

NEW RESEARCH

Integrating Youth Readiness Intervention and Entrepreneurship in Sierra Leone: A Hybrid Type II Cluster Randomized Trial

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Objective: Conflict-affected youth are at risk for poor psychological and social outcomes, yet few receive mental health services. Strategies to expand access and sustain evidence-based interventions (EBIs) across novel delivery platforms must be tested. The present study was a hybrid type II implementation-effectiveness trial using a cluster randomized design. The primary goal was to evaluate feasibility and impact of using the collaborative team approach to deliver the Youth Readiness Intervention (YRI), an EBI, integrated into a youth entrepreneurship program (ENTR) with quality control in post-conflict Sierra Leone.

Method: Youth were screened and randomly assigned to control, ENTR, or combined YRI and ENTR (YRI+ENTR). Implementation outcomes were dissemination and implementation indicators, competence, and fidelity. Effectiveness outcomes were emotion regulation, psychological distress, and interpersonal functioning. Secondary outcomes were third-party reporter assessments of youth functioning and behavior.

Results: Data were collected and analyzed from 1,151 youth participants and 528 third-party reporters. Scores on implementation constructs, competence, and fidelity demonstrated acceptable intervention response and quality. YRI+ENTR participants showed overall improvements in depression ($\beta = -.081$, 95% CI -0.124 to -0.038 , $d = -0.154$) and anxiety ($\beta = -.043$, 95% CI -0.091 to -0.005 , $d = 0.082$) symptoms compared with control participants. Community leaders indicated that YRI+ENTR participants demonstrated improvements in overall work or training performance compared with control participants ($\beta = -.114$, 95% CI 0.004 to 0.232 , $d = 0.374$).

Conclusion: Integration of EBIs such as the YRI into youth employment programs has the potential to address limited reach of EBIs in conflict and post-conflict settings. A collaborative team implementation approach can facilitate integration and fidelity.

Diversity & Inclusion Statement: We worked to ensure sex and gender balance in the recruitment of human participants. We worked to ensure that the study questionnaires were prepared in an inclusive way. We worked to ensure race, ethnic, and/or other types of diversity in the recruitment of human participants. One or more of the authors of this paper self-identifies as a member of one or more historically underrepresented racial and/or ethnic groups in science. One or more of the authors of this paper self-identifies as a member of one or more historically underrepresented sexual and/or gender groups in science. We actively worked to promote sex and gender balance in our author group. We actively worked to promote inclusion of historically underrepresented racial and/or ethnic groups in science in our author group. The author list of this paper includes contributors from the location and/or community where the research was conducted who participated in the data collection, design, analysis, and/or interpretation of the work. One or more of the authors of this paper received support from a program designed to increase minority representation in science.

Clinical trial registration information: Youth FORWARD Phase 2 YRI and EPP Study; <https://clinicaltrials.gov/>; NCT03542500.

Key words: hybrid type II; mental health; youth; conflict; implementation science

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The global burden of mental health disorders continues to impact low- and middle-income countries disproportionately, with up to 85% of residents with untreated mental health disorders.¹ Youth and young adults in post-conflict settings are among those most adversely affected by mental health disorders, which are

currently the leading contributor to global disability in this population.^{1,2} This large unmet need has consequences for youth across the life course, including reduced participation in the labor market and poorer quality of life and health.^{3,4}

Such implications of unmet mental health needs among youth are apparent in Sierra Leone, a country with 80% of the

population younger than the age of 35 and compounded adversities from an 11-year civil war, the 2014–2016 outbreak of Ebola virus disease, several natural disasters, and economic and social stressors from the ongoing COVID-19 pandemic.⁵ Longitudinal research on war-affected youth in Sierra Leone has shown high levels of comorbid mental health problems, which can impede the ability of youth to pursue educational and livelihood opportunities.^{6,7} There are many challenges to delivering mental health services to youth using evidence-based interventions (EBIs) in post-conflict settings such as Sierra Leone.^{5,6,8,9} Limited community-based mental health service availability, including shortages in mental health care providers, has contributed to a large mental health treatment gap in Sierra Leone, estimated at 89%.^{6,10,11} Implementation strategies that are feasible and cost-effective are critical to expanding the reach of mental health EBIs. Such interventions can help contribute to economic development by improving not only mental health, but also the ability of youth to make the most of opportunities such as education and employment.^{12–18} Relatively few studies have investigated the integration of EBIs into alternative delivery platforms such as schools and livelihood programs in low-resource settings.^{12–18} To address the mental health treatment gap among youth in conflict-affected settings, the Youth Functioning and Organizational Success for West African Regional Development (Youth FORWARD) implementation science research hub was launched in 2017. The purpose of this study was to test a collaborative team approach (CTA) to integrate an EBI for youth mental health, the Youth Readiness Intervention (YRI), into a youth entrepreneurship program (ENTR) in post-conflict Sierra Leone.^{8,19} Specifications of this research included evaluating the CTA as a quality-improvement strategy to support EBI delivery by nonspecialists and investigating the clinical effectiveness of the YRI in improving youth mental health and functioning within this new delivery setting and population.^{19,20} The CTA draws from the interagency CTA as an evidence-based strategy for scaling and sustaining behavioral EBIs with quality, defined as fidelity and competence of intervention delivery by nonspecialists.¹³ A process evaluation of the Youth FORWARD approach demonstrated strong feasibility and acceptability of such integration as well as success in overcoming barriers that arose during implementation.¹¹ Agency leaders and interventionists who implemented the YRI integrated into an ENTR reported an increase in the promotion of local ownership, local capacity building, and increased collaboration across organizations.¹¹

