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Moderators of treatment response to trauma-focused cognitive behavioral therapy among youth in Zambia

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Abstract

Background—The effectiveness of mental health interventions such as trauma-focused cognitive behavioral therapy (TF-CBT) may vary by client, caregiver, and intervention-level variables but few randomized trials in low- and middle-income countries (LMIC) have conducted moderation analyses to investigate these characteristics. This study explores moderating factors to TF-CBT treatment response among a sample of orphans and vulnerable children (OVC) in Zambia.

Methods—Data were obtained from a completed randomized trial of TF-CBT among 257 OVC in Zambia. Trauma symptoms and functioning were measured at baseline and following the end of treatment. Mixed effects regression models were estimated for each moderator of interest: gender, age, number of trauma types experienced, history of sexual abuse, orphan status, primary caretaker, school status, and parental involvement in treatment.

Results—Treatment effectiveness was moderated by history of sexual abuse with greater reductions in both outcomes (trauma, $p<.05$; functioning, $p<.01$) for those that experienced sexual abuse. Primary caretaker was also a moderator with greater trauma reductions in those who identified their mother as the primary caretaker ($p<.01$), and better functioning in those that identified their father as the primary caretaker ($p<.05$). Non-orphans and single orphans (mother alive) showed greater reduction in functional impairment ($p<.01$) compared to double orphans.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Change in trauma and functioning outcomes stratified by treatment arm and sexual abuse history

Table S1. Trauma types measured with the PTSD-RI

There was no significant moderator effect found by gender, age, number of trauma types, school status, or caregiver participation in treatment.

Conclusions—This study suggests that TF-CBT was effective in reducing trauma symptoms and functional impairment among trauma-affected youth overall and that it may be particularly effective for survivors of child sexual abuse and children whose primary caretaker is a biological parent. Scale-up of TF-CBT is warranted given the wide range of effectiveness, and prevalence of child sexual abuse. Future randomized trials of interventions in LMIC should power for moderation analyses in the study design phase when feasible.

Keywords

PTSD; orphans and vulnerable children; Zambia; trauma-focused cognitive behavioral therapy; moderation analysis

Introduction

Trauma-focused cognitive behavioral therapy (TF-CBT; (Cohen, Mannarino, & Deblinger, 2006; http://tfcbt.musc.edu/) is an effective evidence-based treatment for the management of mental health and psychosocial problems among children and adolescents who have experienced traumatic events (Jensen et al., 2014; Silverman et al., 2008). Studies from high income countries (HIC) have established effectiveness in specialized and community settings, as well as with multiply traumatized populations with varied experiences (e.g., sexual abuse, physical abuse, domestic violence, disasters) (Cohen, Mannarino, & Iyengar, 2011; Cohen, Mannarino, & Knudsen, 2005; Deblinger, Lippmann, & Steer, 1996; Jaycox et al., 2010; Jensen et al., 2014).

There have been three clinical trials of TF-CBT in lower resource settings. The authors recently completed a randomized clinical trial in Zambia comparing TF-CBT to treatment as usual (TAU) among orphans and vulnerable children (OVC), ages 5 to 18 years who had significant trauma symptoms. We found that TF-CBT was both clinically and statistically significantly superior to TAU with effect sizes of 2.39 and 0.34 for trauma symptoms and functional impairment, respectively, based on immediate post-intervention assessments (Murray et al., 2015). Two small randomized controlled trials in the Democratic Republic of Congo among trauma-affected adolescent girls (n=52) and boys (n=50) indicated strong effectiveness of TF-CBT in reducing trauma symptoms, depression, anxiety, and conduct problems (McMullen, O'Callaghan, Shannon, Black, & Eakin, 2013; O'Callaghan, McMullen, Shannon, Rafferty, & Black, 2013).

Clinical trial experts have recommended that subgroup analyses be conducted in randomized controlled trials (Cook, Gebski, & Keech, 2004; Hingorani et al., 2013; Kraemer, Wilson, Fairburn, & Agras, 2002). These analyses can provide important information regarding whether subsets of a population respond differentially to a particular treatment in order to enhance future practice and research (Kraemer et al., 2002). Few studies have explored moderators of child psychological treatment generally, and CBT specifically.

