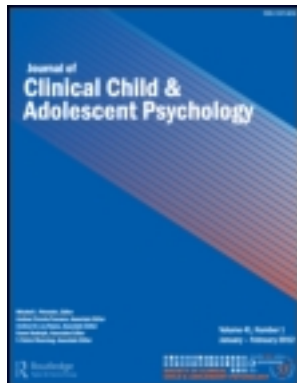


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A Randomized Effectiveness Study Comparing Trauma-Focused Cognitive Behavioral Therapy With Therapy as Usual for Youth

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RANDOMIZED CLINICAL TRIALS

A Randomized Effectiveness Study Comparing Trauma-Focused Cognitive Behavioral Therapy With Therapy as Usual for Youth

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The efficacy of trauma-focused cognitive behavioral therapy (TF-CBT) has been shown in several randomized controlled trials. However, few trials have been conducted in community clinics, few have used therapy as usual (TAU) as a comparison group, and none have been conducted outside of the United States. The objective of this study was to evaluate the effectiveness of TF-CBT in regular community settings compared with TAU. One hundred fifty-six traumatized youth (M age = 15.1 years, range = 10–18; 79.5% girls) were randomly assigned to TF-CBT or TAU. Intent-to-treat analysis using mixed effects models showed that youth receiving TF-CBT reported significantly lower levels of posttraumatic stress symptoms (est. = 5.78, d = 0.51), 95% CI [2.32, 9.23]; depression (est. = 7.00, d = 0.54), 95% CI [2.04, 11.96]; and general mental health symptoms (est. = 2.54, d = 0.45), 95% CI [0.50, 4.58], compared with youth in the TAU group. Youth assigned to TF-CBT showed significantly greater improvements in functional impairment (est. = -1.05, d = -0.55), 95% CI [-1.67, -0.42]. Although the same trend was found for anxiety reduction, this difference was not statistically significant (est. = 4.34, d = 0.30), 95% CI [-1.50, 10.19]. Significantly fewer youths in the TF-CBT condition were diagnosed with posttraumatic stress disorder compared to youths in the TAU condition, $\chi^2(1, N = 116) = 4.61, p = .031, \Phi = .20$. Findings indicate that TF-CBT is effective in treating traumatized youth in community mental health clinics and that the program may also be successfully implemented in countries outside the United States.

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A significant number of children and youth throughout the world experience traumatizing events (Copeland, Keeler, Angold, & Costello, 2007; Norris, Friedman, & Watson, 2002); if left untreated, trauma exposure may result in a variety of mental health problems (Dube, Felitti, Dong, Giles, & Anda, 2003; Finkelhor, Ormrod, & Turner, 2009; Ford, Elhai, Connor, & Frueh, 2010). Studies have identified an association between traumatization and increases in anxiety and mood disorders (Famularo, Fenton, Kinscherff, & Augustyn, 1996) and severe behavioral problems (Saigh, Yasyk, Oberfield, Halamandaris, & McHugh, 2002), but post-traumatic stress symptoms (PTSS) are the most commonly reported symptoms of psychological distress. Clinically significant PTSS levels have been reported in the aftermath of a wide variety of traumatic experiences, such as violence (Kilpatrick et al., 2003), war trauma (Ajdukovic, 1998), abuse (Ackerman, Newton, McPherson, Jones, & Dykman, 1998), chronic illness (Connolly, McClowry, Hayman, Mahony, & Artman, 2004), burns (Saxe et al., 2005), traffic accidents (Meiser-Stedman, Smith, Glucksman, Yule, & Dalgleish, 2008), child sexual abuse (Finkelhor, 1994), and natural disasters (Jensen, Dyb, & Nygaard, 2009; La Greca, Silverman, Vernberg, & Prinstein, 1996).

Given the impairing effects of severe PTSS and other mental health problems that children and adolescents

may develop in the aftermath of a traumatic event, effective treatments are needed. A review examining the evidence on psychosocial treatments for children and adolescents exposed to traumatic events concluded that trauma-focused cognitive behavioral therapy (TF-CBT) met the well-established criteria for evidence-based practices (Silverman et al., 2008). TF-CBT has been tested in several randomized controlled trials, which have all demonstrated the efficacy of the program in reducing PTSS and other emotional problems in children (Cohen & Mannarino, 2008; Silverman et al., 2008). (See Table 1).

Follow-up studies have also shown that the positive treatment gains are maintained (Cohen, Mannarino, & Knudsen, 2005; Deblinger, Mannarino, Cohen, & Steer, 2006; Deblinger, Steer, & Lippmann, 1999). The program was originally developed and investigated in children exposed to sexual abuse (Cohen, Deblinger, Mannarino, & Steer, 2004; Cohen & Mannarino, 1996, 1997, 1998; Deblinger, Lippman, & Steer, 1996; King et al., 2000). However, one recent study documented the use of TF-CBT in children experiencing domestic violence (Cohen, Mannarino, & Iyengar, 2011), and two pilot studies have demonstrated the effective use of TF-CBT in treating childhood traumatic grief (Cohen, Mannarino, & Knudsen, 2004; Cohen, Mannarino, & Staron, 2006). The use of TF-CBT has

TABLE 1
Description of Randomized Controlled Trial Studies Investigating TF-CBT

<i>Study</i>	<i>Type Trauma</i>	<i>N</i>	<i>Age</i>	<i>% Girls</i>	<i>Study Context (TF-CBT)</i>	<i>Comparison Group(s)</i>
Cohen & Mannarino (1996) ^a	Sexual abuse	67	3–6	58	Trauma clinic	Nondirective supportive therapy
Deblinger, Lippman, & Steer (1996) ^a	Sexual abuse	90	7–13	83	Trauma clinic	Parent only Child only community control
Cohen & Mannarino (1998) ^a	Sexual abuse	49	7–14	69	Trauma clinic	Nondirective supportive therapy
King et al. (2000)	Sexual abuse	36	5–17	69	Trauma clinic	Child alone; Family CBT; waitlist
Deblinger, Stauffer, & Steer (2001) ^a	Sexual abuse	44	2–8	61	Trauma clinic	Supportive group vs. group CBT
Cohen, Deblinger, Mannarino, & Steer (2004) ^a	Sexual abuse	229	8–14	79	Trauma clinics	Child-centered therapy
Cohen, Mannarino, & Knudsen (2005) ^a	Sexual abuse	82	8–15	68	Trauma clinic	Nondirective supportive therapy
Cohen, Mannarino, Perel, & Staron (2007) ^a	Sexual abuse	24	10–17	100	Trauma clinic	Setraline; Placebo
Jaycox et al. (2010)	Hurricane Katrina	118	9–13	56	Community clinic & schools	CBT in school (CBITS)
Cohen, Mannarino, & Iyengar (2011) ^a	Domestic violence	124	7–14	55	Community IPV center	Child-centered therapy
Deblinger, Mannarino, Cohen, Runyon & Steer (2011) ^a	Sexual abuse	210	4–11	61	Trauma clinics	Dismantling study (without trauma narrative & 8 sessions)
Scheeringa, Weems, Cohen, Amaya-Jackson, & Guthrie (2011) ^a	Heterogeneous types of trauma	64	3–6	34	Trauma clinic	Waitlist

