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Effect of Shamiri Layperson-Provided Intervention vs Study Skills Control Intervention for Depression and Anxiety Symptoms in Adolescents in Kenya
A Randomized Clinical Trial

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IMPORTANCE Low-cost interventions for adolescent depression and anxiety are needed in low-resource countries such as those in Sub-Saharan Africa.

OBJECTIVE To assess whether Shamiri, a 4-week layperson-delivered group intervention that teaches growth mindset, gratitude, and value affirmation, can alleviate depression and anxiety symptoms in symptomatic Kenyan adolescents.

DESIGN, SETTING, AND PARTICIPANTS This school-based randomized clinical trial included outcomes assessed at baseline, posttreatment, and 2-week and 7-month follow-up from 4 secondary schools in Nairobi and Kiambu County, Kenya. Adolescents aged 13 to 18 years with elevated symptoms on standardized depression or anxiety measures were eligible. Intent-to-treat analyses were used to analyze effects. Recruitment took place in June 2019; follow-up data were collected in August 2019 and February 2020.

INTERVENTION Adolescents were randomized to the Shamiri intervention or to a study skills control. All adolescents in both conditions met in groups (mean group size, 9) for 60 minutes per week for 4 weeks.

MAIN OUTCOMES AND MEASURES Primary outcomes were depression (Patient Health Questionnaire–8 item) and anxiety (Generalized Anxiety Disorder–7 item) symptoms. Analyses of imputed data were hypothesized to reveal significant reductions in depression and anxiety symptoms for adolescents assigned to Shamiri compared with those in the study skills group.

RESULTS Of 413 adolescents, 205 (49.6%) were randomized to Shamiri and 208 (50.4%) to study skills. The mean (SD) age was 15.5 (1.2) years, and 268 (65.21%) were female. A total of 307 youths completed the 4-week intervention. Both Shamiri and study skills were rated highly useful (4.8/5.0) and reduced symptoms of depression and anxiety, but analyses with imputed data revealed that youths receiving Shamiri showed greater reductions in depressive symptoms at posttreatment (Cohen *d* = 0.35 [95% CI, 0.09-0.60]), 2-week follow-up (Cohen *d* = 0.28 [95% CI, 0.04-0.54]), and 7-month follow-up (Cohen *d* = 0.45 [95% CI, 0.19-0.71]) and greater reductions in anxiety symptoms at posttreatment (Cohen *d* = 0.37 [95% CI, 0.11-0.63]), 2-week follow-up (Cohen *d* = 0.26 [95% CI, −0.01 to 0.53]), and 7-month follow-up (Cohen *d* = 0.44 [95% CI, 0.18-0.71]).

CONCLUSIONS AND RELEVANCE Both the Shamiri intervention and a study skills control group reduced depression and anxiety symptoms; the low-cost Shamiri intervention had a greater effect, with effects lasting at least 7 months. If attrition is reduced and the clinical significance of outcome differences is established, this kind of intervention may prove useful in other global settings where there are limited resources, mental illness stigma, or a shortage of professionals and limited access to mental health care.

TRIAL REGISTRATION Pan-African Clinical Trials Registry Identifier: PACTR201906525818462

Visual Abstract

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Supplemental content

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Adolescent depression and anxiety account for 45% of the global burden of disease in youths aged 10 to 24 years,[1] based on worldwide estimates per disability-adjusted life-years, and are linked to important medical and life outcomes.[2,3] Both are prevalent in Sub-Saharan Africa,[4] but youths with these problems in Sub-Saharan Africa may not find help. Few mental health professionals exist,[5,6] and social stigma surrounding mental illness prevents help seeking.[7] Attempts to improve the psychological well-being of youths in Sub-Saharan Africa have had mixed success.[8,9] As the population of Sub-Saharan Africa becomes increasingly youthful,[10,11] developing interventions to overcome these barriers is a global health priority.[12]

One approach to expanding access to care may involve using brief theory-driven treatments that are sometimes called *wise interventions*.[13,14] Wise interventions differ from most evidence-based treatments in that they (1) are often delivered by laypersons rather than trained clinicians, an approach the World Health Organization recommends for low-resource settings,[15,16] (2) focus on simple psychological concepts rather than behavioral and cognitive skills, (3) are often delivered in nonclinical settings, and (4) invoke positive human attributes and principles rather than psychopathology. One example is growth-mindset intervention, which conveys the concept that one's traits and characteristics are malleable and can be improved via effort[17-19] and has been shown in US samples to reduce symptoms of depression and anxiety and to improve functioning.[18-21] Similar effects have been found in the US for gratitude interventions, which teach individuals to notice and appreciate good things in their lives and express their gratitude.[22] A third form of wise intervention is value affirmation: encouraging individuals to identify and reflect on their self-defining values and plan actions consistent with those values.[23]

