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## Effectiveness of Trauma-Focused Cognitive Behavioral Therapy Among Trauma-Affected Children in Lusaka, Zambia:

### A Randomized Clinical Trial

Laura K. Murray, PhD, Stephanie Skavenski, MSW, MPH, Jeremy C. Kane, PhD, John Mayeya, MSc, Shannon Dorsey, PhD, Judy A. Cohen, MD, Lynn T. M. Michalopoulos, PhD, Mwiya Imasiku, PhD, Paul A. Bolton, MBBS

Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Murray, Skavenski, Kane); Ministry of Health, Lusaka, Zambia (Mayeya); Department of Psychology, University of Washington, Seattle (Dorsey); Allegheny General Hospital, Pittsburgh, Pennsylvania (Cohen); School of Social Work, Columbia University, New York, New York (Michalopoulos); School of Medicine, University of Zambia, Lusaka (Imasiku); Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Bolton).

### Abstract

**IMPORTANCE**—Orphans and vulnerable children (OVC) are at high risk for experiencing trauma and related psychosocial problems. Despite this, no randomized clinical trials have studied evidence-based treatments for OVC in low-resource settings.

**OBJECTIVE**—To evaluate the effectiveness of lay counselor–provided trauma-focused cognitive behavioral therapy (TF-CBT) to address trauma and stress-related symptoms among OVC in Lusaka, Zambia.

**DESIGN, SETTING, AND PARTICIPANTS**—This randomized clinical trial compared TF-CBT and treatment as usual (TAU) (varying by site) for children recruited from August 1, 2012,

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**Corresponding Author:** Laura K. Murray, PhD, Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Hampton House, 624 N Broadway, Eighth Floor, Baltimore, MD 21205 (lmurra15@jhu.edu).

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*Study concept and design:* Murray, Skavenski, Cohen, Imasiku, Bolton.

*Acquisition, analysis, or interpretation of data:* Murray, Skavenski, Kane, Mayeya, Dorsey, Cohen, Michalopoulos.

*Drafting of the manuscript:* Murray, Skavenski, Kane, Dorsey, Cohen.

*Critical revision of the manuscript for important intellectual content:* Murray, Mayeya, Dorsey, Cohen, Michalopoulos, Imasiku, Bolton.

*Statistical analysis:* Kane, Michalopoulos.

*Obtained funding:* Murray, Skavenski, Cohen, Bolton.

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*Study supervision:* Murray, Skavenski, Dorsey, Cohen, Imasiku.

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through July 31, 2013, and treated until December 31, 2013, for trauma-related symptoms from 5 community sites within Lusaka, Zambia. Children were aged 5 through 18 years and had experienced at least one traumatic event and reported significant trauma-related symptoms. Analysis was with intent to treat.

**INTERVENTIONS**—The intervention group received 10 to 16 sessions of TF-CBT (n = 131). The TAU group (n = 126) received usual community services offered to OVC.

**MAIN OUTCOMES AND MEASURES**—The primary outcome was mean item change in trauma and stress-related symptoms using a locally validated version of the UCLA Posttraumatic Stress Disorder Reaction Index (range, 0–4) and functional impairment using a locally developed measure (range, 0–4). Outcomes were measured at baseline and within 1 month after treatment completion or after a waiting period of approximately 4.5 months after baseline for TAU.

**RESULTS**—At follow-up, the mean item change in trauma symptom score was  $-1.54$  (95% CI,  $-1.81$  to  $-1.27$ ), a reduction of 81.9%, for the TF-CBT group and  $-0.37$  (95% CI,  $-0.57$  to  $-0.17$ ), a reduction of 21.1%, for the TAU group. The mean item change for functioning was  $-0.76$  (95% CI,  $-0.98$  to  $-0.54$ ), a reduction of 89.4%, and  $-0.54$  (95% CI,  $-0.80$  to  $-0.29$ ), a reduction of 68.3%, for the TF-CBT and TAU groups, respectively. The difference in change between groups was statistically significant for both outcomes ( $P < .001$ ). The effect size (Cohen  $d$ ) was 2.39 for trauma symptoms and 0.34 for functioning. Lay counselors participated in supervision and assessed whether the intervention was provided with fidelity in all 5 community settings.

**CONCLUSIONS AND RELEVANCE**—The TF-CBT adapted for Zambia substantially decreased trauma and stress-related symptoms and produced a smaller improvement in functional impairment among OVC having experienced high levels of trauma.