Note. TF-CBT = trauma-focused cognitive behavioral therapy.

^aStudy by treatment developers.

also been explored with children exposed to catastrophes, such as the September 11 terrorist attacks (Hoagwood, Radigan, Rodriguez, Levitt, & Foster, 2006) and hurricane Katrina (Jaycox et al., 2010); these studies all yielded promising results. Furthermore, a group-based TF-CBT protocol for sexually abused children and their mothers has been tested and showed positive effects (Deblinger, Stauffer, & Steer, 2001). The next step in advancing this research base is to examine whether TF-CBT is also applicable outside the United States, where the program was developed. In addition, because few of the available studies were conducted in community clinics, few have included patients with multiple types of traumatic experiences, and only one has compared TF-CBT with usual care; more studies are needed to document the benefits of TF-CBT compared to usual clinical care in community clinics. The results obtained in specialized clinics may not be transferrable to community clinics for several reasons. First, studies have found that children and adolescents who are referred to community clinics often have higher levels of co-occurring problems and less family support than samples from university-based research clinics (Ehrenreich-May et al., 2011; Schoenwald & Hoagwood, 2001; Shirk, Karver, & Brown, 2011; Southam-Gerow, Weisz, & Kendall, 2003). In addition, therapists' working conditions often differ. For example, therapists in regular clinics treat a wide variety of disorders, and workloads tend to differ (Kazdin, 2002; Southam-Gerow, Rodríguez, Chorpita, & Daleiden, 2012; Weisz & Addis, 2006; Weisz & Gray, 2008; Weisz et al., 2009).

In this study, we tested whether TF-CBT was superior to therapy as usual (TAU) in eight community clinics for children and adolescents with trauma-related symptoms in Norway. Because youth referred to community clinics often present with a variety of symptom clusters, several different disorders were assessed, including PTSS, depression, anxiety, and general mental health, and clinical evaluations of posttraumatic stress disorder (PTSD) were performed. Based on studies that have shown that receiving any type of treatment leads to better outcomes than no treatment (Wampold et al., 1997), we predicted that youth in both treatment conditions would improve. However, based on previous TF-CBT studies, we predicted that participants in the TF-CBT condition would report significantly greater improvements in all the aforementioned symptom levels compared to participants in the TAU group posttreatment. We also predicted that the number of youth diagnosed with PTSD would be significantly lower in the TF-CBT group compared to the TAU group posttreatment. Finally, we hypothesized that the TF-CBT group would report significantly greater improvements in daily functioning compared with the TAU group.

METHOD

Procedure

The study was approved by the Regional Committee for Medical and Health Research Ethics. In addition, written, active consent to participate was provided by both the children and their parents. The target sample was youth between the ages of 10 and 18 years who had been referred to one of eight community mental health outpatient clinics in Norway between April 2008 and February 2011. Normal referral procedures were followed, as all of the children were referred to treatment by their primary physician or Child Welfare Services. To be eligible for the study, the youth had to have experienced at least one traumatizing event and suffered from significant PTS reactions. The exclusion criteria were acute psychosis, suicidal behavior, and a need for an interpreter.

To assess trauma experiences, we developed a checklist based on the items described in the Traumatic Events Screening Inventory for Children (Ribbe, 1996). This checklist included the following experiences: (a) severe accident, (b) natural disaster, (c) sudden death or severe illness of a person close to the participant, (d) extremely painful or frightening medical procedures, (e) violence or threats of violence outside the family, (f) robbery or assault, (g) kidnapping, (h) witnessing violence outside the family, (i) witnessing violence within the family, (j) physical abuse within the family, (k) sexual abuse outside the family, (l) sexual abuse within the family, and (m) other frightening or overwhelming experiences. If the parent or youth reported exposure to one or more of these events, the youth was assessed for PTSS using the Child PTSD Symptom Scale (CPSS; Foa, Johnson, Feeny, & Treadwell, 2001). Those with scores of 15 or above on the CPSS and at least one symptom in each of the three PTSD symptom criteria (reexperiencing, avoidance, and hyperarousal) were invited to participate in the study. A total of 454 children and adolescents were screened for eligibility using the CPSS. Out of these, 200 children scored above the established cutoff of 15, and 156 agreed to participate in the study (Figure 1).

If the inclusion criteria were met and consent was provided, the youth were randomly assigned to receive either TF-CBT or TAU. At each clinic, a computer-generated, randomization procedure allocated participants into random blocks of four or six in random order with an equal probability of four or six with half (i.e., two or three) assigned to TF-CBT and half to the control group. This procedure was used to enhance the balance between TF-CBT and TAU and also to protect the blind for raters. The randomization was not stratified by any variables. The youth were then further

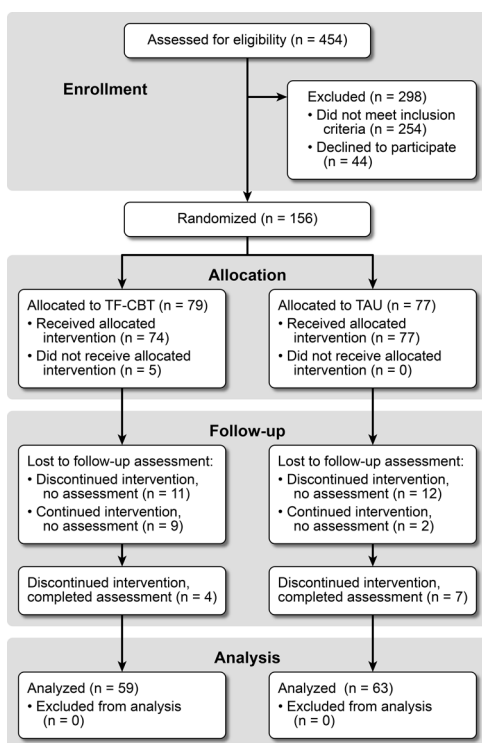


FIGURE 1 Flow chart: Participants.

assessed with a battery of instruments measuring mental health. The assessments were computer assisted and conducted by a clinician who was not employed at the clinic and was blinded to the treatment conditions. Symptoms were reassessed midtreatment (after the sixth session) and posttreatment (after 15 sessions). All measures were administered in the same order for all participants. The youths received a small gift card (e.g., a movie pass) after completing the posttreatment assessment, but no other economic compensation was given.

