Compare the effectiveness and cost of stepped care trauma-focused cognitive behavioral therapy (SC-TF-CBT), a new service delivery method designed to address treatment barriers, to standard TF-CBT among young children who were experiencing posttraumatic stress symptoms (PTSS).

Methods—A total of 53 children (ages 3-7 years) who were experiencing PTSS were randomly assigned (2:1) to receive SC-TF-CBT or TF-CBT. Assessments by a blinded evaluator occurred at screening/baseline, after Step One for SC-TF-CBT, post-treatment, and 3-month follow-up. Trial registration: ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/show/NCT01603563

Results—There were comparable improvements over time in PTSS and secondary outcomes in both conditions. Non-inferiority of SC-TF-CBT compared to TF-CBT was supported for the primary outcome of PTSS, and the secondary outcomes of severity and internalizing symptoms, but not for externalizing symptoms. There were no statistical differences in comparisons of changes over time from pre- to post-treatment and pre- to 3 month follow-up for PTSD diagnostic

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status, treatment response or remission. Parent satisfaction was high for both conditions. Costs were 51.3% lower for children in SC-TF-CBT compared to TF-CBT.

Conclusions—Although future research is needed, preliminary evidence suggests that SC-TF-CBT is comparable to TF-CBT, and delivery costs are significantly less than standard care. SC-TF-CBT may be a viable service delivery system to address treatment barriers.

Keywords

Stepped care; TF-CBT; young children; PTSD; trauma

Introduction

Young children are exposed to a wide variety of potentially traumatic events (e.g., physical and sexual abuse, witnessing domestic violence and accidents), with some studies documenting trauma exposure as high as 70% (Roberts, Ferguson, & Crusto, 2013; Roberts, Huang, Crusto, & Kaufman, 2014). Approximately 16-33% of children exposed to traumatic events will develop posttraumatic stress disorder (PTSD) (Alisic et al., 2014), although these estimates may vary based on location and type of trauma. Without effective treatment, childhood PTSD and associated deleterious outcomes persist (Scheeringa, Zeanah, Myers, & Putnam, 2005). There are effective psychotherapies for young children after trauma, but these treatments require weekly therapist-led sessions ranging from three months to one year (Cohen, Deblinger, Mannarino, & Steer, 2004; Lieberman, Ghosh Ippen, & Van Horn, 2006; Scheeringa, Weems, Cohen, Amaya-Jackson, & Guthrie, 2011). For some families, the time commitment, costs, stigma, and transportation needed for in-office therapy meetings are treatment barriers that limit access to care (Bringewatt & Gershoff, 2010). Further, some parents may not seek treatment for their child due to wanting to solve the problem independently (Thurston & Phares, 2008). Newer service delivery models are needed to address treatment barriers and provide alternative treatments that are accessible, efficient, affordable, and effective.

Stepped care models are designed to provide first-line interventions that are easily accessible, lower cost, convenient for patients, and require less therapist time than standard treatment methods, such as weekly in-office therapist-directed treatment. Importantly, the first step must provide active mechanisms such that a substantial number of patients will improve. These models include a priori criteria for defining early treatment response after each step which is used to guide subsequent treatment. Stepped care models reserve resources, such as therapist time and costs, for those needing more intensive treatment (Bower & Gilbody, 2005).

Trauma-focused cognitive behavioral therapy (TF-CBT) is a well-established evidence-based treatment for children ages 3-18 (Silverman et al., 2008) that is widely disseminated (Cohen & Mannarino, 2008;). TF-CBT is a therapist-led treatment requiring weekly sessions with the parent and child for three to six months. Recently, TF-CBT was developed into a stepped care model called Stepped Care TF-CBT (see online supplementary Figure S1) in which the first step, Step One, is a parent-led treatment where the majority of the treatment is provided at home by the parent. The at-home treatment is supported with three in-office

sessions with the therapist, phone support, and web-based psychosocial information and video demonstrations (Salloum, Scheeringa, Cohen, & Storch, 2013). An a priori early responder status criterion after Step One is used to indicate if the child needs more treatment or can end treatment (Salloum, Scheeringa, Cohen & Storch, 2015). Children who need more treatment step up to Step Two, which consists of nine weekly TF-CBT therapist-led sessions. Children ending treatment after Step One enter the maintenance phase for six weeks where they continue parent-child meetings and practice skills they learned (Salloum, Scheeringa, et al., 2013). A parent-led treatment may be well-suited for young children as this age group is still very dependent on the parent and it allows the parent an opportunity to help solve the child's problems.

