ORIGINAL ARTICLE

Controlled Trial of Psychotherapy for Congolese Survivors of Sexual Violence

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ABSTRACT

BACKGROUND

Survivors of sexual violence have high rates of depression, anxiety, and post-traumatic stress disorder (PTSD). Although treatment for symptoms related to sexual violence has been shown to be effective in high-income countries, evidence is lacking in low-income, conflict-affected countries.

METHODS

In this trial in the Democratic Republic of Congo, we randomly assigned 16 villages to provide cognitive processing therapy (1 individual session and 11 group sessions) or individual support to female sexual-violence survivors with high levels of PTSD symptoms and combined depression and anxiety symptoms. One village was excluded owing to concern about the competency of the psychosocial assistant, resulting in 7 villages that provided therapy (157 women) and 8 villages that provided individual support (248 women). Assessments of combined depression and anxiety symptoms (average score on the Hopkins Symptom Checklist [range, 0 to 3, with higher scores indicating worse symptoms]), PTSD symptoms (average score on the PTSD Checklist [range, 0 to 3, with higher scores indicating worse symptoms]), and functional impairment (average score across 20 tasks [range, 0 to 4, with higher scores indicating greater impairment]) were performed at baseline, at the end of treatment, and 6 months after treatment ended.

RESULTS

A total of 65% of participants in the therapy group and 52% of participants in the individual-support group completed all three assessments. Mean scores for combined depression and anxiety improved in the individual-support group (2.2 at baseline, 1.7 at the end of treatment, and 1.5 at 6 months after treatment), but improvements were significantly greater in the therapy group (2.0 at baseline, 0.8 at the end of treatment, and 0.7 at 6 months after treatment) ($P<0.001$ for all comparisons). Similar patterns were observed for PTSD and functional impairment. At 6 months after treatment, 9% of participants in the therapy group and 42% of participants in the individual-support group met criteria for probable depression or anxiety ($P<0.001$), with similar results for PTSD.

CONCLUSIONS

In this study of sexual-violence survivors in a low-income, conflict-affected country, group psychotherapy reduced PTSD symptoms and combined depression and anxiety symptoms and improved functioning. (Funded by the U.S. Agency for International Development Victims of Torture Fund and the World Bank; ClinicalTrials.gov number, NCT01385163.)

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Mental health problems such as depression, anxiety, and post-traumatic stress disorder (PTSD) are common in survivors of sexual violence.[1-6] In high-income countries, there are effective treatments for trauma related to sexual violence,[7-10] but these treatments have not been adequately tested in low-income, conflict-affected countries with few mental health professionals and low literacy rates. The few studies of effectiveness have had methodologic limitations, including a lack of controls and high attrition rates.[11]

Eastern Democratic Republic of Congo is a low-income, conflict-affected region in which political and economic instability are ongoing problems and nearly 40% of women have experienced sexual violence.[12] The development of effective mental health services has important implications for the recovery of sexual-violence survivors in the Democratic Republic of Congo and similar countries.

We evaluated an adaptation of group cognitive processing therapy provided by community-based paraprofessionals (psychosocial assistants), supervised by psychosocial staff at a nongovernmental organization (NGO) and by clinical experts based in the United States. Cognitive processing therapy has shown efficacy in high-income countries, with effects lasting for 5 or more years.[13-15] We evaluated the benefits of adding this therapy to services offered by workers trained only in case management and individual supportive counseling.

METHODS

SETTING, PARTICIPANTS, AND ASSESSMENT MEASURES

We selected 14 villages in South Kivu province and 2 villages on the border in North Kivu province, from among 23 villages served by three Congolese NGOs. Selection was based on accessibility, security, and the availability of psychosocial assistants. All psychosocial assistants had 1 to 9 years of experience providing case management and individual supportive counseling to survivors of sexual violence and at least 4 years of post–primary-school education. All underwent a 5-to-6-day training session conducted by the International Rescue Committee (IRC) in case management and specific topics, including counseling, family mediation, stress management, clinical care of survivors, and prevention of human immunodeficiency virus infection and other sexually transmitted diseases.

Using a mixed-methods approach described previously,[16] we selected, adapted, and tested measures. We conducted qualitative studies in three linguistically different communities to identify salient mental health problems of sexual-violence survivors. Abandonment and rejection by family and friends, concerns about providing for self and family, fear, and stigma were major issues. Informants described psychological symptoms that were consistent with depression, anxiety, and PTSD.