Participants

A detailed description of the sample is presented in Tables 2 and 3. The youths reported being exposed to an average of 3.6 different types of traumas ($SD = 1.8$, range = 1–10). In total, the children reported the following traumatizing events: 60.9% ($n = 95$) sudden death or severe illness of a person close to them, 59% ($n = 92$) violence or threats of violence outside the family context, 45.5% ($n = 71$) physical abuse within the family, 42.9% ($n = 67$) witnessing violence within the family, 27.6% ($n = 43$) witnessing violence outside the family, 27.6% ($n = 43$) sexual abuse outside the family, 20.5% ($n = 32$) severe accident, 16% ($n = 25$) extremely painful or frightening medical procedures, 10.9% ($n = 17$) robbery or assault, 7.7% ($n = 12$) sexual abuse

TABLE 2
Description of Sample

Demographics of the Children ($N = 156$)	n (%)
Gender ($N = 156$)	
Girls	124 (79.5)
Boys	32 (20.5)
Age ($N = 156$)	
Range	10–18
Mean	$M = 15.1$ ($SD = 2.2$)
Ethnicity ($N = 156$)	
Norwegian	115 (73.7)
Asian	17 (10.9)
One parent Norwegian	13 (8.3)
Western European countries	2 (1.3)
Eastern European countries	2 (1.3)
African countries	3 (1.9)
South/Central American countries	2 (1.3)
Nordic countries	1 (0.6)
Other	1 (0.6)
Living situation ($N = 156$)	
Live together with both parents	35 (22.4)
Live same amount with the mother and father	4 (2.6)
Live mostly or only with the mother	81 (51.9)
Live mostly or only with the father	14 (9)
Foster care	12 (7.7)
Other (alone, institution, with boyfriend or girlfriend)	10 (6.4)
Household income ^a ($n = 128$)	
<NK 200,000	20 (15.6)
<USD 35,000	
[NK 200,000, NK 500,000), [USD 35,000, USD 87,000)	49 (38.3)
[NK 500,000, 1,000,000 NK) [USD 87,000, USD 174,000)	38 (29.7)
\geq NK 1,000,000 NK \geq USD 174,000	9 (7.0)
Do not know	12 (9.4)
Traumatic experiences—Total ($N = 156$)	
Accident	32 (20.5)
Natural disaster	9 (5.8)
Sudden death/injury of a close person	95 (60.9)
Hospitalization	25 (16)
Violence outside the family	92 (59)
Robbed	17 (10.9)
Kidnapped	8 (5.1)
Witnessed physical abuse outside the family	43 (27.6)
Witnessed physical abuse inside the family	67 (42.9)
Exposed to physical abuse inside the family	71 (45.5)
Sexual abuse outside the family	43 (27.6)
Sexual abuse inside the family	12 (7.7)
Other	48 (30.8)
Total number of trauma experiences ($N = 156$)	
Range	1–10
Mean	$M = 3.6$ ($SD = 1.8$)

^aMean household income for 2010 was \$75,000 USD.

within the family, 5.8% ($n = 9$) natural disaster, 5.1% ($n = 8$) kidnapping, and 30.8% ($n = 48$) other frightening or overwhelming experiences.

TABLE 3
Description of Participating Parent

<i>Demographics of the Parents (n = 128)</i>	<i>n (%)</i>
Person who completed the questionnaire (<i>n</i> = 128)	
Mother	92 (71.9)
Father	22 (17.2)
Foster parents	11 (8.6)
Other	3 (2.3)
Caregiver's employment situation ^a (<i>n</i> = 119)	
Working full time	64 (53.8)
Working part time	18 (15.1)
Job seeker	4 (3.4)
Student	4 (3.4)
Welfare recipient/Other	29 (24.4)
Caregiver's education ^b (<i>n</i> = 120)	
Completed junior high school	17 (14.2)
Completed high school	44 (36.7)
Completed vocational school	15 (12.5)
≤4 years of college/university	37 (30.8)
>4 years of college/university	7 (5.8)

^aIn 2012, 68% of the population was working full time.

^bIn 2010, 30% of the population had completed high school as their highest level of education.

Therapists

The therapists were recruited from the participating clinics and delivered the treatment at the clinic where they were employed. The TF-CBT therapists (*n* = 26) were selected by the clinic leader and volunteered to receive training in TF-CBT and provide therapy to the participants who were randomly selected to receive TF-CBT. The TAU therapists (*n* = 45) received the case through the referral process, and they provided their usual treatment. The therapist group was predominantly female (84.5%), which reflects the gender distribution of therapists in child clinics in Norway. In the TF-CBT condition, each therapist treated an average of 3.0 participants (*SD* = 1.4, range = 1–6). The group consisted of 80.8% (*n* = 21) psychologists, 7.7% (*n* = 2) psychiatrists, 7.7% (*n* = 2) educational therapists, and 3.8% (*n* = 1) social workers. When asked to specify their theoretical orientation, 66.7% (*n* = 16) described their orientation as cognitive-behavioral, 23.1% (*n* = 6) as psychodynamic, 7.7% (*n* = 2) as systemic/family therapy, and 7.7% (*n* = 2) did not report a theoretical orientation. On average, the TF-CBT therapists had 10.2 years of experience (*SD* = 6.4, range = 3–28). In the TAU condition, each therapist treated an average of 1.7 participants (*SD* = 1.3, range = 1–9). This group consisted of 51.1% (*n* = 23) psychologists, 26.6% (*n* = 12) social workers, 17.8% (*n* = 8) educational therapists, and 4.4% (*n* = 2) psychiatrists. In this group, 24.4% (*n* = 11) described their theoretical orientation as cognitive-behavioral, 40.0% (*n* = 18) as psychodynamic, and 17.8% (*n* = 8) family/systemic. The remaining 17.8%

(*n* = 8) did not report their orientation. On average, the therapists had 12.5 years of experience (*SD* = 10.3, range = 1–40). The two groups were comparable in terms of the therapists' gender ($\chi^2 = 0.22$, *p* = .639) and years of experience, $t(64) = -1.0$, *p* = .320. However, there were significant differences in the therapists' educational backgrounds ($\chi^2 = 12.9$, *p* = .024) and theoretical orientations ($\chi^2 = 8.24$, *p* = .041). In addition, the TF-CBT therapists performed significantly more study treatments compared to TAU therapists, $t(69) = 4.0$, *p* < .001.