Taylor and colleagues (2015) argue that caregiver, child, and intervention characteristics may all be theoretically important in moderating the effectiveness of CBT treatment for youth trauma symptoms. Regarding caregiver characteristics, in a meta-analysis of evidence-based psychological treatments for traumatized youth, Silverman et al. (2008) found that parental involvement in treatment did not modify trauma symptom outcomes. A separate meta-analysis on trauma treatments for sexually abused youth, however, found that interventions that included the family were superior in reducing trauma symptoms to those that had no family involvement (Harvey & Taylor, 2010). Parental characteristics, such as maternal depression and unhelpful trauma beliefs were also associated with poorer response to CBT among trauma-affected children (Nixon, Sterk, & Pearce, 2012). Similarly, Weems and Scheeringa (2013) found that maternal depressive symptoms were associated with potential PTSD relapse among their children.

The analysis by Silverman et al. (2008) indicated that treatment effect sizes were larger for addressing internalizing symptoms when sexual abuse was the focus compared to interventions focused on other types of trauma, and smaller for externalizing symptoms when sexual abuse was the focus compared to other trauma. Several studies conducted in the U.S. have specifically investigated other child-level moderators (e.g., gender, age, race, ethnicity) of TF-CBT effectiveness and have mostly found null effects (Cohen, Deblinger, Mannarino, & Steer, 2004; Cohen et al., 2011; Deblinger, et al. 2011). Two moderator studies of other mental health interventions for youth in LMIC found that treatment gains were larger among girls compared to boys (Betancourt et al., 2012; Tol et al., 2010).

Two studies assessed treatment dose as an intervention-level moderator for TF-CBT. Cohen et al. (2011) found no effect of the number of treatment sessions on effect size. Deblinger et al. (2011), however, found significant effects of treatment dose with a16 session version of TF-CBT significantly more effective than an 8 session version.

Findings from moderator studies have been inconsistent and limited by small sample sizes and suboptimal comparison groups (Wiles et al., 2014). To our knowledge, these types of analyses have not been conducted following a randomized clinical trial of TF-CBT in a low resource setting, where arguably there are significant contextual differences that may affect the role of moderators. Understanding moderators in LMIC is particularly important because these analyses can help policy decisions on which populations to prioritize given limited resources.

In this study, we utilize data from a RCT among trauma-affected OVC to explore if TF-CBT treatment effects vary by several factors: gender, age, number of trauma types experienced, having experienced sexual abuse, orphan status, the child's primary caretaker (i.e., mother, father, or someone else), current school status, and whether the primary caretaker participated in therapy sessions with the child. Based on previous studies, we hypothesize that treatment effects will moderated by gender, sexual abuse history, number of traumas experienced, and school status with larger effects among: a) females, b) those who experienced sexual abuse; c) those who experienced a greater number of trauma types, and d) those currently in school. We investigated additional factors due to lack of data within low resource settings, and mixed results within existing literature.

Methods

This was a secondary analysis of data from a completed randomized controlled trial of TF-CBT compared to treatment as usual (TAU) among OVC in Zambia, conducted between August 2012 and July 2013 (Murray et al., 2015) (clinicaltrials.gov identifier: NCT01624298).

Participants and procedure

The trial was conducted in five low resource communities within Lusaka: a home-based care center, a public health clinic, two schools, and a center for street children. Children and one of their primary caretakers were recruited by site staff members. Inclusion criteria were: age (5–18), traumatic event history (one or more events reported), and significant levels of trauma symptoms (average score ≥1) as measured by the Post-traumatic Stress Disorder Reaction-Index (PTSD-RI) (Murray, Bass, et al., 2011). Children were excluded if they were not mentally competent to provide informed consent (determined by a child's ability to orient to person, place and time and respond to the questionnaires), were currently receiving psychiatric treatment, or their caretaker did not provide permission.

The final sample size was 257 (86.2 % of those screened). Sample size for the study was based on our desired ability to detect a 25% difference in mean trauma symptom score change between the treatment arms. The sample size was calculated with power of 80%, α=0.05, and an estimated loss to follow-up rate of 20%. Retention was adequate with 210 participants (81.7% of those enrolled) completing the intervention/control monitoring phase and a post-assessment.