Given the apparent clinical, conceptual, and practical advantages of these 3 simple interventions, our multicultural Kenya-US team brought elements of the 3 together to form a combined intervention for anxiety and depression symptoms in Kenyan youths. This intervention, Shamiri (Kiswahili for *thrive*), is designed for implementation with adolescents meeting in groups led by trained laypersons. A preliminary proof-of-concept trial tested Shamiri with 51 Kenyan youths (aged 14-17 years) who showed elevated anxiety and/or depression symptoms.[19] Youths randomly assigned to Shamiri (n = 28) showed significantly greater reductions in depression and anxiety symptoms than youths randomized to a study skills control (n = 23).[24] That study was weakened by small sample size and limited follow-up.

Here, we built on that initial pilot by conducting a trial with a large sample and follow-up extended to 7 months. We predicted that symptomatic adolescents randomized to Shamiri would experience greater reductions in depression and anxiety symptoms than those assigned to the study skills control. We chose a study skills control intervention because such control conditions provide a more rigorous comparison than passive controls (eg, waiting list).[25,26]

Key Points

Question Can scalable psychological interventions that invoke simple psychological principles, rather than explicit references to psychopathology, alleviate depression and anxiety symptoms in Kenyan adolescents?

Findings In this randomized clinical trial of 413 high school students, Shamiri, a 4-week layperson-delivered group intervention that teaches growth mindset, gratitude, and value affirmation, appears to significantly reduce depression and anxiety symptoms in symptomatic adolescents compared with a control group, although both groups showed symptom reductions. Effects persisted at 7 months.

Meaning Simple psychological interventions that focus on positive human attributes rather than psychopathology, are delivered by laypersons, and are developed through multicultural collaboration may reduce depression and anxiety symptoms and should be considered for use in low-resource settings.

Methods

Study Setting

This single-blind, parallel-group randomized clinical trial took place in 4 Kenyan public secondary schools in Nairobi and Kiambu County that differed markedly on several characteristics, providing sample diversity. The study protocol is published elsewhere[27] and is available in Supplement 1. The characteristics included sex, location, and tribe (eAppendix 1 in Supplement 2). School A (all boys) and school B (all girls) had a student body drawn from all counties in Kenya. School C (all girls) and school D (boys and girls) were day schools serving primarily local students.

Participants

All students aged 13 to 18 years were eligible if they had elevated scores on baseline depression or anxiety symptom measures (below). The study design, which was approved by the Maseno University Ethics Review Committee and the National Commission for Science, Technology, and Innovation, was consistent with the requirements of the Declaration of Helsinki.[28] Parental consent was sought for adolescent minors (age <18 years) per research ethics procedures approved by the Maseno University Ethics Review Committee. All students provided written informed consent or assent before screening. This study was preregistered prior to participant enrollment in the Pan-African Clinical Trials Registry (PACTR201906525818462).

Procedures

Recruitment and Resulting Sample

From June 20, 2019, through July 5, 2019, 2192 students completed baseline questionnaires in their classrooms. In all 4 schools, administrators required that all willing students participate in screening: 715 of 2192 youths assessed for eligibility met the inclusion criteria. In 2 schools, more students met criteria than could be accommodated and we did not know a priori how may would meet cutoffs (eAppendix 2 in

Supplement 2). As a result, we randomly selected 180 of 211 students at school A and 192 of 316 students at school B. In total, 560 total students were invited across the 4 schools (schools differed in population). We used a random assignment code generated in R version 4.0.3 (R Foundation), stratified by sex and form (school grade). During the baseline screening, all students were invited to contact the study team if they had questions or needed support, and a tiered system of support was made available (eAppendix 2 in Supplement 2). Staff estimated that 40 students contacted the study team with questions and concerns.