On the basis of these findings, we selected the Hopkins Symptom Checklist (HSCL-25)[17,18] to assess depression (15 items) and anxiety (10 items) and the PTSD Checklist — Civilian Version[19] to assess PTSD symptoms (16 items). The checklists were adapted and pilot-tested in each language group. Both the HSCL-25 and the PTSD Checklist have been used internationally with sexual-violence survivors[20] and have solid psychometric properties with conflict-affected samples[21-23]; locally derived psychometric properties of both measures are presented in the Supplementary Appendix, available with the full text of this article at NEJM.org. Participants rated the frequency of each symptom in the prior 4 weeks on a four-point Likert scale (with 0 denoting not at all, 1 a little bit, 2 a moderate amount, and 3 a lot). Average per-item scores were generated for each measure, with scores ranging from 0 to 3 and higher scores indicating greater severity. An average HSCL-25 score of 1.75 or higher and an average PTSD Checklist score of 1.75 or higher were considered to be predictive of clinically significant depression or anxiety and PTSD, respectively, on the basis of data from other conflict-affected populations.[24,25]

Assessment of functional impairment was based on the degree of difficulty in performing important tasks of daily living that were identified on the basis of qualitative data from the study villages, with the use of methods described elsewhere.[16,26] For each of 20 tasks, participants were asked to rate the degree of difficulty in performing the task on a five-point Likert scale (with 0 denoting no difficulty, 1 little difficulty, 2 a moderate amount of difficulty, 3 a lot of difficulty, and 4 often unable to perform the task). An average per-item score was generated for each participant, with scores ranging from 0 to 4 and higher scores indicating greater impairment. The

items used to assess depression, anxiety, and PTSD symptoms as well as functional impairment are shown in Table S3 in the Supplementary Appendix.

Women who had experienced or witnessed sexual violence (translated as "rape" locally) were eligible for the study if they had a total symptom score of at least 55 (i.e., an average score of 1 for each of 55 symptoms, comprising the HSCL-25 items, the PTSD Checklist items, and additional locally relevant symptoms) and a functional-impairment score of at least 10 (i.e., dysfunction on at least half the activities). Suicidality that was judged by clinical staff to require immediate treatment was a criterion for exclusion. Study measures were translated into five local languages: Kibembe, Kifuliro, Kihavu, Mashi, and Swahili.

STUDY DESIGN

The 16 study villages, each with one psychosocial assistant, were grouped into blocks of 2 to 4 villages on the basis of proximity and shared language and were randomly assigned to provide cognitive processing therapy or individual support. After therapy training, one psychosocial assistant was excluded because training-based quizzes and skill observation raised competency concerns; therefore, the village in which she worked was excluded. The trial included 15 study villages (7 that provided therapy and 8 that provided individual support). The study protocol and statistical analysis plan are available at NEJM.org.

Recruitment occurred in December 2010. Psychosocial assistants reviewed their files of current and prior clients to identify women with clinically significant psychological problems. They invited the women to their offices, where research assistants, who were unaware of the village treatment assignments, obtained informed consent and administered the study questionnaires. Interviews were continued until 28 to 30 eligible women had been identified per village. Questionnaires were reviewed to confirm eligibility, and lists of eligible women were given to the psychosocial assistants, who invited the women to participate. In villages that provided therapy, psychosocial assistants recruited up to 24 participants (with a maximum of 8 women per treatment group). Psychosocial assistants ordered the list of eligible women in their village by proximity to the NGO office and selected those who were closest, continuing down the list until treatment groups were filled. In villages that provided individual support, where there was no limit to the number of participants, psychosocial assistants invited all eligible women.

The intervention period lasted from April through July 2011. Follow-up data were collected within 1 month after treatment ended and 6 months later. For both follow-up assessments, two research assistants, who were unaware of the village treatment assignments, spent 1 week in each village assessing the study participants. Scores for PTSD symptoms and combined depression and anxiety symptoms were the primary outcomes, and the score for functional impairment was a secondary outcome.

Institutional review boards at the Johns Hopkins Bloomberg School of Public Health and Kinshasa School of Public Health approved the protocol. Study participants provided oral informed consent, and none received compensation. The research was sponsored by the U.S. Agency for International Development Victims of Torture Fund and the World Bank. The sponsors had no role in the trial design or conduct; the collection, management, analysis, or interpretation of data; or manuscript preparation, review, or approval. All authors vouch for the completeness and accuracy of the data and analysis and the fidelity of the study to the protocol.