In a previous randomized controlled trial testing the efficacy of the YRI when integrated into an educational program for students ages 15 to 24, the students receiving the YRI showed improvements in mental health, emotion

regulation skills, and daily functioning as well as improved classroom behavior and school attendance.¹² Because deficits in emotion regulation and interpersonal functioning can also impede engagement in livelihood opportunities among youth, a hybrid type II trial was designed to examine impact on mental health and functioning as well as barriers and facilitators of integrating the EBI, the YRI, within an ENTR serving young adults ages 18 to 30.³ The primary goal of this study was to evaluate the feasibility of using a CTA to deliver an EBI through the ENTR platform. We built on prior feasibility and acceptability findings in the present study by examining effectiveness of the integrated program and quantitative implementation perceptions across each level of the implementation ecology to examine how well the CTA supported a quality EBI by nonspecialist interventionists.¹¹ We examined, first, the implementation of the YRI using the CTA for overcoming barriers and integrating the YRI, and, second, the effectiveness of the YRI in this new delivery setting and approach.

METHOD

Study Design and Participants

This study used a hybrid type II cluster randomized trial design to simultaneously test the CTA strategy and the effectiveness of the YRI as integrated into a youth ENTR. Youth in 3 rural districts of Sierra Leone (Kailahun, Kono, and Koinadugu) were recruited through outreach conducted under the ENTR recruitment, including radio advertisements and involvement of local youth councils linked to the Government of Sierra Leone. Inclusion criteria were as follows: male and female youth aged 18 to 30 (consistent with the Government of Sierra Leone and program's target youth population), not enrolled in formal education or engaged in full-time employment, elevated *t* scores on the World Health Organization Disability Assessment Schedule (WHODAS), and elevated *t* scores on the Difficulties in Emotion Regulation Scale (DERS). Exclusion criteria were severe, active suicidal ideation or psychosis (as determined by study social workers), for which referrals were made for a higher level of mental health care; serious cognitive impairments limiting participant understanding of informed consent/assessment procedures; and current pregnancy, given inability to complete all study procedures, for which prenatal care referrals were made. Local research assistants administered a screening tool in the local language, mainly Krio, to determine eligibility.

Data were also collected from third-party reporters (TPRs), whom youth identified in their eligibility screeners. Eligible youth were asked to identify up to 3 TPRs, who could be a community leader or elder or a

previous work supervisor. Youth provided the contact information for each TPR and permission for the study team to contact each TPR. Included TPRs were older than age 18, were nominated by the youth participant, provided oral consent to participate in the quantitative assessments, and had daily to weekly contact with the youth participant throughout the duration of the study. TPRs were excluded if they presented with severe mental illness (eg, psychosis) or serious cognitive impairment limiting understanding of informed consent/assessment procedures (as determined by a study social worker).

All participants provided oral informed consent before eligibility screening and enrollment. The Boston College Institutional Review Board, Sierra Leone Scientific Review Committee, and National Institute of Mental Health Data and Safety Monitoring Board approved and oversaw the study (NCT03542500). The study protocol is available at <https://ps.psychiatryonline.org/doi/10.1176/appi.ps.202000009>.¹⁹

Randomization and Masking

Geographic clusters were created based on locations of eligible youth. Clusters were matched into triads based on youth characteristics (demographics, mental health scores, prior skills training, and income-generating activities) and geographic characteristics (access to highways, total population, hub-village status) to avoid the risk of bias due to dissimilarities among sites. Once the triads were formed, clusters (N = 59) were randomly assigned to YRI+ENTR clusters, where participants received both the mental health, YRI, and youth entrepreneurship, ENTR, interventions; ENTR clusters, where participants received only the ENTR intervention; or control clusters, where participants received neither the YRI+ENTR nor ENTR intervention. Clusters that could not be matched (n = 8) were flagged as stand-alone localities. More information on the matching procedure can be found in Betancourt *et al.*¹⁹ Youth participants were blinded to their intervention assignment at the time of baseline assessment, and enumerators responsible for data collection were blinded to group allocation throughout the entire study. The study team randomly selected 7 youth participants who provided at least 2 TPRs in the eligibility screeners for each cluster. The TPRs of the randomly selected participants were contacted and enrolled into the study upon informed consent.

Procedures

The YRI is a 12-module transdiagnostic, common elements-based group mental health intervention for youth that integrates practice elements from cognitive-behavioral

therapy, interpersonal therapy, and mindfulness techniques. A full description of the YRI can be found in Betancourt *et al.*¹² The YRI was delivered twice weekly in Kailahun and Kono and 3 times per week in Koinadugu via in-person, same-gender groups. Koinadugu, the last district of implementation, requested an accelerated delivery of the YRI due to youth idleness and the advent of planting season. The average session duration was 90 minutes.