Interventions

TF-CBT

TF-CBT is a short-term, component-based intervention consisting of 12 to 15 sessions. The program integrates cognitive, behavioral, interpersonal, and family therapy principles as well as trauma interventions. Each component is offered to the child and parent in both parallel sessions and co-joint sessions. The components are as follows: psycho-education, teaching relaxation and affective modulation skills, learning cognitive coping skills, working through the trauma narrative, cognitive processing, in vivo mastery of trauma reminders, enhancing safety, and future development. In addition, the parent receives interventions aimed at improving parenting skills (see Cohen, Mannarino, & Deblinger, 2006). The TF-CBT therapists were trained by the developers of the treatment and other approved TF-CBT trainers. All therapists received between 4 and 6 days of initial training. TF-CBT therapists were encouraged to read the treatment manual (Cohen, Mannarino, & Deblinger, 2006) and complete a web-based learning course for trauma-focused cognitive behavioral therapy (<http://www.musc.edu/tfcbt>). Treatment adherence was supported by initial session-by-session supervision provided by trained TF-CBT therapists based on reviews of audio-recorded sessions. As the therapist became more familiar with the program, supervision was reduced to biweekly sessions.

Therapy as Usual

In the TAU condition, therapists were asked to provide the treatment they believed would be effective for the particular case. All participants received individual treatment (no group treatment), but in 55.3% (*n* = 42) of the cases, parents were also involved in the therapy process. The therapists reported receiving an average of 1.4 hr of supervision (*SD* = 5.3, range = 0–40) per case.

Treatment Adherence

All therapy sessions were audio recorded. Treatment fidelity was examined by trained TF-CBT therapists. In

the TF-CBT group, all sessions were coded using the TF-CBT Fidelity Checklist (Deblinger, Cohen, Mannarino, Murray, & Epstein, 2008). The checklist contains 11 items (rated present vs. absent) that follow the treatment components. The core components that had to be completed in order for a therapy to be defined as TF-CBT were as follows: psychoeducation, relaxation skills, affect regulation, instruction in the cognitive triangle, working through the trauma narrative, working with dysfunctional thoughts, and the parenting component. Based on these criteria, five cases failed to reach an acceptable level of fidelity.

In the therapy as usual group, at least five sessions were coded in each case (the first, second, third, sixth, and ninth sessions). These sessions were selected to provide information regarding whether the core aspects of TF-CBT were provided. Because the primary aim was to ensure that the therapists were not providing any of the core aspects of TF-CBT, the TF-CBT Fidelity Checklist was used. In cases in which elements of the core components were provided, additional sessions were investigated to rule out treatment overlap; this analysis resulted in 392 coded sessions. In the TAU condition, none of the cases met the adherence criteria for TF-CBT, although some TAU cases may have used certain elements similar to TF-CBT, such as psychoeducation.

Measurements

Youth exposed to traumatizing events and referred to community child mental health clinics often have multiple problems, including PTSS, depressive symptoms, other anxiety problems, and externalizing problems. Therefore, we assessed a range of possible mental health problems. The primary outcome measure was PTSS. These symptoms were measured using the CPSS and the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA). Secondary outcome measures included the Mood and Feelings Questionnaire (MFQ), the Screen for Child Anxiety-Related Disorders (SCARED), and the Strengths and Difficulties Questionnaire (SDQ).

CPSS

The CPSS is a self-report questionnaire developed for children and youth between 10 and 18 years of age that examines the PTSS described in the *Diagnostic and Statistical Manual of Mental Disorders* (4th ed. [DSM-IV]; American Psychiatric Association, 1994; criterion B, reexperience; C, avoidance; and D, hyperarousal; Foa et al., 2001). The CPSS consists of 17 items. The child rated the symptom frequency during the last 2 weeks using a 4-point scale ranging from 0 (*not at all*) to 3 (*5 or more times a week almost always*). In the screening sample of 454 participants, the three subscales showed internal consistencies of $\alpha = .84$ for the reexperience factor, $\alpha = .80$ for

the avoidance factor, $\alpha = .75$ for the hyperarousal factor, and $\alpha = .91$ for the total scale. The PTSS were assessed based on the children's self-reported "worst" trauma.

The CPSS contains an additional scale that measures the influence of PTSS on daily functioning (fCPSS). The child answered *yes* or *no* depending on whether the symptoms affect daily functioning in six areas: friendship, family, school, hobbies and activities, household duties, and general life satisfaction. A 2-point scale was used: 1 indicated an impact on areas of daily functioning, and 2 indicated no impact on areas of functioning. The Norwegian translation of the scale was approved by the developers. The instrument was completed within 10 to 20 min.

The CAPS-CA

The CAPS-CA is a structured clinical interview that has been adapted to be suitable for children and adolescents younger than 15 (Nader et al., 1996; Nader et al., 2004). The CAPS-CA measures trauma exposure and the frequency and intensity of the 17 DSM-IV-defined symptoms of PTSD. In addition, the impact of symptoms in terms of overall distress and functional impairment is assessed, as well as associated features (survivor guilt, shame, and dissociation). In this study, only the diagnostic PTSS were used. Items were scored on 5-point frequency scales from 0 (*none of the time*) to 4 (*most of the time*) and 5-point intensity rating scales from 0 (*not a problem*) to 4 (*a big problem, I have to stop what I am doing*) assessing the past month. Items were scored based on both the youth's answers and clinical judgment during the interview. The total scale showed satisfactory internal consistency ($\alpha = .90$), as did the DSM-IV defined tripartite model (reexperience: $\alpha = .87$, avoidance: $\alpha = .77$, hyperarousal: $\alpha = .79$).

