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Responder Status Criterion for Stepped Care Trauma-Focused Cognitive Behavioral Therapy for Young Children

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Abstract

Background—In order to develop Stepped Care Trauma-Focused Cognitive Behavioral Therapy (TF-CBT), a definition of early response/non-response is needed to guide decisions about the need for subsequent treatment.

Objective—The purpose of this article is to (1) establish criterion for defining an early indicator of response/nonresponse to the first step within Stepped Care TF-CBT, and (2) to explore the preliminary clinical utility of the early response/non-response criterion.

Method—Data from two studies were used: (1) treatment outcome data from a clinical trial in which 17 young children (ages 3 to 6 years) received therapist-directed CBT for children with PTSS were examined to empirically establish the number of posttraumatic stress symptoms to define early treatment response/non-response; and (2) three case examples with young children in Stepped Care TF-CBT were used to explore the utility of the treatment response criterion.

Results—For defining the responder status criterion, an algorithm of either 3 or fewer PTSS on a clinician-rated measure or being below the clinical cutoff score on a parent-rated measure of childhood PTSS, and being rated as improved, much improved or free of symptoms functioned well for determining whether or not to step up to more intensive treatment. Case examples demonstrated how the criterion were used to guide subsequent treatment, and that responder status criterion after Step One may or may not be aligned with parent preference.

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Conflict of Interest
The authors declare that they have no conflict of interest.

Conclusion—Although further investigation is needed, the responder status criterion for young children used after Step One of Stepped Care TF-CBT appears promising.

Keywords

stepped care; TF-CBT; young children; PTSD; adaptive treatment

Young children are exposed to a wide range of traumatic events. For example, Finkelhor, Ormrod, Turner, and Hamby (2005) found that young children (ages 2 to 5) had the same rate or higher than other age groups for witnessing domestic violence (38 per 1,000) and neglect (17 per 1,000). Similarly, young children (younger than age 8) have higher reported rates of maltreatment (e.g., neglect, physical abuse, sexual abuse) than older children (U.S. Department of Health and Human Services, 2012). Another type of traumatic event that young children may be exposed to is accidents. In fact, for children ages 3 to 7, the leading causes of death were motor vehicle accidents (38.1%), drowning (22.5%), and fire/burns (13.5%) (National Vital Statistics System, 2013). Other types of traumatic events that young children may be exposed to include: disasters, life-threatening illness, witnessing or learning about serious injury or death, and terrorist attacks (American Psychological Association (APA), 2013). Exposure to traumatic events among young children has been associated with experiencing posttraumatic stress disorder (PTSD; Levendosky, Huth-Bocks, Semel, & Shapiro, 2002; Scheeringa & Zeanah, 2008). Most children exposed to traumatic events experience some posttraumatic stress symptoms (PTSS) and rates of PTSD among young children exposed to various types of trauma events ranges from .6% to 69% (Scheeringa, Zeanah, & Cohen, 2011). Without effective treatment, childhood PTSD persists over time (Scheeringa, Zeanah, Myers, & Putnam, 2005). Research suggests there are comparable levels of functional impairment whether the child meets full PTSD diagnostic criteria or has significant posttraumatic stress symptoms (PTSS) (Carrion, Weems, Ray, & Reiss, 2002; Scheeringa et al., 2005). Therefore, effective treatment is needed for young children with PTSS that have not remitted and for children with PTSD.

Trauma-focused cognitive behavioral therapy (TF-CBT) was initially developed and tested to treat preschool children with PTSS and PTSD (Cohen & Mannarino, 1996). Trauma-focused cognitive behavioral therapy has since undergone several randomized clinical trials demonstrating TF-CBT to be superior to other active psychosocial treatments (e.g., child-centered therapy, non-directive supportive therapy, treatment as usual) (Cohen, Deblinger, Mannarino, & Steer, 2004; Deblinger, Stauffer, & Steer, 2001) and to waitlist controls (King et al., 2000; Scheeringa, Weems, Cohen, Amaya-Jackson, & Guthrie, 2011). In fact, TF-CBT, an evidence-based practice for children who are experiencing PTSS/PTSD is being widely disseminated in the United States (Cohen & Mannarino, 2008; Sigel, Benton, Lynch, & Kramer, 2013). Trauma-focused Cognitive Behavioral Therapy consists of approximately 12 to 16 therapist-led sessions with the parent and child. Trauma-focused treatment components include psychoeducation and parenting skills, relaxation techniques, affect expression and modulation, cognitive coping and processing, trauma narrative and processing, in vivo exposure, conjoint parent/child sessions, enhancing personal safety and future growth (Cohen, Mannarino, & Deblinger, 2006).

Despite the widespread dissemination of TF-CBT, the current practice of providing every child the "full treatment package" that is therapist-led and provided in-office does not address common barriers to treatment. Barriers to treatment include limited availability of trained therapists, costs, stigma, logistical barriers (e.g., time, work demands, child care, and transportation) (Bringewatt & Gershoff, 2010) and parents' desire to be able to solve the child's problem on their own (Thurston & Phares, 2008). Therefore, an alternative delivery approach called Stepped Care TF-CBT that is designed to be efficient (e.g., early treatment responders do not have to complete the full treatment), accessible (e.g., limited in-office sessions), parent-led (e.g., the first-line treatment involves the parent leading the treatment), and cost-effective (e.g., less therapist and patient time resulting in less cost than standard TF-CBT) is being developed ("removed for blind review') (see Study 2, for a description of Stepped Care TF-CBT).

Stepped care models provide a lower-intensity first step (e.g., less therapist and/or patient time, convenient treatment) as the initial treatment with the assumption that the first step will lead to an equivalent outcome compared to the higher-intensity, full protocol of care for a proportion of clients. Accordingly, stepped care interventions are designed to be more efficient and less costly for providers (i.e., less therapist time) than models in which there is one treatment protocol in which all patients complete all components (Bower & Gilbody, 2005). Stepped care models are also known as adaptive treatment strategies. However, unlike stepped care models that start all patients with the "least restrictive" treatment in terms of cost and patient inconvenience (Bower & Gilbody, 2005), adaptive treatments are designed to match the patient to the type of treatment and dosage based on the patient's needs such that some patients may begin with high intensive services followed by stepped down subsequent treatment based on the client's need; others may start with less intensive services with additional treatment added as needed (Collins, Murphy, & Strecher, 2007). A critical element of stepped care models is that there is an early indicator of treatment response/non-response that is used to guide subsequent treatment. In adaptive treatment strategies, these criteria are called tailoring variables and are used to determine subsequent treatment options (Almirall, Compton, Gunlicks-Stoessel, Duan, & Murphy, 2012; Collins, Murphy, & Bierman, 2004; Lei, Nahum-Shani, Lynch, Oslin, & Murphy, 2012).