An open trial with nine parents and children who participated in SC-TF-CBT found that five of nine responded to Step One, parents were satisfied with the treatment, and costs of delivering the treatment were low (Salloum, Robst, et al., 2014). The current study addressed the next step in the development of SC-TF-CBT in that it compares the effectiveness and costs of SC-TF-CBT relative to standard TF-CBT among young children ages 3-7. We hypothesized that SC-TF-CBT would be comparable over time to TF-CBT in terms of child posttraumatic stress symptoms (PTSS: primary outcome), PTSS severity, internalizing and externalizing symptoms (secondary outcomes), parental expectation and credibility of treatment, and parent satisfaction, and that SC-TF-CBT would cost significantly less than TF-CBT.

Methods

Participants

Participants were recruited consecutively between May 2012 and August 2014 from a community mental health non-profit agency in an urban area where the study treatment occurred. Participants were recruited via phone when the parent called the agency seeking services. Referrals came from community sources (e.g., child welfare organizations, victim services, schools, hospitals, mental health clinics). These referral sources were the typical referrals to the agency, and most sources were provided with information about the study. Fifty-three young children (ages 3-7; M=5.04, SD=1.49) and their parent/guardian (ages 22-57; M=32.81, SD=8.42) were enrolled. Inclusion criteria included: (a) Child experienced ≥1 traumatic event after the age of 36 months; (b) child had ≥5 DSM-IV PTSD symptoms, with at least one symptom in re-experiencing or avoidance; (c) child was between the ages of 3-7 years. Exclusion criteria were: (a) any condition that limited the child's or caregiver's ability to comprehend the treatment or follow instructions (e.g., psychosis, mental retardation, or autism); (b) caregiver substance use disorder within past three months; (c) child or caregiver suicidality; (d) child or caregiver not fluent in English; (e) if child was on medication, the regimen was not stable for at least four weeks before enrollment; and (f) the caregiver was the perpetrator or the perpetrator was living in the same residence as the child. See Figure 1 for patient flow of enrollment and retention, and Table 1 for demographic information.

Procedures

This study was approved by the University of South Florida Institutional Review Board. Written informed consent was obtained from caregivers; children age 7 provided written assent and younger children were provided a brief verbal explanation about the study and assent was waived. The independent evaluator (IE), a master level clinician trained by the first, fourth, and last authors, and blinded to treatment conditions, administered the screening/baseline assessments. Child-caregiver dyads who met criteria were randomly assigned to one of the study conditions using a 2 (SC-TF-CBT) to 1 (TF-CBT) ratio. A 2:1 ratio was used since SC-TF-CBT is in the developmental phase and there are numerous outcome studies on TF-CBT (Cohen et al., 2004; Deblinger, Mannarino, Cohen, Runyon, & Steer, 2011). A computerized randomized block procedure generated by the second author using Splus was used by the Project Coordinator to assign cases to a condition. After randomization, parents completed the Expectancy Rating Form (ERF; Borkovec & Nau, 1972) before being scheduled for therapy the following week. Caregivers assigned to SC-TF-CBT were asked if they had access to the internet (91.67% had access). Parents who did not have access were provided printed psychoeducational information from the National Child Traumatic Stress Network (NCTSN) website.

There were four assessment periods, all conducted by the IE: screening/baseline, after Step One, post-treatment, and 3-month follow-up. Caregivers were provided compensation for their participation in assessments ($25 for baseline, a lower amount to minimize inducement to participate, $50 for each remaining assessments), but not for therapy. This trial was registered in ClinicalTrials.gov (see https://www.clinicaltrials.gov/ct2/show/NCT01603563).