The DSM-IV algorithm was used to determine a PTSD diagnosis. At least one symptom of the B criterion, three of the C criterion, and two of the D criterion were needed. A frequency score of 1 and an intensity score of 2 were required for a particular symptom to meet the criterion (Weathers, Ruscio, & Keane, 1999).

MFQ

The MFQ is a self-report questionnaire designed to assess depressive symptoms in children and youth between 8 and 18 years of age (Angold, Costello, Messer, & Pickles, 1995). The questionnaire consists of 34 items measuring both the full range of DSM-IV diagnostic criteria for depressive disorders and additional items reflecting common affective, cognitive, and somatic features of childhood depression. The child rated the problem frequency during the previous 2 weeks using a 3-point scale: 0 (*not true*), 1 (*sometimes*

true), and 2 (*true*). A score of 27 or more was considered to be within clinical range. The instrument showed good internal consistency in this sample ($\alpha = .91$).

SCARED

The SCARED is a self-report questionnaire developed by Birmaher et al. (1999) to measure anxiety symptoms in children and youth aged 8 to 18 years. The instrument consists of 41 items that cover five specific anxiety disorders: panic disorder or significant somatic symptoms, generalized anxiety disorder (GAD), separation anxiety disorder, social anxiety disorder, and school avoidance. The child or youth rated the problem frequency during the previous three months using a 3-point scale: 0 (*not true or hardly ever true*), 1 (*somewhat true or sometimes true*), and 2 (*very true or often true*). A total score of 25 or more was considered to be within the clinical range for anxiety. In this sample, the instrument showed satisfactory internal consistency in terms of the total scale ($\alpha = .93$) and the subscales for panic disorder/significant somatic symptoms ($\alpha = .90$), generalized anxiety disorder ($\alpha = .83$), separation anxiety disorder ($\alpha = .78$), social anxiety disorder ($\alpha = .85$), and school avoidance ($\alpha = .81$).

SDQ

The SDQ is a self-report questionnaire that covers general mental health problems in children and youth (Goodman, 2001). The SDQ contains 25 items that cover five areas of clinical interest: hyperactivity/inattention (e.g., “restless, overactive”), emotional symptoms (e.g., “has many worries”), conduct problems (e.g., “often has temper tantrums”), peer relation problems (e.g., “picked on or bullied by other children”), and prosocial behavior (e.g., “kind to younger children”). The child rated each item with *not true*, *somewhat true*, and *certainly true* based on their experiences during the previous 6 months (0 to 2 for negatively worded items and 2 to 0 for positively worded items). The general difficulties total score is based on four problem-oriented subscores and a Norwegian norm-sample; a total score of 18 or more was within the 90th percentile (Rønning, Handegaard, Sourander, & Mørch, 2004). In this sample, the total scale showed a satisfactory internal consistency of $\alpha = .73$.

Data Analyses

A power analysis was performed prior to recruitment. Using an estimated difference between intervention and control groups of approximately 0.5 *SD* and requiring a power of 0.80 and $\alpha = .05$, this analysis showed that 62 participants were required in each treatment group. Descriptive statistics were used to investigate

the characteristics of the sample. A mixed effects model was performed on each of the outcome measures. Mixed effects models account for the nested nature of the data, and they can handle missing data under the missing at random assumption. In addition, mixed effects models have the advantage of estimating measures of random variation both between and within participants (Pineiro & Bates, 2000). Given the longitudinal design of this study, the data set was nested by participants. Outcomes were analyzed with various approaches. First, intention-to-treat (ITT) analyses were conducted; data from all recruited participants (including the dropouts) were analyzed in the condition into which they were originally randomized. Next, only the completed cases (defined as completing at least six sessions) were included. The cutoff of six sessions was chosen because this cutoff included participants who had completed at least half of the program and could thus be assumed to have gained some effect from the treatment. Finally, a per-protocol (PP) approach was followed, that is, the data were analyzed with regard to the type of treatment the participants *actually* received. Participants who were randomized to the TF-CBT condition but did not receive allocated treatment were first treated as cases in the TAU-condition (PP1) and then removed from the analyses (PP2). To investigate the association between the diagnostic status of PTSD and therapy condition, an exact chi-square test for independence was conducted. Effect sizes were calculated using Cohen's *d* to show the strength and magnitude of changes within each treatment group and the difference between the interventions. To determine whether changes in symptom levels were clinically significant, we first determine the proportion of participants who met the diagnostic criteria for PTSD posttreatment. Second, we calculated how many participants moved from a dysfunctional to functional level posttreatment, where functional level was defined as being below the clinical cutoff in scales for which norms were available (i.e., MFQ, SCARED, and SDQ). Because there are no available data from normal samples on the CPSS, a clinically significant change was defined as 2 *SD* below the mean T1 score (Wise, 2004). The differences between the two groups were investigated with chi-square statistics. We performed Holm correction in the ITT analyses (five tests) and the completer analyses (five tests) as described in Aickin and Gensler (1996). Briefly, the *p* values were ordered from lowest to highest. With adjustment within a group of *k* tests, the i^{th} ($i = 1, \dots, k$) lowest *p* value is multiplied with $k - i + 1$, starting with the lowest one. If an adjusted *p* value is made ≥ 1 by this procedure it is set to 1, and so are all the following *p* values.

All analyses were conducted using the statistics program R (Hornik, 2012) and SPSS, version 17.

RESULTS

Analyses

Attrition and Baseline Comparisons

Of the 156 children and youth who completed the intake assessments, 122 (77.6%) participated in the post-treatment assessment (T3). The attrition group consisted of 23 youth who dropped out of treatment prior to Session 6 (11 in TF-CBT vs. 12 in TAU) and 11 participants who continued treatment but did not complete the assessments (nine in TF-CBT vs. two in TAU). The attrition rate was not significantly different between the two therapy groups, $\chi^2(1) = 1.17, p = .281, \Phi = -.09$). There were no significant differences between the retention group and the attrition group with regard to basic characteristics, such as gender, parent/background information, or primary and secondary outcome variables. However, the attrition group was significantly older than the retention group, $t(54.67) = 2.11, p = .040$, and the attrition group

reported being exposed to significantly higher numbers of different traumatic events, $t(154) = -3.07, p = .003$.