The early response/non-response tailoring variables have to be a well-operationalized *a priori* measure(s). In other words, the definition of early response/non-response is part of the stepped care intervention and is established prior to the patient starting treatment. The early response/non-response tailoring variable(s) is used to guide clinical practice and is unlike "treatment response," a specified meaningful reduction of symptoms (Ginsburg et al., 2011), or "remission," the absence of the disorder or minimal symptoms, (Frank et al., 1991) which are determined after the patient completes treatment and are typically used for research purposes. Also, unlike clinical trials that often include lengthy assessments to determine clinical effectiveness, it is important that the early response/non-response tailoring variable(s) be easily administered in the real world so that clinicians can quickly determine response or non-response and subsequent interventions that may or may not be needed (Almirall et al., 2012).

Since early treatment response criterion have not been established in the child trauma treatment field, and the development of Stepped Care TF-CBT is in the early stages, indicators of treatment response or remission at the completion of trauma-focused treatment for young children may provide guidance in establishing treatment response criteria for a stepped care trauma-focused treatment. In a 12-session CBT protocol for PTSD in preschoolers, Scheeringa et al. (2011) reported that at baseline 72% of the children met criteria for PTSD with the alternative algorithm as measured by the Preschool Age Psychiatric Assessment (PAPA; Egger et al., 2006). Of the 25 completers of the preschool PTSD treatment, 17 met criteria for PTSD at pre-treatment and 3 children (17.65%) met criteria at post-treatment. The mean number of PTSD symptoms was 7.9 (2.9) at pre-treatment and 3.6 (2.9) at post-treatment for the children who received preschool PTSD treatment. In another clinical trial with preschoolers (ages 3 to 5) who had been exposed to marital violence, Lieberman, Van Horn and Ghosh Ippen (2005) used a clinician-administered caregiver interview of young child traumatic stress disorder (TSD) from the Diagnostic Classification Manual for Mental Health and Developmental Disorders of Infancy and Early Childhood (DC: 0–3; Zero to Three/National Center for Clinical Infant Programs, 1994) to examine posttraumatic stress symptoms and PTSD diagnostic criteria. Children were assigned to participate in Child-Parent Psychotherapy (CPP; 50 weekly sessions) versus case management plus treatment as usual. At intake, 50% of the children met criteria for Traumatic Stress Disorder. Among these children, there were significant differences in remission at post-treatment with 6% of the CPP group and 36% of the comparison group meeting criteria. The mean number of PTSD symptoms was 8.03 (3.50) at pre-treatment and 4.42 (2.86) at post-treatment for the children who received CPP. A clinical trial with older children (e.g., 8 to 14) that also used a semi-structured interview to measure the primary outcome of child PTSS suggested that after 12 sessions of TF-CBT, approximately 21% of the children still had PTSD and the average number of PTSS was approximately 4 post-treatment (Cohen, et al., 2004). In summary, these treatment studies, all of which used clinician administered interviews, suggest that most children will obtain remission for PTSD post-treatment, although not all children will remit, and that four or less PTSS is the average number or symptoms post-treatment.

Aggregate averages of PTSS post-treatment include those who remitted and those who did not. Therefore, indicators other than number of PTSS symptoms may need to be taken into consideration when establishing an early response/non-response criterion for stepped care after childhood trauma, such as severity of symptoms, degree of improvement and parent impression of treatment response. Given that early indicators of response/non-response within a stepped care model for children with PTSS has not been established, we sought to (1) establish a criterion for defining an early indicator of response/non-response to the first step within Stepped Care TF-CBT based on the number of PTSS, and (2) to explore the preliminary clinical utility of the early response/non-response tailoring variables (e.g., usefulness in determining subsequent treatment options and acceptability to parents) used within Stepped Care TF-CBT.

General Method

Overview and Participants

Data for this article are from two studies. Data from Study 1 was used to address the first aim to establish a criterion for defining an early indicator of response/non-response to the first step within Stepped Care TF-CBT based on the number of PTSS. Study 1 data involved a clinical trial in which 64 young children (ages 3 to 6 years) were randomly assigned to receive 12 weeks of CBT for PTSD or participate in a waitlist of equal duration (Scheeringa et al., 2011). The 17 children who were randomized to immediate treatment and were able to complete treatment were used in Study 1 to describe how the number of PTSS used in the responder status criterion was empirically derived from actual cases. As described in Scheeringa et al. (2011) there were no significant differences on the pre-treatment number of PTSD, depression, separation anxiety, oppositional defiant, or attentiondeficit/ hyperactivity symptoms between drop outs and treatment/waitlist completers. After the wait-list period, all children were offered treatment, but this small number of children (n = 6) was not included here because the current study (e.g., Study 2) did not include a wait period.

The 17 treatment completers had a mean age of 5.1 years old (*SD* = 0.9), were 47% male, and race/ethnicity was 65% Black, 29% White, and 6% other. Fathers lived in the households in 35% of the cases. Mean maternal age was 36.5 years (*SD* = 9.4), and maternal years of education was 14.4 (*SD* = 2.9). Primary type of traumatic events were 53% Hurricane Katrina, 24% experienced repeated events (primarily witnessing domestic violence), and 24% suffered single events (primarily accidental injuries). Included in this sample were 65% with PTSD, 47% with oppositional defiant disorder, 41% with major depression, 24% with separation anxiety disorder, and 24% with attention-deficit/ hyperactivity disorder (Scheeringa et al., 2011).