Treatment

SC-TF-CBT

Step One consisted of three in-office therapist-led sessions (60 minutes), 11 parent-child meetings at-home over six weeks using an empirically-informed workbook that was based on the Preschool PTSD Treatment manual (Salloum, Scheeringa, Cohen & Amaya-Jackson, 2009), weekly brief phone support, psychoeducation information from NCTSN website, and a website with video demonstrations of relaxation exercises and imaginal and *in vivo* exposures. For a complete description of Step One see Salloum, Scheeringa, et al., 2013. If the child responded to Step One, the child proceeded to the maintenance phase for six weeks to practice the skills learned. Early responder status criteria was defined as ≤3 PTSS, or a Trauma Symptom Checklist for Young Children (Briere, 2005) PTS score of ≤39, and an IE Clinical Global Impression-Improvement (CGI-Improvement; Guy, 1976) rating of 3 (improved), 2 (much improved), or 1 (free of symptoms)(Salloum et al., 2015). If the child did not respond, s/he stepped up to Step Two which consisted of nine TF-CBT sessions.

Standard TF-CBT

Standard TF-CBT, 12 (90-minute) in-office therapist-led sessions, was provided to the child with active parent involvement. Treatment consisted of the core components of TF-CBT (e.g., psychoeducation; parenting skills; relaxation; affective expression and modulation;

cognitive coping and processing; trauma narrative; conjoint child-parent sessions; and enhancing future safety and development)(Cohen, Mannarino, & Deblinger, 2006).

Treatment Fidelity and Number of Sessions

Four master-level mental health therapists employed by a community agency provided therapy. The average experience post-masters was 4 years, 9 months (range 5 months to 14 years, 10 months). Therapists provided both treatments and completed treatment fidelity checklists for each session. Therapy session audio files were reviewed (e.g., 41.03% for SC-TF-CBT and 31.71% for TF-CBT) for inter-rater agreement by the project coordinator (PC); inter-rater agreement was .93 ($p<.001$) for SC-TF-CBT and .95 ($p<.001$) for TF-CBT. The PC was a master level licensed professional who was not blinded to treatment. The average number of therapist-led in-office therapy sessions was 2.6 (.98) for Step One, 6.3 (4.62) for Step Two, and 11.06 (2.6) for TF-CBT. Three parents who qualified for Step Two chose not to participate, but continued with the assessments. One of these parents indicated that she did not think more treatment was needed as the child was being reunited with her biological parent. One parent became homeless, went to a shelter and did not have transportation. The reason for non-participation of the third parent was unknown. The average number of parent-child meetings in Step One was 7.91 (4.02).

Measures

Primary Outcome Measure

Trauma Symptom Checklist for Young Children (TSCYC; Briere, 2005) measures the frequency of children's trauma symptoms. The 27-item posttraumatic stress (*PTS*) subscale was used for the present study (total score range=27-108, ≥40 in the clinical range; current sample α=.92; administered at all four assessments periods).

Secondary Outcome Measures

Clinical Global Impression-Severity (CGI-Severity; National Institute of Mental Health, 1985) is a 1-item 7-point Likert scale ranging from 0 (no illness) to 6 (extremely severe symptoms/completely nonfunctional) to measure symptom severity. This rating was completed by the IE after each assessment period. The last author and IE, both blind to study condition, reviewed the CGI-Severity scores together for agreement. Inter-rater reliability between an independent rater and the IE was good (Kappa=.75, $p < .001$).

Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2000, 2001) is a widely used, psychometrically sound parent-report of children's emotional and behavioral problems. The current study utilized the 1½ to 5-year old and 6 to18-year old versions. T-scores for internalizing and externalizing behavior problems were used. This measure was administered at baseline, post and follow-up assessments.

Diagnostic Assessment and Improvement

Diagnostic Infant and Preschool Assessment (DIPA; Scheeringa & Haslett, 2010) is a semi-structured clinical interview with the parent/guardian to assess for mental health disorders in young children. The PTSD module was used to determine inclusion and PTSD diagnostic

status (e.g., DSM-IV PTSD and an alternative algorithm for PTSD (PTSD-AA) for young children) (Scheeringa, Zeanah, Myers, & Putnam, 2003). For the PTSD module, 29.25% of interviews were reviewed by a psychology doctoral student and inter-rater reliability was excellent (Kappa=.93, $p < .001$). This measure was administered at all assessment periods.

CGI-Improvement (Guy, 1976) is a 1-item 8-point Likert scale to measure overall symptom improvement with scores ranging from 1 (free of symptoms) to 8 (very much worse). An IE rating of 1, 2, or 3 was used as treatment response, and a rating of 1 was used as remission. The IE score was reviewed by the last author (who was blinded to treatment) and a consensus rating was obtained. This rating was completed after Step One, and at post and follow-up assessments.