TREATMENTS

Individual Support

Psychosocial assistants in the comparison villages provided access to individual support. When women were informed of their eligibility, psychosocial assistants invited them to receive individual support services as desired, including psychosocial support and economic, medical, and legal referrals. Psychosocial assistants were available throughout the treatment period for women who sought their services. IRC supervisors monitored the services provided by means of monthly visits and reviews of interim monitoring forms.

Therapy

Cognitive processing therapy is a protocol-based therapy for treating depression, anxiety, and PTSD in sexual-violence survivors.[9,27-29] The group format was chosen to reach large numbers of women. We used the cognitive-only model (i.e., without a trauma narrative) because its efficacy is similar to that of the full version of the therapy,[14] while

providing greater ease of administration in groups and greater retention by participants.[13,27,28] The treatment included 1 individual session (1 hour) and 11 sessions with six to eight women per group (2 hours each). Each psychosocial assistant concurrently led three groups. Participants in the therapy group had access to the psychosocial assistants as desired outside the therapy.

Psychosocial assistants who provided therapy underwent 2 weeks of in-person training with trainers based in the United States (the fourth and fifth authors), with the use of a manual[30] that was adapted and translated locally. Ongoing supervision was provided through a multitiered supervision system that was first used in Uganda[31] and subsequently expanded.[32] Congolese psychosocial supervisors who were employees of the IRC provided direct supervision to psychosocial assistants through weekly telephone or in-person meetings; a bilingual clinical social worker trained in the United States provided in-country supervision and communicated with the U.S. trainers through weekly calls for supervision and quality assurance. Fidelity to the therapy protocol was assessed with the use of checklists of key treatment elements and global ratings of treatment knowledge and skills, as observed by supervisors during group sessions.

The therapy was adapted for illiterate participants and those potentially exposed to ongoing violence. The adaptations included an initial individual psychoeducational session, oral completion of assignments during group sessions, and simplification of materials to facilitate understanding and memorization. Further details about modifications are presented in the Supplementary Appendix.

STATISTICAL ANALYSIS

Assuming a 20% dropout rate, we calculated that enrollment of 180 participants in each study group would provide 80% power to detect at least a 0.5-point difference between groups with respect to the reduction in average symptom scores, adjusting for a variance-inflation factor of 2.0. After excluding one village that was to provide therapy, we expected fewer than 180 participants in the therapy group.

Baseline characteristics were compared between study groups with the use of the chi-square test and Student's t-test. Factors associated with loss to follow-up were identified with the use of logistic regression; those at a significance level of less than 0.20 were used to generate weighting estimates to adjust for loss to follow-up (data were missing for 135 participants [33%] at the end of treatment and for 92 participants [23%] at 6 months after treatment). Indicators of treatment effect were derived by comparing mean changes in HSCL-25, PTSD Checklist, and functional-impairment scores between groups from baseline to each follow-up assessment. Analyses were performed on data from all participants, regardless of the level of participation. Item-level missing data were imputed on the basis of mean values for other items in the scale.

Random-effects models were used for hypothesis testing and to predict the relative risk of meeting the criteria for probable depression or anxiety or probable PTSD at each follow-up assessment.[33] Four random effects were evaluated: randomization block, village, assigned treatment group, and participant. Models with and those without the randomization block were not significantly different ($P=0.99$) according to the Hausman test,[34] so the three-level model was used. Time and treatment condition (therapy or individual support) were included as fixed effects. Effect sizes reflecting regression adjustments were calculated with the use of Cohen's d statistic,[35] which represents the mean between-group differences standardized with the use of the baseline pooled standard deviation. Effect sizes are equivalent to a z score of a standard normal distribution (i.e., an effect size of 1.0 would mean that the average symptom score for participants in the therapy group was 1.0 SD above the average symptom score for participants in the individual-support group).

All comparisons were prespecified, and all tests were two-sided. A P value of less than 0.05 was considered to indicate statistical significance. Analyses were conducted with the use of Stata software, version 12 (StataCorp).