There were no significant differences between participants in the two treatment conditions at baseline in terms of age, $t(154) = -0.15, p = .883$; gender, $\chi^2(1) = 2.27, p = .132$; ethnicity, $\chi^2(8) = 6.92, p = .545$; living/care situation, $\chi^2(5) = 6.72, p = .243$; total number of traumas experienced, $t(154) = 0.53, p = .595$; household income, $\chi^2(4) = 5.46, p = .244$; or the parent's level of education, $\chi^2(4) = 3.43, p = .488$. Furthermore, the groups had comparable T1 scores on the CPSS, $t(154) = -0.05, p = .962$; MFQ, $t(154) = 0.05, p = .958$; SCARED, $t(149) = .30, p = .958$; and SDQ, $t(152) = -0.20, p = .840$.

Treatment Outcomes

The means and standard deviations are presented by treatment condition and time, treatment effects, interaction effects, and effect sizes (d) in Table 4.

TABLE 4
Descriptions of Outcome Variables: Means and Standard Deviations by Treatment Condition and Time and Effect Sizes

Outcome	Therapy as Usual			d^1	TF-CBT			d^2	d^3
	Time 1 M (SD) n	Time 2 M (SD) n	Time 3 M (SD) n		Time 1 M (SD) n	Time 2 M (SD) n	Time 3 M (SD) n		
CPSS	26.88 (7.90) n = 77	20.68 (11.63) n = 60	16.87 (11.49) n = 63	1.27	26.82 (8.05) n = 79	18.90 (10.79) n = 63	11.34 (10.52) n = 59	1.92	0.51
fCPSS	7.99 (1.40) n = 76	8.47 (1.89) n = 60	9.22 (2.09) n = 63	-0.88	8.03 (1.84) n = 79	8.90 (1.82) n = 62	10.33 (1.99) n = 58	-1.25	-0.55
CAPS	60.65 (21.20) n = 77	-	42.05 (26.58) n = 61	0.88	60.19 (19.90) n = 79	-	30.55 (25.30) n = 55	1.49	0.46
MFQ	35.32 (13.32) n = 77	27.82 (15.87) n = 60	22.66 (16.24) n = 62	0.95	35.43 (11.77) n = 79	24.73 (14.69) n = 62	14.40 (13.67) n = 57	1.79	0.54
SCARED	33.32 (16.70) n = 76	30.38 (17.84) n = 60	24.82 (17.15) n = 61	0.51	34.12 (15.97) n = 75	28.56 (16.56) n = 62	19.67 (17.27) n = 54	0.90	0.30
SDQ	19.09 (5.47) n = 76	-	14.54 (6.12) n = 59	0.83	18.92 (4.90) n = 78	-	11.95 (6.51) n = 56	1.42	0.45

Note. CPSS = Child PTSD Symptom Scale; fCPSS = PTS symptoms influence on daily functioning; CAPS = Clinician-Administered PTSD Scale; MFQ = Mood and Feelings Questionnaire; SCARED = Screen for Child Anxiety-Related Disorders; SDQ = Strengths and Difficulties Questionnaire.

d^1 = calculated based on differences between T1 and T3 in the TAU condition:

$$\frac{\bar{x}_{TAU T1} - \bar{x}_{TAU T3}}{SD_{TAU T1}}$$

d^2 = calculated based on differences between T1 and T3 in the TF-CBT condition:

$$\frac{\bar{x}_{TFCBT T1} - \bar{x}_{TFCBT T3}}{SD_{TF-CBT T1}}$$

d^3 = calculated based on differences between the two conditions at T3:

$$\frac{\bar{x}_{TAU T3} - \bar{x}_{TFCBT T3}}{Spooled}$$

ITT Analyses

Primary outcome measure

Child PTSS. There was a main effect of treatment condition on child PTSS (measured by the CPSS), in which participants in the TF-CBT group scored significantly lower ($M=11.34$, $SD=10.52$) at T3 compared with participants in the comparison group ($M=16.87$, $SD=11.49$); $d=0.51$, $t(154)=3.30$, $p=.001$ with Holm adjustment: $p=.006$; there was also a significant Time \times Group interaction effect, $F(2)=5.01$ $p=.007$, with Holm adjustment: $p=.037$. In addition, there was a main effect of treatment in both groups, indicating that participants showed significant reductions in PTSS between the pre- and posttherapy assessments: TF-CBT, $t(241)=-12.01$, $p<.001$; TAU: $t(241)=-7.80$, $p<.001$. Measurement of the impact of PTSS on daily functioning (as measured by the fCPSS subscale) revealed a main effect of treatment condition on functional impairment. The results showed that trauma influenced daily functioning significantly less (indicated by higher scores) in the TF-CBT group ($M=10.33$, $SD=1.99$) than in the TAU group ($M=9.22$, $SD=2.09$) at the end of therapy ($d=-0.55$), $t(154)=-3.32$, $p=.001$, with Holm adjustment: $p=.006$. In addition, in terms of functional impairment, there was a main effect of treatment on time in both groups.

Secondary outcome measures

Symptoms of depression, anxiety, and general mental health problems. There was a main effect of

treatment condition on children's depressive symptoms. Participants in the TF-CBT condition ($M=14.40$, $SD=13.67$) scored significantly lower than those in the TAU condition ($M=22.67$, $SD=16.24$) on depressive symptoms at T3 ($d=0.54$), $t(154)=2.79$, $p=.006$, with Holm adjustment: $p=.018$. Furthermore, there was a main effect of treatment condition on children's general mental health problems. Participants in TF-CBT group had significantly lower scores ($M=11.95$, $SD=6.51$) than the youths in the TAU group ($M=14.54$, $SD=6.12$) at the end of therapy ($d=0.45$), $t(152)=2.46$, $p=.015$, with Holm adjustment: $p=.030$. There was no main effect of treatment condition on child anxiety symptoms ($d=0.30$), $t(150)=1.47$, $p=.144$, with Holm adjustment: $p=.144$. To further investigate this finding, we analyzed the SCARED subscales separately and found that only generalized anxiety disorder showed a main effect of treatment condition, $t(150)=2.10$, $p=.037$. For a more detailed description of these results, see Tables 4 and 5.