Group Leader Selection, Training, and Group Assignment

Lay group leaders (aged 18-26 years; 8 of 13 female [61.54%]) for the Shamiri and study skills groups were Kenyan high school graduates fluent in English and Kiswahili who were hired and trained by the study team. They were selected via a semistructured interview that gauged past experiences and interpersonal skills; they underwent 10 hours of training (trial protocol in Supplement 1 and previously published[29]), covering content of Shamiri and study skills interventions, and including counseling techniques, role play of intervention and control content, and safety protocols. Leaders were randomly assigned to groups; all leaders led both Shamiri and study skills groups. Because all leaders delivered Shamiri and study skills content, the study team led weekly supervision meetings for both conditions (eAppendix 3 in Supplement 2).

Group Sessions

Groups included 7 to 15 youths (mean [SD] group size, 9 [2.3]). Each group had 4 weekly meetings lasting 1 hour, which were conducted in a combination of English and Kiswahili because all participants spoke both languages. Groups met in the schools during the afternoon time designated for extracurriculars. Group sessions were conducted between July 1, 2019, and August 2, 2019, with 7-month outcome assessment on July 28, 2020.

Intervention Arms

Shamiri

The Shamiri intervention included 3 modules: growth mindset (2 sessions), gratitude (1 session), and value affirmation (1 session). In session 1, group leaders explained growth and personal improvement, and participants learned about neuroplasticity through a video and article and heard testimonials about personal growth. They wrote stories about their experiences of personal growth and about how they could use growth to solve a specific problem. In session 2, participants discussed strategies for overcoming challenges, learned a framework for problem solving, wrote a letter to a friend explaining what they had learned, and wrote about applying problem solving to a specific and current life challenge. In session 3, students discussed the importance of gratitude, then wrote a gratitude letter to someone. Participants also listed 3 things for which they were grateful on each day of the following week. In session 4, participants learned about values (called virtues), selected (from a list) values that were important to them, wrote about a time when they had demonstrated one of their values, considered how they might live one of their values in the future, and planned a specific action to promote that value. eAppendix 4 in Supplement 2 contains intervention materials.

Study Skills Control

The study skills control condition was developed, in collaboration with Kenyan educational and research experts, to help students address the intense academic expectations of secondary school, thought to be stressful and potentially a source of depression and anxiety symptoms. The skills included note-taking, effective study strategies, time management, and the study cycle. To control for nonspecific aspects of the intervention, the study skills and Shamiri intervention sessions had the same structure (ie, didactics, exercises, discussions, and homework) and equal duration. See eAppendix 2 in Supplement 2 for study skills control development and eAppendix 4 in Supplement 2 for intervention materials.

Intervention Fidelity

Intervention fidelity was assessed using session audio recordings, via a rubric (eAppendix 5 in Supplement 2) to evaluate layperson adherence to and competence in protocol components. Two independent raters, who were not affiliated with the study team, independently rated a randomly selected 10% of sessions. Interrater agreement was assessed using Gwet AC2 for ordinal ratings using the *rel* package in R version 4.0.3 (R Foundation).[30] Mean ratings (maximum, 7.00) and AC2s (with 1.0 indicating perfect reliability) for each domain, all in the acceptable range, were 6.65 (AC2 = 0.84) for delivering protocol content, 6.76 (AC2 = 0.87) for completing specific tasks (eg, distributing worksheets), 6.18 (AC2 = 0.95) for thoroughness, 6.03 (AC2 = 0.95) for skillfulness, 6.26 (AC2 = 0.96) for clarity, and 6.11 (AC2 = 0.84) for including content exclusively from the relevant session protocol.

Outcomes

Timing of Assessments

Outcome measures were administered at baseline, midpoint (after 2 weeks), end point (after 4 weeks), and at 2-week and 7-month follow-up. Prior to and during the study, it appeared that national education regulations might ban research activity beyond 2 weeks postintervention, so we did not preregister a later assessment on the Pan-African Clinical Trials Registry. The ban occurred but was eventually lifted, permitting a 7-month follow-up assessment with all the study participants whom we could locate (n = 118 for Shamiri; n = 105 for study skills).

