Published in final edited form as:

Child Psychiatry Hum Dev. 2014 February ; 45(1): 65–77. doi:10.1007/s10578-013-0378-6.

Step One within Stepped Care Trauma-Focused Cognitive Behavioral Therapy for Young Children: A Pilot Study

Alison Salloum,

School of Social Work, University of South Florida, 13301 Bruce B. Downs Blvd., MHC 1400, Tampa, FL 33612-3870, USA

John Robst,

Department of Mental Health Law and Policy and Department of Economics, University of South Florida, Tampa, FL, USA

Michael S. Scheeringa,

Department of Psychiatry, Section of Child and Adolescent Psychiatry, Tulane University, New Orleans, LA, USA

Judith A. Cohen,

Center for Traumatic Stress in Children and Adolescents, Allegheny General Hospital, Pittsburgh, PA, USA

Wei Wang,

College of Public Health, Department of Epidemiology and Biostatistics, University of South Florida, Tampa, FL, USA

Tanya K. Murphy,

Departments of Pediatrics, University of South Florida, St. Petersburg, FL, USA

David F. Tolin, and

Anxiety Disorders Center, The Institute of Living, Hartford, Connecticut, Yale University School of Medicine, New Haven, CT, USA

Eric A. Storch

Departments of Pediatrics, University of South Florida, St. Petersburg, FL, USA

Alison Salloum: asalloum@usf.edu; John Robst: jrobst@usf.edu; Michael S. Scheeringa: mscheer@tulane.edu; Judith A. Cohen: jcohen1@wpahs.org; Wei Wang: wwang@health.usf.edu; Tanya K. Murphy: tmurphy@health.usf.edu; David F. Tolin: dtolin01@harthosp.org; Eric A. Storch: estorch@health.usf.edu

Abstract

This pilot study explored the preliminary efficacy, parent acceptability and economic cost of delivering Step One within Stepped Care Trauma-Focused Cognitive Behavioral Therapy (SC-TF-CBT). Nine young children ages 3–6 years and their parents participated in SC-TF-CBT. Eighty-three percent (5/6) of the children who completed Step One treatment and 55.6 % (5/9) of the intent-to-treat sample responded to Step One. One case relapsed at post-assessment. Treatment gains were maintained at 3-month follow-up. Generally, parents found Step One to be acceptable and were satisfied with treatment. At 3-month follow-up, the cost per unit improvement for posttraumatic stress symptoms and severity ranged from \$27.65 to \$131.33 for the responders and from \$36.12 to \$208.11 for the intent-to-treat sample. Further research on stepped care for young

children is warranted to examine if this approach is more efficient, accessible and cost-effective than traditional therapy.

Keywords

Stepped care; Trauma-Focused Cognitive Behavioral Therapy; Young children; Trauma

Introduction

Given the prevalence of traumatic events experienced by young children [1], limited number of trained therapists [2], and barriers to treatment [3], alternative methods of delivering evidence-based trauma-focused treatments are needed. Stepped care models that provide less therapist intensive intervention as a first-line treatment with more intensive care for those who need to “step up” are being developed to address treatment barriers [4]. Stepped care has the potential to substantially improve service delivery by providing an effective first-line treatment that is easily accessible and less costly.

Stepped care models provide first-line treatments that are designed to minimize therapist time, costs, and patient inconvenience with “steps” to more intensive treatment for those who need additional care. Stepped care models incorporate monitoring systems to inform decisions about when more intensive treatment is indicated. Treatment is provided in “steps” according to the individualized needs of the patients with measures of response or non-response determining if additional steps are needed. The potential advantages of stepped care models are that they may be more efficient, accessible and cost-effective than standard methods of treatment delivery which often include weekly therapist-directed “full treatment packages” (i.e., the entire evidence-based treatment package for all patients) [5, 6]. While stepped care models are being designed for various conditions such as eating disorders [7], substance abuse [8], depression [9] and anxiety [4], we do not know if stepped care is indicated or contraindicated for certain conditions with specific populations. Also, it is important to learn who responds to the first-line treatment of different stepped care interventions, and who may need to proceed directly to more intensive care so that treatment is not delayed for those patients who are not likely to respond to step one [10]. Further, for conditions where stepped care may be beneficial, we do not know the proportion of patients who might benefit from first steps versus those who need all of the steps [6].

Stepped care interventions for children are in the early stages of development. In one of the first studies of stepped care for childhood anxiety (e.g., separation anxiety, social phobia, specific phobia and generalized anxiety), 133 children (ages 8–12) participated in an open trial of three step cognitive behavioral therapy (CBT) in which more sessions with intensifying parent involvement were added with each step. The intent-to-treat analysis from this stepped care study found that 45 % of the children responded at step one (10 child and 4 parent CBT sessions), 17 % responded at step two (5 parent–child CBT sessions) and 11 % responded at step three (an additional 5 parent–child CBT sessions) for a total of 74 % of children no longer meeting criteria for an anxiety disorder [11]. Stepped care interventions for children after traumatic events, such as disasters and war, are being developed within school settings. These models provide group intervention to children as a first-line treatment with the final step consisting of referring to outpatient treatment for more intensive care [12, 13]. However, stepped care models for children after trauma that can be used within community settings are needed in order to address common barriers to treatment such as time constraints, inconveniences [14, 15], costs [16], availability of trained therapists, and logistical barriers such as work demands, childcare, and transportation [17].