RESULTS

STUDY PARTICIPANTS

A total of 494 women were screened for eligibility (Fig. 1). Of these women, 434 (88%) met the inclusion criteria; 7 women with severe suicidality requiring immediate assistance by psychosocial assistants and IRC staff were not deemed eligible. Of the 434 eligible women, 402 (93%) agreed to

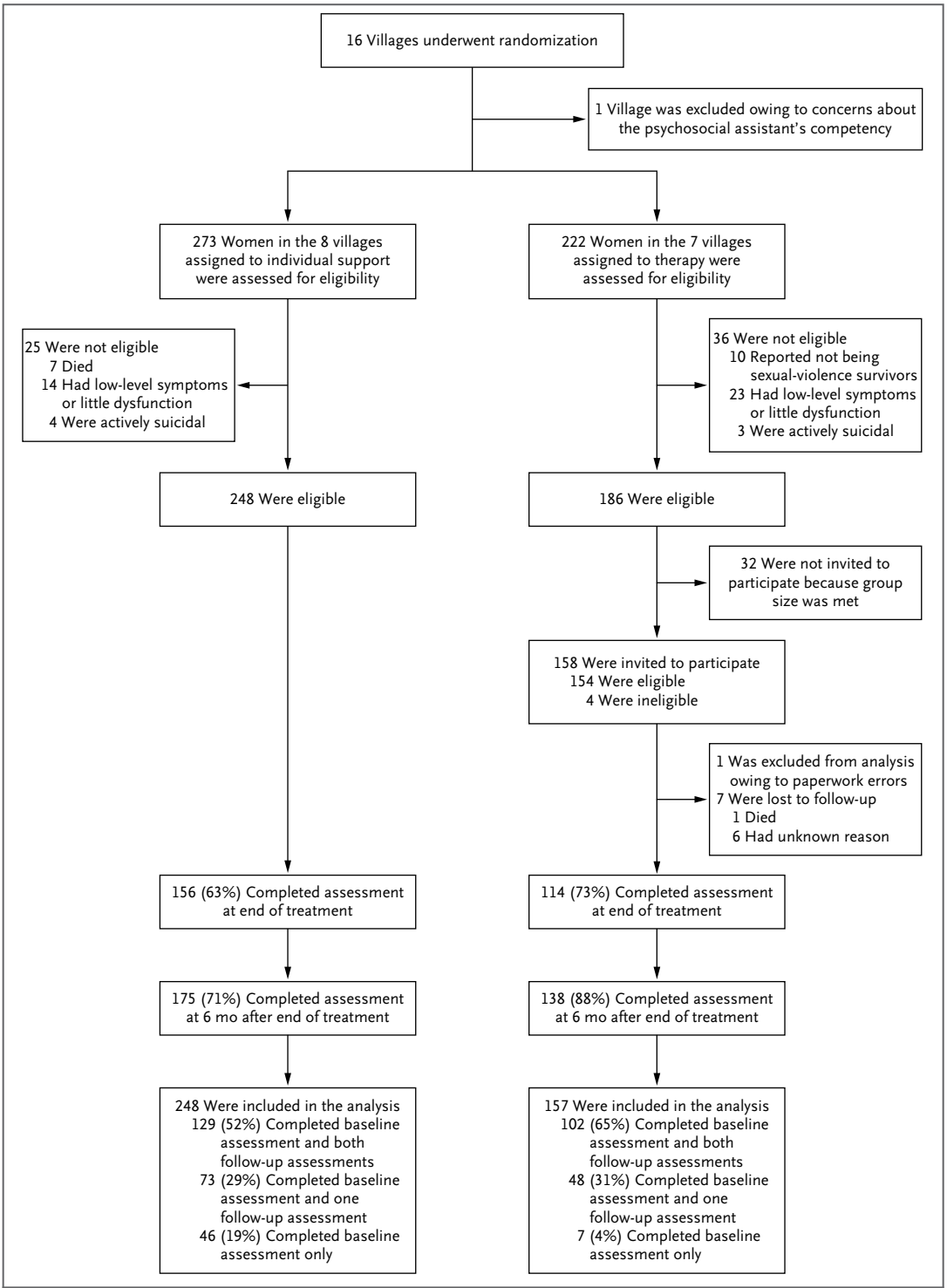

Figure 1. Enrollment and Follow-up of the Study Participants.