After consent, eligible participants completed a full baseline assessment battery and were randomized to: 1) TF-CBT, which would begin within one month, or 2) Treatment as usual (TAU), with TF-CBT offered following the completion of the trial. Randomization was conducted immediately following completion of the baseline assessment. A study assessor opened a sealed envelope that was attached to the consent form only after completion of the assessment. Inside the envelope was the randomization assignment (TF-CBT or TAU) for the ID that had been assigned to the child. A master list of randomization assignments for each ID number was generated a priori by a U.S.-based statistician. Random assignment of the ID numbers was conducted through a random number generator in Microsoft Excel.

A post-assessment including the same battery of instruments as the baseline was administered following the final treatment visit for the TF-CBT participants (approximately 4 months following baseline for the TAU participants). Study assessors were blind to randomization status at both baseline and post-assessments. By nature of the intervention, counselors and participants were not blinded to their randomization assignment.

Treatment arms

TF-CBT. TF-CBT is an approximately 10 to 12 week intervention comprised of weekly 60 to 90 minute therapy sessions (Cohen et al., 2006). The sessions may include the child, his/her caretaker, or both of them together. There are nine core components of TF-CBT including: psychoeducation, parenting skills, relaxation skills, affective modulation skills,

cognitive coping skills, trauma narration and processing, in vivo mastery of trauma reminders (live exposure), conjoint session (with caregiver), and enhancing safety skills. The treatment was delivered by lay counselors who were trained and supervised using an apprenticeship model (Murray, Dorsey, et al., 2011). This included an initial 10-day in-person training of counselors and local supervisors followed by practice cases that were completed before the treatment trial, and weekly meetings between counselors and local supervisors and local supervisors and TF-CBT experts during the trial.

TAU. Participants randomized to the TAU arm continued to receive services as usual from their respective community sites. There is no currently established standard of care for treating traumatized OVC populations in Zambia. The TAU services included education, support groups, primary healthcare services, nutrition education, HIV/AIDS counseling, and/or psychosocial counseling. The TAU participants were monitored weekly by study assessors for safety checks but otherwise were not contacted by the study team or any TF-CBT counselors until after the post-assessment.

Measures

Interviews were conducted in-person by trained assessors. The assessment was translated from English into two local languages, Bemba and Nyanja, and back-translated to check accuracy.

Primary outcomes—Trauma symptoms were measured with the UCLA PTSD Reaction Index for DSM-IV-TR (PTSD-RI) (Steinberg et al., 2013), which was previously adapted and validated for use in Zambia (Murray, Bass, et al., 2011). The adapted measure included the original 20 items as well as 18 additional locally defined symptoms. Participants responded to each item by indicating how often they experienced the symptom on a scale ranging from 0 (never) to 4 (all of the time). An average trauma score was calculated across the 38 items (α=.83). We used an average score of >=1 as our inclusion criterion. This translates to a total score of >=38, which is the standard cut-off score for the original 20-item version of the PTSD-RI based on studies in the United States. Our validation paper did not suggest specific cut-off scores for the PTSD-RI in low resource settings like Zambia, but rather a range of possible choices. Our choice of >=1 also followed our suggestion in our validation manuscript of maximizing sensitivity and serving more people when working within a community.

Functional impairment was measured with a locally developed gender-specific scale. Items in the scale represented regular daily tasks and activities (e.g., going to school) and prompted participants to respond how much difficulty they had doing those tasks or activities in the past month on a scale from 0 (no difficulty) to 4 (cannot do) (Johns Hopkins Bloomberg School of Public Health, 2013). An average functional impairment score was calculated across the 20 items in the scale with higher scores suggesting greater impairment (α=.90).

Moderators—Moderators were included in the analysis based on previous research, *a priori* theory of variables that were thought to have potential to impact treatment

effectiveness, and clinical judgment by the authors (LM, JC, SD, SSvW) through their experience delivering TF-CBT in lower resource settings.

Demographic moderators included: gender, age, orphan status (both parents alive/mother alive/father alive/neither parent alive), primary caretaker (mother/father/someone else or no one), and current school status (currently in school/currently not in school). The “someone else” category incorporated a variety of caregiver types including grandparents, stepparents, siblings, or “other caregiver not listed.” We collapsed these into the “someone else” category due to small numbers across the additional categories. Similarly, the “no one” category was combined with “someone else” in analysis because the “no one” category accounted for less than 2% of the sample. Additional moderators included lifetime experiencing of sexual abuse, the number of trauma types experienced (see Supporting Information for the specific trauma types included), and caretaker participation in TF-CBT.