One barrier to treatment for parents seeking and completing child or family focused treatment is their desire to solve the problem related to their child on their own [18-20]. Parent-delivered treatment in which parents take responsibility for their children's improvement may address this barrier [21]. There is evidence that supports parenting training models for children with behavioral problems where the parent receives the treatment and in turn helps the child [22]. However, for children with posttraumatic stress symptoms (PTSS), research suggests that while parent-only treatment is helpful in terms of increasing parenting skills and addressing child externalizing behavior, child participation in therapy results in greater improvements in child PTSS than parent-only treatment [22-24]. Therefore, while a parent-delivered treatment for children after trauma may be an acceptable treatment for parents, research suggests that for children both the parent and the child need to be involved in the treatment.

Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) for children ages 3–17 after trauma is a well-established evidence-based treatment [25] as there have been several randomized clinical trials (RCT) comparing TF-CBT to other treatments or waitlist conditions. For example, in one of the first RCTs with 67 preschoolers who had been sexually abused, TF-CBT (12 weekly 90 min sessions) was found to be superior to nondirective supportive therapy in improving internalizing and externalizing behaviors, and PTSS, as well as reducing sexually inappropriate behaviors [26]. Similarly, in an RCT with 129 older children (ages 8–12) who were sexually abused and 90 % of whom also experienced other forms of traumatic events, children in TF-CBT (12 weekly parent–child 90 min sessions) had significantly better improvements in PTSS, depression, behavior problems, shame, and abuse-related attributions than children who received child-centered therapy. In terms of clinical significance, there were comparable percentages of children who met criteria for PTSD at pre-intervention, but there were significant differences between the percentage of children who still met criteria for PTSD at post-intervention (21 % for TF-CBT vs. 46 % for child-centered treatment) [27]. In a more recent RCT with preschool children (36–83 months) who received 12 weeks of therapist-led CBT for PTSD that involved the parent and the child and was tailored for preschool children versus a waitlist control group, there were significantly more improvements in PTSS than for children in the waitlist group, and treatment gains in the treatment condition were maintained at 6 months. Using a developmentally specific alternative algorithm to diagnose PTSD in young children, this study found that 82.4 % of the treatment completers no longer met criteria for PTSD. Importantly, this study included children exposed to heterogeneous types of traumas [28].

In TF-CBT the therapist meets individually with the parent and the child, and also has conjoint parent–child sessions [29]. In TF-CBT, the therapist directs the treatment, and the treatment components are designed to be delivered as a “full treatment package.” Within a stepped care model, it is suggested that the “treatment package” could be delivered in steps, thereby potentially minimizing therapist and parent time, and increasing availability of treatment. Since TF-CBT has the largest evidence base of controlled trials for children after trauma [25], and many therapists are already trained in TF-CBT [29], we have developed a stepped care model for young children after trauma based on TF-CBT. Step One is a parent-led therapist-assisted intervention that incorporates existing knowledge of the effectiveness of cognitive behavioral therapy for posttraumatic stress specifically for preschool children [28] and TF-CBT [27]. Step Two is standard therapist-directed TF-CBT [27]. In the current pilot study of Stepped Care TF-CBT, we included young children (as opposed to older children) because they may be the best age group for a parent-directed intervention since young children are still very dependent on their parents, embedded in and dependent on the family system, have fewer outside significant figures (e.g., peers), and are still interested in engaging in activities with their parents. Indeed, relationship-based interventions are

recommended for young children since the relationship with the primary caregiver is central to healthy development of the child [30].

A case study of a parent and young child who participated in Step One provided preliminary support for the concept of Stepped Care TF-CBT. In this study, a 4 year and 9 month old boy (who was physically abused, removed from his biological parents, and witnessed a fight between his biological father and grandfather) and his grandmother completed Step One. The child responded to Step One and ended treatment. From baseline to 5-week follow up there were significant improvements in PTSD symptoms (12 symptoms to 0), behavioral problems (clinical range to normal range), and parent stress (clinical range to normal range). The grandmother found Step One to be acceptable and was satisfied with the treatment, and the therapist time delivering Step One was limited (4.8 h) [31]. The current study on Step One is part of the next step in the development of Stepped Care TF-CBT in which we gathered preliminary data on the percentage of children who responded to Step One, the extent to which treatment gains at Step One were maintained, and the extent of parent acceptability of Stepped Care TF-CBT. In addition to examining clinical outcomes and patient acceptability, it is critical for the development of a stepped care model to examine the economic costs of providing Stepped Care TF-CBT. Indeed, the evidence of promising clinical outcomes, high patient acceptability, and low costs would provide a strong case for continuing with a larger clinical trial on Stepped Care TF-CBT. Therefore, the purpose of this pilot study was to examine the preliminary efficacy, parent acceptability, and economic cost of delivering Stepped Care for young children after trauma. Three research questions were addressed: (1) What percentage of children responded to Step One? (2) To what extent did children who responded to Step One maintain treatment gains? and (3) To what extent did parents find Step One acceptable? Additionally, the economic costs of delivering Stepped Care were explored.