A minimum of one month was required from the most recent trauma to the time of assessment to be consistent with PTSD diagnostic criteria. Because the durations of time from trauma events to the start of treatment were skewed, the medians are reported. The median duration from the earliest trauma to the time of treatment was 25 months (range 1–80 months), and from the latest trauma to the time of treatment was 6 months (range 1–33 months). The post-treatment assessment occurred after 12 therapy sessions (Scheeringa et al., 2011).

The purpose of Study 2 was to address the second aim of this article which was to explore the preliminary clinical utility of the early response/non-response tailoring variables (e.g., usefulness in determining subsequent treatment options and acceptability to parents) used within Stepped Care TF-CBT. Data from Study 2 are from three cases that have participated in Stepped Care TF-CBT. The cutoff number of PTSS established from Study 1 was incorporated into the responder status criterion piloted in these three cases. More detailed demographic information for the three case examples was not presented to protect the identity of the participants.

Procedures

Study procedures were approved by ("names removed for blind review") The Institutional Review Boards. Written consents were provided by a parent/guardian. For the case examples, parents/guardians provided consent for information to be used for case examples provided no identifiable information about the parent/caregiver and child was reported. Procedures for the clinical trial in which the 17 children who were randomized to immediate treatment are described in detail elsewhere (see Scheeringa et al., 2011). In brief, an independent evaluator (IE) conducted all of the assessments (pre- and post-treatment scores are used in the current study) and patients were compensated for participating in the trial.

For the three case examples, a masters-level IE, trained by the second and last author, conducted the assessments. There were four assessments: baseline, after Step One, post-treatment (e.g., after Step Two or after the maintenance phase) and 3-month follow-up. Participants were compensated $25.00 for the initial assessment and $50.00 for each assessment thereafter. All Clinical Global Impression-Severity and -Impairment IE ratings were reviewed by the last author.

Study 1

Method

Treatment—Treatment consisted of a structured 12 session, in-office therapist-led cognitive behavioral therapy. Mothers or maternal caregivers participated with the child by observing (via a TV monitor) the therapist provide treatment to the child, and then the therapist discussed the session with the parent/caregiver afterwards. Conjoint sessions with the parent and child and therapist were held three times. Treatment components consisted of PTSD psychoeducation, identification of feelings, coping skills, graduated exposures to trauma-related reminders using drawings, imaginal and in vivo exposure, and safety planning (Scheeringa et al., 2011).

Measures—The Preschool Age Psychiatric Assessment (PAPA; Egger et al., 2006) is a semi-structured psychiatric interview with the caregiver about the child. For this study, the PTSD module, which covered all 17 PTSD symptoms corresponding to the DSM-IV was included (see Table 2). In addition, five items about impairment were included: relationships with parents, siblings, daycare/school teachers, and peers, and ability to function outside the home. Each item was rated yes/no. Good reliability (test–retest reliability kappa = .73) for the PTSD module has been found (Egger et al., 2006). In Scheeringa et al. (2011), interviewers received extensive training prior to conducting the assessments with the parents/caregivers. Throughout the study, the second author met individually with the interviewers to watch on videotape and critique their interviews with the most symptomatic patients and to address any drift or coding errors. The DSM-IV criteria for PTSD as well as the modified definition of PTSD for young children were used in Scheeringa et al. Internal consistency of the PTSD symptoms in this study was acceptable, Cronbach's alpha = 0.67.

Data Analysis—The mean number of PTSS and the mean number of impaired domains were examined pre- and post-treatment for the subset of treatment completers. The percentage of treatment responders was determined for different cutoffs.

Results and Discussion

The mean number of PTSS prior to treatment from the first dataset was 7.9 (*SD* = 2.9) and after treatment this decreased to 3.6 (*SD* = 2.9) for a 54% reduction in symptoms. For determining an early treatment responder cutoff based on the number of post-treatment PTSS, only cutoffs of 0, 1, 2, or 3 or fewer symptoms were considered because few children in Study 1 started with 4 symptoms pre-treatment and ending treatment with 4 symptoms was considered too severe clinically. In young children 4 PTSD symptoms meets DSM-V criteria for full PTSD diagnosis (APA, 2013). Using a cutoff of 3 or fewer symptoms to indicate a treatment responder, 53% would be considered treatment responders. If a cutoff of 2 or fewer symptoms was used, 47% would be considered treatment responders. If 1 or 0 symptoms were the cutoff, 29% would be treatment responders.

Functional impairment was examined to empirically validate the cutoff for responder status. The mean number of impaired domains prior to treatment was 2.4 (*SD* =1.5) and was reduced to 0.8 (*SD* = 1.2) for a 67% reduction. In this study, 100% of the children had functional impairment pre-treatment (n = 17 treatment completers). Of the five children with 0 or 1 symptoms post-treatment, 20% still had any functional impairment (i.e., impairment occurred in at least one domain). Three children had 2 symptoms post-treatment, and 0% still had any functional impairment. Only one child had exactly 3 symptoms post-treatment, and she still had some impairment in two domains (although PTSS had decreased 40% from five to three symptoms). Of the eight children who had 4 or more symptoms at post-treatment, 63% still had impairment.

The most commonly used definition of clinically significant change is a score on the post-treatment measure that: (1) has decreased by at least 1.96 times the standard deviation of that measure and (2) is within the non-clinical range of scores (Jacobson & Truax, 1991). The pre-treatment mean number of symptoms was 7.9 with a standard deviation of 2.9. A decrease of 1.96 times the standard deviation would be a decrease of 5.7 symptoms at baseline to a post-treatment score of 2.2 symptoms.