Statistical analyses

Analysis followed an intent-to-treat approach. Missing data were determined to be missing at random (MAR) following analysis that indicated study drop out and loss to follow-up were associated with: being male, older age, a greater number of traumatic event types, not currently enrolled in school, and study site. We conducted multiple imputation procedures using chained equations (MICE) with the mi impute and mi estimate commands in Stata (StataCorp, 2013). The MICE approach conditionally specifies a prediction model for each variable with missing data and imputes variables of different type (e.g., categorical and continuous) simultaneously (Azur, Stuart, Frangakis, & Leaf, 2011; Royston, P & White, 2011). Results with imputed and non-imputed data were comparable. We therefore present results from the MICE analysis in which all participants were included.

Linear mixed effects regression models were estimated for the trauma outcome to measure the difference in trauma symptom change between the TF-CBT and TAU groups and whether that change varied by levels of the moderators of interest. Separate models were estimated for each moderator. For the functional impairment outcome, generalized linear mixed effects models with a log link and Poisson distribution were used to account for non-normally distributed functioning data. Separate functioning models were also estimated for each moderator.

All models included fixed direct effects of treatment arm (TF-CBT=1; TAU=0), time (post-assessment=1; baseline=0), and moderator. A three-way interaction term of moderator X time X treatment arm and all lower order interactions were also included. The three-way interaction was the coefficient of interest in assessing whether treatment effects varied by levels of the moderator. Random effects included participant, site, and counselor. Robust standard errors were estimated for all models. The models took the following form:

$$y_{ijkl}=\beta x_{ijkl}+\beta_0+\pi_l+\gamma_{kl}+\Omega_{jkl}+\varepsilon_{ijkl}$$

In the model, π_l, γ_{kl}, Ω_{jkl} were the random intercepts for site, counselor and patient, respectively, and ε_{ijkl} were the residuals. The *l* represented the site, *k* was the counselor

nested within the site, *j* was the client nested within the counselor and *i* was the observation within each client.

Where we found statistically significant three-way interactions ($p<.05$), we re-estimated the models stratified by levels of the moderator. The stratified models included only direct fixed effects of treatment and time and a treatment X time interaction. Effect sizes using Cohen's D were calculated to assess the size of treatment effect within each level of the moderator (Cohen, 1986). Analyses were conducted using Stata, version 13 (StataCorp, 2013).

Ethical approval

Informed consent was obtained from all study participants. The study and secondary analysis was approved by Institutional Review Boards at Johns Hopkins Bloomberg School of Public Health in the United States and ERES Converge in Zambia.

Results

Demographic characteristics of the trial sample are summarized in Table 1. Overall, the two groups were similar with respect to the moderator variables. The effect sizes of TF-CBT for the trauma symptom and functioning outcomes were 2.39 and 0.34, respectively. The effectiveness of TF-CBT was not significantly moderated by gender, age, number of trauma types experienced, caregiver participation in treatment, or school status for either of the two outcomes (Table 2).

History of sexual abuse was a significant moderator of both the trauma and functioning outcomes ($p<.05$ for both). Effect sizes were larger for those who experienced sexual abuse ($d=2.75$ for trauma; $d=0.81$ for functioning) than those who did not ($d=2.42$ for trauma; $d=0.19$ for functioning). We explored whether the variation in treatment response by sexual abuse history was attributable to girls having reported sexual abuse at a higher rate than boys (22.7% and 13.2%, respectively). After controlling for gender in the regression models, however, the three-way interaction of sexual abuse, time, and treatment arm remained significant in both the PTSD and functioning models. We also tested whether the effect may have been an artifact of youth who experienced sexual abuse having higher baseline symptoms or experiencing a larger number of trauma types than youth who did not experience sexual abuse. In both cases, after controlling for these factors, the moderation effect of sexual abuse remained significant. A graphical representation of treatment response stratified by sexual abuse history is displayed in Supporting Information.

Primary caretaker also significantly modified both outcomes. For the trauma outcome, effect sizes were largest among those whose primary caretaker was their mother ($d=3.48$), followed by the father ($d=2.15$), and someone else or "no one" ($d=1.58$). For the functioning outcome, effect size was largest among those whose primary caretaker was the father ($d=0.98$), followed by the mother ($d=0.27$), and someone else/no one ($d=0.23$).