Treatment credibility and satisfaction

The ERF (Borkovec & Nau, 1972) is a parent self-report, 4-item, 10-point Likert scale (1=low to 10=high) assessing the parent's expectations regarding the success and credibility of the treatment at baseline. Scores were averaged such that the total score ranged from 0 to 10. A fifth item that measured on a scale of 0 to 100% how much the parent expected the child's symptoms to improve by the end of the treatment was included (current sample α=.84).

Client Satisfaction Questionnaire (CSQ; Nguyen, Attkisson, & Stegner, 1983) has 8-items on a 4-point Likert scale to measure parent's satisfaction with the treatment. Responses range from 1 (low) to 4 (high) with higher scores indicating greater treatment satisfaction (range 8 to 32; current sample α=.91; administered at post-treatment).

Parenting measure

Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version (SCID-RV; First, Spitzer, Miriam, & Williams, 2002) is a structured, clinician-administered interview for adult DSM-IV criteria disorder diagnosis. The SCID-RV was administered only at baseline to screen for exclusion criteria, parent PTSD and depression.

Cost measures

The Therapist/Patient Time Tracking System (TTTS; Salloum, Robst, et al., 2013) records, by the therapist, the amount of time that therapist and client spend throughout treatment, including face-to-face therapy sessions, phone calls, documenting treatment notes, and client homework.

Cost Characteristics Information (CCI; Salloum, Robst, et al., 2013) estimates indirect treatment costs, such as insurance co-payments/deductibles or cost of treatment, gas, and compensation from missing work or therapy appointments.

Data analyses

In general, we conducted two analyses, ‘difference tests’ and non-inferiority tests. Difference tests were conducted using linear mixed-effects models (for continuous outcomes) or generalized linear mixed-effects models (for non-continuous outcome) to

accommodate correlations among repeated measures. Included in the model were treatment status, time, and treatment by time interaction. The presence of a non-significant interaction would suggest that the children in the two conditions changed at comparable rates. For non-inferiority tests, we followed the recommendation of Greene, Morland, Durkalski, and Frueh (2008) and concluded non-inferiority if the SC-TF-CBT values were within at least 80% of TF-CBT. Since there were only a few incomplete cases and drop outs, intent-to-treat (ITT) analysis based on multiple imputation method was conducted for the child primary and secondary outcomes and for the diagnostic and improvement status ratings. Ten imputations were generated at item level, and the aforementioned analyses were repeated on these imputed data sets and results then were aggregated (Schafer, 1997). Since we had less than 10% missing cases, 10 imputations would carry a 99% efficiency and thus were adequate (Rubin, 1987). All four participants who dropped out were included in the ITT analysis (two had complete data for all time points that was used; two cases had missing post-treatment and follow-up data which were imputed). Follow-up data were imputed for the two lost-to-follow-up cases. Since the ITT and completer results were comparable, we reported the ITT results. From the original design, we had anticipated that the power would fall between .29 (small non-inferiority margin) to .44 (medium non-inferiority margin). For the actual sample size, power ranged from .34 (small non-inferiority margin) to .52 (medium non-inferiority margin). While multiple comparisons were unavoidable, we opted not to impose any corrections due to the piloting/exploratory nature of the study. The analyses were conducted using Splus for generalized linear models and SPSS for multiple imputation.

Costs were analyzed instead of cost effectiveness based on the findings below that children receiving SC-TF-CBT improved at the same rate as children receiving TF-CBT. Cost effectiveness ratios are based on a difference in treatment efficacy, and in the absence of such differences can be reduced to a comparison of costs. Statistical significance of cost differences was assessed using SAS Proc Genmod with a log-link to account for the non-normal distribution of costs. Based on the expert panel recommendations of Gold, Seigel, Russell, and Weinstein (1996), costs are examined from a societal perspective, meaning the costs to the health care system and the patient/parents are included. Treatment is typically paid for by private or public insurers in the US healthcare system; thus, we present the cost analysis under the scenario in which payments are by insurers (i.e., payer direct cost). Payer direct cost consisted of the cost of a session and phone calls paid by a third party (e.g., Medicaid rate). Social costs also include the value of patient and (uncompensated) provider time. Patient indirect cost included indirect cost of participating in treatment including, cost of travel and lost wages from time spent in treatment, driving to and from treatment, waiting for treatment sessions, or doing homework. Provider indirect costs included time not reimbursed, including time preparing and documenting sessions. Total cost includes all direct and indirect costs. Masters level therapist time was valued at the Florida Medicaid payment rate of $18.33 per quarter hour. Patient/parent travel costs to and from sessions was 23 cents per mile (U.S. Department of Labor, 2011). Parent time was valued at the median hourly wage ($18.06 for college graduates and $11.79 for high school graduates) (Internal Revenue Services, 2011). The sample size provides marginal power (.77 with α=.05) to detect large effect sizes (Cohen's d=.8) using a two-tailed test.