Completer Analyses

PTSS. The analysis of the completer cases yielded similar results as the ITT analyses. There was a main effect of treatment condition on children's PTSS (as measured by CPSS); youth in the TF-CBT group scored significantly lower on PTSS at T3 than participants in the comparison group, $t(120)=2.96$, $p=.004$ with Holm adjustment; $p=.011$; and there was a significant Time \times Group interaction effect, $F(1)=3.73$, $p=.0008$, with Holm adjustment: $p=.040$. Again, there was a main effect of treatment in both groups; these youth exhibited significant reductions in PTSS after therapy. Furthermore, the

TABLE 5
Treatment Effects Between Conditions and Interaction Values

Outcome	Treatment Effect (ITT)			Interaction Time \times Group	Treatment Effect (Completers)			Interaction Time \times Group
	Val. (Est.)	95% CI	<i>p</i>		Value (Est.)	95% CI	<i>p</i>	
CPSS								
T2	1.73	-1.72, 5.16	.324	$p=.007$	1.30	-2.52, 5.12	.502	$p=.008$
T3	5.78	2.32, 9.23	.001		5.53	1.83, 9.23	.004	
fCPSS								
T2	-0.38	-1.00, 0.24	.227	$p=.011$	-0.44	-1.12, 0.24	.203	$p=.026$
T3	-1.05	-1.67, -0.42	.001		-1.13	-1.79, -0.48	.001	
MFQ								
T2	2.21	-2.70, 7.12	.375	$p=.022$	4.11	-1.27, 9.50	.133	$p=.065$
T3	7.00	2.04, 11.96	.006		8.26	3.03, 13.48	.002	
SCARED								
T2	0.59	-5.15, 6.33	.839	$p=.150$	1.79	-4.64, 8.22	.583	$p=.186$
T3	4.34	-1.50, 10.19	.144		5.15	-1.13, 11.44	.107	
SDQ								
T3	2.54	0.50, 4.58	.015	$p=.026$	2.60	0.49, 4.70	.016	$p=.036$

Note. CPSS = Child PTSD Symptom Scale; fCPSS = PTS symptoms influence on daily functioning; MFQ = Mood and Feelings Questionnaire; SCARED = Screen for Child Anxiety-Related Disorders; SDQ = Strengths and Difficulties Questionnaire.

negative impact of trauma symptoms on daily functioning was significantly reduced in the TF-CBT group compared to the TAU group at the end of therapy, $t(118) = -3.42$, $p = .001$, with Holm adjustment: $p = .004$.

Completer analyses also showed a main effect of treatment condition on depressive symptoms, $t(117) = 3.13$, $p = .002$, with Holm adjustment: $p = .009$, and children's general mental health symptoms, $t(113) = 2.44$, $p = .016$, with Holm adjustment: $p = .032$. However, there was no main effect of treatment condition on children's anxiety symptoms, $t(113) = 1.62$, $p = .107$, with Holm adjustment: $p = .107$. See Table 5 for a more detailed description of these results.

Per-protocol analyses. Five cases from the TF-CBT group did not receive TF-CBT, and following a per-protocol approach, the five cases were treated as cases in the comparison group (PP1) or taken out of the analyses (PP2). Both the PP1 and PP2 analyses yielded similar results as the ITT and completer analyses.

Diagnostic criteria for PTSD. Diagnostic CAPS interviews conducted on all participants prior to treatment showed that 66.7% of the participants met the diagnostic criteria for full PTSD. At this time, there was no significant relationship between therapy condition and PTSD diagnosis, $\chi^2(1, N = 116) = 1.55$, $p = .213$, $\phi = .10$. However, there was a significant association between therapy condition and PTSD diagnosis posttreatment, $\chi^2(1, N = 116) = 4.61$, $p = .031$, $\phi = .20$. In the TF-CBT group, 18.2% of the participants ($n = 10$ of 55) fulfilled the diagnostic criteria compared to 36.1% ($n = 22$ of 61) of participants in the TAU group. In terms of diagnostic remission, significantly more participants in the TF-CBT group lost their PTSD diagnosis from T1 to T3 (77.8%, $n = 28$ of 36) compared to the TAU group (54.8%, $n = 23$ of 42), $\chi^2(1, N = 78) = 4.54$, $p = .033$, $\phi = -.24$. Of those participants with no diagnosis at T1, two participants in the TF-CBT and three in the TAU group fulfilled diagnostic criteria at T3.

Clinically significant change. Pretreatment, all participants were above the clinical range for CPSS (≥ 11), and this number was reduced to 45.8% ($n = 27$) in the TF-CBT group and 65.1% ($n = 41$) in the TAU group, $\chi^2(1, N = 122) = 4.61$, $p = .032$, $\phi = .19$, posttreatment. Regarding the MFQ, 72.4% ($n = 113$) of participants were above the clinical range pretreatment. After treatment, this number was reduced to 19.3% ($n = 11$) in the TF-CBT group and 38.7% ($n = 24$) in the TAU group, $\chi^2(1, N = 119) = 5.39$, $p = .020$, $\phi = .21$. Group differences were not present for (a) the SCARED, pretreatment: 64.7% ($n = 101$); posttreatment: 40% ($n = 20$) in the TF-CBT group and 37.7% ($n = 23$) in the TAU group; $\chi^2(1, N = 115) = 0.01$, $p = .941$, $\phi = .01$, or (b) the SDQ,

pretreatment: 50.6% ($n = 91$); posttreatment: 25.0% ($n = 14$) in the TF-CBT group and 27.1% ($n = 16$) in the TAU group; $\chi^2(1, N = 115) = 0.07$, $p = .796$, $\phi = .02$.

DISCUSSION

The purpose of this study was to evaluate the effectiveness of TF-CBT by comparing it to the therapy that is usually provided in community clinics. This is the first randomized study to evaluate the effectiveness of TF-CBT outside of the United States, where the program was developed. This study is also one of the few studies to use a participant sample consisting of multitraumatized youths exhibiting a wide range of psychological symptoms. As expected, the youth in both treatment groups showed significant improvement from pre- to posttherapy in terms of PTSS, depression, anxiety, and general mental health functioning. In addition, in line with our hypotheses, there were significant differences between groups. Regarding total PTSS scores, the negative impact of PTSS on daily functioning, depressive symptoms, and general mental health problems, participants in the TF-CBT condition scored significantly lower compared to those in the TAU group posttreatment. In addition, significantly fewer participants in the TF-CBT condition met the diagnostic criteria for full PTSD posttreatment. In contrast, there were no significant differences in anxiety symptoms between the two treatment conditions. Taken together, these results add to the existing body of research on TF-CBT (Silverman et al., 2008) and indicate that TF-CBT may also be more effective in reducing a wide range of symptoms than usual care, at least as usual care was practiced in these clinics.