Orphan status did not moderate treatment effectiveness for the trauma outcome but did modify response to functioning ($p<.001$). The largest effect size was among those who had both parents alive ($d=0.36$), followed by mother alive ($d=0.34$), neither parent alive

(*d*=0.29), and father alive (*d*=0.16). Stratified model results are included in Table 3 (PTSD) and 4 (functioning).

Discussion

This study is one of the first to investigate moderators of TF-CBT treatment effectiveness for trauma symptoms and functional impairment in a LMIC. A number of researchers have called for moderator and subgroup analyses following randomized trials to determine who may (or may not) particularly benefit from various treatment options (Kraemer et al., 2002; Ventevogel & Spiegel, 2015). This is critical for low-resource settings where access to such services will likely be limited. Significant moderators in our study included sexual abuse history (trauma and functioning), orphan status (functioning), and primary caretaker (trauma and functioning).

For both the PTSD and functioning outcomes, effect sizes were larger among those children who reported a history of sexual abuse than among those who had reported other types of traumatic experiences without sexual abuse. The finding is consistent with a meta-analysis by Silverman et al. (2008), which found that interventions focused on addressing sexual abuse trauma were more effective at reducing internalizing symptoms than interventions focused on other trauma types. It is possible that youth who report sexual abuse are more motivated to get help and thus may show better treatment outcomes.

Notably, although the moderation analysis resulted in a statistically significant finding, the effect sizes for treatment response were also very large among those who did not experience sexual abuse. We therefore do not recommend that our finding be used to prioritize the provision of TF-CBT to those who experienced abuse over those who did not. We do believe, however, that this is an important result given the very high estimated rates of child sexual abuse in Zambia (Michalopoulos et al., 2015), the stigma associated with sexual abuse in the HIV/AIDS era, and skepticism among many organizations and policy-makers that CBT-based treatment can be effective for African HIV- affected sexually abused youth. The finding is of significance to organizations working with OVC populations affected by sexual abuse and should have significant policy and programmatic implications by providing a treatment option with demonstrated impacts on trauma symptoms and functional impairment.

The significant moderator effects of primary caretaker and orphan status suggest that the presence of one or more biological parents in the home serving as the primary caregiver may enhance effects of the treatment. This is in line with other research on the powerful impact of caregivers, and that in Zambia there are often feelings of being a “second class citizen” when an orphan is taken care of by others (Kanjanda, 2014). This is a critical finding given that over 15 million children have been orphaned or made otherwise vulnerable by the HIV/AIDS epidemic (UNAIDS, 2010). Consequently, future research should investigate efforts to augment engagement with foster or extended family caregivers to improve results for orphaned populations (Dorsey et al., 2014).

Contrary to our hypothesis, we found no statistically significant moderation effect by gender, although it did approach significance (p=.10), with girls displaying slightly greater effect sizes than boys for the trauma outcome. Betancourt et al. (2012) found that female youth in northern Uganda experienced a greater reduction in depressive symptoms compared to males following interpersonal therapy and Tol et al. (2010) also found a larger effect of a CBT-based treatment among girls in Indonesia. No moderating effect of gender has been found in any TF-CBT studies conducted in the U.S. (Cohen et al., 2004, 2011; Deblinger et al., 2011), however, and so this should be further investigated with larger sample sizes.

There was no difference found in treatment effectiveness by age, even with a large range (5–18) included in the trial. This is consistent with findings from the U.S. (e.g., Cohen et al., 2004). There was also no identified moderator effect by number of trauma types reported despite a large range (1–11). Previous studies have found that trauma exposure and trauma symptoms may increase in a dose-response relationship (Mollica, McInnes, Poole, & Tor, 1998). We measured the number of different trauma *types* youth reported experiencing, but not the number of exposures within each type.