Primary Outcomes: Depression and Anxiety

The primary outcome was change in depression and anxiety symptoms from baseline to the 4-week end point. To qualify for the study, participants had to self-report elevated symptoms of anxiety or depression. We assessed depression symptoms with the Patient Health Questionnaire–8 item (PHQ-8); the 8-item version of the PHQ-9.[31] Per the study protocol,[27] we used the PHQ-8 because school administrators believed the societal stigma associated with the suicidal ideation item

might upset or alienate students. PHQ-8 scores are highly correlated with PHQ-9 scores and have the same cutoffs for depression severity.[32] Scores range from 0 to 24 (most severe symptoms). Psychometrics of the PHQ have been reported for adolescent and adult community samples in Kenya,[33,34] and the measure has been used in recent trials with Kenyan youths.[24,35] Cronbach α was 0.78 in the present sample. We used cutoff norms from PHQ studies with adolescents in the US[31] and in Kenya,[24,33] requiring a score of 15 or higher (moderately severe to severe depression symptoms).[31]

We assessed anxiety symptoms with the Generalized Anxiety Disorder-7 item (GAD-7).[36] GAD-7 scores range from 0 to 21 (most severe symptoms). The GAD-7 has been used and has met psychometric standards in prior studies with Kenyan adolescents.[33,35] Cronbach α was 0.82 in the present sample. We used cutoffs from GAD-7 studies with adolescents in the US[36] and in Kenya,[24,33] requiring a score 10 or higher (moderate to severe anxiety symptoms).[36]

Secondary Outcomes: Feasibility and Acceptability

At the end of the last session, participants completed a program evaluation survey. On a scale of 1 to 5, participants rated "How helpful was the program as a whole to you?" and "How likely would you be to recommend the program to a friend?"

Power Analysis

Per study protocol,[27] we conducted a power analysis using Optimal Design[37] to estimate sample size required for power of 0.80 to detect an effect of $d = 0.30$ with $\alpha = .05$ and 5 measurement points: we arrived at 200 participants per condition, assuming 10% attrition. We invited 560 participants to participate, assuming that approximately 30% of those eligible would not be available for or wish to participate.[27]

Data Description: Nesting, Missingness, and Imputations

Our data had 4 levels of clustering: school (level 4), group leader (level 3), groups (level 2), and participant (level 1). Because a group leader could lead multiple groups (groups in each school met on different days), they were cross-classified in an unstructured manner. Groups were strictly nested within group leaders as were participants within groups (structured cross-classification). See eAppendix 6 in Supplement 2.

To address attrition, we conducted multiple imputations of the primary outcome measures (ie, depression and anxiety symptoms) using the *mice* package[38] in *R* version 4.0.3 (R Foundation) under the assumption that data were missing at random. We conducted sensitivity analyses, using the δ method,[39] imputing under the assumption that data were missing not at random. The results held up for situations with data missing not at random in which we overestimated the missing values (ie, assigned higher values to missing data). For situations with data missing not at random in which imputations underestimated missing values, our results held up qualitatively, although some of the treatment differences were no longer significant (eAppendix 6 in Supplement 2).

Statistical Analysis

Given the hierarchical nature of our data, we ran random-intercept linear mixed-effects models with the *lme4* package[40] in *R* version 4.0.3 (R Foundation) with crossed random effects for schools and group leaders and strict hierarchical nesting for observations in participants, participants in groups, and groups in group leaders. This addressed dependencies that may have arisen from the nested design and adjusted standard errors accordingly. We operationalized our primary question of interest: differences in symptoms between the 2 conditions (with Shamiri as reference) at different time points as a time × condition interaction. Time was coded as a categorical variable with the 4-week end point acting as the reference point; the main effect of condition was estimated as the difference between Shamiri vs study skills control at end point. Because the variables sex and form (school grade) were used for stratified randomization, we included them as covariates in our model, thus addressing any dependencies that may have arisen during randomization.[41] We plotted the primary effects of condition × time (as marginal means) and conducted pairwise comparisons for the effects of condition at the end point and at 2-week and 7-month follow-up. We used inference provided by the package *lmerTest*.[42] Analyses were done on 7 imputed data sets and we pooled results. Details of the statistical analyses, plus underlying *R* code and explanations, are in eAppendix 6 in Supplement 2.

Because of rather high attrition, we ran 2 models for each primary outcome. First, per our protocol, we used an intent-to-treat approach including all randomized participants in our analyses. Missing data were imputed 7 times as described earlier. Second, we ran models for actual observations (ie, unimputed). Because estimation of variance of the random effects hinges on the number of groups at each nesting level and because our highest nesting level (school) included only 4 groups, we conducted sensitivity analyses by building models with school introduced as a covariate. We further extended the random intercept models to random slope models as a sensitivity check. These sensitivity analyses and their results are described in eAppendix 6 in Supplement 2. Results from our random intercept models held up for these sensitivity models. We used mean gain scores (Cohen *d*) pooled from the imputations to calculate effect sizes for changes in depressive and anxiety symptoms. Finally, clinically reliable change thresholds were calculated using $s\sqrt{(1 - r)} \times 1.96$,[43,44] using SDs at baseline and reliability (r) from psychometric publications for the PHQ-8 and GAD-7 administered to Kenyan adolescents.