The CTA was adapted from the interagency CTA.²¹ The CTA model incorporated 5 principles of system-wide implementation informed by the Exploration, Preparation, Implementation, Sustainment framework, including optimizing resources and engaging in Plan-Do-Study-Act (PDSA) cycles to address implementation challenges.²² Integration was achieved through leadership buy-in and organizational alignment, resource and knowledge sharing such as in shared recruitment activities, and cross-site communication with stakeholders.²⁰

The CTA leadership included a seed team comprising 3 YRI experts who provided 2 weeks of YRI training session to all nonspecialists employed by the same agency also delivering the ENTR (N = 12, n = male facilitators, 42.0%). The seed team provided weekly in-person and remote supervision to interventionists. YRI training consisted of didactics, group discussions, and role plays to assess fidelity and competence. CTA quality improvement cycles involved weekly clinical supervision calls with the study leaders, including 2 clinical psychologists, to discuss implementation challenges and engage in PDSA cycles to problem solve implementation barriers in real time.

Seed team members supported integration of the ENTR and YRI via discussion of how improved interpersonal and self-regulation skills could facilitate entrepreneurial success. Systematic use of PDSA cycles enabled the CTA to address on the ground realities, such as the request for accelerated YRI delivery in Koinadugu. In this instance, the CTA team was able to adjust the schedule and availability of interventionists to respond to the needs of the beneficiary population while maintaining delivery quality.

The ENTR aimed to equip trainees with the basic concepts of entrepreneurship and knowledge of business planning and finance essential for small enterprise success, focusing on underemployed youth in rural Sierra Leone. The ENTR was designed for youth with low literacy and comprised 15-lesson plans delivered over 15 training days for a total of 75 training hours. Program content focused on market research, product costing and marketing, accounting, legal regulations, access to financial services, managing business growth, and business plan development. Interventionists from the same agency delivered both the YRI and the ENTR.

The YRI was delivered first to the clusters assigned to YRI+ENTR. The ENTR was second in the intervention sequence to clusters assigned to YRI+ENTR and ENTR. Data were collected from all youth participants at baseline and the end of the ENTR (endline), approximately 8-9 weeks from baseline. To assess mental health effects of the YRI, data were also collected following the completion of the YRI (midline), approximately 6-7 weeks from baseline, with an assessment administered to a random subsample ($n = 396$ youth participants, $N = 59$ clusters) of participants across the 2 study arms. This assessment was completed to capture possible immediate YRI effects on psychosocial outcomes, which might decay over the course of the ENTR portion. Data were collected from TPRs at baseline and midline.

Outcomes

Outcome measures were selected based on prior research in Sierra Leone.^{7,20,23} All instruments were forward and backward translated into Krio using a standard protocol and demonstrated strong reliability and validity.²⁴ Implementation outcomes were fidelity and competence. Effectiveness outcomes were emotion regulation, psychological distress (anxiety/depression), and interpersonal functioning. Secondary outcomes were TPR assessments of youth functioning and behavior.

Implementation Outcomes. Quality of EBI delivery was assessed using a YRI module-specific fidelity rating checklist as well as a cross-cutting competence assessment of interventionist skills as completed by seed team supervisors via direct observation or review of audio recordings of sessions. The competence assessment included items such as “checked-in on goals.” The session-specific items evaluated intervention content delivery for each module. The seed team members first assessed if each item on the checklist was completed. Seed team members then rated fidelity of completed items on a scale of 1 (poor) to 4 (excellent). For each module, an adherence score was calculated for session-specific and cross-cutting items to determine the percentage of items on the checklist completed. Session-specific fidelity and competence scores were also calculated for each module by dividing the sum score of the session items by the total possible sum score.

Effectiveness Outcomes. Emotion regulation was assessed using an adapted version of the 36-item (scored 1-5) DERS. The DERS assesses 6 domains of emotion regulation: nonacceptance of emotions, goal-directed behaviors, impulse control, emotional awareness, access to emotion

regulation strategies, and emotional clarity.²⁵ Higher scores reflect poorer emotion regulation. We adapted the DERS based on research indicating that rewording of negatively worded/reverse-scored items improves scale psychometrics, particularly among non-English-speaking populations, and because negatively worded items performed poorly in previous work in Sierra Leone.²⁶ This adapted version of the DERS has demonstrated strong internal consistency ($\alpha = .91$) in previous work in Sierra Leone.¹² Functional impairment was assessed using the WHODAS 12-item (scored 0-4) short form, which assesses interpersonal and daily functional impairment across 5 domains: understanding and communicating, mobility, self-care, life activities, and participation in society.²⁷ Higher scores on the WHODAS indicated higher functional impairment. Anxiety and depression symptoms were assessed using the 25-item Hopkins Symptom Checklist (HSCL-25). The HSCL-25 had been previously validated for use in adults in sub-Saharan Africa and adapted to Sierra Leone as a combined symptom inventory scale comprising anxiety (10 items) and depression (15 items), showing good internal reliability (0.87-0.93).^{28,29} Items were rated on a 4-point scale. Higher scores on the HSCL-25 indicated more severe depression and anxiety symptoms.