Results

Baseline equivalence between conditions indicated that there were significant differences for parent/guardian race and PTSD diagnosis status (see Table 1). However, since these two variables were not significantly associated with outcome variables, they were not included in the model. There were no significant differences in demographics, primary and secondary outcome measures, and ERF ratings between completers (n=49) and drop outs (n=4: 11.4% in SC-TF-CBT due to transportation, scheduling difficulty and medical issues). The average number of traumatic events was 2.75 (±1.22), which was not different by condition, $t(51) = -.33$, $p = .741$. In SC-TF-CBT, 22 responded to Step One (see Figure 1). One parent in Step One was court-ordered to therapist-directed treatment due to possible on-going domestic violence. Of Step One participants, the response rate was 71% (22/31; ITT 22/35, 63%), and responder status criteria was maintained at post and follow-up assessment.

Primary and secondary outcomes

Table 2 provides descriptive data. Online supplementary Table S1 summarizes the results from both difference and non-inferiority tests. With respect to the primary outcome, TSCYC-PTS total, and secondary outcomes, CGI-Severity, CBCL Internalizing and Externalizing T scores, results from difference tests showed that participants in SC-TF-CBT changed at comparable rates, if not better, in comparison to those in standard TF-CBT (p-values ranged between .023 to .597). SC-TF-CBT was not inferior to standard TF-CBT on all variables except for externalizing T scores ($p = .09$).

Diagnostic status and improvement (ITT)

For the PTSD-DSM-IV diagnostic status, there was no statistical difference at post-treatment between SC-TF-CBT (48.6% at baseline to 0%) and TF-CBT (33.3% at baseline to 0%), $p = .443$ ($\chi^2(1) = 0.59$). Similarly, there was no significant difference in PTSD-DSM-IV criteria at follow-up (SC-TF-CBT = 8.6% vs. TF-CBT = 0%), $p = .861$ ($\chi^2(1) = 0.03$). For the PTSD-AA, there were no significant differences at post-treatment between SC-TF-CBT (91.4% baseline to 14.3%) and TF-CBT (88.9% at baseline to 5.6%), $p = .866$ ($\chi^2(1) = 0.03$), and the differences at follow-up were not significant (SC-TF-CBT = 14.3% vs. TF-CBT = 5.6%, $p = .866$, $\chi^2(1) = 0.03$).

There were no statistical differences in treatment response between SC-TF-CBT and TF-CBT at post-treatment (94.3% vs. 100%, $p = .785$, $\chi^2(1) = 0.07$) and follow-up (91.4% vs. 94.4%, $p = .694$, $\chi^2(1) = 0.15$), respectively. Similarly, there were no statistical differences in remission between SC-TF-CBT and TF-CBT at post-treatment (42.9% vs. 27.8%, $p = .439$, $\chi^2(1) = 0.60$) and follow-up (45.7% vs. 33.3%, $p = .567$, $\chi^2(1) = 0.33$).

Treatment credibility and satisfaction

There was no significant difference in parent ERF ratings between SC-TF-CBT (M=9.19, SD=88) and TF-CBT (M=9.14, SD=1.21), $p = 0.563$. Similarly, on the rating of parent expectation of improvement, there was no significant difference between conditions (M=81.11, SD = 19.06 vs M=86.57, SD=12.11, SC-TF-CBT and TF-CBT, respectively, $p = 0.443$).

Satisfaction scores were high for both conditions (SC-TF-CBT = 30.03±2.74; TF-CBT= 29.50±4.02). There were no significant differences on CSQ scores between the two conditions (see Table S1).