Method

Participants

Eligibility criteria included: (a) children aged 3–7; (b) at least one traumatic event after the age of 3; (c) consistent with Cohen and associates [27], there had to be at least five DSM-IV-defined PTSS. Similar to Scheeringa et al. [28] it was necessary for there to be at least one symptom of re-experiencing or one symptom of avoidance for the exposure exercises to be salient; and (d) parental consent had to be obtained, and the parent had to attend the first session. Exclusion criteria included: (a) any condition that limited the parent's ability to understand CBT and the child's ability to follow instructions; (b) parent substance use disorder within the past 3 months; (c) parent or child suicidality; (d) non-English speaking; (e) if the child was taking psychotropic medication, medication was not stable at least 4 weeks pre-enrollment; (f) child received concurrent trauma-focused psychotherapy; and (g) parent leading treatment was the perpetrator, or the child was abused by a person who still lived in the home.

Participants were recruited from a community agency where the study treatment occurred. An initial phone screening occurred with 72 parents who called the agency for services. Of those who called the agency, 20 met the initial phone screening criteria that assessed for age, trauma history, guardianship, substance abuse, English speaking, medication, current treatment status, location of perpetrator, and interest in participating. Of the 20 who met the phone screening criteria, 15 attended the eligibility/baseline assessment and 9 met study criteria and attended the first meeting of Step One (see Fig. 1). The reasons why children screened out included that the trauma occurred before the age of 3, relative caregiver could not sign consent due to guardianship issues, there were not enough PTSS symptoms (2 children), current suicidal ideation, and did not attend the first session.

The pilot sample consisted of 9 parent–child dyads. The parents (age $M = 33$ years, $SD = 3.39$) and children (age $M = 4.7$ years, $SD = 0.87$) were 77.78 % Caucasian, 11.11 % African American, and 11.11 % Hispanic/Latino. Child participants were 77.8 % male. For all children, mothers led the treatment in Step One. The child index traumas were three sexual abuse, one physical abuse, two domestic violence, two illness/medical, and one home invasion robbery. Thirty-three percent of the children experienced more than one traumatic event. None of the children were taking psychotropic medication, and none of the children were receiving therapy outside of the study. Six mothers were employed, five were married, five had a household income below \$50,000, and the mean years in school was 15.33 ($SD = 2.59$).

Measures

Child Posttraumatic Stress—The *Diagnostic Infant and Preschool Assessment (DIPA)* [32] is a structured interview specifically developed to assess for disorders in very young children including PTSS and PTSD. The PTSD module also assesses child exposure to 11 different types of traumatic events and includes an “other” item for traumatic events not included, and PTSD symptomology. A continuous measure of a frequency count of the number of symptoms ranging from 0 to 17 was used to measure treatment responder status and the DIPA PTSD module was also used to indicate presence or absence of PTSD for clinical significance. Consistent with other studies to determine PTSD diagnosis with preschool children [22], the DSM-IV algorithm for PTSD was used as well as an alternative algorithm that requires only one symptom in criterion C (e.g., persistent avoidance and numbing) instead of the DSM-IV requirement of three symptoms. The alternative algorithm for preschool children is currently being proposed for DSM-V [33]. A test–retest (times varied from less than 2 weeks to 4 months) coefficient for the PTSD module was .87 with a sample of 50 young children [32]. Inter-rater agreement for the current sample was good (unweighted kappa = .92, $p < .001$). The DIPA was also used to screen for suicidality.

Parent report of severity of child posttraumatic stress symptomatology was assessed using the *Trauma Symptom Checklist for Young Children* posttraumatic stress total score (TSCYC-PTS) [34]. The TSCYC-PTS was used for determining responder status and for change in PTSS. The three posttraumatic stress scales (re-experiencing, numbing and avoidance and hyperarousal) were summed to provide a total level of posttraumatic stress. A raw score of 40 or greater on the TSCYC-PTS total was considered the clinical cut-off score. High internal consistency for the total scale ($\alpha = .87$) and for the TSCYC-PTS ($\alpha = .93$) scale had been found [27] with a correlation of .87 for the test–retest for the TSCYC-PTS. Acceptable sensitivity (.72) and specificity (.75) have been found with the TSCYC-PTS total [35]. Internal consistency (α) for the current sample was .81.

Child Severity Rating—The *Clinical Global Impression—Severity* (CGI-Severity; [36]) is a widely used 7-point rating of severity of psychopathology. Severity ratings are 0 = no illness; 1 = illness slight, doubtful, transient (no functional impairment); 2 = mild symptoms (little functional impairment); 3 = moderate symptoms (functions with effort); 4 = moderate–severe symptoms (limited functioning); 5 = severe symptoms (functions mainly with assistance); 6 = extremely severe symptoms (completely nonfunctional). The CGI-Severity was completed by the independent evaluator (IE) to assess change in severity of trauma psychopathology and functional impairment. Inter-rater agreement (unweighted kappa) for the current sample was .71, $p < .001$.

Treatment Improvement Rating—The *Clinical Global Impression—Improvement* (CGI–Improvement [37]) modified version based on an 8-point rating was used to indicate treatment response [38]. The ratings are 8 = very much worse; 7 = much worse; 6 =

minimally worse; 5 = no change; 4 = minimally improved; 3 = improved; 2 = much improved; 1 = free of symptoms. A rating of 1, 2, or 3 was used for treatment response. The CGI-Improvement ratings were reviewed by the first and last author with the IE for each case.

Parental Mental Health—The *Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Patient Edition With Psychotic Screen* (SCID-RV) [39] was used for screening to assess exclusionary criteria such as substance use disorder, suicidality, and psychosis. Diagnosis of parent PTSD and depression was also assessed at baseline for descriptive data.