We found that for both trauma and functioning, there was no identified difference in outcome between children whose parents participated in one or more sessions versus no participation. The same results were obtained by a trial in the U.S. (Deblinger et al., 1996). Future studies should continue to investigate the effectiveness of TF-CBT among youth whose parents do not participate in treatment given that in Zambia (and likely in many other LMIC and HIC), employment obligations, livelihood activities, caring for additional children, and economic difficulty (e.g., inability to travel to sessions) often preclude caregivers from regularly attending therapy sessions, or from attending them at all. An investigation in the U.S. found that maternal depression may adversely impact the long-term effectiveness of child trauma symptom treatment (Weems & Scheeringa, 2013). We did not measure caregiver mental health in our study but believe that this is an important area of future research in LMIC.

Limitations

Our sample size was robust for detecting direct treatment effects of TF-CBT but it was not originally designed to conduct moderator analyses. Given the lack of corroborating studies on moderators of TF-CBT, the findings from this singular study should not be used at this time to guide clinical practice. Based on recommendations by Brookes et al. (2001) on moderation analysis of clinical trials, the results are best utilized by informing future studies that have the ability to build subgroup analyses into their study designs. Decisions on informing clinical practice should be done with evidence across several moderation studies, preferably following meta-analyses (Fournier et al., 2010; Wiles et al., 2014). Our investigation makes a significant contribution to the literature given the small number of moderator studies on CBT approaches to trauma treatment among youth in LMIC, and can provide the foundation for such meta-analyses and subsequent recommendations or guidelines for treatment.

Limitations from the original randomized trial remain applicable for the current analysis as well. First, the trial included only a single post-assessment so it is unknown whether the

moderation effects found in this study persist over time. Second, the study was single-blind meaning that participants were (by necessity) aware of their treatment assignment and, although we have no evidence of this occurring, had the ability to divulge this to the blinded assessors at post-assessment. Finally, the baseline values of the functioning measure were overall very low. This may have resulted in floor effects in which it was more difficult to evaluate effect modification.

Conclusions

Our previous work in Zambia indicated that TF-CBT is an effective intervention for reducing trauma symptoms and improving functioning among trauma-affected children (Murray et al., 2015) and that the therapy is feasibly delivered by lay counselors and acceptable in a low resource setting (Murray et al., 2013). The present study found that youth who reported having experienced sexual abuse (among other traumatic events) significantly benefitted from the intervention. Moderator analyses are a critical method for evaluating whether and to what extent current interventions adequately address behavioral health disparities. This is not only an important scientific question but also an ethical imperative as currently mandated in federally funded research. Given the prevalence of sexual abuse and the stigma associated with it in Zambia, research on TF-CBT may focus on ways to scale-up and expand services specifically to sexually abused youth. Future randomized clinical trials should also include the ability to measure treatment moderators when feasible. Building the evidence base for moderators of mental health treatments in low resource settings has the potential to inform clinical care, funding, and policy decisions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Key points

- Trauma-focused cognitive behavioral therapy is a feasible and effective treatment for trauma symptoms and functional impairment among trauma-affected youth in Zambia
- We conducted moderator analyses on data from a completed randomized controlled trial of TF-CBT vs. treatment as usual among trauma-affected youth in Zambia to explore whether treatment effectiveness for trauma symptoms and functioning varied across several key characteristics.
- TF-CBT was particularly effective among children who had experienced sexual abuse in the context of multiple other traumas.
- We did not find a moderator effect of gender, age, number of traumas experienced, or caregiver participation in therapy on TF-CBT effectiveness.
- Our results should be replicated in larger samples and future randomized clinical trials should build moderation analyses into their study designs.

Table 1

Baseline characteristics of study sample (n=257)[a]

Characteristic	TF-CBT arm (n=131)	TAU arm (n=126)
Male	68 (51.9%)	61 (48.4%)
Age	14.0 (2.8)	13.3 (3.0)
Number of trauma types experienced	5.0 (2.4)	5.2 (2.1)
Experienced sexual abuse	22 (16.8)	24 (19.1)
Orphan status		
Both parents alive	54 (41.2)	43 (34.1)
Single orphan/Mother alive	31 (23.7)	27 (21.4)
Single orphan/Father alive	16 (12.2)	18 (14.3)
Double orphan/Neither parent alive	30 (22.9)	38 (30.2)
Primary caretaker		
Mother	39 (29.8)	24 (19.1)
Father	15 (11.5)	13 (10.3)
Someone else/no one[b]	77 (58.8)	89 (70.6)
Currently in school	111 (84.7)	112 (88.9)
Caregiver participated in ≥1 treatment session	75 (57.3)	-

Mean (SD) reported for continuous measures; *N* (column %) reported for discrete measures

TF-CBT, trauma-focused cognitive behavioral therapy; TAU, treatment as usual

[a] Table includes all available data at baseline. Multiple imputation not conducted on data included in this table.