This assortment of data suggested that a treatment response cut-off should be set at either 2 or 3 symptoms post-treatment. Three symptoms were chosen for the following reasons. First, even though the single child with 3 symptoms post-treatment showed functional impairment, her symptoms had decreased 40%. Second, 20% of those with 0 or 1 symptoms post-treatment still had some impairment, so complete absence of impairment seemed an unrealistic goal. Third, we also kept in mind that using the number of PTSS as an outcome may be an overly conservative metric because it does not capture the reduction in severity within an individual symptom. A child may manifest a symptom severely before treatment and then show reduction to a mild manifestation of the symptom after treatment, but it is still counted as a symptom after treatment. A child who, for example, showed a reduction from 6 symptoms to 3 symptoms probably experienced greater reduction in symptom severity than was evident by this outcome. Fourth, it was felt that a lower cutoff (2 or fewer symptoms)

would step up children with 3 symptoms to more extensive treatment that would likely yield minimal benefit. Fifth, we realized that clinicians might want to be more conservative with the established criterion and offer more treatment rather than less especially when improvements could still be gained, but since the early response/non-response criterion for Stepped Care TF-CBT are in the pilot phase, we decided to set the criterion at 3 symptoms and offer an additional two sessions for those parents who wanted more treatment. We also decided on the higher cut off given that it is likely that some parents in the current study terminated treatment early because they were satisfied with their child's treatment response even though the child continued to experience symptoms. In view of all of the above data, a cutoff of 3 or fewer symptoms was chosen to determine treatment response status.

Study 2

Method

Stepped Care TF-CBT—Stepped Care TF-CBT consists of two-main steps. Step One in Stepped Care TF-CBT is a six week parent-led therapist-assisted treatment which consists of three face-to-face meetings with a therapist, bibliotherapy where the parent and child have 11 parent-child meetings at home working in an empirically-based CBT workbook called *Stepping Together* ("removed for blind review") which was adapted from the preschool PTSD treatment manual (Scheeringa, Amaya-Jackson, & Cohen, 2008) that was used in Study 1, weekly telephone support, and web-based psychoeducation and video demonstrations. The duration of six weeks in Step One of Stepped Care TF-CBT was chosen as it is half the time usually needed in standard TF-CBT and it allowed time for three bi-weekly in-office sessions. Also, if the child needs Step Two (which lasts approximately 6 to 8 weeks), the total timeframe to complete Stepped Care TF-CBT is similar to the total timeframe of standard TF-CBT.

If a child responds to Step One (as indicated by the early response/non-response tailoring variable), therapy ends although the parent and child participate in a maintenance phase where they are encouraged to continue to utilize the skills they learned in Step One. The therapist makes one phone contact during the maintenance phase to encourage them to practice what they learned in Step One such as relaxation skills, communicating feelings and scheduling time for parents and children to spend positive time together every week. If the child responds to Step One, but the parent still wants additional treatment, two sessions are offered to address any remaining concerns while the parent and child participate in the maintenance phase. In fact, two additional sessions may be provided within Step One, the maintenance phase, or Step Two to allow for the flexibility that is common in community practice and to address any individualized clinical concerns. If the child does not respond to Step One, the child steps up to Step Two. Step Two is 9 sessions of standard therapist-directed weekly TF-CBT delivered over six to eight weeks.

Consideration for Early Response/ Non-response Criterion—The definition of early response/non-response was based on two main considerations: (1) The threshold of severity for early responder status criterion needed to be high enough so that treatment did not end prematurely after Step One, yet low enough that children and parents were not stepped up to more extensive treatment that would yield minimal benefit, and (2) the early

indicator of response/non-response after Step One needed to approximate treatment response after current evidence-based full treatment package models for young children and be established empirically from actual cases from a randomized clinic trial. For example, we used the number of PTSS from Study 1 to inform the number of PTSS to be used in the criterion. Even though different semi-structured interview protocols were used to measure PTSS in Study 1 and Study 2, both interviews assessed for the same 17 items (see Table 2). Other factors that were taken into account when establishing the thresholds but were not directly examined in terms of varying these approaches were as follows: (1) Given the pilot nature of the development of Stepped Care TF-CBT and the lack of consensus as to how best to operationalize treatment response, both clinician-administered and parent report measures needed to be used as semi-structured measures are often used for diagnosing and self-report checklists are more common in clinical practice (Stover & Berkowitz, 2005); (2) The measures had to be easily administered and capture diagnostic status (presence and absence of symptoms) as well as measure on a continuous basis the frequency of symptoms; (3) Impairment in functioning needed to be taken into account; and (4) Parent preference to end treatment or not after Step One had to be considered.

Measures

Measures to determine the early response/non-response criterion: The Diagnostic Infant and Preschool Assessment (DIPA; Scheeringa & Haslett, 2010) is a structured interview specifically developed to assess for disorders, including PTSD, in very young children. A continuous measure of a frequency count of the number of PTSS ranging from 0 to 17 (see Table 1) was used to measure treatment responder status criterion. The PTSD module also includes 6 developmentally appropriate items that measure impairment in functioning, such as deterioration in a child's relationships with their daycare providers/teachers. The PTSD module includes an assessment of child exposure to 11 different types of traumatic events and includes an "other" item for traumatic events not included. Test-retest for the PTSD module (times varied from less than 2 weeks to 4 months) with a sample of 50 young children was high (.87) (Scheeringa & Haslett, 2010).

In Study 2, the number of PTSS and impairment were assessed at baseline, after Step One, post-treatment (either after the maintenance phase or Step Two) and at 3-month follow. The exposure to traumatic events was assessed at baseline. We also used the DIPA-PTSD module to ascertain if the child met the DSM-IV PTSD diagnosis criteria (APA, 2000) and/or the alternative DSM-IV PTSD criteria for preschool children (Scheeringa, Zeanah, Myers, & Putnam, 2003; Scheeringa et al., 2005), which consisted of 6 versus 4 symptoms, respectively. We selected the DIPA PTSD module (Scheeringa & Haslett, 2010) instead of the PAPA used in Study 1 as it was developed to be less burdensome than other clinician-administered measures (i.e., shorter and easier to administer) (Scheeringa & Haslett, 2010).

The Trauma Symptom Checklist for Young Children (TSCYC-PTS; Briere, 2005; Briere et al., 2001) is a parent-reported measure of symptoms of young children who have been exposed to traumatic events. The TSCYC Posttraumatic Stress Total (TSCYC-PTS) consists of three subscales (posttraumatic stress-intrusion, posttraumatic stress-avoidance, and posttraumatic stress-arousal) with 27-items that are summed for a PTSS total. Responses to

items are based on a four-point Likert scale ranging from not at all, sometimes, often and very often. The TSCYC-PTS total ranges from 27 to 108. A raw score of 40 or greater on the TSCYC-PTS is considered the clinical cut-off score. High internal consistency for the total (α = .87) and the TSCYC-PTS (α = .93) scales has been reported with a correlation of . 87 for the test-retest for the TSCYC-PTS (Briere et al., 2001). Acceptable sensitivity (.72) and specificity (.75) have been found with the TSCYC-PTS (Briere, 2005).