**TRIAL REGISTRATION**—[clinicaltrials.gov](https://clinicaltrials.gov) Identifier: [NCT01624298](https://clinicaltrials.gov/ct2/show/study/NCT01624298)

There are 15.1 million youth orphaned by AIDS in sub-Saharan Africa, with numbers predicted to increase.<sup>1,2</sup> Orphans and vulnerable children (OVC) (groups of children that experience negative outcomes, such as the loss of their education, morbidity, and malnutrition, at higher rates than do their peers) experience multiple traumatic experiences, including abuse and exploitation, premature parental death, human immunodeficiency virus (HIV) infection and stigma, poor health care, poverty, reduced social support, and abbreviated childhood and education.<sup>3–5</sup> Given the association of childhood trauma with skill deficits and unhealthy decision making,<sup>6–8</sup> as well as with long-term negative health outcomes,<sup>9</sup> early and effective mental health intervention is critical to the care of OVC. However, little evidence exists about what types of programs enhance the well-being of OVC.<sup>10</sup>

We have conducted studies in Zambia to understand local mental and behavioral health problems, validate mental and behavioral assessment instruments, and examine the cross-cultural feasibility of evidence-based treatment.<sup>11–15</sup> These studies culminated in the randomized clinical trial reported in this article, which tests the effectiveness of trauma-focused cognitive behavioral therapy (TF-CBT; <http://tfcbt.musc.edu/>)<sup>16</sup> for OVC compared with treatment as usual (TAU) provided by lay counselors without previous mental health

care training. This trial was a collaboration with Serenity Harm Reduction Programme Zambia, a local nongovernmental organization.

## Methods

### Participants

This study included children recruited from August 1, 2012, through July 31, 2013, and treated until December 31, 2013, for trauma-related symptoms. The 5 study sites included a home-based care program, program for street children, government health clinic, public school, and school or residential program. Inclusion criteria were age of 5 through 18 years, living within a site catchment area, history of at least one traumatic event, and significant trauma-related symptoms (mean item score of  $\geq 1.0$  on the locally validated UCLA Posttraumatic Stress Disorder Reaction Index [PTSD-RI]).<sup>12</sup> Exclusion criteria were child or legal caregivers not mentally competent to give consent or currently receiving psychiatric treatment. Assessors were trained in signs of psychosis and called a supervisor for further assessment if any signs were present.

### Recruitment and Consent

Participants were recruited from existing clients at the study sites. Site staff members were familiar with the clientele and referred potentially eligible children to a study assessor. Eleven trained study assessors, selected by the sites based on set requirements, obtained oral informed consent from the caretaker and child for screening and, if eligible, the full study. All interviews were conducted in a confidential location at the 5 study sites in the participant's preferred language via interview format.

### Study Protocol

Each trial consent form contained a participant identification number. Once an eligible child consented, the child was assigned that number and completed a baseline assessment. The assessor then opened a sealed envelope stapled to the consent form, which indicated random assignment (TF-CBT vs TAU). Random assignment was performed offsite by a Johns Hopkins University investigator (J.C.K.) who kept a master list of identification numbers to enable checks of fidelity. All participants were informed that they could continue receiving community services as they wished, including counseling services. The study protocol can be found in the trial protocol in Supplement 1.

Postassessments were completed within 1 month after TF-CBT completion (for the TAU participants, approximately 4 months after baseline). To ensure masked assessment, assessors from a site other than where the participant received services completed the postassessment. At postassessment, all TAU participants were offered TF-CBT.

### Safety Protocol

A safety protocol was developed as part of the standard assessment procedures for both conditions.<sup>17</sup> The protocol specified steps for assessing risk, a notification tree, and possible referrals. The Institutional Review Board of Johns Hopkins Bloomberg School of Public

Health and the local Zambian institutional review board, ERES Converge, approved the study protocol.

### Intervention

The TF-CBT is typically conducted in weekly 60- to 90-minute sessions with the child and caregiver (if available) and involves provision of 9 components<sup>16</sup> (Box). Twenty adult counselors (11 from the sites and 12 external) were trained in TF-CBT via the apprenticeship model: a 10-day on-site training of counselors and supervisors, followed by weekly meetings of local supervisors with groups of counselors and weekly supervisor consultation with TF-CBT experts.<sup>18</sup> Backgrounds varied, but all counselors had at least a high school education and basic communication and social skills. One supervisor had been a TF-CBT counselor in a previous study, and another supervisor was selected from the counselor group given her strong understanding of the model and clinical skills.