Because the sample was recruited from client lists of nongovernmental organizations serving survivors of sexual violence, we can assume that 100% of the sample had experienced rape. However, not all women wish to share this information, so it was not surprising that a small proportion (22 of 434 eligible women [5%]) reported witnessing but not experiencing rape. For 1 participant who received therapy, paperwork errors meant that the study identification (ID) could not be verified; therefore, this participant could not be included in any analysis.

participate. An additional 4 women who did not meet the inclusion criterion of a total symptom score of at least 55 were mistakenly recruited in one village that provided therapy; these women were included in the analysis. After the exclusion of 1 participant who received therapy owing to paperwork errors, the study included 405 women.

A total of 231 women (57%) completed all three assessments; 352 (87%) completed the baseline assessment and at least one follow-up assessment. Factors that were significantly associated with loss to follow-up were older age (with age as a continuous variable), assignment to individual support, pregnancy at baseline, experience with or witnessing of a wider range of traumas, and language spoken. Problems with security and cases in which the wrong women were interviewed reduced the number of follow-up assessments. Participants in the therapy group attended an average of 8.5 of 12 sessions offered, with 141 participants (90%) completing at least 9 sessions (defined as treatment completion). Women in the therapy group who missed a session were visited by psychosocial assistants to identify the reason for their absence and were encouraged to rejoin. A total of 182 participants in the individual-support group (73%) attended at least 1 session with the psychosocial assistant. Among these women, the average number of sessions attended during the treatment period was 5.

DEMOGRAPHIC CHARACTERISTICS

Despite regional instability, 80% of the women were living in their territory of origin. As compared with participants in the therapy group, those in the individual-support group were younger and less likely to be married, and they lived with fewer people (Table 1). Participants presented with clinically significant distress at baseline (Table 2), with participants in the individual-support group having higher symptom scores at baseline than those in the therapy group across all measures.

CLINICAL CHARACTERISTICS AND TREATMENT RESPONSE

Both the individual-support and therapy groups had significant improvements during treatment, with effects maintained at 6 months (Fig. 2). For PTSD symptoms (PTSD Checklist) and combined depression and anxiety symptoms (HSCL-25), participants in the therapy group had significantly greater improvements than those in the individual-support group (Table 2) at both follow-up assessments, with all treatment-effect sizes greater than 1.0.

Approximately 70% of participants in the therapy group met our criteria for probable depression or anxiety at baseline, with 10% or less meeting the criteria at either follow-up assessment (Table 2). In the individual-support group, the proportions of participants who met the criteria were as follows: 83% at baseline, 53% at the end of treatment, and 42% at 6 months after treatment. The relative risks of meeting the criteria for depression or anxiety and PTSD were significantly greater with individual support than with therapy at the end of treatment and 6 months after treatment ($P<0.001$ for all comparisons).

DISCUSSION

In our study, cognitive processing therapy, as compared with individual support alone, was effective in reducing PTSD symptoms and combined depression and anxiety symptoms and improving functioning in female survivors of sexual violence in eastern Democratic Republic of Congo. The ben-

Table 1. Characteristics of the Study Participants at Baseline.*

Variable	Therapy Group (N=157)	Individual-Support Group (N=248)
Age — yr†	36.9±13.4	33.8±12.4
Education completed — yr	1.8±2.8	2.3±3.1
People living in the home — no.†	7.4±3.2	6.8±3.3
Children for whom participant was responsible — no.	4.0±2.7	4.1±2.8
Language of assessment — no. (%)†		
Kibembe	0	46 (19)
Kifuliro	30 (19)	64 (26)
Kihavu	58 (37)	81 (33)
Mashi	45 (29)	0
Swahili	24 (15)	57 (23)
Marital status — no. (%)†		
Single	20 (13)	35 (14)
Married	93 (59)	107 (43)
Divorced	1 (1)	11 (4)
Separated	19 (12)	43 (17)
Widowed	24 (15)	52 (21)
Living in territory of origin — no. (%)	130 (83)	194 (78)

* Plus–minus values are means ±SD.
† $P<0.05$ for the difference between the groups.