The TSCYC-PTS (Briere, 2005) was used as the parent measure of frequency of the child's PTSS as part of the responder status criterion after Step One. Adding this criterion allowed for improvement in symptoms to occur since each item is rated on a Likert scale instead of only the presence or absence of the symptom. The TSCYC-PTS was administered at baseline, after Step One, post-treatment and at 3-month follow-up.

The modified version of the Clinical Global Impression-Improvement scale (CGI-Improvement; Guy, 1976) was used for treatment responder status criterion (The Research Unit on Pediatric Psychopharmacology Anxiety Study Group (RUPP), 2001). The 8-point rating consisted of: 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. The CGI-Improvement (Guy, 1976) was selected to assess improvement and has been commonly used in anxiety trials. Although a 1 or 2 rating usually indicates treatment response status (e.g., Ginsburg et al., 2011), we used the rating of 1, 2 or 3 to define treatment response similar to RUPP (2001). Given that the establishment of the early response/non-response criterion is in the pilot phase, we decided to allow for a slightly wider rating of improvement by including the rating of 3. The CGI-improvement was rated by the IE after Step One, at post-treatment and at 3-month follow-up.

Secondary measures used to compare to the early response/non-response measures:
The Child Behavior Checklist for children (CBCL) ages 1½ to 5 (Achenbach & Rescorla, 2000) is a broadband parent-report of the child's emotional and behavior problems consisting of 99-items with a Likert response format (0 = not true, 1 = somewhat or sometimes true, or 2 = very true or often true). The CBCL has demonstrated strong reliability (e.g., 8 day test-retest using the total problem score = .90) and validity (e.g., correlations with similar behavior problem measures ranging from .56 to .77) coefficients. The CBCL provides a total problem score that is based on development and gender with a total T score > 63 considered in the clinical range (Achenbach & Rescorla, 2000). The CBCL is frequently used in child clinical trials with young children exposed to trauma (e.g., Cohen et al., 2004; Lieberman, Van Horn, & Ippen, 2005). The CBCL was administered at baseline, post-treatment and 3-month follow-up.

The CGI-Severity is a widely used 7-point therapist rating of severity of psychopathology (National Institute of Mental Health, 1985). 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 IE to rate level of PTSD severity and impairment and rated at all four assessment periods.

Parent acceptability: To obtain parents' impression of treatment response and whether additional treatment was needed, parents were asked after Step One to answer the following question: "Do you feel like your child needs more trauma-focused treatment (yes or no), or do you feel like you could comfortably stop at this point (yes or no)?"

Data Analysis—For Study 2, an algorithm of three measures was used to determine responder status criterion because of a lack of prior data in a stepped care trial in this population. The algorithm to determine responder status criterion was 3 or fewer PTSD symptoms from the DIPA (based on Study 1), or a score of 40 or less on the TSCYC-PTS, and an independent evaluation rating of 3 (Improved), 2 (Much Improved), or 1 (Free of Symptoms) on the CGI-Improvement. The "and" rule for the CGI-Improvement measure was used so that a rating of global improvement had to be me, and to prevent children with only slight changes in scores (e.g., four PTSS to three PTSS) from meeting responder status criterion. Parent preference for ending treatment or not was also considered after Step One by using the parent acceptability question. Three cases are presented to illustrate how the early treatment responder status criterion was used to guide treatment.

Case A: Responder status criterion met after Step One, status matched parent's preference and gains were maintained: A 6-year-old girl and her 28-year-old mother participated in Stepped Care TF-CBT due to the child being repeatedly sexually abused by an older cousin. The last known incident of abuse occurred one month prior to starting treatment. The mother reported that her daughter had also witnessed domestic violence two years prior between the mother and her ex-husband. At baseline, 10 symptoms of PTSD were endorsed on the DIPA, and the mother reported a TSCYC score of 53, which was in the likely PTSD range. The child met criteria for PTSD based on DSM-IV and the modified definition of PTSD for young children (Table 1). The mother reported that her daughter was having intrusive memories, saying she was mad at her aunt since the abuse occurred in the aunt's home. The mother reported the following: the child reenacted the trauma with her bears by putting the bears on top of each other; experienced nightmares; was hesitant to have conversations about what happened; needed reassurance that she was not in trouble; did not want to have sleepovers anymore; wanted to stay with mother more frequently; had difficulty falling asleep occasionally; became startled easily, and had increased irritability/ temper tantrums. The IE assigned a CGI-Severity rating of a 4 ("Moderate-Severe symptoms, limited functioning").

After Step One, there were no PTSS endorsed on the DIPA and the score on the TSCYC-PTS total was a 29, which is below the clinical range. The parent reported that her daughter had significantly improved and the child no longer met PTSD criteria based on the DSM-IV or the modified definition of PTSD for young children. The child was given a CGI-Severity rating of 0 ("No illness") and CGI-Improvement rating of 1 ("Free of Symptoms"). Responder status criterion was met and the child ended treatment after Step One. The mother reported at the mid assessment that she felt that she could comfortably stop trauma-focused treatment at that time.

At post-treatment and follow-up assessments, the parent continued to report that her child was not experiencing any symptoms or impairment, which was congruent with IE ratings; the CBCL total score changed from within the clinical range at baseline to within the normal range at post and follow-up assessment.