Results

In total, 205 adolescents (mean [SD] age, 15.4 [1.2] years) were randomized to Shamiri and 208 adolescents (mean [SD] age, 15.7 [1.2] years) were randomized to study skills (**Figure 1**). Baseline characteristics of the 413 participants (268 female [65.21%]) are in the **Table** (eAppendix 7 in Supplement 2 shows characteristics of all adolescents assessed at baseline). No significant group differences emerged on baseline demo-

graphic or symptom measures. Of 413 youths, 310 (75.06%) completed midpoint assessment, 307 (74.33%) completed end point assessment, 244 (59.07%) completed 2-week follow-up assessment, and 223 (54.00%) completed 7-month follow-up assessment (Figure 1).

Treatment Outcomes

Depression and Anxiety Symptoms at End Point

The model using imputed values revealed significant differences in depression symptoms between Shamiri and study skills control at end point (B = 1.11 [95% CI, 0.15-2.07]; t = 2.27; df = 1282.54; P = .02). The model using only unimputed values revealed similar significant differences in depression symptoms (B = 1.24 [95% CI, 0.16-2.31]; t = 2.26; df = 761.36; P = .02). Similarly, youths in Shamiri experienced greater declines in depression symptoms from baseline to end point than control group youths (Cohen d = 0.35 [95% CI, 0.09-0.60]; **Figure 2** and eAppendix 8 in Supplement 2).

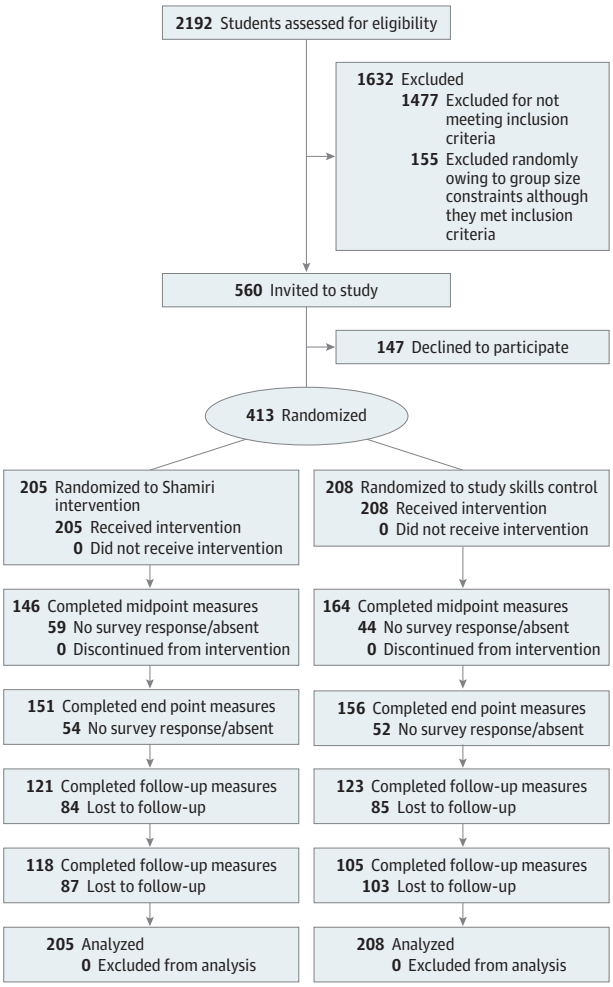
The model using imputed values revealed significant differences in anxiety symptoms between Shamiri and study skills control at end point (B = 1.37 [95% CI, 0.35-2.39]; t = 2.63; df = 109.07; P = .009). The model using only unimputed values revealed similar significant differences in anxiety symptoms (B = 1.68 [95% CI, 0.65-2.70]; t = 3.21; df = 109.07; P = .002). Similarly, youths in Shamiri experienced greater declines in anxiety symptoms from baseline to end point than youths in the control group per the model using unimputed values (Cohen d = 0.37 [95% CI, 0.11-0.63]; Figure 2 and eAppendix 8 in Supplement 2).