TPR evaluation of youth functioning was measured using an adapted version of the Barkley Deficits in Executive Functioning Scale (BDEFS). The BDEFS, a 21-item scale, assesses several dimensions of daily life executive functioning impairments.³⁰ Items were rated on a 4-point scale. Higher scores in the BDEFS indicated increased deficits in executive functioning. TPRs also evaluated behaviors of youth participants using an adapted version of the Classroom Performance Scale, a 20-item scale that assesses youth performance, including ability to complete tasks according to deadlines, and behaviors, such as cooperation in group efforts and demonstration of respect.³¹ TPRs rated each item on a 3-point scale. A higher score on the TPR rating scale indicated better youth performance. Finally, TPRs were asked to rate youth attendance at work, a workshop, training, or other related programs over the past month. TPRs scored attendance ranging from 1 (poor) to 3 (good).

Statistical Analysis

Based on our previous randomized control trial of the YRI in schools, we adopted a standardized effect size d of 0.30 as potentially achievable by the YRI and clinically significant for youth participants. Assuming a standard α level of .05 with a 0.5 correlation (r) across 2 time points, 1,200 participants across 60 clusters (an average of 20 youth

participants per cluster) were required to have 0.8 power to detect an effect size of 0.3, allowing for 20% attrition, with an intraclass correlation of 0.05. Each cluster was intended to have 20 participants: 10 women and 10 men. Under intent-to-treat assumptions, attrition ($n = 16$, 1.4%) was addressed using a hybrid imputation by a chained equations approach that allowed for imputation at the item level.³² Ten complete datasets were generated and analyzed. Midline (post-YRI) data were imputed using only the random subsample across time points ($n = 396$), estimated via restricted maximum likelihood. Imputation models accounted for the longitudinal nature of the data and included participants' mental health and functioning scores, demographics (age, gender, educational attainment), cluster allocation, and treatment arm.

Descriptive data were summarized by means and standard deviations for continuous variables or frequencies and proportions for binary variables. Implementation outcomes were summarized by means and standard deviations or frequencies and proportions and disaggregated by gender and district. Intervention sessions 1 and 2 were not properly recorded or observed and were subsequently dropped from this analysis. The fidelity and competence analysis dataset included YRI sessions 3 through 12.

Primary clinical effectiveness analyses were conducted using linear mixed-effects models to account for the nested structure of the data (ie, participants nested within time points and time points nested within clusters) and for the difference in the estimation sample size at midline ($n = 396$). All models included time, study arm, their two-way interaction, participants' characteristics (age, gender, education), district, and a variable flagging stand-alone clusters as a fixed effect.

Due to geographical dissimilarities across intervention regions, and to account for possible remaining imbalances after the matching of clusters, all the cluster-level variables used for the matching of triads were also used in a principal components analysis. Five components were extracted and included as fixed effects in the models (Supplement 1, available online). Interactions between district and each cluster-level component were also included as fixed effects.

Effectiveness was determined by evaluating group differences in the average change over time (time \times treatment interaction) for each mental health outcome and evaluating the differences in marginal mean estimates for each group at each time point: baseline to post-YRI and baseline to post-ENTR. TPR analyses were also conducted using linear mixed-effects models with TPRs nested within time points and time points nested within clusters. All models included time, study arm, their two-way interaction, characteristics of TPRs (gender and age), and district. The 2 types of TPRs,

work supervisors and community leaders, were modeled separately. Significance was defined as $p < .05$ (two-tailed). All analyses were conducted in Stata/MP, version 16 (StataCorp LLC, College Station, TX).