Case B: Responder status criterion met after Step One, parent's preference did not match, but treatment gains were maintained with additional improvement: A 4-year-old girl participated in Stepped Care TF-CBT due to being sexually abused by her 13-year-old cousin. During the baseline assessment, the mother (age 26) endorsed 10 PTSS and 3 areas of impairment on the DIPA-PTSD module. The mother reported that her child was experiencing intrusive memories, that she reenacted inappropriate sexual play with her dolls and that she tried to pull down her 9-year-old brother's pants. The mother reported that her daughter was having daily night terrors where she screamed and cried in her sleep but did not remember it the next day. The child often refused to go to bed and woke up often during the night. The mother reported that the child was experiencing flashbacks, and that during the flashbacks she "shuts down." A major concern was that the child was experiencing psychological and physiological distress at reminders, especially when being bathed. During bath time the mother reported that the child appeared embarrassed, ashamed and complained of stomachaches. The child avoided conversations about the abuse, became uncomfortable when the cousin's name was mentioned, and avoided going to the grandmother's house where the sexual abuse occurred. The mother reported heightened startle response, and hypervigilance where she described her daughter as more attentive and more alert. For example, she would scream and cry when her brother surprised her whereas before the trauma that made her laugh. There had been a significant increase in temper tantrums, and aggressive behavior towards her brother. The mother reported that the child had become very clingy and always wanted to be right by her side. The child did not meet criteria for PTSD based of the DSM-IV criteria but did meet criteria based on the modified definition of PTSD. The score on the TSCYC-PTS total was a 62 and the IE provided a CGI-Severity rating of a 5 ("Severe symptoms, functions mainly with assistance").

The responder status criterion was met after Step One. There were 3 symptoms reported on the DIPA PTSD module (with a 70% decrease from baseline), a score of 32 on the TSCYC-PTS total, which is below the cutoff score (with a 48% decrease from baseline), and an improvement rating of 2 (Much improved). The mother reported that the child still experienced difficulty with falling and staying asleep, and had an exaggerated startle response. The mother reported that the child had stopped physically interacting inappropriately with her brother but continued to make inappropriate sexual comments to him. While the impairment rating remained the same as baseline, the child had a decrease in frequency and overall number of symptoms. Overall, the mother reported that the child had improved significantly since baseline. A CGI-Severity rating of 2 was given which is indicative of little functional impairment and a mild severity of PTSD. After discussing the overall improvements with the parent and that responder status criterion was met, the parent was informed that the maintenance phase would begin. However, given the persistence of the impairment and that the parent reported that she felt like more trauma treatment was needed, especially to address the inappropriate sexual comments, an additional session was

scheduled. The therapist offered to see the parent for two additional sessions to address these remaining concerns. An appointment was scheduled but the parent did not attend.

At post-treatment, the mother reported 3 PTSS on the DIPA-PTSD module, the same as she did after Step One. However, there was a slight increase in the impairment score as well as on the TSCYC-PTS total. The symptoms that the mother endorsed on the DIPA-PTSD module were the same symptoms that were endorsed as being the most severe on the TSCYC-PTSD total. While the child was no longer reenacting the sexual abuse with her brother, the child was now wanting increased privacy and not wanting to be bathed in her private areas due to distressing reminders. The mother reported that while the impairment had slightly increased, the child no longer appeared distressed at her own behaviors. The CGI-Severity and CGI-Improvement remained the same as the assessment after Step One (e.g., Mild symptoms, little functional impairment, and Much Improved). The parent was offered to schedule additional sessions to address the noted areas of impairment and an appointment was scheduled, however, the parent did not attend.

At the follow-up assessment there were no PTSS endorsed (with a 100% decrease) and the score on the TSCYC-PTS (with a 50% decrease) was below the clinical cutoff, as was the total CBCL score (with a 37% decrease). The mother noted at follow-up that she noticed after the post-treatment when she stopped accommodating to her child's distress (e.g., the mother still bathing her), her child became less distressed and began to improve even more. They also continued to use many of the coping strategies that they learned in Step One. The mother reported that the child was sleeping much better than when she started treatment and that the temper tantrums had significantly decreased to age-appropriate levels. The mother reported a 31 on the TSCYC-PTS total, which was below clinical range. Due to no presenting symptoms and below clinical severity, the IE reported a CGI-Severity of 0 (Illness slight, doubtful, transient, no functional impairment) and CGI-Improvement of 1 (Free of Symptoms) (see Table 1).

Case C: Responder status criterion was not met after Step One, child was stepped up, and responder status criterion was met after Step Two: At baseline the mother (age 33) of a 5-year-old boy who was sexually abused by a camp counselor about one month prior to starting treatment reported that her child was experiencing 12 PTSS. These symptoms included reenacting the trauma in his play, nightmares, dissociation, distress at reminders such as driving by the camp, physiological distress such as shortness of breath when faced with trauma reminders such as the playground slide, avoidance of the camp and conversations about camp, inability to recall important reminders about what happened, loss of interest in activities he used to do such as swimming and biking, and decreased concentration. The mother reported that since the abuse the child has had difficulty getting to sleep at night, and has become more irritable and aggressive. She reported that since the trauma, he started to have temper tantrums. The child met criteria for PTSD based on DSM-IV and the alternative definition of PTSD, and consistently the TSCYC-PTS was 76. Due to the severity and frequency of the symptoms, a CGI-Severity rating of 5 ("Severe symptoms, function mainly with assistance") was given at baseline.

After Step One there were noted improvements on all measures (see Table 1) and a CGI-Improvement rating of 3 (improved) was given. However, early responder status criterion was not met as there were 8 DIPA-PTSS and the TSCYC-PTS was 59. The child continued to have re-experiencing (e.g., nightmares, play reenactment), avoidance (e.g., avoided parks, and became distressed at reminders) and arousal symptoms (e.g., irritable, difficulty staying on task). The child met criteria for PTSD based on the alternative definition of PTSD. Since responder status criterion was not met, the child proceeded to Step Two. When the parent was asked if she felt that her child needed more trauma-focused treatment, or if she felt that she could comfortably stop at this point, the parent indicated that she felt more trauma-focused treatment was needed which was congruent with the *a priori* early responder status criterion.

At post-treatment after Step Two treatment, responder status criterion was met. The mother reported that the child still became psychologically and physiologically distressed at reminders, but the severity of these symptoms had decreased, and no impairment was reported. There were only two symptoms noted on the DIPA-PTSD assessment, and the TSCYC-PTS total was 31, below the clinical cutoff score. The CGI-Improvement rating was a 2 (“much improved"). The child no longer met criteria for PTSD based on DSM-IV or the alternative definition of PTSD. At the three-month follow-up assessment, the child no longer met criteria for PTSD as there were no symptoms of PTSD or impairment reported. Consistent with the improvements noted from baseline to follow-up, the CGI-Severity rating was a 0 (“No illness”) and the CBCL at the follow-up assessment was well below the clinical range (see Table 1).