Studies in the United States have found TF-CBT to be highly effective in treating the sequelae of child trauma<sup>19,20</sup> with sustained benefit at 6 to 24 months after treatment.<sup>21–23</sup> Research suggests broad applicability across a wide range of trauma types and acceptability among ethnically diverse therapists, children, and parents.<sup>24</sup> We previously modified TF-CBT for Zambia<sup>13</sup> and documented its feasibility in an open trial.<sup>15</sup>

At the time of this study, there were no other evidence-based programs for trauma-related symptoms among OVC against which to compare TF-CBT. However, OVC commonly receive various forms and amounts of psychosocial programming in Zambia, including counseling (eg, support groups and nonspecific counseling), education, nutrition, and HIV-related services,<sup>10</sup> which could affect mental health. Participants randomized to the TAU group continued to receive these types of regular services specific to each site (Box). Participants in the TAU group were telephoned weekly and visited once a month by a study assessor to evaluate safety (eg, suicidal ideation) and need for referral to other critical services (eg, medical assistance). For participants without a telephone, assessors attempted to provide in-person visits.

### Intervention Fidelity

Counselors documented how they provided each component according to specific steps detailed in the manual. Supervisors elicited (from counselors) and recorded session details (techniques used and homework assigned) during weekly supervision meetings. If a component (eg, relaxation) or component step was missed (eg, assigning homework), the supervisor requested completion in the next session. The local supervisor and counselor discussed and/or role-played the component and planning for the next session. A TF-CBT expert (L.K.M., S.S., or S.D.) recorded detailed notes from the supervisors' weekly verbal reports, checking that all TF-CBT components were provided with proper technique or, if not, asked for those components to be provided again.

### Outcome Measurements

The PTSD-RI was used to identify traumatic events a child had experienced or witnessed and the associated PTSD symptoms.<sup>25</sup> The PTSD-RI was translated into 3 Zambian

languages, validated, and adapted for local use, including the addition of 18 local symptoms to the original 20 items (eTable 1 in Supplement 2).<sup>12</sup> Participants reported whether they had ever experienced 13 events. Responses were summed to create a total traumatic event score (range, 0–13). Response options for the 38 symptoms ranged from 0 (never) to 4 (most of the time) and were used to calculate a mean trauma symptom score for each respondent (the primary outcome). Internal consistency for the PTSD-RI 38-item trauma symptom scale at baseline was very good ( $\alpha = .83$ ), with similar results for children (aged 5–12 years) ( $\alpha = .79$ ) and adolescents (aged 13–18 years) ( $\alpha = .84$ ). Given no clear cutoff recommendation from our validation study, but taking into account the receiver operating characteristic curves, we decided to maximize sensitivity so that a response of 1 or more per item would be indicative of symptoms appropriate for TF-CBT.

Functional impairment was measured using locally developed scales and developed using methods described elsewhere.<sup>26</sup> Items included tasks and/or activities that respondents frequently reported as regular aspects of caring for self, family, and/or community. Respondents reported current difficulty doing each activity compared with other children (0 for no difficulty to 4 for often cannot do). A mean item score (range, 0–4) was calculated for each participant. Internal consistency for the functional impairment scale was excellent ( $\alpha = .90$ ), with similar results for children (aged 5–12 years) ( $\alpha = .92$ ) and adolescents (aged 13–18 years) ( $\alpha = .89$ ).

Caretakers of child participants were asked to complete the Child Behavior Checklist.<sup>27</sup> Adolescent respondents (aged 12–18 years) who reported sexual activity were asked about HIV risk behavior using the World AIDS Foundation measure,<sup>28</sup> and those reporting alcohol or other substance use were assessed with the Alcohol, Smoking, and Substance Involvement Screening Test.<sup>29</sup>

### Statistical Analysis

Analysis was with intent to treat. Baseline sample characteristics for the intervention and TAU conditions were compared to indicate whether randomization resulted in balanced groups. Multiple imputation (11 imputations) with chained equations was used to account for participant loss to follow-up and item-level missing data.<sup>30</sup> Factors associated with dropout included sex (males more likely to drop out), age (older age associated with dropout), school status (those not currently in school more likely to drop out), trauma history (those with greater number of traumatic events more likely to drop out), and site (children in St Paul's school more likely to drop out).

We used mixed-effects regression modeling to evaluate TF-CBT effectiveness for trauma symptoms and functional impairment outcomes. The trauma symptom outcome was a linear mixed-effects model; the functioning outcome model was a generalized linear mixed-effects model with a Poisson distribution and log link to account for right skewed data. Random effects for both models included the participant, site, and counselor. Fixed effects included intervention group, time, and an interaction term of intervention group  $\times$  time. For the trauma symptom outcome, we estimated this model for the full 38-item modified PTSD-RI and also separately for the original 20 items and the local 18 items. We also estimated a version of these models adjusting for possible confounders; covariates were included in

the adjusted model if they differed meaningfully between intervention and TAU groups at baseline or if they were significantly associated with change in the mean trauma symptom score or functional impairment score from baseline to postassessment (significance threshold of  $P < .05$ ).