Depression and Anxiety Symptoms at 2-Week and 7-Month Follow-up

Both models using imputed and unimputed data showed nonsignificant differences in depressive symptoms at 2-week follow-up between Shamiri and study skills groups (imputed values model: B = 0.82 [95% CI, −0.19 to 1.83]; t = 1.58; df = 273.78; P = .11; unimputed values model: B = 1.14 [95% CI, −0.07 to 2.33]; t = 1.85; df = 974.37; P = .06). Thus, although youths in the Shamiri group showed lower symptoms than control group youths at 2-week follow-up, this difference was not significant. For anxiety symptoms, the model using imputed data revealed a significant difference at 2-week follow-up between the Shamiri and study skills groups (imputed values model: B = 1.01 [95% CI, 0.01-2.00]; t = 1.99; df = 161.73; P = .048; unimputed values model: B = 1.07 [95% CI, −0.076 to 2.19]; t = 1.85; df = 329.48; P = .07). Similarly, anxiety symptoms were reduced significantly more for youths in Shamiri than for youths in the control group at 2-week follow-up (Figure 2 and eAppendix 8 in Supplement 2).

Both models using imputed and unimputed data revealed significant differences in depressive symptoms at 7-month follow-up between youths in the Shamiri and study skills groups (imputed values model: B = 1.68 [95% CI, 0.53-3.03]; t = 3.08; df = 103.59; P = .002; unimputed values model: B = 2.28 [95% CI, 1.04-3.51]; t = 3.6; df = 977.58; P < .001). Similarly, both models revealed significantly lower anxiety symptoms at 7-month follow-up for the Shamiri

Figure 1. CONSORT Flow Diagram



than study skills groups (imputed values model: B = 1.78 [95% CI, 0.53-3.03]; t = 2.8; df = 25.54; P = .01; unimputed values model: B = 2.25 [95% CI, 1.08-3.4]; t = 3.8; df = 345.25; P < .001).

Clinical Significance Assessed via the Reliable Change Index

In the intervention group, depression symptom outcomes met the threshold for clinically reliable change (3.40) from baseline to end point, 2-week follow-up, and 7-month follow-up. In the control group, depression symptom outcomes met the threshold for clinically reliable change from baseline to end point and 2-week follow-up. In the intervention and control groups, anxiety symptom outcomes met the threshold for clinically reliable change (2.24) from baseline to midpoint, end point, 2-week follow-up, and 7-month follow-up.

Feasibility and Acceptability

An independent-samples t test revealed high mean ratings and no significant difference in usefulness ratings between the Shamiri (mean [SD], 4.84 [0.52]) and study skills (mean [SD], 4.82 [0.69]) groups; t_{289} = −0.7; P = .72). Participants' ratings of whether they would recommend the program to their peers

Table. Sample Characteristics at Baseline

Variable	No. (%)		
	Total (N = 413)	Shamiri (n = 205)	Study skills (n = 208)
Age, mean (SD), y	15.5 (1.2)	15.4 (1.2)	15.7 (1.2)
Sex			
Female	268 (65.2)	138 (67.7)	130 (62.8)
Male	143 (34.8)	66 (32.4)	77 (37.2)
Symptom levels, mean (SD)			
PHQ-8	12.5 (4.7)	12.9 (4.6)	12.4 (4.8)
GAD-7	13.3 (3.4)	13.3 (3.4)	13.3 (3.4)
Form (school grade)			
1	163 (39.5)	89 (43.4)	74 (35.6)
2	140 (33.9)	67 (32.7)	73 (35.1)
3	86 (20.8)	37 (18.0)	49 (23.6)
4	21 (5.1)	11 (5.4)	10 (4.8)
School			
A	120 (29.1)	56 (27.3)	64 (31.8)
B	152 (36.8)	76 (37.1)	76 (36.5)
C	85 (20.6)	46 (22.4)	39 (18.8)
D	56 (13.6)	27 (13.2)	29 (13.9)
Home[a]			
Rural area	118 (28.6)	57 (27.8)	61 (29.3)
Small town	185 (44.8)	94 (45.9)	91 (43.8)
Big town	70 (16.9)	39 (19.0)	31 (14.9)
City	34 (8.2)	14 (6.8)	20 (9.6)
Tribe			
Kalenjin	36 (8.7)	16 (7.8)	20 (9.6)
Kamba	31 (7.5)	15 (7.3)	16 (7.7)
Kikuyu	194 (47.0)	102 (49.8)	92 (44.2)
Kisii	24 (5.8)	14 (6.8)	10 (4.8)
Luhya	40 (9.7)	17 (8.3)	23 (11.1)
Luo	31 (7.5)	19 (9.3)	12 (5.8)
Meru	21 (5.4)	7 (3.4)	14 (6.7)
Mixed tribe	7 (1.7)	4 (2.0)	3 (1.4)
Others	25 (6.1)	11 (5.4)	14 (6.7)