Results and Discussion—Case A provides a clear example of how all measures of the early responder status criterion indicated an early treatment response, and parent preference supported the decision to end treatment. All measures at post-treatment (at the end of the maintenance phase) continued to support the decision to end treatment as treatment gains were maintained.

For Case B, the early responder status criterion indicated an early treatment response, but parent preference was to continue treatment. Case B stated twice that she thought more treatment was needed, but did not show for follow-up appointments suggesting that her preference to continue and ability/motivation to come into the office for additional treatment differed. It may be that the residual symptoms were not problematic enough for the parent to come into the office for treatment. It may also have been that since the parent knew that she would not be receiving the full next step, she did not think that few additional sessions would be enough and therefore did not attend. However, at the 3-month assessment, the child met the treatment response criterion.

Case C provided an example of the utility of the *a priori* early responder status criterion after Step One that indicated that subsequent treatment was needed. Even though the child had improved as indicated by a CGI-Improvement rating of 3, a decrease of 33% on the DIPA-PTSD module and a 22% decrease on the TSCYC-PTS, the responder status criterion indicated that more treatment was needed. In this case the responder status criterion and the parent preference for continued treatment were congruent. With Step Two, the therapist-led

TF-CBT sessions, the child made substantial improvement and responder status criterion was met at post-treatment.

Summary and Concluding Discussion

This article established a criterion for defining an early indicator of response/non-response to Step One within Stepped Care TF-CBT based on the number of PTSS, and provided a description of how the early treatment responder criterion performed in three cases in Stepped Care TF-CBT. Case examples illustrate how responder status criterion was implemented, and highlight that parent preference for subsequent treatment may or may not always be congruent with an *a priori* responder status criterion. A stringent algorithm approach was used after Step One that incorporated both reduction of symptoms (determined by at least one of two symptom severity instruments) and impairment rating of improvement. This algorithm approach appeared accurate for the three cases in Study 2; however, the approach may be overly complicated. Responder status criterion would have been the same if any of the three measures had been used alone (Table 1). For example, given that the early response/non-response tailoring variable(s) needs to be easily administered to quickly determine response or non-response and subsequent interventions (Almirall et al., 2012), it may be that only one of the measures should be used. Whether the algorithm of three measures has added value beyond one of the measures alone awaits further empirical testing.

Considering parent preference when deciding subsequent treatment decisions is important as it is the parent who ultimately decides if the child receives more treatment or not since the parent is the one who consents for treatment and brings the child to the appointment or not. The statement that a parent is not comfortable ending treatment may not match the behavior of attending in-office therapy. For example, it is possible that some parents state that their preference is to continue treatment out of concern for denying their child help; yet, in reality coming to the office for additional treatment is not a priority. Also, it may be that some parents do not know if enough progress has been made to conclude treatment and therefore state that their preference is to continue. Perhaps if parents were presented with the results of the responder status criterion they may make a more informed decision, relying on their own impressions as well as the total of the results, although this may also bias some parents' decision. Another possibility would be to provide the responder status criterion information to the parent and then allow them to decide if they want to proceed or not to the next step (e.g., van der Leeden et al., 2011). However, while this approach values patient preference, children whose parents do not continue to the next step despite not meeting responder status criterion may continue to suffer, and for children whose parents continue treatment even though the child remitted, optimal resource use may not occur especially if this prevents other children who are symptomatic from receiving additional help or if there are no more gains from the additional treatment.

Congruency between parent preference to continue treatment or not and responder status criterion also may depend on the type of residual symptoms. For example, if the child is continuing to have temper tantrums this may be more problematic for the parent than if the child gets physiologically distressed at trauma reminders. Approximately 30% to 50% of

children who obtain remission status post-treatment may still have residual symptoms (Ginsburg et al., 2011). In fact in a stepped care CBT study for anxiety disorders, van der Leeden et al. (2011) found that the intent-to-treat analysis indicated that 45% of the children responded to step one, 17% responded to step two and 11% responded to step three for a total of 74% of the children no longer meeting criteria for an anxiety disorder. While treatment trials have indicated low percentages still meeting criteria for PTSD at the end of a clinical trial (e.g., Cohen et al., 2004; Lieberman et al., 2005; Scheeringa et al., 2011) it is likely that many of these children, whether modified criteria were used or not, still experienced residual symptoms. For example in the Scheeringa et al. (2011) study, 52% who did not meet criteria for PTSD still had three or fewer symptoms of PTSD after post-treatment.

The responder status criterion were specifically developed for young children as Study 1 data was from a clinical trial of young children, only parent measures were included, and the symptom measures are specifically for young children. Responder status criterion for older children may differ due to needing to include child and parent reports, difference in symptoms, and the number of symptoms needed to meet criteria for PTSD. For example, in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (APA, 2013), there are different criteria for PTSD for children six years and younger. The number of symptoms needed to meet criteria of PTSD is four for young children; for older children the number of symptoms needed to meet criteria for PTSD is six (APA, 2013). The early response/non-response criterion described in this study is currently being used in a randomized clinical trial comparing Stepped Care TF-CBT to standard TF-CBT with young children, and with older children ages 8 to 12 with a slightly modified responder status criterion (e.g., 4 PTSS instead of 3 PTSS). These trials will provide more data on the definition of early responder status criterion after Step One.

The pilot results from the current study raise two points that will need to be addressed as Stepped Care TF-CBT is developed further. First, as with the Study 1 trial where the dropout rate was high, there may need to be tailoring variables that are used to identify early indicators of treatment dropout and then additional treatment methods to keep these families engaged. Second, as with Case C who did not respond to Step One, future research is needed to identify characteristics of children who are more likely to respond to Step One. Thus, the Stepped Care model may include tailoring variables that help distinguish at the baseline assessment which child should be matched to Step One and which child should receive standard therapist-led TF-CBT immediately. Through the use of tailoring variables and various effective treatment components, Stepped Care TF-CBT can be optimized to provide more individualized treatment options to match the needs of the child.