Estimates of effect size using the Cohen  $d$  statistic were calculated for each outcome by dividing the difference in mean change between treatment groups by the pooled baseline SD.<sup>31</sup> All analyses were conducted using STATA software, version 13 (Stata Corp).

Sample size calculations were based on the comparison of difference between mean baseline and follow-up trauma symptom scores between the 2 study groups. We decided that the ability to detect a 25% difference in mean change would be substantial and worth finding. Using a  $t$  test assuming unknown but equal SDs, 80% power, and an  $\alpha$  level of .05, we calculated that 100 children would be required in each study group. This was increased to 120 per group assuming a 20% loss to follow-up based on previous experience.

## Results

Of 298 children screened, 257 (86.2%) were eligible and agreed to participate. These children were randomized to TF-CBT ( $n = 131$ ) or TAU ( $n = 126$ ) (Figure 1).

### Baseline Characteristics

The only variable that appeared different between the groups was the length of time between baseline and postassessments, which was longer on average for the TF-CBT group (150.83 days) compared with the TAU group (116.03 days). Otherwise, baseline characteristics were similar between the groups (Table 1). Mean baseline trauma symptom scores (1.88 in the TF-CBT group and 1.75 in the TAU group) and functional impairment scores (0.85 in the TF-CBT group and 0.79 in the TAU group) were comparable between groups. The mean number of trauma events reported was 5.07, and Figure 2 summarizes the types.

### Outcomes of the TF-CBT vs TAU Groups

Mean trauma symptom score change from baseline to postassessment was  $-1.54$  (95% CI,  $-1.81$  to  $-1.27$ ) for the TF-CBT group and  $-0.37$  (95% CI,  $-0.57$  to  $-0.17$ ) for the TAU group. The larger reduction in the TF-CBT group compared with the TAU group was significant ( $P < .001$ ), rendering an effect size of 2.39 (Table 2). We also conducted this analysis separately for the 20-item original PTSD-RI scale (effect size, 2.57) and the 18 item local symptom scale (effect size, 1.68) (eTable 2 in Supplement 2).

Mean functional impairment score change from baseline to postassessment was  $-0.76$  (95% CI,  $-0.98$  to  $-0.54$ ) for the TF-CBT group and  $-0.54$  (95% CI,  $-0.80$  to  $-0.29$ ) for the TAU group. The larger reduction in the TF-CBT group compared with the TAU group was significant ( $P < .001$ ), giving an effect size of 0.34 (Table 2).

These results were comparable to models adjusted for potential confounders (eTable 3 in Supplement 2) in which effect sizes were 2.41 and 0.26 for trauma symptoms and functioning, respectively. Therefore, only the unadjusted models are presented in the main

article. In the adjusted models, covariates included length of time between assessments and primary caretaker (trauma and functioning models) and school status (functioning model).

Secondary outcomes of the trial are not reported. Only 58 participants (22.6%) reported ever having had sex at baseline, and only those respondents were eligible to respond to the HIV risk behavior questions. A total of 16 (47.1%) of those who responded that they ever had sex subsequently changed their answer and reported never having had sex at follow-up. Similarly, 14 (73.7%) of the participants who reported using tobacco, 38 (79.2%) who reported drinking alcohol, and 8 (61.5%) who reported using inhalants changed their responses at postassessment to never having used these substances. Because of the small sample size and inconsistent responses, no additional analyses were performed. We did not analyze the caretaker Child Behavior Checklist<sup>32</sup> because of a very low response rate (33.9% at baseline and 6.2% at follow-up) due to competing demands (eg, other children and selling at the market).

## Implementation Results

Counselors completed a mean of 7 sessions during the year (range, 2–12). Those who completed treatment (n = 107) received a mean (SD) of 11.77 (2.80) sessions (range, 6–21). Within the TAU group (n = 104), 82 expressed interest in TF-CBT and were assigned a counselor, suggesting treatment acceptability within the community. Eighteen high-risk cases were identified: child sexual abuse (n = 5), physical abuse (n = 2), severe neglect and verbal abuse (n = 1), suicidal ideation or plan (n = 8), and homicidal ideation (n = 2). All were successfully managed with the safety protocol.<sup>17</sup> The Child Protection Unit was informed, and investigations took place for child abuse and neglect cases; only one case resulted in outside placement.