RESULTS

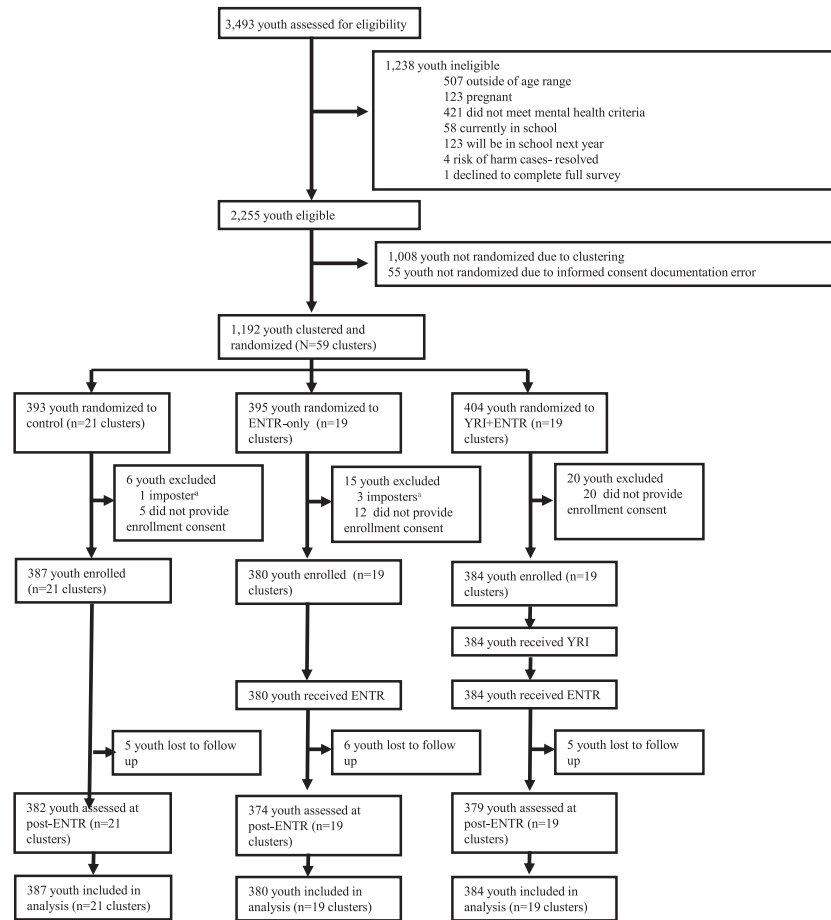
Participants were recruited and enrolled in August 2019. After accounting for imposters ($n = 4$) and youth who did not complete baseline enrollment consent after screening ($n = 37$), the final study sample consisted of 1,151 participants ($N = 59$ clusters) allocated to the 3 treatment groups (Figure 1). The 4 imposters were identified through a verification process during the study enrollment phase. Enumerators were able to determine that these 4 individuals were not the original youth participants who submitted the study application, and they were subsequently removed from the study. Youth participants had a mean age of 24.82 years old, and 47.4% were female. Among the sample, 74.4% had ever attended school, and 84.0% were married or had an intimate partner. Sample characteristics for youth and TPRs nominated by youth participants are presented in Table 1.

Implementation

Figure 2 displays trends in fidelity and competence across districts and YRI gender groups. Intervention fidelity was highest for session 4 with a mean fidelity score of 71.9% across all interventionists. Session 4 focused on self-efficacy and emotion regulation, introducing topics related to self-care and deep breathing. Session 8 had the second highest intervention fidelity score (mean = 70.6%) and highest competence score (mean = 74.1%). Session 8 focused on interpersonal skills and relationship management. Across male and female interventionists, fidelity scores were slightly higher in male intervention groups (mean [SD] = 68.2% [6.7%]) compared with female groups (mean [SD] = 67.8% [7.5%]). Across districts, Koinadugu (fidelity: mean [SD] = 71.6% [8.556%]; competence: mean [SD] = 79.9% [8.5%]), the final delivery district, reported higher fidelity and competence across YRI modules compared with Kailahun (fidelity: mean [SD] = 66.8% [5.2%]; competence: mean [SD] = 68.6% [7.1%]) and Kono (fidelity: mean [SD] = 66.0% [6.5%]; competence: mean [SD] = 70.6% [7.0%]).

Effectiveness

Results from the linear growth models, estimated marginal effects, and effect sizes are presented in Table 2. Raw means, standard errors, and intraclass correlations from imputed models for each outcome are reported in

FIGURE 1 Cluster Sampling Strategy and Flow Chart of Participants in the Youth FORWARD Trial

Note: ENTR = entrepreneurship program; YRI = Youth Readiness Intervention.

^aFour imposters were identified before youth enrollment. Through a verification process during the study enrollment phase, data collectors were able to determine that these 4 youth participants were imposters and removed them from the study.

Table S1, available online. When looking at marginal effects, pre- to post-YRI intervention indicated significant improvements in emotion regulation ($\beta = -.280$, 95% CI -0.416 to -0.139 , $d = -0.506$) and reductions in total combined anxiety and depression symptoms ($\beta = -.188$, 95% CI -0.302 to -0.074 , $d = -0.383$) and depression symptoms ($\beta = -.277$, 95% CI -0.393 to -0.146 , $d = -0.526$) in YRI+ENTR clusters compared with control clusters. Similarly, significant improvements in emotion regulation ($\beta = -.213$, 95% CI -0.355 to -0.071 , $d = -0.379$) and reductions in total combined anxiety/depression symptoms ($\beta = -.236$, 95% CI -0.354 to -0.119 , $d = -0.486$), anxiety symptoms ($\beta = -.159$, 95% CI -0.285 to -0.033 , $d = -0.306$), and depression symptoms ($\beta = -.294$, 95% CI -0.421 to -0.168 , $d = -0.576$) were found in the YRI+ENTR group compared with the ENTR group. These results are

consistent with the study design, as the ENTR-only group had not received any intervention yet.