Table 2. Effect of Therapy and Individual Support at the End of Treatment and 6 Months after the End of Treatment.*

Variable	Therapy Group	Individual-Support Group	Effect Size or Relative Risk (95% CI)†	P Value
HSCL-25 score for combined depression and anxiety‡				
Baseline	2.0±0.5	2.2±0.5		<0.001
End of treatment	0.8±0.6	1.7±0.7	1.8	<0.001
6 mo after end of treatment	0.7±0.6	1.5±0.6	1.6	<0.001
PTSD Checklist score‡				
Baseline	1.9±0.6	2.2±0.5		<0.001
End of treatment	0.8±0.6	1.7±0.8	1.4	<0.001
6 mo after end of treatment	0.7±0.6	1.5±0.7	1.3	<0.001
Functional-impairment score‡				
Baseline	1.7±0.7	2.5±0.8		<0.001
End of treatment	0.8±0.7	1.9±0.9	1.1	<0.001
6 mo after end of treatment	0.9±0.7	1.8±0.9	1.2	<0.001
Probable depression or anxiety — no./total no. (%)§				
Baseline	111/157 (71)	206/248 (83)		
End of treatment	11/114 (10)	82/156 (53)	7.3 (3.4–16.8)	<0.001
6 mo after end of treatment	12/138 (9)	73/175 (42)	4.6 (2.1–11.1)	<0.001
Probable PTSD — no./total no. (%)§				
Baseline	94/157 (60)	205/248 (83)		
End of treatment	9/114 (8)	85/156 (54)	12.3 (5.2–30.5)	<0.001
6 mo after end of treatment	12/138 (9)	73/175 (42)	5.5 (2.5–13.2)	<0.001

* Plus–minus values are means ±SD on the basis of available data at each time point. PTSD denotes post-traumatic stress disorder.

† The effect size is shown for the Hopkins Symptom Checklist (HSCL-25) score for combined depression and anxiety, the PTSD Checklist score, and the functional-impairment score, and the relative risk (95% CI) is shown for probable depression or anxiety and probable PTSD. Effect sizes (Cohen's d statistic) at the end of treatment and 6 months after treatment were generated by subtracting the regression coefficient for treatment effect from the observed mean in the individual-support group and dividing by the baseline pooled standard deviation (HSCL-25, 0.5; PTSD Checklist, 0.5; and functional assessment, 0.8). Regression analyses included all available data, with adjustment for variables that differed significantly between the study groups at baseline and that were related to the change in symptoms over time (age, pregnancy status, marital status [married vs. not married], language, duration of residence in the village, total number of people living in the home, number of children for whom the participant was responsible, and range of traumas that the participant had experienced or witnessed), as well as random effects for village, treatment group within a village, and individual participant over time.

‡ The range for the average HSCL-25 score and PTSD Checklist score was 0 to 3; the range for the functional-impairment score was 0 to 4, with higher scores indicating worse symptoms or greater impairment in functioning. In the therapy group, the number of participants who were lost to follow-up was 43 at the end of treatment (27%) and 19 at 6 months after treatment (12%). In the individual-support group, 92 participants (37%) and 73 participants (29%) were lost to follow-up at the respective assessments.

§ Women with average scores of 1.75 or higher on the HSCL-25 scale were classified as having probable depression or anxiety; women with scores of 1.75 or higher on the PTSD Checklist scale were classified as having probable PTSD. Case counts reflect mean scores of 1.75 or higher on the basis of available data at each time point. The relative risk is the risk of meeting the score criteria among participants in the individual-support group as compared with participants in the therapy group. Regression analyses included all available data, with adjustment for the same variables as those listed above.

efits were large and were maintained 6 months after treatment ended. Participants who received therapy were significantly less likely to meet the criteria for probable depression or anxiety or probable PTSD. Our findings are consistent with the results of trials conducted in high-income countries, both for cognitive behavioral interventions in general[36] and for cognitive processing therapy

specifically,[14,27] with effect sizes of 0.62 and 2.7 in the latter two studies.

Prior research has suggested that short-term therapies may not be effective for populations exposed to ongoing trauma or multiple severe traumas.[37,38] In our study, all villages reported at least one major security incident during the trial, including attacks, displacement due to fighting, and robbery by armed groups. In addition, there was concern that providing therapy to illiterate persons would be challenging. Our findings suggest that despite illiteracy and ongoing conflict, this evidence-based treatment can be appropriately implemented and effective.

Limitations of the study include baseline differences in symptom severity between study groups that may limit comparability. Randomization was performed within blocks of two to four villages grouped on the basis of language and proximity, with the assumption that villages close to one another would be similar; however, this assumption was not empirically confirmed. The small number of village clusters (six) made randomization less likely to result in comparability. There may also have been biases in recruitment that resulted in higher average symptom scores in villages that provided individual support because psychosocial assistants recruiting patients knew ahead of time whether they would be providing therapy or individual support. To assess whether higher baseline scores in the individual-support group biased the results, we performed sensitivity analyses restricted to women with baseline HSCL-25 scores higher than 2.0 (84 women in the therapy group and 171 in the individual-support group) and found that effect sizes remained greater than 1.0.