## Discussion

### Summary and Interpretation of Results

We evaluated the effectiveness of an individually provided, evidence-based mental health treatment (TF-CBT) for OVC with histories of experiencing traumatic events. The TF-CBT was significantly superior to TAU in reducing trauma and stress-related symptoms when provided by lay counselors.

This study adds to a small body of literature examining evidence-based treatments for youth in low- and middle income countries (LMICs), mostly among war-affected populations.<sup>33–36</sup> Together, these studies indicate that it is feasible to implement evidence-based practices in lower-resource settings. Trauma-focused interventions (narrative exposure therapy and TF-CBT) revealed strong effect sizes (effect sizes, 0.5–1.80) on trauma symptoms in previous studies,<sup>33–35</sup> with maintenance at longer-term follow-up. Our study adds to the literature by revealing that TF-CBT is also effective for other types of wide-ranging trauma and stressors as reported by the OVC in our sample. Studies examining a newly developed stabilization and skill-focused group intervention,<sup>36</sup> art therapy,<sup>37</sup> and school-based interventions,<sup>38</sup> however, have found nonsignificant effects in reducing trauma-related symptoms in youth.

Trauma-affected populations therefore may be better served by trauma-focused interventions as opposed to other psychosocial programs.

The effect size for TF-CBT on trauma symptoms was large compared with other trials of TF-CBT in the United States (effect sizes, 0.4–0.7)<sup>19</sup> and Norway (Cohen  $d = 0.5$ ).<sup>39</sup> In high-resource settings, TAU is likely to be effective because these conditions are treated by highly trained and licensed mental health care professionals. In our study, like most LMICs, TAU consisted of diverse services with no established effectiveness on trauma-related symptoms provided by lay counselors with limited or no mental health education. Our effect sizes are similar to trials comparing interventions to controls or similar TAU conditions in other LMICs.<sup>33,35,40</sup> The results should be generalizable to other OVC populations because there were few exclusion criteria and participants were exposed to a wide range of traumatic events.

The trial had some important limitations. First, for financial and grant-life reasons, postassessments were completed only once, approximately 1 month after treatment completion. It is unknown whether the results were maintained over time and thus must be interpreted carefully. However, multiple trials in the United States have sustained superior outcomes during follow-up periods of 1 to 2 years.<sup>21–23</sup> An open trial in Tanzania using the TF-CBT also found improvements in psychological symptoms sustained at 3 and 12 months after treatment (all  $P < .001$ ).<sup>41</sup> Second, this was a single-blind study. At postassessment, assessors were masked; however, participants were aware of their own study status and could have divulged this or been biased based on expectations. Third, TF-CBT ideally includes regular caregiver participation. Most caregivers in our study were not involved because of livelihood activities, caring for other children, and/or lack of transport funds. Other trials have also found positive results with no caregiver involvement,<sup>42</sup> suggesting that this may not be critical. Fourth, the sample of the PTSD-RI validity study differed from the study population in terms of sex and sexual abuse as a common experience; however, most participants also reported other types of traumatic experiences. Finally, our functioning measure had many items that would be considered critical or basic, such as playing and bathing, resulting in a floor effect that made demonstration of change more difficult. Despite this, we observed a significant, though small, effect size.

Our results agree with other studies in the LMICs that have found that lay counselors can provide psychotherapeutic interventions with fidelity and effectiveness.<sup>33,40,43–46</sup> Our study found challenges with workload and availability of counselors, indicated by completion of only a mean of 7 sessions during a year. The literature is increasing on the challenges inherent in a task-sharing approach, including, among others, workload of the new tasks, lack of funding or infrastructure, and the incentives provided to ensure workforce retention.<sup>47</sup> The field needs to better understand how to create a place for trained lay counselors in the workforce and ensure the time needed to implement mental health treatments.



## Conclusions

Abuse, neglect, and violence among children present serious global health challenges. Evidence-based treatments, such as TF-CBT, are commonly conceptualized as specialized services only needed by a small percentage of the population,<sup>48</sup> with less specific interventions provided to larger numbers of children. However, research reveals that high numbers of OVC present with psychological distress,<sup>8,49,50</sup> which represents a highly prevalent need for specific services. Findings that nonspecific interventions are minimally effective for psychological problems in youth after conflicts<sup>33,36,38,45</sup> in combination with the current trial raise important questions for OVC programming. Further studies are needed to evaluate the effectiveness of widely funded psychosocial support interventions within OVC programs relative to interventions such as the TF-CBT for addressing mental health problems.