Parent Acceptability and Effort—Parent acceptability of treatment was measured in three ways. (1) The *Expectancy Rating Form* [40], an adapted 3-item measure concerning the parent's expectations of treatment success and treatment credibility, was administered at baseline after the stepped care treatment was explained to parents. Higher scores indicated higher treatment expectations and credibility (range 3–30). Internal consistency (α) for the current sample was .70. (2) The *Client Satisfaction Questionnaire* [41], an 8-item self-report with scores ranging from 8 (very dissatisfied) to 32 (very satisfied), was administered at mid-assessment and post-assessment. Internal consistency (α) for the current sample was .97. (3) At the end of Step One, parents were asked, “Do you feel like your child needs more trauma-focused treatment, or do you feel like you could comfortably stop at this point?” After parents answered this question the first author discussed the mid-assessment responder status with parents and informed the parents if the child would be “stepped up” to additional treatment or enter the maintenance phase. To assess parents' level of effort for completing Step One, parents were asked at mid-treatment to rate on a 5-point scale (0 = no effort, 1 = minimal effort, 2 = some effort, 3 = much effort and 4 = best effort) how much effort they applied to Step One.

Treatment Costs—The *Time Tracking System* was developed for this study by the first and second authors to track therapist and patient time. It consists of codes (e.g., 1 = face to face therapy session, 2 = phone call with parent, 3 = homework, 4 = documenting treatment notes, 5 = failed session or phone call, etc.) to track therapist and patient time and activities working on this treatment. The Time Tracking System was completed by the study therapists after every contact with parents. A *parent direct cost form* developed by the second author was used to gather information such as time spent traveling to and from the treatment center, number of miles from the parent's home to the center, employment status and hourly wage, education level, insurance information and lost pay in order to come to the session.

Costs included direct and indirect costs for therapists and patients, as well as patient opportunity costs. Therapist direct costs were based on time in therapy while indirect costs were based on time preparing for sessions, documenting sessions, and time spent on failed sessions. Patient/parent direct costs included travel costs to and from sessions, and indirect costs were the value of uncompensated lost work time. Many cost studies incorrectly omit the value of patient time [42]. Such time, even when wages are not lost, has an opportunity cost. Parent opportunity costs included the value of time spent on therapy, phone support, and parent–child meetings at home.

An economic analysis of costs is often concerned with the value of the intervention, typically referred to as cost-effectiveness. The value of the intervention is based on both the costs of an intervention and the improvement in outcome measures due to the intervention. In this study, the value was measured using average cost effectiveness ratios, which were computed by dividing the total economic cost of the intervention by the changes in outcome

measures from baseline. While preferable to examine cost-effectiveness of an intervention relative to usual care (or a different intervention) the scope of the analysis was limited because the pilot study did not use a comparison group.

Procedures

Study procedures were approved by the University of South Florida Institutional Review Board. The first author or project coordinator explained the purpose of the study, risks and benefits, and obtained written informed consent to participate from the parents. Parents were consented to allow the assessments and therapy sessions to be audio-taped. Parents consented to participate prior to the baseline assessment and the child was not in attendance. Since all children were under the age of 7, written assent was not required; however, at the first therapy appointment study therapists reviewed with the child in a developmentally appropriate manner the purpose of the study.

A masters-level independent evaluator, trained by the third and last authors, conducted the assessments. There were four assessment periods: baseline, mid-assessment, post-assessment and 3-month follow-up. Parents were compensated for the assessments and therapy was provided at no-cost to the participants. Thirty-eight percent of the DIPA PTSD module and CGI-I assessments and 32 % of the therapy session audio tapes were randomly selected for review. A doctoral psychology student, trained by the last author, reviewed the assessments for rater drift and to rate the symptoms to assess for agreement on the DIPA PTSD module and CGI-Severity.

Treatment Fidelity

In-office therapy sessions were reviewed by the first author to ensure that the treatment protocol was being followed and to rate fidelity using a checklist indicating whether the therapist performed a specified activity. Treatment was provided by two masters-level therapists who were trained by the first, third and fourth authors. Therapists were given a treatment manual for Step One and for Step Two. In addition, the study therapists met with the first author for weekly supervision for an hour and a half. Treatment fidelity exceeded 95 %.

Stepped Care Treatment

Stepped Care TF-CBT consists of two steps with three therapist sessions in Step One and for those children who need Step Two, 9 sessions. However, to allow for the flexibility that is common in community practice two additional sessions could be provided in either phase to address additional concerns such as safety and boundaries or to repeat a treatment component that needed to be further discussed.

Step One consisted of three (1 h) in-office therapist-led sessions every other week, weekly phone meetings (15 min), National Child Traumatic Stress Network web-site (<http://www.nctsn.org/>) information, and a parent-child workbook. The purpose of the three meetings was to provide a general orientation to Step One (materials, structure, rationale, schedule and time commitment, guidelines) in session one; technical assistance for relaxation strategies and to help establish the exposures (which are called Draw It, Imagine It and "Next Step") in session two; and to provide support and motivation to complete Step One in session three. The phone meetings provided general support and motivation and technical assistance if needed. Parents were provided with the address of the website of the National Child Traumatic Stress Network (NCTSN) for psychoeducation. All parents in this study had access to the internet.