Cost results

Costs were 51.3% lower ($\chi^2(52)=36.3$, $p < .0001$) for children in SC-TF-CBT ($n=35$, $M=$ \$953.17, $SD=645.43$) compared to standard TF-CBT ($n=18$, $M=$\$1,957.19, $SD=64.38$). Direct and indirect costs to parents/patients and providers were significantly lower for children in SC-TF-CBT. Patient/parent indirect costs were lower for SC-TF-CBT due to the overall lower time requirements, particularly for office visits (see Table 3).

Discussion

There has been considerable research on the effectiveness of TF-CBT (Cohen et al., 2004; Deblinger et al., 2011; Mannarino, Cohen, Deblinger, Runyon, & Steer, 2012); however, innovative service delivery approaches to provide TF-CBT are limited. Results of this trial comparing SC-TF-CBT to TF-CBT are encouraging. Outcomes in both treatments changed at comparable rates and SC-TF-CBT was not inferior to TF-CBT on PTSS, PTSS severity and internalizing symptoms, but not for externalizing symptoms. There were no significant differences in changes in diagnostic status, treatment response and remission between conditions. Importantly, there were no significant differences by condition in parents' perceived treatment credibility, anticipated improvements and treatment satisfaction. SC-TF-CBT was significantly less costly than TF-CBT.

The majority of children in Step One responded to the parent-led therapist-assisted treatment and did not require further treatment. This high early response rate to a parent-led treatment potentially addresses the treatment barrier of parents wanting to help their children. Step One may be more convenient for parents as it limits the number of times parents have to attend in-office visits. Research is needed to identify characteristics that may determine who is likely to respond to Step One and who may need to be assigned directly to standard TF-CBT. Matching children at baseline to the best level of care may minimize dropouts, as having parents complete Step One without the child responding may contribute to parents dropping out and not proceeding to Step Two.

SC-TF-CBT and TF-CBT both had mean externalizing T scores below the clinical range at post-treatment, large effect sizes, and improvements were comparable across the two conditions. However, the non-inferiority test, which is more stringent than difference tests, did not suggest that SC-TF-CBT was at least 80% as effective as TF-CBT in reducing externalizing behaviors. Additional strategies for addressing externalizing symptoms in Step One for children with high externalizing scores may lead to non-inferiority between SC-TF-CBT and TF-CBT. Research with the inclusion of supplementary behavioral strategies in Step One and larger samples to test non-inferiority of externalizing symptoms is needed.

In the current study, cost was the main treatment barrier assessed, and the potential for over a 50% savings is promising. The cost to patients in SC-TF-CBT was 1.8 times less than TF-CBT and the payer costs were 2.27 times lower in SC-TF-CBT than TF-CBT. Beyond these

encouraging numbers, the meaning of this type of improvement to standard care may have several implications for practice and policy. First, more parents may have access to treatment for their children. Second, therapy would be more efficient with early responders requiring fewer weeks in therapy and more resources would be available for children needing more intensive care. Third, the therapist role in Step One is one of an assistant rather than a direct provider. Fourth, payers and policy makers may require large child serving systems and agencies and/or private therapists to provide stepped care approaches such as SC-TF-CBT.

There are notable study limitations. First, the small sample size is a limitation and does not allow for more advanced analyses. Future trials on SC-TF-CBT need larger, more diverse samples, including non-English speaking participants, that allow for moderators of treatment to be tested and identification of candidate baseline characteristics that could be used to match children to the appropriate level of care prior to treatment. Testing differing outcomes, satisfaction, and attrition by race, ethnicity and/or cultural practices, as well as conducting qualitative studies with therapists and patients to learn about possible cultural modifications for specific groups, are needed for the future development of SC-TF-CBT. Second, research with a longer follow-up is needed to ensure that treatment gains are maintained for children who receive parent-led therapist-assisted treatment compared to therapist-led treatment. Third, cost data was limited in that other mental health and health services were not collected. Future research will need to address these costs limitations.