This is the first trial we are aware of that tested an evidence-based intervention specifically for OVC—a major population of concern in LMICs. Rigorous intervention trials for youth in LMICs are few compared with adult populations, despite the fact that 90% of the world's children and adolescents live in LMICs.<sup>51</sup> Close collaboration by funders, programmers, and researchers is needed so that the progress in child mental health does not lag behind that of adults.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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**At a Glance**

- Orphans and vulnerable children (OVC) are at high risk for experiencing trauma and related psychosocial problems, yet little is known about what interventions may be effective.
- Purpose: To evaluate the effectiveness of lay counselor–provided trauma-focused cognitive behavioral therapy (TF-CBT) compared with treatment as usual to address trauma and stress-related symptoms among OVC in Lusaka, Zambia.
- Results: Trauma symptom score decreased by 81.9% among those who received TF-CBT, a statistically significantly greater reduction than the 21.1% reduction in symptoms among the treatment as usual group, resulting in an effect size of 2.39 (large effect).
- The TF-CBT adapted for Zambia substantially decreased trauma and stress-related symptoms and produced a smaller improvement in functional impairment among OVC.

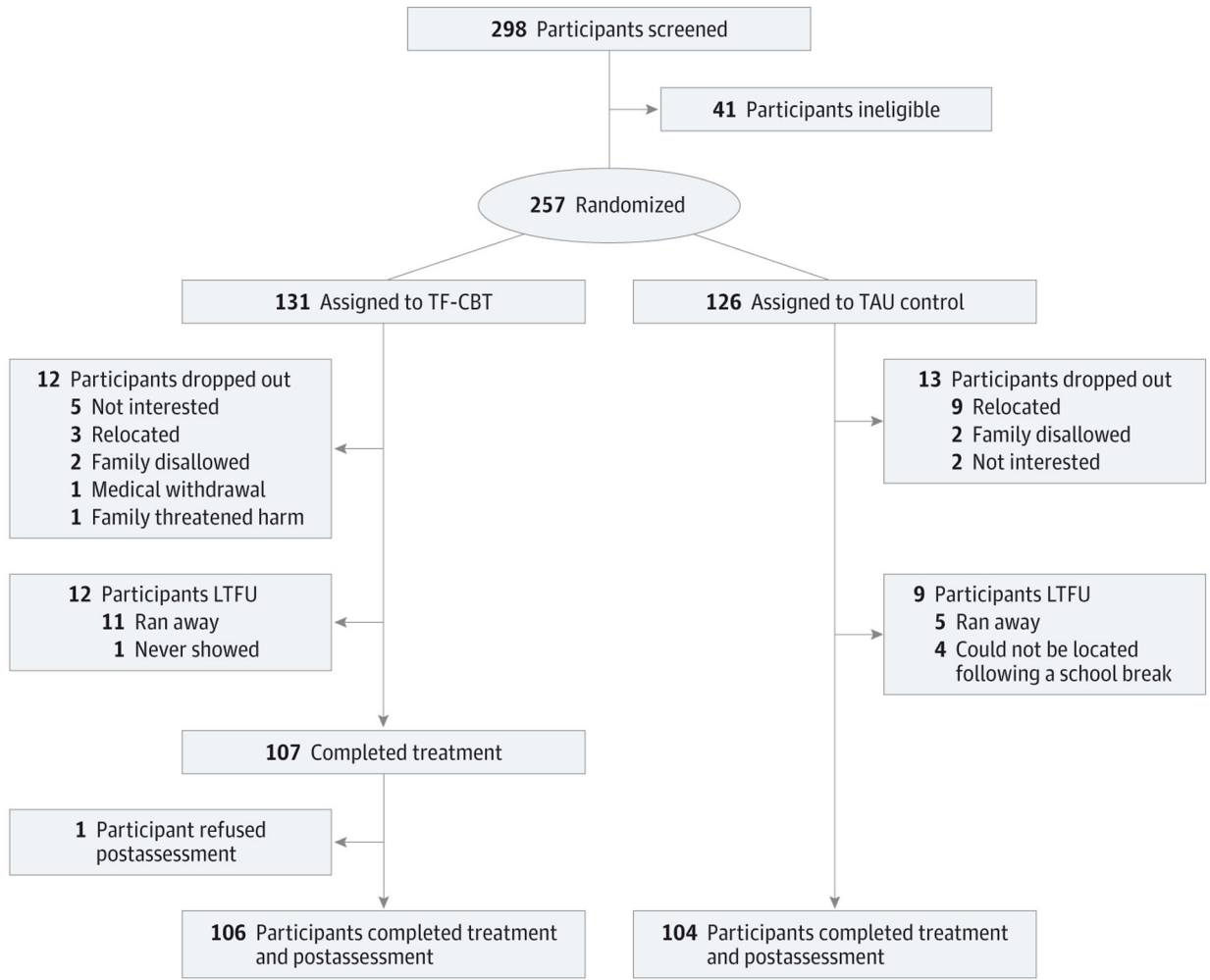
**Box.****Description of TF-CBT Components and TAU Services**