The parent–child workbook, called *Stepping Together*, is based on the CBT Preschool PTSD Treatment manual [28]. *Stepping Together* provides activities for the parent to work with the child to complete the child’s book called *My Steps*. *Stepping Together* focuses on coping skills and exposures. There are a total of 11 parent–child meetings that occur at home: 4 parent–child meetings after in-office session 1; 4 parent–child meetings after in-office session 2; and 3 parent–child meetings after in-office session 3. Parent–child meetings 1–4 focus on behavior management, relaxation, affect identification and regulation, and developing a scary ladder (i.e., stress hierarchy) of trauma reminders. Parent–child meetings 5–8 include trauma exposures activities. For each trauma reminder identified on the scary ladder, the child draws a picture of the reminder, imagines it for 30 s and then with the parent completes a “Next Step” which is an in vivo activity (e.g., Draw It, Imagine It and “Next Step”). Parent–child meetings 9–11 are used to complete the trauma exposure activities, discuss a relapse plan, and for the parent and child to review the child’s *My Steps* book. For more information about Step One, see [31].

Children who meet responder status (defined below) after Step One enter the maintenance phase. During this phase, parents are encouraged to: (1) Provide consistent discipline. (2) Practice the relaxation exercises three times a week with their child; (3) Help their child use the feelings score to identify and communicate feelings; (4) Meet one time a week for a parent–child meeting for at least 30 min to do something relaxing and/or fun; and (5) Attend the next assessment meeting.

Children who do not meet responder status “step up” to Step Two which consists of 9 (90 min) therapist-directed in-office TF-CBT sessions. These sessions are based on the components of TF-CBT: parenting, relaxation, affect expression and modulation, cognitive coping, trauma narrative and processing, in vivo exposures, conjoint parent–child sessions, and enhancement of safety and future development (see [43]).

Responder Status—Responder status was used to determine if the child should end treatment after Step One, or if the child needed Step Two. It was important that the threshold for responder status was stringent so that treatment did not end prematurely. Responder status was defined as three or fewer PTSS as measured by the Diagnostic Infant and Preschool Assessment, PTSD module (DIPA PTSS; [32]) or a total score of 40 or less on the Trauma Symptom Checklist for Young Children—PTS [34] and an independent evaluation rating of 3 (improved), 2 (much improved), or 1 (free of symptoms) on the Clinical Global Impression–Improvement scale (CGI-Improvement; [38]). The number of symptoms for responder status (i.e., three or fewer PTSS) was established in this study to be slightly below the average number of PTSS children had after participating in 12 weekly therapist-directed CBT sessions [28].

Data Analysis

Descriptive statistics were calculated for all study variables. We also calculated percentage decrease in outcome variables from baseline to mid-assessment, baseline to post-assessment, and baseline to 3-month assessment. Due to the small sample size, the Mann Whitney U test was used when differences among means was compared. Cohen’s *d* statistic was calculated [44] for baseline to post-assessment and baseline to 3-month assessment. An intent-to-treat analysis was conducted with all outcome variables as well as for the costs analysis using the Last Observation Carried Forward Method (LOCF). All analyses were completed using IBM SPSS Statistics 20.0 and Excel 10.0 for adding costs. There were no missing items on the assessment measures.

Results

As shown in Fig. 1, six children did not meet inclusion criteria (one parent did not start treatment after the initial assessment), two dropped out, and one was withdrawn from the study because the parent was hospitalized for a medical procedure and had scheduling difficulty afterwards. Only one parent met criteria for PTSD and this was the parent who never started treatment. No parent met criteria for depression.

There was no significant difference between the three children who did not complete the treatment and the six children who did complete the treatment on means score on the baseline DIPA PTSS ($p > .05$), TSCYC-PTS ($p > .05$) and CGI-Severity ($p > .05$). Parents utilized different components of the stepped care model. For example, 50 % of the parents attended all three in-office therapy sessions and 50 % of the parents utilized the web-based information. All parents had at least 3 h of treatment. The child (Case A) with the most therapist and parent time spent on treatment was the only child who did not respond to Step One, although this child did respond after Step Two.

Percentage of Children Who Responded to Step One

Of the children who completed Step One, 83.3 % (5/6) responded (see Fig. 1; Table 1). The same five children who responded upon completion of Step One are the same five children who responded in the intent-to-treat analyses. Therefore, when the intent-to-treat sample was included, 55.6 % (5/9) responded to Step One. At baseline, all six children who completed Step One met criteria for the modified PTSD algorithm and three children met PTSD criteria based on DSM-IV criteria. At mid-assessment, only one child met criteria for the PTSD modified algorithm and this was Case A who did not respond to treatment. None of the children met criteria for PTSD based on DSM-IV at mid-assessment. Consistent with these findings, all children were above the clinical cut off score on the TSCYC at baseline and only Case A, the non-responder, remained above the clinical level at mid-assessment (see Table 1).

Step One Treatment Gains Maintained

Treatment gains were maintained at post-assessment and follow-up (see Table 2), except for one case. Case E no longer met responder status at post-assessment, although the child's PTSS were still 50.0 % less than at baseline. The parent reported that the child had experienced two new traumatic events since mid-assessment. Step Two was recommended after the post-assessment, but the parent did not participate.