Conclusion

The current study provides preliminary support for the effectiveness and cost of SC-TF-CBT relative to standard TF-CBT among young children. The parent-led therapist-assisted treatment may be a viable option for many parents and children. However, research is needed to develop an algorithm that matches children at baseline to either weekly therapist-directed treatment or to the parent-led therapist-assisted treatment so that treatment for potential non-responders of Step One is not delayed. We highlight the need for additional research on SC-TF-CBT as this service delivery model may be a viable alternative for many parents seeking an accessible, efficient, affordable, and effective trauma-focused treatment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Key Points

- TF-CBT is a well-established treatment, but alternative delivery systems to address treatment barriers are limited; thus Stepped Care TF-CBT, with a parent-led therapist-assisted treatment as a first step and standard TF-CBT for the second step, was developed.
- There were comparable improvements over time in PTSS, symptom severity, internalizing and externalizing symptoms, PTSD diagnostic status, remission and response for Stepped Care and standard TF-CBT.
- SC-TF-CBT was not inferior to TF-CBT on PTSS, severity, internalizing symptoms, parent credibility and satisfaction, but non-inferiority for externalizing symptoms was not supported.
- Costs were 51.3% lower in SC-TF-CBT compared to standard TF-CBT. SC-TF-CBT offers a promising new service delivery system, but more research is needed.

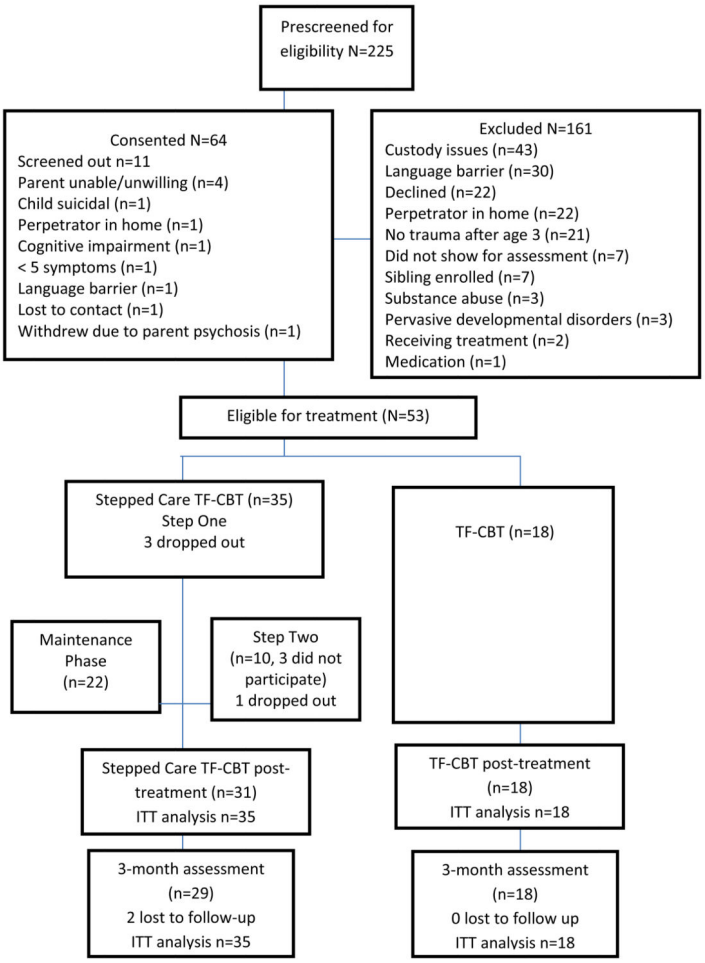

Figure 1. Consolidated standards of reporting trials flow diagram of study (N=53)

Table 1
Demographics and Characteristics by Condition (N=53)

Characteristic	SC-TF-CBT (n=35) *n* (%)	TF-CBT (n=18) *n* (%)	*p*-value[a]
Child gender			.59
Male	19 (54.3)	8 (44.4)	
Female	16 (45.7)	10 (55.6)	
Child ethnicity			.38
Hispanic or Latino	14 (40)	10 (55.6)	
Child race			.15
American Indian/Alaskan Native	1 (2.9)	0 (0)	
African American	6 (17.1)	8 (44.4)	
White	25 (71.4)	9 (50)	
Mixed Race	3 (8.6)	1 (5.6)	
Child index trauma[b]			.33
Sexual abuse	11 (31.4)	7 (38.9)	
Domestic violence	12 (34.3)	6 (33.3)	
Death/grief	4 (11.5)	2 (11.1)	
Physical abuse	1 (2.9)	1 (5.6)	
Accidents	3 (8.6)	0 (0.0)	
Community violence	1 (2.9)	0 (0.0)	
Crime	1 (2.9)	0 (0.0)	
Witnessed parent arrest	1 (2.9)	0 (0.0)	
Removal from parent/home	0 (0.0)	2 (11.1)	
Illness/medical	1 (2.9)	0 (0.0)	
Parent/Guardian relationship			.16
Biological mother	30 (85.7)	16 (88.9)	
Biological father	3 (8.6)	0 (0)	
Grandmother	2 (5.7)	0 (0)	
Great aunt	0 (0)	1 (5.6)	
Aunt	0 (0)	1 (5.6)	
Parent/Guardian ethnicity			.24
Hispanic/Latino	11 (31.4)	9 (50)	
Parent/Guardian race			.03*
American Indian/Alaskan Native	0 (0)	2 (11.1)	
African American	6 (17.1)	6 (33.3)	
White	29 (82.9)	10 (55.6)	
Household income[c]			.95
$0 – 9,999	5 (14.3)	7 (38.9)	
$10,000 – 24,999	9 (25.7)	5 (27.8)	
$25,000 – 34,999	11 (31.4)	1 (5.6)	
$35,000 – 49,999	4 (11.4)	0 (0)	