<b>TF-CBT<sup>a</sup></b>	
Component	Enhancing safety skills
Brief description	Developing a safety plan linked to the trauma experience and possible future challenges
Psychoeducation (introduction)	<b>TAU</b>
Program information (duration, content, and expectations)	Site
Normalization of symptoms and problems	Services offered <sup>b</sup>
Parenting skills	Barefeet (community outreach)
Praise	Psychosocial counseling
Rewards	Peer education
One-on-one time	Prevention of HIV and AIDS
Relaxation	City of Hope (community school or residence)
Strategies to reduce physiological tension and stress	Education and assistance (school fees)
Affective modulation	Nutrition
Identifying feelings, linking them to situations, and rating intensity of emotions	Room and board for adolescent girls
Cognitive coping	Kaunda Square Ministry of Health Clinic
Distinguish and connect thoughts, feelings, and behaviors	Primary health care services
Evaluate and restructure thoughts to be more accurate and/or helpful	St Paul's School
Trauma narrative (imaginal gradual exposure)	Education
Facing feared and/or avoided traumatic memories through writing or drawing	Psychosocial and guidance counseling
Identifying related thoughts and feelings	Ngombe home-based care
Restructuring unhelpful thoughts from the trauma narrative	Medical support and referrals
In vivo exposure (live exposure)	Support groups
Facing innocuous triggers or reminders in the client's environment	Community outreach
Conjoint session	
Sharing of the trauma narrative and restructured thoughts between child and supportive caregiver (if available)	

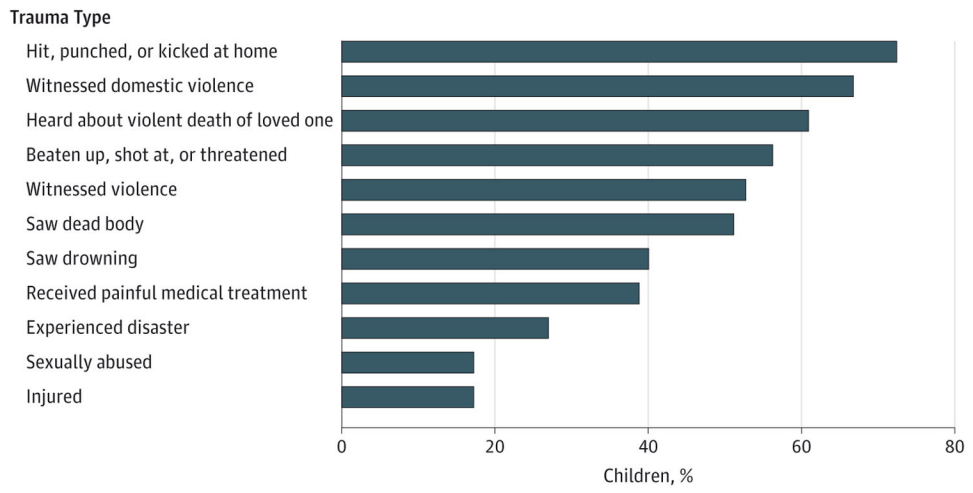
Abbreviations: HIV, human immunodeficiency virus; TAU, treatment as usual; TF-CBT, trauma-focused cognitive behavioral therapy.

<sup>a</sup>See Cohen et al<sup>16</sup> for a more detailed description.

<sup>b</sup>In addition to site-specific services received, additional services included spiritual care, medical, HIV and AIDS treatment, and/or voluntary counseling and testing.



**Figure 1.** Flowchart of Study Participants Siblings were randomized together to the same treatment group. LTFU indicates lost to follow-up; TAU, treatment as usual; TF-CBT, trauma-focused cognitive behavioral therapy.