The finding that participants in the TF-CBT group experienced a significant reduction not only in PTS reactions but also other symptoms is in agreement with the findings of previous TF-CBT studies (Cohen, Deblinger, et al., 2004; Cohen et al., 2011; Deblinger et al., 1996). Because PTSD often co-occurs with other disorders, this is an important finding for clinicians. The reduction in depression is particularly interesting to note, as some evidence-based treatments for depression reported in other studies do not outperform treatment as usual (Kerfoot, Harrington, Harrington, Rogers, & Verduyn, 2004; Weisz et al., 2009). Although we did not specifically examine which components may have been particularly beneficial for treatment outcomes in this study, teaching skills with which to regulate emotions and correct maladaptive appraisals appears to be fundamental for many effective interventions (Berliner, 2005). The cognitive and affect regulation components incorporated in TF-CBT may address symptoms related to both depression and posttraumatic stress. Alternatively, the reduction in depressive symptoms may be a result of

a decline in PTS reactions. Traumatized youth may, for example, begin to feel hope about the future when they experience an alleviation of PTSS. It is also interesting to note that participants receiving TF-CBT showed a significantly greater reduction in general mental health problems, such as externalizing behavior, emotional problems, social and peer problems, hyperactivity and concentration problems, compared to participants in the TAU group. This finding appears to support the claim of TF-CBT developers that TF-CBT is a broad-based treatment that targets the range of symptoms that traumatized youth typically present in community mental health clinics (Cohen, Mannarino, & Deblinger, 2006).

Contrary to our expectations and findings from other TF-CBT studies, we did not find significant differences in the reduction of anxiety symptoms across treatment conditions. Interestingly, an examination of the different subgroups of anxiety revealed that GAD scores were significantly more reduced in the TF-CBT group than in the TAU group. It is possible that social anxiety, panic disorder, specific phobias, and school avoidance require more targeted exposure interventions than provided in TF-CBT. In contrast, the nature of the “free-floating” anxiety often associated with GAD may be more easily changed by nonspecific techniques, such as cognitive restructuring, affect regulation, and relaxation. Future studies should examine this further.

It is also noteworthy that we did not need to make any significant cultural adaptations while implementing the program in Norway. This finding may reflect the flexible nature of the program, in which therapists are encouraged to specifically tailor the interventions to each child. This cultural flexibility suggests that TF-CBT may be a promising treatment program that can be transported, without extensive adaptation, to countries outside of the United States. In fact, researchers in other European countries who are working on implementing TF-CBT have reported similar experiences (Murray & Skavenski, 2012). However, the implementation efforts that are currently ongoing in several low-resource countries, such as Zambia, Tanzania, Cambodia, and the Democratic Republic of Congo, suggest that cultural differences and the limited availabilities of educated therapists require modifications in TF-CBT implementation. These modifications are described as minor though, suggesting that TF-CBT may translate well to cultures outside the United States (Murray & Skavenski, 2012).

This study has several methodological strengths. In addition to using a randomized controlled trial design, which is considered to be the gold standard for studying treatment efficacy, participants were recruited through standard referral procedures and were thus more likely to reflect regular cases. Furthermore, the assessments

were conducted by evaluators who were naïve to the treatment condition, thereby reducing the risk of researcher allegiance bias. Finally, there was extensive fidelity reporting. However, the results must be viewed in light of some important limitations. First, there were significantly more psychologists with postgraduate training among the TF-CBT therapists compared to the TAU therapists. Second, the TF-CBT therapists received substantially more supervision than the TAU therapists. Therefore, the results may also be a consequence of clinical supervision. On the other hand, all the TF-CBT therapists were new to the intervention, and the enhanced supervision was part of their TF-CBT training. One might thus expect even more improvement in outcomes as the therapists become more familiar with the program and more at ease with tailoring the program to each child’s needs. However, studies have also shown that therapists tend to “drift” away from treatment protocols over time; therefore, it cannot be definitively concluded that increasing therapists’ exposure to TF-CBT would improve outcomes (Saunders & Hanson, *in press*). Another limitation is that the therapists were not randomized. The TF-CBT therapists volunteered to learn TF-CBT. Randomizing therapists could have reduced the possible effect of therapist variables. Most of the therapist in the TF-CBT group described their theoretical orientation as cognitive-behavioral, whereas most of the TAU therapists describe their orientation as psychodynamic, and this could have influenced the results. It is also reasonable to assume that the TF-CBT therapists were highly motivated, and this may have affected the results. Therapists who volunteered for TF-CBT training may also have been more likely to use the program with success and fidelity than other clinicians at the same clinic. Finally, although the findings suggest that TF-CBT is equally effective in helping boys and girls, the number of boys in the study was small. Future studies should make an effort to include more boys to determine whether there are gender differences.

Implication for Research, Policy and Practice

There is reason to believe that many youth often suffer from undiagnosed PTSD and that they often do not receive adequate treatment. Documenting effective treatments that can be provided within the realm of regular clinical care is therefore of vital importance. The findings from this study indicate that TF-CBT may be an effective treatment for traumatized youth in community clinics in Norway and thus emphasize the promise of this program in being successfully transported to countries outside of the United States. The developers of TF-CBT have conducted an impressive amount of their own research documenting the usefulness of TF-CBT, and they have

inspired many other studies as well. However, on the basis of meta-analyses, in which the authors claim that the positive results found in studies using manualized treatments are, in part, explained by researcher bias (Leykin & DeRubeis, 2009), independent replications are needed to minimize the possible attribution of the previous findings of the effectiveness of TF-CBT to expectancy effects. This study demonstrates that although both treatment groups experienced significant reductions in symptoms, the type of treatment appeared to play an important role in alleviating PTSS and other mental health problems. However, it is noteworthy that some participants did not respond as well to the treatment program, and further research should focus on achieving a greater understanding of why some groups of children do not respond well to the program. In summary, it is promising that the treatment results appear to hold up across trauma experiences that include multiple and severe interpersonal traumas. Whether these treatment effects will persist in follow-up analyses 18 months after treatment remains undetermined.

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