Table 2 provides means, standard deviations and effect sizes of the outcome variables for the responders. Effect sizes are large for all measures from baseline to post-assessment and baseline to 3-month follow-up. There was a 79.2 and 96.6 % reduction on DIPA PTSS from baseline to post-assessment and baseline to follow-up assessment, respectively. On the TSCYC-PTS, there was a 29.8 and 36.6 % reduction in posttraumatic stress scores from baseline to post-assessment and baseline to follow-up assessment, respectively. Similarly, there was a 76.2 and 92.1 % reduction on the CGI-Severity ratings from baseline to post-assessment and baseline to follow-up assessment.

When the intent-to-treat sample and LOCF were included ($n = 9$), DIPA PTSS scores were reduced from 9.67 ($SD = 1.73$) at baseline to 4.11 ($SD = 4.17$) at follow-up ($d = 1.74$), a 57.5 % reduction in symptoms. TSCYC-PTS scores were reduced from 51.78 ($SD = 10.66$) at baseline to 38.33 ($SD = 9.98$) at follow-up ($d = 1.74$), a 26.0 % reduction. CGI-Severity was reduced from 4.11 ($SD = 0.78$) at baseline to 1.78 ($SD = 1.72$) at follow-up ($d = 1.31$), a 56.7 % reduction.

Parent Acceptability

Overall, parents' expectations that treatment would be successful were high. The parent expectancy rating was slightly higher for parents who completed Step One ($M = 28.17$; $SD = 1.33$) than non-completers ($M = 22.67$; $SD = 11.02$), $U = 8$, $p > .05$. All treatment satisfaction scores were high (above 29), except Case C which had a low satisfaction rating at mid-assessment (13) and was the only parent who rated "minimal effort" toward Step One. At mid-assessment, mean satisfaction scores were 28 ($SD = 7.45$) and at post-assessment mean satisfaction scores were 31.50 ($SD = 1.00$). In 83.3 % (5/6) of the cases, the indication of responder status was consistent with parents' comfort level of ending treatment or stepping up. Case E was the only responder whose parent was not comfortable ending treatment (see Table 1).

Average Cost-Effectiveness

Average cost-effectiveness ratios were computed for the intent-to-treat ($n = 9$) and responder ($n = 5$) samples. Total costs averaged \$486 for the intent-to-treat sample and \$433 for the responder sample. Average total costs per responder were comprised of \$172 in therapist direct costs, \$59 in therapist indirect costs, \$8 in patient direct costs, \$96 in patient indirect costs, and \$98 in parent opportunity costs. Effectiveness is the difference between baseline and post-assessments, and baseline and follow-up assessments. The goal is to minimize the cost per unit improvement. Three outcomes were examined: DIPA PTSS, TSCYC-PTS, and CGI-Severity (Table 3). For example, a one point DIPA PTSS improvement for responders (or 10 % of average baseline of 9.6, see Table 2) cost \$55.30, and a one-unit reduction in the CGI-Severity (24 % of average baseline) cost \$131.33. The cost per unit improvement in outcomes was lower for responders than the intent-to-treat sample due to the larger improvement in outcomes for the responder sample. In addition, because the outcome measures were stable between the post and follow-up measurements, the cost-effectiveness ratios also exhibited little variation between post and follow-up.

Discussion

The aim of this open trial was to gather initial data on the efficacy, parent acceptability and economic cost of Step One of Stepped Care TF-CBT. Stepped Care TF-CBT may provide an alternative method of delivering an evidence-based practice that is accessible, cost-effective and addresses treatment barriers that prevent young children from receiving needed treatment after trauma. Results from this pilot study suggest that Stepped Care TF-CBT may be an effective, acceptable and cost-effective treatment. In summary, 83.3 % of completers and 55.6 % of the intent-to-treat sample responded to Step One, most parents had high expectations of treatment and were satisfied with treatment, there was an 83.3 % congruence between responder status criteria and parents' comfort level ending treatment, and cost per unit of improvements were reasonable. Importantly, treatment gains for the Step One responders (and the Step Two responder) were maintained at the 3-month assessment. Also, given the prevalence of children being exposed to multiple traumatic events [1], it is very promising that the two children who had experienced multiple traumatic events responded to Step One. Including children with different types of traumas as well as with multiple traumas in this study and future studies on Stepped Care TF-CBT is important for the generalizability of the study results.

This study provides further evidence for the concept that parents, with therapist-assistance, can provide a first-line treatment to their child after trauma. Also, preliminary findings of efficacy and satisfaction are consistent with clinical trials of therapist-directed treatment [27, 28] suggesting that future research on Stepped Care TF-CBT is warranted. The next step in the development of Stepped Care TF-CBT will be to compare Stepped Care versus Standard

Care TF-CBT to examine equivalence on outcome measures, parent satisfaction, and economic costs.

This pilot study raises important questions for further exploration. First, will parents who have PTSD be able to effectively lead their child's treatment? The only parent who was diagnosed with PTSD did not begin treatment, although this parent agreed to participate, understood the purpose of the study and the type of treatment. It is possible that factors related to or resulting from the parent's diagnosis affected the parent's decision to participate or it may have been factors other than her PTSD that led to the parent not returning. Future research will need to include parents who have PTSD to determine if parental distress is a predictor of Step One completion and outcome. In addition, other characteristics that may impact Step One completion and outcomes (i.e., parent-child relationship, comorbidity, parent's education level, etc.) will need to be examined.