Abbreviations: GAD-7, Generalized Anxiety Disorder–7 item; PHQ-8, Patient Health Questionnaire–8 item.

[a] Students self-reported the location of family's primary home.

were also high for the Shamiri (mean [SD], 4.87 [0.44]) and study skills (mean [SD], 4.85 [0.53]) groups, with no significant group difference (t_{291} = −0.23; P = .82).

Discussion

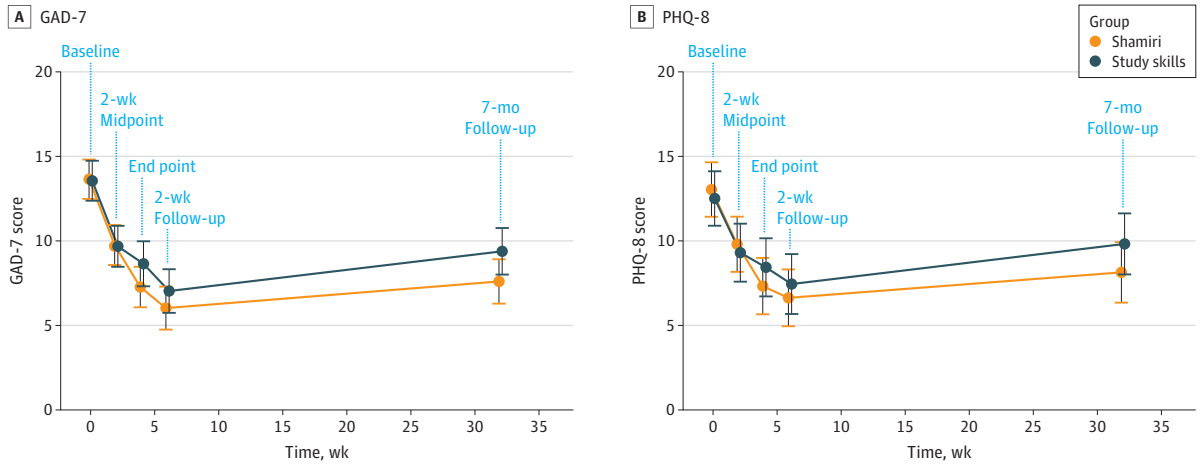
Our multicultural team of Kenya-US researchers created and tested Shamiri, an intervention for youth depression and anxiety symptoms that focuses on positive human attributes and is designed for the Kenyan cultural context, in which resource limitations, stigma, and a shortage of health care professionals limit access to mental health care. Both the Shamiri and the study skills control led to symptom reductions among Kenyan adolescents, and these reductions generally met clinically reliable change criteria. The novel layperson-provider Shamiri intervention led to greater reductions in symptoms of depression and anxiety posttreatment and extending to 7-month follow-up. Both interventions received similar high ratings on helpfulness and likelihood of being recommended to a friend, suggesting that the significant differential effects of Shamiri on symptoms were not attributable to acceptability or appeal, but rather that Shamiri was more successful than the study skills control in specifically targeting mental health problems.

To our knowledge, this is one of the first adequately powered tests in this population of a scalable intervention grounded in simple positive psychological elements. The results align with findings on wise interventions in Western settings,[14,19,20] our small-sample pilot study,[17] and a recent test in Kenya of a digital single-session adaptation of Shamiri.[35] Our effect sizes, within the range of effects reported for other global mental health interventions,[45,46] may warrant attention given Shamiri's brevity, simplicity, low cost, and use of minimally trained laypersons. Finally, using Kenyan group leaders who were familiar with the local context may have enhanced Shamiri's feasibility and acceptability.