Following the ENTR training, significant reductions in combined total anxiety/depression symptoms ($\beta = -.131$, 95% CI -0.209 to -0.053 , $d = -0.263$), depression symptoms ($\beta = -.162$, 95% CI -0.247 to -0.078 , $d = -0.309$), and anxiety symptoms ($\beta = -.086$, 95% CI -0.169 to -0.002 , $d = -0.165$) were still observed in the YRI+ENTR group compared with the control group. However, significant improvements in emotion regulation at midline in the YRI+ENTR group were not sustained over time (post-ENTR). Consistent with the above, when looking at the average change over time, significant improvements in combined total anxiety/depression symptoms ($\beta = -.065$, 95% CI -0.105 to -0.025 , $d = -0.130$), depression symptoms ($\beta = -.081$, 95% CI -0.124

TABLE 1 Descriptive Statistics of Youth and Third-Party Reporter (TPR) Study Participants at Enrollment

	Youth study participants					
	Control (n = 387 youth, 21 clusters)		ENTR (n = 380 youth, 19 cluster)		YRI+ENTR (n = 384 youth, 19 clusters)	
	n	(%)	n	(%)	n	(%)
Gender, female	175	(45.2)	182	(47.9)	188	(49.0)
	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age, y	25.04	(3.42)	24.64	(3.39)	24.78	(3.53)
	n	(%)	n	(%)	n	(%)
District						
Kailahun	150	(38.8)	117	(30.8)	143	(37.2)
Koinadugu	88	(22.7)	121	(31.8)	120	(31.2)
Kono	149	(38.5)	142	(37.4)	121	(31.5)
Ever attended school	274	(73.3)	285	(75.8)	277	(74.1)
Married or has a partner	265	(84.1)	242	(85.2)	249	(82.7)
TPR study participants						
	Control (n = 186)		ENTR only (n = 187)		YRI+ENTR (n = 244)	
	n	(%)	n	(%)	n	(%)
Sex, female	31	(16.67)	30	(16.04)	44	(18.03)
	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age, y	42.75	(13.98)	43.27	(14.56)	39.08	(13.26)
	n	(%)	n	(%)	n	(%)
District						
Kailahun	71	(36.55)	61	(32.62)	88	(36.07)
Koinadugu	47	(25.27)	51	(27.27)	80	(32.79)
Kono	68	(36.56)	75	(40.11)	76	(31.15)
Reporter type						
Community leader or elder	92	(49.46)	93	(49.73)	114	(46.72)
Work supervisor	94	(50.54)	94	(50.27)	130	(53.28)

Note: ENTR = entrepreneurship program; YRI = Youth Readiness Intervention.

to -0.038 , $d = -0.154$), and anxiety symptoms ($\beta = -.043$, 95% CI -0.091 to -0.005 , $d = .082$) were observed for the YRI+ENTR group compared with the control group. No statistically significant differences in emotion regulation, total anxiety/depression symptoms, or anxiety symptoms were found when comparing the YRI+ENTR group with the ENTR groups. For depression symptoms, the ENTR+YRI group had a marginally significant sustained reduction in depression ($\beta = -.079$, 95% CI -0.164 to -0.007 , $d = -0.148$).

Results from the linear growth models for TPR youth outcomes are presented in Table S2, available online. Community leaders and elders reported significant improvements in youth behavior for YRI+ENTR participants ($\beta = .126$, 95% CI -0.004 to 0.256 , $d = 0.419$) and ENTR participants ($\beta = .152$, 95% CI 0.017 to 0.288 , $d = 0.511$) as well as improvements in overall

performance ($\beta = .114$, 95% CI -0.004 to 0.232 , $d = 0.374$) in YRI+ENTR participants compared with control participants.

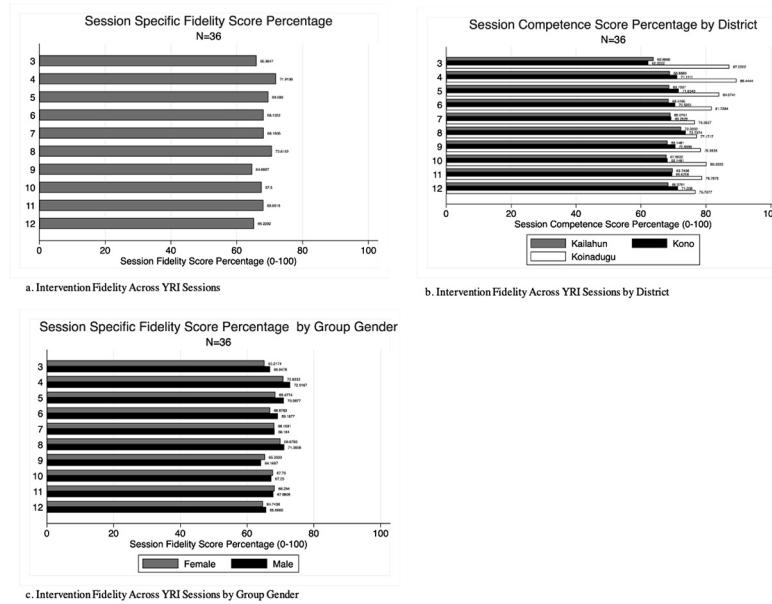
DISCUSSION

Findings from this hybrid type II implementation-effectiveness trial evaluating use of a CTA to integrate and scale-out the YRI within ENTR indicate that delivering evidence-based mental health programs to youth in low-resource settings through alternative delivery platforms is effective and that nonspecialist workers can deliver the program with competence and fidelity. Youth receiving the EBI demonstrated significant improvements in mental health compared with controls immediately after intervention, with some attenuation of effects over time. Further, both the integrated YRI+ENTR program