**Figure 2.** Proportion of the 257 Children Reporting Lifetime Experience for Each Trauma Type at Baseline

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**Table 1.****Baseline Sociodemographic and Clinical Characteristics of the 257 Study Children<sup>a</sup>**

<b>Characteristic</b>	<b>TF-CBT Group (n = 131)</b>	<b>TAU Group (n = 126)</b>
Male sex	68 (51.9)	61 (48.4)
Age, mean (SD) [range], y	14.02 (2.77) [5–18]	13.29 (2.99) [5–18]
Currently in school	111 (84.7)	112 (88.9)
Highest grade of school achieved		
1–3	41 (31.3)	40 (31.8)
4–5	21 (16.0)	33 (26.2)
6–7	42 (32.0)	36 (28.6)
8–9	26 (19.9)	15 (11.9)
Ethnicity		
Ngoni	29 (22.1)	26 (20.6)
Bemba	42 (32.1)	39 (31.0)
Other	60 (45.8)	59 (46.8)
Primary caretaker		
Mother or father	54 (41.2)	37 (29.4)
Someone else	75 (57.3)	86 (68.3)
No one	2 (1.5)	3 (2.4)
Mother alive	85 (64.9)	70 (55.6)
Father alive	70 (53.4)	61 (48.4)
Score, mean (SD) [range]		
Trauma symptoms	1.88 (0.52) [1.0–3.24]	1.75 (0.45) [1.0–3.03]
Functional impairment	0.85 (0.67) [0–2.94]	0.79 (0.64) [0–2.41]
No. of trauma types experienced, mean (SD) [range]	4.96 (2.35) [0–11]	5.18 (2.08) [0–10]
Time between assessments, mean (SD) [range], d	150.83 (67.51) [47–384]	116.03 (56.43) [31–328]

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

<sup>a</sup>Table includes all available data at baseline. Multiple imputation not conducted for data included in this table. Data are presented as number (percentage) of children unless otherwise indicated.

Table 2.

Predicted Mean Outcome Scores, Mean Change Scores, and Between-Treatment Group Effect Sizes, Adjusted for Clustering by Counselor, Site, and Participant

Outcome	TF-CBT Group (n = 131) <sup>a</sup>				TAU Group (n = 126) <sup>a</sup>				P Value <sup>c</sup>	Effect Size <sup>d</sup>	
	Mean (95% CI) <sup>b</sup>		Change, %	Mean Change (95% CI) <sup>b</sup>	Mean (95% CI) <sup>b</sup>		Change, %	Mean Change (95% CI) <sup>b</sup>			
	Baseline	Postassessment			Baseline	Postassessment					
Trauma symptoms <sup>e</sup>	1.88 (1.73 to 2.03)	0.34 (0.20 to 0.48)	-81.9	-1.54 (-1.81 to -1.27)	1.75 (1.58 to 1.93)	1.38 (1.20 to 1.57)	-21.1	-0.37 (-0.57 to -0.17)	-1.17 (-1.45 to -0.89)	<.001	2.39
Functional impairment <sup>e</sup>	0.85 (0.65 to 1.12)	0.09 (0.08 to 0.12)	-89.4	-0.76 (-0.98 to -0.54)	0.79 (0.58 to 1.06)	0.25 (0.22 to 0.27)	-68.3	-0.54 (-0.80 to -0.29)	-0.22 (-0.32 to -0.11)	<.001	0.34

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

<sup>a</sup>All 257 participants were included in the analysis after multiple imputation procedures for loss to follow-up and item-level missing data.

<sup>b</sup>The range for the trauma symptom and functional impairment outcomes was 0 to 4, with higher scores reflecting greater symptom severity and greater functional impairment, respectively. Estimates for mean, change, mean change, and mean change difference were calculated from the coefficients of the mixed-effects models accounting for clustering by participant, site, and counselor as described above after multiple imputation. The coefficients for the functioning model were back-transformed from the log scale by exponentiation.

<sup>c</sup>*P* is the significance level of the mean change difference from the mixed-effects model indicating statistical significance of the difference in change of outcome score between the treatment and control groups from baseline to postassessment.

<sup>d</sup>The Cohen *d* effect size was calculated by dividing mean change difference predicted from the unadjusted models (trauma symptom score, -1.17; functional impairment score, -0.22) by the pooled baseline SD (posttraumatic stress disorder score, 0.49; functional impairment score, 0.65). The absolute value of the effect size is presented.

<sup>e</sup>The trauma symptoms model was a linear mixed-effects model, and the functional impairment model was a generalized linear mixed-effects model with a log link. Both models included random effects of participant, site, and counselor. The fixed effects included treatment group, time, and an interaction term of treatment group × time. Adjusted models that included additional fixed effects to control for potential confounding were also estimated and are included in eTable 2 in Supplement 2. There was no substantial difference in statistical significance or effect sizes between the adjusted and unadjusted models for either outcome; therefore, we present the more parsimonious unadjusted models.