[b] "Someone else" includes stepparents, grandparents, siblings and "other caretaker". No one" accounted for <2% of the population and so was combined with someone else category.

Table 2

Results from mixed effects regression models testing for moderation of treatment effects (n=257)[a]

	PTSD outcome	Functioning outcome
Moderator[b]	***B* (*SE*)[c]**	
Sex	0.28 (0.17)	0.70 (0.51)
Age	−0.01 (0.03)	−0.04 (0.08)
Number of trauma types experienced	−0.02 (0.04)	−0.05 (0.09)
Sexual abuse	−0.49 (0.24)*	−1.45 (0.56)**
Orphan status		
Both parents alive	REF	REF
Single orphan/Mother alive	−0.11 (0.30)	0.89 (0.28)**
Single orphan/Father alive	0.07 (0.58)	1.13 (0.34)**
Double orphan/Neither parent alive	−0.04 (0.22)	−0.30 (0.66)
Primary caretaker		
Someone else/no one[d]	REF	REF
Mother	−0.62 (0.16)**	−0.51, (0.49)
Father	−0.35 (0.33)	−1.43 (0.70)*
Caregiver participation[e]	−0.16 (0.16)	−0.04 (0.30)
School status	−0.03 (0.35)	−1.50 (0.93)

*$p<.05$,

**$p<.01$

SE, robust standard error

[a]All participants included in analysis following multiple imputation

[b]Each moderator was tested in a separate regression model.

[c]Betas are the coefficient of the three-way interaction term in the mixed effects regression model (moderator X treatment arm X time). The PTSD model was a linear mixed effects model and the functioning model was a generalized linear mixed effects model with a log link.

[d]Someone else" includes stepparents, grandparents, siblings and "other caretaker". No one" accounted for <2% of the population and so was combined with someone else category.

[e]Model estimated only on TF-CBT sample. Beta is coefficient of two-way interaction of parent participation (coded as 1 if participated and 0 if not) and time.

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Table 3

Predicted mean PTSD scores, difference in mean change, and between-treatment group effect sizes stratified by moderator level[a]

	TF-CBT arm		TAU arm			
	Mean (95% CI)[b]		Mean (95% CI)[b]			
Moderator	**Baseline**	**Post-assessment**	**Baseline**	**Post-assessment**	**Difference in mean change (95% CI)[b]**	**Cohen's *d*[c]**
Overall (n=257)	1.88 (1.73, 2.03)	0.34 (0.20, 0.48)	1.75 (1.58, 1.93)	1.38 (1.20, 1.57)	−1.17 (−1.45, −0.89) ****	2.39
Experienced sexual abuse						
Yes (n=46)	2.24 (2.13, 2.35)	0.44 (0.24, 0.65)	1.86 (1.63, 2.08)	1.63 (1.27, 2.00)	−1.57 (−1.88, −1.26) ****	2.75
No (n=211)	1.81 (1.62, 2.00)	0.31 (0.16, 0.47)	1.72 (1.53, 1.91)	1.31 (1.12, 1.51)	−1.09 (−1.43, −0.74) ****	2.42
Primary caretaker						
Mother (n=63)	2.03 (1.86, 2.19)	0.28 (0.17, 0.39)	1.56 (1.42, 1.70)	1.41 (1.21, 1.61)	−1.60 (−1.94, −1.26) ****	3.48
Father (n=28)	2.08 (1.69, 2.47)	0.43 (0.21, 0.65)	1.73 (1.61, 1.85)	1.41 (1.11, 1.70)	−1.33 (−1.87, −0.79) ****	2.15
Someone else/no one (n=166)[d]	1.76 (1.65, 1.88)	0.34 (0.16, 0.52)	1.82 (1.59, 2.04)	1.38 (1.14, 1.61)	−0.98 (−1.29, −0.67) ****	1.58

TF-CBT, trauma-focused cognitive behavioral therapy; TAU, treatment as usual

**** $p<.001$, represents p value for difference in mean score change between treatment groups from baseline to post-assessment

[a] All participants included in analysis following multiple imputation

[b] Predicted means, difference in mean change estimates, and corresponding 95% confidence intervals are from the linear mixed effects regression model. The same model was estimated for each level of the specified moderator. Range of the PTSD outcome was 0–4 with higher scores indicating greater symptom severity. A negative value for the difference in mean change suggests a greater difference in change among the TF-CBT group compared to the TAU group.