Limitations

Although the psychometric properties of our measures have been assessed and found adequate for Kenyan youths,[24,33,35] the measures were not designed or fully validated for Kenyan

Figure 2. Symptom Trajectories



GAD-7 indicates Generalized Anxiety Disorder–7 item; PHQ-8, Patient Health Questionnaire–8 item.

youths, as suggested for cross-cultural research.[47] Second, the absence of a suicide item on the PHQ-8 limited our ability to gauge intervention effects on suicidality and to compare findings with PHQ-9 studies. Third, the government ban described previously led to significant attrition at 7-month follow-up. Fourth, we lack definitive information on any treatments students might have received between the 2-week and 7-month follow-ups; however, no participant asked the study team for further treatment, and formal mental health treatment is largely inaccessible locally. Fifth, we were underpowered for, and thus did not preregister or conduct, tests of potential moderators (eg, sex, tribe). Sixth, supervisory meetings were held for both treatments at the same time, which differs from standard practice. Seventh, students in both Shamiri and study skills showed symptom reduction, and the Shamiri vs study skills effect sizes for anxiety symptoms (averaging 0.37 across assessment points) were below those reported in recent meta-analyses of more intensive treatment (0.61,[25] 0.66[48]); however, effect sizes for depression symptoms (averaging 0.36) exceeded those in recent meta-analyses (0.29,[25] 0.30[48]), and most outcome assessments met criteria for reliable clinical change.[43,44] The school setting of this study may be both a strength and a limitation. It provided a test in real-world conditions, with implementation supported by the school structure, and students generally liked the intervention; however, we learned that government educational policies can change suddenly, limiting opportunities for extended evaluation.

Conclusions

Low-burden interventions such as Shamiri and a study skills control can lead to clinically reliable change in symptoms of depression and anxiety in a low-resource setting where formal mental health care is generally not available. The Shamiri intervention led to greater symptom reductions compared with the control intervention. Given high attrition rates and some nonsignificant findings at 2-week follow-up, Shamiri, the study skills control, and other simple, brief interventions warrant further study. Shamiri was created, and the study designed and implemented, by a multicultural team with combined expertise in intervention science and the relevant cultural context—an approach that may have value for global mental health research.[49] The positive findings suggest the testable possibility that interventions that are simple in design, low in cost, focused on positive human attributes and character strengths, and delivered by laypersons may contribute usefully to global mental health.

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Editor's Note

Considerations in Publishing a Psychiatric Randomized Clinical Trial With Kenyan Children

Dost Öngür, MD, PhD

The article by Osborn and coauthors[1] in this issue of *JAMA Psychiatry* underscores several challenges conducting clinical research in an underresourced environment, such as Kenya. In this study, the investigators screened schoolchildren for moderately severe anxiety and depression and offered a subset of them entry into a randomized clinical trial. Those eligible but not offered entrance into the trial were instead informed of the services that were available to them within their school, and in addition, they were encouraged to contact the study team if they had questions about mental health issues or needed help or support. Those who did enter were randomized to the Shamiri intervention or a Study Skills control arm, both of which are described in the article in detail. The control is not a treatment directed at moderately severe anxiety and depression. As noted by the reviewers of the manuscript,[1] this design raises ethical questions about whether the investigators met their duties toward the participants in the conduct of this research. These questions are even more intense because this study was conducted with a vulnerable pediatric population. We considered these questions in detail, as described here, and ultimately decided to publish this article.

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First, with regard to only offering the randomized clinical trial to a subset of those screened, the authors[1] noted that they were required by some of the schools where the study took place to screen all students and did offer certain supports and resources to all individuals who underwent screening. They shared information about help and support available from the students' schools and the study team and encouraged all who would like to receive help and support to contact the study team, whether or not they were involved in the study. The authors also noted that there is no network of community mental health clinics in Kenya, and there are few mental health professionals of any kind to whom students could be referred. Therefore, they offered tiered mental health support based on available resources to all individuals who underwent screening and asked for it at any point. This included evaluation by school counseling staff where available and referral to an on-site, clinically credentialed mental health specialist and ultimately senior credentialed mental health professionals, both associated with the study. The authors[1] pointed out that an estimated 40 students of more than 150 who were deemed eligible but not offered entry into the study took advantage of these services, although outcomes for these students were not examined.

Second, with regard to the choice using Study Skills as a control (and not an evidence-based treatment, such as cognitive-behavioral therapy), the authors'[1] reasoning was that a major source of anxiety and depressive symptoms among chil-