Studies with older children receiving TF-CBT have found that demographics and characteristics such as the number of sessions [27], gender, ethnicity/race, age, total number of traumas before treatment and having a parent as a perpetrator [45] as well as parental emotional reaction to the child's sexual abuse [46] were not significant predictors of TF-CBT treatment outcome. Similarly, studies with preschool children have found that characteristics such as gender, race and ethnicity as well as abuse-related characteristics such as identity of the perpetrator, type of abuse and duration of abuse were not predictors of TF-CBT outcomes. However, for sexually abused preschool children, parental distress related to the child's sexual abuse, parental support, and maternal support to the child have all been shown to be important predictors of TF-CBT treatment outcomes [26]. Therefore, it is likely that mediators related to parent distress and support may be predictors of PTSS responder status in Step One.

Second, the question of the extent to which fidelity to the parent-child meetings impact outcomes will need to be examined. The one parent who indicated that she put "minimal effort" into the program also indicated low satisfaction levels, but her child still improved. One benefit of a parent-led treatment may be that parents, who know their children better than a therapist, may be able to individualize the treatment to the child's needs, and provide emotional support to the child that may not be captured in the number of parent-led activities and meetings that are completed. Also, since parents are the ones learning the tools (i.e., parenting skills, ways to help the child calm down) and helping their children (i.e., opening communication about feelings and what happened), they may continue to use these strategies more consistently, thus leading to improvement. It will be important to learn how closely parents follow the parent-child workbook and what association this may have with outcomes. Also, future research on the development of Stepped Care TF-CBT will need to explore what components parents find most useful (i.e., therapist meetings, phone support, web-based information, parent-child workbook), or like least. In addition, follow-up assessments will need to explore what strategies parents learned that they continue to utilize over time with their children.

In the current study, the time parents spent on Step One varied, and the child of the parent who spent the most time on Step One did not respond. This finding suggests that there may be factors other than the amount of time spent on Step One that predict responder status. All of the children who responded had parents who spent at least 3 hours on Step One treatment. Prior research suggests at least three completed sessions are needed for the child to benefit, and many child treatment studies use three sessions as the benchmark for including these children as "completers" [21, 27, 47].

The utilization of the NCTSN website also varied with 50 % of the parents reporting that they did not spend any time at the website. This non-use of the website was surprising considering recent studies have successfully utilized parenting training via the internet for children with conduct problems [21]. However, a recent study on parents' usage of informational sources about attention deficit hyperactivity disorder found that while parents obtained information from the internet, they also reported equal use of and preference for seeking information from a health professional [48]. Therefore, in this study parents may have gathered psychoeducation information from the therapist rather than using the website. Other possible reasons for the low utilization rate may be due to some parents assuming that the website was optional since the workbook contained the main treatment components and/or that the information on accessing the website was provided in the beginning of the workbook and not mentioned again. The revised workbook will include reminders to parents to use the website.

The cost analysis suggests that the cost of providing Stepped Care TF-CBT is quite low. Ten-percent improvements in the DIPA PTSS and CGI-Severity had an economic cost of \$55.30 and \$54.72 respectively. Based on the direct therapist cost of \$18.33 per quarter hour, the total economic cost of Stepped Care TF-CBT to achieve a 10 % improvement in outcomes is equivalent to the direct cost for a 45-min therapist session. However, the cost of improvement in the TSCYC-PTS was higher. A one-unit improvement in the TSCYC-PTS had an economic cost of \$28.78. Given the average baseline of 48.4, a 10 % improvement (or 4.84 units) in the TSCYC-PTS had an economic cost of \$139.30.

Prior research on Standard Care TF-CBT in the United States has focused on establishing the effect of TF-CBT on outcomes [49]. Consequently, the average cost-effectiveness of Stepped Care TF-CBT could not be compared to prior research on Standard Care TF-CBT. One study that examined the cost-effectiveness of standard CBT versus usual care for the treatment of depression in children found a \$285 cost per 10 % improvement in outcome [50]. Given the association between depression and trauma, the relatively low cost for Stepped Care TF-CBT provides further support for the use of Stepped Care TF-CBT in treatment. It remains for future research to compare Stepped Care TF-CBT to Standard Care TF-CBT to determine which is more cost-effective.

Limitations

This initial study has several limitations that are often inherent in small open trials. First, without a comparison or control group, there are many threats to internal validity such as other supportive factors (i.e., outside parental support), maturation or passage of time that may have contributed to treatment acceptability and treatment response. Second, the small sample size limits the generalizability of the findings and prohibits more advanced methods for determining treatment effectiveness and cost-effectiveness. Third, data were limited in that there were parents who dropped-out, were withdrawn, or who were lost to follow up. Fourth, process data on what parents and children actually did during the parent-child meetings would be important to know in terms of understanding parent-led treatment fidelity. Fifth, child treatment outcomes were limited, and with the small sample size we were not able to examine if type of trauma experienced may influence outcomes, as different types of trauma exposure could possibly bias results. Future studies on Stepped Care TF-CBT need to include other child treatment outcome measures that are often associated with PTSD such as separation anxiety disorder, depression, and oppositional defiance as well as parent measures of distress since co-morbidity and other issues often complicate childhood PTSD and treatment.

Summary

The present study explored the preliminary efficacy, parent acceptability and costs of delivery of Step One within a Stepped Care Trauma-Focused Cognitive Behavioral Therapy (SC-TF-CBT) model. Nine young children ages 3–6 years and their parents participated in Stepped Care TF-CBT. Results suggest that 83 % (5/6) of the children who completed Step One treatment and 56 % (5/9) of the intent-to-treat sample responded to Step One.