[c] The effect size was calculated as Cohen's *d* by dividing the difference in mean change by the baseline pooled standard deviation.

[d] Someone else includes stepparents, grandparents, siblings and "other caretaker". No one" accounted for <2% of the population and so was combined with someone else category.

Table 4

Predicted mean functioning scores, difference in mean change, and between-treatment group effect sizes stratified by moderator level[a]

	TF-CBT arm Mean (95% CI)[b]		TAU arm Mean (95% CI)[b]			
Moderator	**Baseline**	**Post-assessment**	**Baseline**	**Post-assessment**	**Difference in mean change (95% CI)[b]**	**Cohen's *d*[c]**
Overall (n=257)	0.85 (0.65, 1.12)	0.09 (0.08, 0.12)	0.79 (0.58, 1.06)	0.25 (0.22, 0.27)	−0.22 (−0.32, −0.11)	0.34
Experienced sexual abuse						
Yes (n=46)	0.98 (0.68, 1.39)	0.05 (0.02, 0.11)	0.72 (0.49, 1.05)	0.34 (0.23, 0.49)	−0.54 (−0.91, −0.18) **	0.81
No (n=211)	0.83 (0.63, 1.09)	0.10 (0.08, 0.12)	0.80 (0.58, 1.12)	0.22 (0.19, 0.27)	−0.15 (−0.28, −0.01) *	0.19
Orphan status						
Both parents alive (n=97)	0.81 (0.55, 1.20)	0.08 (0.05, 0.11)	0.79 (0.48, 1.32)	0.31 (0.22, 0.43)	−0.25 (−0.51, 0.01)	0.36
Mother alive (n=58)	1.09 (0.79, 1.54)	0.12 (0.07, 0.23)	0.91 (0.65, 1.27)	0.18 (0.11, 0.28)	−0.24 (−0.53, 0.06)	0.34
Father alive (n=34)	0.61 (0.35, 1.03)	0.18 (0.07, 0.45)	0.58 (0.38, 0.89)	0.23 (0.14, 0.41)	−0.08 (−0.20, 0.04)	0.16
Double orphan (n=68)	0.77 (0.64, 0.92)	0.04 (0.02, 0.79)	0.77 (0.64, 0.92)	0.22 (0.18, 0.28)	−0.17 (−0.46, −0.12)	0.29
Primary caretaker						
Mother (n= 63)	1.09 (0.96, 1.26)	0.09 (0.04, 0.21)	1.15 (0.90, 1.45)	0.33 (0.20, 0.55)	−0.19 (−0.50, 0.12)	0.27
Father (n=28)	0.81 (0.48, 1.39)	0.06 (0.03, 0.12)	0.53 (0.29, 0.98)	0.35 (0.26, 0.48)	−0.57 (−1.20, 0.05)	0.90
Someone else/no one (n=66)[d]	0.76 (0.56, 1.03)	0.10 (0.06, 0.17)	0.73 (0.53, 0.99)	0.21 (0.18, 0.24)	−0.14 (−0.23, −0.04) **	0.23

TF-CBT, trauma-focused cognitive behavioral therapy; TAU, treatment as usual

* $p<.05$,

** $p<.01$, represents p value for difference in mean score change between treatment groups from baseline to post-assessment

[a] All participants included in analysis following multiple imputation

[b] Predicted means, difference in mean change estimates, and corresponding 95% confidence intervals are from the generalized linear mixed effects regression model. The same model was estimated for each level of the specified moderator. Range of the functioning outcome was 0–4 with higher scores indicating greater functional impairment. A negative value for the difference in mean change suggests a greater difference in change among the TF-CBT group compared to the TAU group.

[c] The effect size was calculated as Cohen's *d* by dividing the difference in mean change by the baseline pooled standard deviation.

[d] Someone else includes stepparents, grandparents, siblings and "other caretaker". No one" accounted for <2% of the population and so was combined with someone else category.