A Stepped Care TF-CBT intervention that provides an alternative delivery approach that is efficient, accessible, parent-led, and cost-effective holds great promise for improving access to evidence-based treatment. However, the child trauma fields lacks clear criteria for determining treatment response or for determining early response/non-response that could be used to guide subsequent treatment decisions. This study contributes to the stepped care and child trauma treatment literature in two ways. First, this study provided preliminary evidence for an early response/non-response criterion to be used in Stepped Care TF-CBT.

Second, this study also highlighted some of the preliminary issues involved in establishing early response/non-response tailoring variables such as use of empirical findings from trials with standard treatments, incorporating impairment into the decision of the criterion, use of presence or absence of symptoms or severity of symptoms or both, how treatment improvement is used to develop the criterion, and the importance of patient agreement with or as part of the responder status criterion. Stepped Care models for mental health conditions are still in the early stages of development (e.g., "removed for blind review"; Tolin, Diefenbach, & Gilliam, 2011; van der Leeden et al., 2011) and as part of these models, researchers will need to establish preliminary tailoring variables for subsequent treatment response to be tested in larger trials.

There are several limitations to this descriptive study. First, the responder status criterion was based on one clinical trial from a small sample. Nonetheless, a strength of utilizing Study 1 data to determine responder status criterion is that these data consisted of young children from diverse racial/ethnic backgrounds who were exposed to multiple traumatic events and participated in 12 weekly CBT sessions for a PTSD clinical trial. However, larger datasets from clinical trials or from multiple clinical trials of CBT for young children with PTSD would allow for more advanced statistical methods to determine responder status criterion (e.g., Caporino et al., 2013; Storch, Lewin, De Nadai, & Murphy, 2010). Second, due to the limited advancement of measures for young children and PTSD, the clinician-rated PTSS/PTSD measure from Study 1 and Study 2 differed. However, both interviews inquired about the same DSM-IV PTSS. Further, we selected the DIPA PTSD module (Scheeringa & Haslett, 2010), instead of the PAPA used in Study 1 since the DIPA was developed to be less burdensome (i.e., shorter and easier to administer) (Scheeringa & Haslett, 2010). Third, the case examples only provide preliminary evidence of the utility of the responder status criterion.

Implications for Research, Policy, and Practice

Future research should include larger samples to examine the congruency between the early responder status measures, measures of associated emotional and behavioral problems, and parent preference to continue treatment or not. With a larger sample size, we will be able to explore the early treatment response criterion ability to predict which children will maintain their treatment gains. From a policy perspective, having a clearly defined treatment response to be used within a stepped care model as well as for post-treatment outcomes will provide a benchmark for defining and funding effective treatments for young children experiencing posttraumatic stress symptoms. For practitioners, having a well-defined *a priori* early treatment response criterion for young children with PTSS can guide decisions about early treatment response or about children who need additional or augmented treatment. As the field moves toward developing stepped care models and adaptive treatment strategies, it is important for the child trauma field to have established *a priori* early treatment response criteria, and this article provides a foundation for this criterion.

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This text is included on the title page with the authors contact information.

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Table 1

Changes in Responder Status Criterion and Secondary Outcomes for Three Cases

Case	Measures	Baseline	After Step One	Post	Follow-up
A	DIPA- PTSD	10	0	0	0
	DIPA impairment	4	0	0	0
	TSCYC-PTS total	53	29	31	27
	CGI-Severity	4	0	0	0
	CGI-I-Improvement	n/a	1	1	1
	CBCL total score	71-clinical range	n/a	48	49
B	DIPA- PTSD	10	3	3	0
	DIPA impairment	3	3	4	0
	TSCYC-PTS total	62	32	42	31
	CGI-Severity	5	2	2	0
	CGI- improvement	n/a	2	2	1
	CBCL total score	67-clinical range	n/a	50	42
B	DIPA- PTSD	12	8	2	0
	DIPA impairment	5	6	0	0
	TSCYC-PTS total	76	59	31	30
	CGI-Severity	5	3	1	0
	CGI- improvement	n/a	3	2	1
	CBCL total score	74-clinical range	n/a	40	35

Note. DIPA = Diagnostic Infant and Preschool Assessment Posttraumatic Stress Symptoms. TSCYC-PTS = Trauma Symptom Checklist for Young Children Posttraumatic Stress Symptom Total. A raw score of 40 or above has been associated with PTSD. CGI = Clinical Global Impression–Severity or Improvement. n/a = not applicable. CBCL = child behavior checklist. T-scores for the CBCL are reported with a score 63 and above in the clinical range.

Table 2

Symptoms of PTSD as Measured by the PAPA and DIPA

	PTSD Symptoms
1	Intrusive recollections (e.g., intrusive memories, brings up trauma on own, distressed when talks about trauma, reenactment plan)
2	Distressing dreams (e.g., nightmares or bad dreams)
3	Acting or Feeling like the traumatic event were reoccurring (e.g., dissociation)
4	Intense psychological distress (e.g., gets upset when reminded about what happened)
5	Physiological reactivity (e.g., heart racing, stomachache when faced with reminders)
6	Avoidance of thoughts, feelings, or conversations related to the trauma
7	Avoidance of activities, places or people related to the trauma
8	Not able to recall important aspects of the traumatic event
9	Diminished interest or participation in significant activities
10	Feeling detached or estranged from others (e.g., more distant from family members and friends)
11	Restricted range of affect (e.g., does not show happy or angry feelings)
12	Sense of foreshortened future (e.g. doesn't think they will live long enough to be a big kid)
13	Difficulty falling or staying asleep
14	Irritability or outburst of anger (e.g., developed extreme outburst or temper tantrums)
15	Difficulty concentrating
16	Hyper vigilance (e.g., on alert for bad things to happen)
17	Exaggerated startle response (e.g., jumps or startles when hears loud noises)

Note. PAPA = The Preschool Age Psychiatric Assessment (Egger et al., 2006); DIPA = Diagnostic Infant and Preschool Assessment (DIPA; Scheeringa & Haslett, 2010). These PTSD symptoms are described in DSM-V-TR (APA, 2000).