FIGURE 2 Trends in Intervention Fidelity (A) and Competence (B) Across 12 Youth Readiness Intervention (YRI) Sessions by District and YRI Gender Group (N = 36)

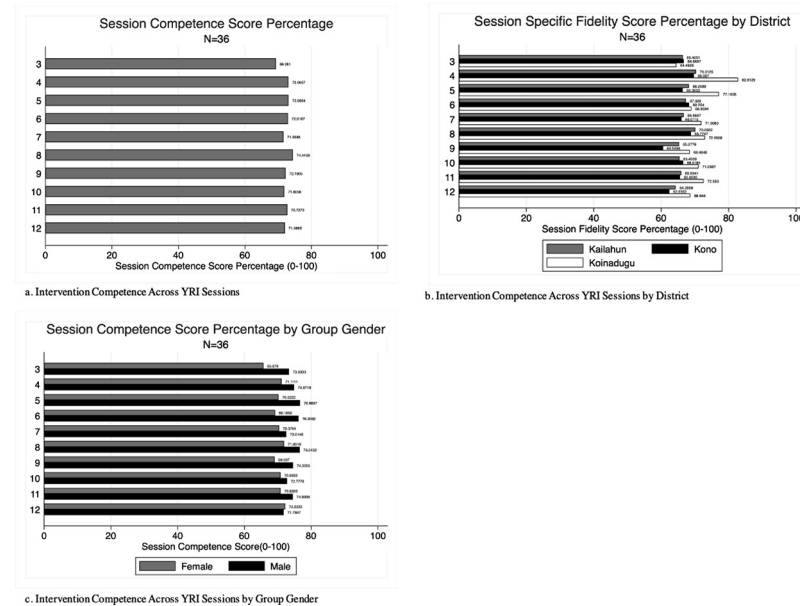
A

Trends in Intervention Fidelity Across 12 YRI Sessions by District and YRI Gender Group (N=36)



B

Trends in Intervention Competence Across 12 YRI Sessions by District and YRI Gender Group (N=36)



and the ENTR program alone had sustained benefits for mental health compared with the no intervention control condition.

Implementation results support the use of the CTA with improvements in the quality of intervention delivery across districts. Our findings indicate that livelihoods programs, such as entrepreneurship training, can be an effective

and acceptable platform for extending the reach of mental health and psychosocial support (MHPSS) programming in post-conflict settings. Integration of EBIs such as the YRI into livelihoods programs also has the potential to influence attitudes and behaviors of youth in their interactions with TPRs, such as community leaders and elders and work supervisors.

TABLE 2 Youth Mental Health Intervention Effectiveness Estimates From Mixed-Effects Models

Outcome	Linear growth models ^a				Baseline to midline (post-YRI) difference (n = 396) ^b			Baseline to endline (post-ENTR) difference (N = 1,151) ^b		
	Estimate	(95% CI)	d ^c	p	Marginal effect	(95% CI)	d ^c	Marginal effect	(95% CI)	d ^c
Difficulties in emotion regulation (DERS)										
ENTR vs control	−0.041	(−0.093 to 0.009)	−0.073	.112	−0.065	(−0.204 to 0.074)	−0.114	−0.083	(−0.181 to 0.015)	−0.146
ENTR+YRI vs control	−0.069	(−0.078 to 0.024)	−0.048	.299	−0.280	(−0.416 to −0.139)	−0.506	−0.054	(−0.152 to 0.045)	−0.094
ENTR+YRI vs ENTR	−0.015	(−0.036 to 0.066)	−0.025	.577	−0.213	(−0.355 to −0.071)	−0.379	0.029	(−0.069 to 0.128)	0.051
Functional impairment (WHODAS)										
ENTR vs control	−0.041	(−0.087 to 0.005)	−0.084	.078	0.121	(0.003 to 0.239)	0.251	−0.082	(−0.164 to 0.005)	−0.169
ENTR+YRI vs control	−0.036	(−0.081 to 0.009)	−0.075	.118	−0.061	(−0.179 to 0.057)	−0.126	−0.072	(−0.154 to 0.009)	−0.149
ENTR+YRI vs ENTR	0.005	(−0.041 to 0.050)	0.009	.838	−0.182	(−0.303 to −0.062)	−0.381	0.009	(−0.073 to 0.092)	0.019
Anxiety and depression total score (HSCL)										
ENTR vs control	−0.037	(−0.076 to 0.003)	−0.073	.110	0.047	(−0.066 to 0.162)	0.094	−0.074	(−0.151 to 0.005)	−0.147
ENTR+YRI vs control	−0.065	(−0.105 to −0.026)	−0.130	.001	−0.188	(−0.302 to −0.074)	−0.383	−0.131	(−0.209 to −0.053)	−0.263
ENTR+YRI vs ENTR	−0.029	(−0.069 to 0.011)	−0.058	.156	−0.236	(−0.354 to −0.119)	−0.486	−0.058	(−0.136 to 0.020)	−0.116
Anxiety (HSCL)										
ENTR vs control	−0.028	(−0.070 to 0.013)	−0.054	.188	0.090	(−0.032 to 0.213)	0.173	−0.057	(−0.140 to 0.026)	−0.108
ENTR+YRI vs control	−0.043	(−0.091 to 0.005)	−0.082	.045	−0.068	(−0.191 to 0.054)	−0.130	−0.086	(−0.169 to 0.002)	−0.165
ENTR+YRI vs ENTR	−0.015	(−0.057 to 0.027)	−0.028	.497	−0.159	(−0.285 to −0.032)	−0.306	−0.029	(−0.114 to 0.055)	−0.056
Depression (HSCL)										
ENTR vs control	−0.042	(−0.085 to 0.001)	−0.080	.057	0.023	(−0.099 to 0.147)	0.045	−0.084	(−0.169 to 0.006)	−0.159
ENTR+YRI vs control	−0.081	(−0.124 to −0.038)	−0.154	<.001	−0.277	(−0.393 to −0.146)	−0.526	−0.162	(−0.247 to −0.078)	−0.309
ENTR+YRI vs ENTR	−0.039	(−0.083 to 0.004)	−0.074	.077	−0.294	(−0.421 to −0.168)	−0.577	−0.079	(−0.164 to 0.007)	−0.148