An additional limitation is the use of measures of unknown validity for identifying clinical cases of PTSD and combined depression and anxiety. Because symptoms of these disorders could be nonpathologic reactions to extreme circumstances, it is unclear what proportions of participants actually met clinical criteria. Although the clinical meaning of standard cutoff scores is therefore uncertain, the score itself can still be meaningfully interpreted: 1.75 indicates that women are reporting that symptoms occur, on average, nearly a "moderate" amount of the time (a score of 2.0). The symptom scores of participants in the therapy group decreased, on average, to less than "a little bit" (a score of 1), whereas the scores of participants in the individual-support group remained closer to a "moderate amount."

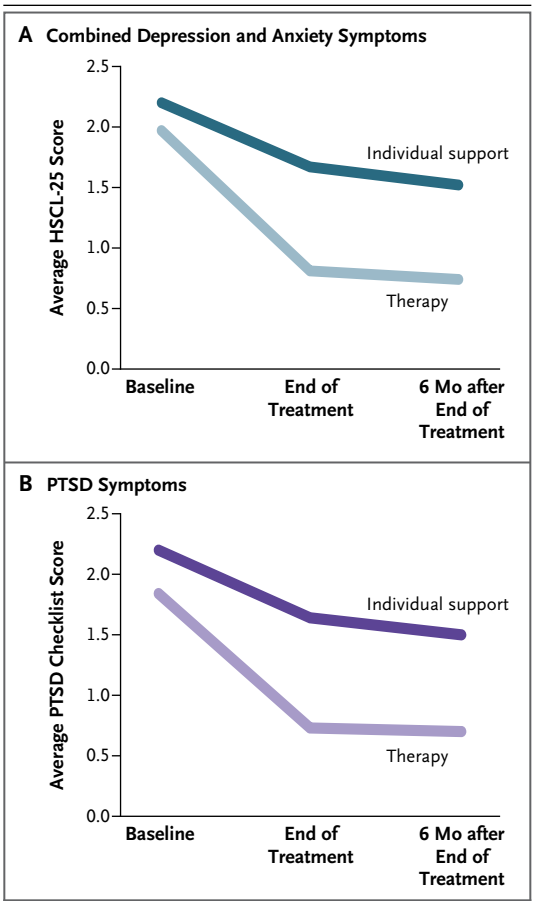

Figure 2. Symptom Scores at Trial Assessment Points.
Panel A shows the average Hopkins Symptom Checklist (HSCL-25) score for combined depression and anxiety, and Panel B shows the average PTSD Checklist score. Scores on both scales range from 0 to 3, with higher scores indicating worse symptoms. Scores of 1.75 or higher are consistent with clinically significant depression or anxiety and with PTSD, respectively. In both panels, $P<0.001$ for the comparisons at all three time points.

Finally, differences in how therapy and individual support were provided may affect our conclusions. Because therapy, but not individual support, was provided in groups, it is unclear how much of the treatment effect was due to the group context. Psychosocial assistants who provided therapy received greater supervision than those who provided individual support. Prior studies have shown that increases in the quality and quantity of clinical supervision can explain some treatment effects.[39,40] Participants in the therapy group attended, on average, a greater number of treatment sessions than did those in the individual-support group. Participants in the therapy group were also told that they could have additional

sessions with the psychosocial assistant. The time commitment required to receive therapy and the lack of reports of additional therapy sessions by the counselors suggest that their use of additional services was much less than that of participants in the individual-support group. The overall therapy effects must therefore be viewed as program effects, which include the therapy itself, the number of sessions, the group process, supervision systems, and possibly some additional counseling sessions.

This trial provides evidence of effectiveness of a mental health intervention for sexual-violence survivors in a low-income, conflict-affected setting. The results indicate that with appropriate training and supervision, psychotherapeutic treatments such as cognitive processing therapy can be successfully implemented and can have an effect in settings with few mental health professionals. This therapy holds promise as a community-based service for sexual-violence survivors in similar contexts and warrants confirmatory studies and scale-up evaluations.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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