Characteristic	SC-TF-CBT (n=35) *n* (%)	TF-CBT (n=18) *n* (%)	*p*-value[a]
$50,000 +	6 (17.1)	5 (27.8)	
Parent/Guardian employed	22 (62.9)	10 (55.6)	.77
Parent/Guardian in treatment	7 (20)	5 (27.8)	.73
Parent/Guardian with PTSD	15 (42.9)	13 (72.2)	.04*
Parent/Guardian with MDD	6 (17.2)	4 (22.2)	.72
Parent/Guardian age, y, *M*(*SD*)	32.80 (7.58)	33.39 (9.99)	.81
Child's age, y, *M*(*SD*)	4.94 (1.47)	5.50 (1.25)	.18

Note.

[a]Non-parametric tests were used for nominal level data; thus no test statistic is provided.

T-tests were used for mean differences in age measured in years (y) for parents ($t(51)$=-.24) and children ($t(51)$=-1.37).

*p<.05

[b]Type of trauma was collapsed into non/interpersonal trauma (e.g., sexual abuse, domestic violence, physical abuse and kidnapping).

[c]Income was collapsed into < or $35,000 > for the significance analysis.

Table 2

ITT Means and SD for Primary and Secondary Outcomes by Condition (SC-TF-CBT n=35; TF-CBT n=18)

Variable	SC-TF-CBT					TF-CBT				
	Baseline M(SD)	Post M(SD)	FU M(SD)	Post ES *d*	FU ES *d*	Baseline M(SD)	Post M(SD)	FU M(SD)	Post ES *d*	FU ES *d*
TSCYC-PTS	56.29 (13.91)	37.19 (10.19)	35.94 (11.59)	1.57	1.59	52.61 (15.84)	38.11 (9.89)	34.94 (8.53)	1.10	1.39
CGI-S	4.26 (0.85)	1.10 (1.21)	1.07 (1.28)	3.02	2.94	3.83 (1.04)	1.44 (1.20)	1.17 (0.99)	2.13	2.62
Internalizing T score	66.86 (8.06)	51.08 (12.31)	50.08 (13.38)	1.52	1.52	63.06 (11.00)	50.61 (11.85)	48.61 (13.61)	1.09	1.17
Externalizing T score	64.94 (11.00)	51.21 (12.31)	50.71 (14.70)	1.18	1.10	66.28 (10.77)	54.28 (12.84)	54.11 (15.62)	1.01	0.91

Note. ES= effect size, d = Cohen's d

Table 3

Differential Costs Between SC-TF-CBT and Standard TF-CBT (N=53)

Cost	SC-TF-CBT Mean (*SD*)	TF-CBT Mean (*SD*)	Effect size (Cohen's *d*)	Wald Chi square	*p* value
Payer direct cost	$466.62 (354.30)	$1,057.03 (257.54)	1.38	36.3	<.0001
Patient indirect cost	$238.30 (154.38)	$436.82 (220.00)	0.99	15.0	<.0001
Provider indirect cost	$248.24 (201.45)	$463.34 (116.20)	1.00	15.5	<.0001
Total cost	$953.17 (645.43)	$1,957.19 (564.38)	1.29	30.5	<.0001

Note. The Wald Chi square and *p* values are from generalized linear models with a log-link to account for non-normal distributions.