Treatment gains were maintained for Step One responders except for one case. Generally, parents found Step One to be acceptable, were satisfied with treatment, and agreed with the responder status determination after Step One. Given that costs were low, clinical outcomes were promising, and parent acceptability was favorable, the next phase in the development of Stepped Care TF-CBT will be to compare outcomes, acceptability and costs to standard TF-CBT. Stepped care treatment for young children after trauma has the potential to be delivered with less therapist time, reducing the cost of treatment for both patients and providers, improving treatment access, and lessening the societal impact and cost of early childhood PTSD.

Acknowledgments

The authors would like to thank the Crisis Center of Tampa Bay, where the study treatment was provided, particularly David Braughton, President & CEO, Melissa Thompson, MSW, Karen Allen, RMHCI, Angela Claudio Torres, LMHC, Aweeet Chandhok, RMFTI, Tia Burr, and Kyra Snyder, and Brittany Kugler, MSW, psychology doctoral student at the University of South Florida. The project was supported by National Institute of Mental Health award R34MH092373 to Dr. Salloum. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Mental Health or the National Institutes of Health.

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Fig. 1.
Diagram of study treatment and outcome

Table 1

Step one: time, pre and mid means and SDs, responder status, parent effort and response to ending treatment

Case	Therapist time ^a (hrs:min)	Patient time ^b (hrs:min)	Internet Time ^c (hrs:min)	Sessions attended	DIPA ^d Baseline	DIPA ^d Mid	TSCYC ^e Baseline	TSCYC ^e Mid	CGI-I ^f	Responder status	Effort ^h	Comfortable ending Tx ⁱ
A	4:30	13:03	8:00	3	12	8	76	59	3	No	4	No
B	3:46	4:16	0:00	3	9	1	43	32	2	Yes	3	Yes
C	2:42	3:01	0:00	2	9	3	47	35	2	Yes	1	Yes
D	2:09	8:22	0:45	2	7	0	45	38	1	Yes	3	Yes
E	3:02	13:22	0:00	3	12	2	56	36	2	Yes	4	No
F	0:58	9:28	3:00	1	11	0	51	29	1	Yes	4	Yes
M (SD) %	2:51 (1:14)	8:35 (4:19)	1:57 (3:11)	2.33 (1.03)	10.0 (2.0)	2.3 (3.0)	53.0 (12.18)	38.2 (10.7)	1.8 (0.8)	83.3 %	2.33 (1.03)	66.7 %

^aTherapist time = face-to-face meetings and phone support

^bPatient time = face-to-face meetings with the therapist, phone support and parent–child meetings at-home

^cInternet time = time parents report spending at the National Child Traumatic Stress Network website

^dDIPA = Diagnostic Infant and Preschool Assessment posttraumatic stress symptoms

^eTSCYC = Trauma Symptom Checklist for Young Children posttraumatic stress symptom total. A raw score of 40 or above has been associated with PTSD

^fCGI-I = Clinical Global Impression–Improvement scale

^hEffort = Parent rating of effort into Step One: no effort = 0, minimal effort = 1, some effort = 2, much effort = 3 and best effort = 4

ⁱComfortable Ending Treatment after Step One: At mid-assessment parents were asked “Do you feel like your child needs more trauma-focused treatment, or do you feel like you could comfortably stop at this point?”

Table 2

Maintenance of treatment gains for Step One Responders: means, SDs, Last Observation Carried Forward (LOCF, $n = 5$) for Step One Responders and effect sizes

Measure	Baseline (n = 5)	Post (n = 2)	Follow up (n = 3)	Post LOCF	Follow-up LOCF	Cohen's d (LOCF) Baseline to post/baseline to follow-up
DIPA PTSS	9.6 (1.95)	2 (3.46)	.33 (.57)	4.8 (4.55)	3.2 (4.09)	1.37/2.00
TSCYC-PTS	48.40 (5.18)	34.00 (5.57)	30.67 (3.21)	33.80 (4.09)	33.40 (4.72)	3.13/3.03
CGI-Severity	4.2 (.84)	1.0 (1.73)	.33 (.58)	2.4 (2.3)	1.6 (1.81)	1.04/1.84

DIPA PTSS Diagnostic Infant and Preschool Assessment posttraumatic stress symptoms, *TSCYC-PTS* Trauma Symptom Checklist for Young Children posttraumatic stress symptom total, *CGI-Severity* Clinical Global Impression-Severity

Table 3

Cost-effectiveness ratios: Cost per unit improvement in outcome measures

	Intent-to-treat	Responders
DIPA PTSS		
Post	\$91.05	\$55.30
Follow-up	\$87.41	\$61.80
TSCYC-PTS		
Post	\$37.04	\$28.78
Follow-up	\$36.12	\$27.65
CGI-Severity		
Post	\$218.51	\$131.33
Follow-up	\$208.11	\$131.33

Data sources for value of time: Master's 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 [51]. Patient/parent indirect cost was the value of lost work time (uncompensated hours missed multiplied by the parent's hourly wage rate). Parent opportunity costs were valued at the median hourly wage (\$18.06 for college graduates and \$11.79 for high school graduates; [52]). The Last Observation Carried Forward method was used for the intent-to-treat sample. Comparisons across outcomes measures should be made with caution due to differing scales