Note: DERS = Difficulties in Emotion Regulation; ENTR = entrepreneurship program; HSCL = Hopkins Symptom Checklist; WHODAS = World Health Organization Disability Adjustment Scale; YRI = Youth Readiness Intervention.

^aAverage change over time in intervention groups youth vs control group youth. Assesses the significance of the difference in difference or time × treatment interaction coefficient.

^bDifference in marginal means estimates between intervention groups at each time point.

^cStandardized mean difference computed from multilevel regression model coefficients.

Implementation findings indicate high acceptability of using the CTA to integrate the YRI into the ENTR and to train and improve the quality of delivery by this new workforce with no specialized training in MHPSS. The modules with the highest fidelity were modules focused on practical and direct approaches to dealing with life challenges, such as deep breathing, effective communication approaches, and finding sources of social support.

In addition, when field-based challenges arose, such as needing to accelerate intervention delivery to be responsive to the planting season, the CTA and use of PDSA cycles allowed the seed team and their interventionists the opportunity to problem solve and be responsive to the needs of youth, which may also have contributed to the highest fidelity in Koinadugu. In all districts and across male and female interventionists, fidelity and competence of intervention delivery improved among the services workers who were trained and supervised as YRI interventionists in this study.

Youth participants who received the YRI+ENTR intervention reported significant improvements in emotion regulation following YRI completion, but effects were not sustained post-ENTR. Youth participants who received YRI+ENTR as well as ENTR alone experienced a significant reduction in depression and anxiety symptoms compared with control youth. These findings are in line with prior research on the YRI delivered within Sierra Leonean schools, which indicated an impact on mental health, but with attenuation of improvements in emotion regulation skills over time.¹⁹

Our findings demonstrated promising results regarding youth attitudes, behaviors, and other psychosocial skills seen as essential for improving youth employment in low- and middle-income countries both for YRI+ENTR and ENTR alone. Because the YRI is designed to be integrated into complementary delivery platforms such as education and livelihoods, blending it into an ENTR program allowed the EBI to reach more vulnerable youth who may not otherwise have benefited.

Taken as a whole, these findings indicate that integrating the EBI into novel delivery platforms such as ENTRs in post-conflict settings may assist youth in developing skills necessary to achieving economic self-sufficiency, including improvements in emotion regulation, and lasting effects on depression and anxiety symptoms over time. These improvements in mental health and functioning were triangulated by TPRs to provide more insight into psychosocial functioning of youth participants. In addition, further use of the CTA as an implementation strategy might focus even more attention on integration and practice of the

EBI skills learned during the ENTR training so that both interventions can be mutually reinforcing and allow youth greater opportunities to internalize and practice the self-regulation and interpersonal skills they learn.³³ However, further research is needed to examine the association between YRI participation, mental health outcomes, and livelihood outcomes longitudinally.

In low-resource settings, particularly post-conflict settings where availability of highly trained mental health professionals is limited, integration of EBIs into novel delivery platforms such as livelihoods programming may promote well-being as well as human capital.¹²⁻¹⁸ Small differences whereby quality of delivery was higher in male groups may also indicate the need to better address appropriate content and efforts to address intervention participation barriers facing male and female participants in such settings.

Study limitations must be noted. First, findings may not generalize to youth residing in more urban areas or youth with higher educational attainment. As opposed to previous studies of YRI integrated into school settings, the current sample was older, more rural, and had lower education. In addition, results from the TPR assessment may not be generalizable to youth who were not socially connected and unable to nominate at least 2 TPRs. An additional limitation is the need for stronger fidelity monitoring, with the lack of fidelity monitoring data for the first 2 sessions of the YRI and inadequate sample and low power for analyzing trajectories linking analysis of the relation between fidelity and intervention outcomes. Additional limitations include the absence of previous effectiveness testing of the ENTR, limited ability to compare YRI+ENTR and ENTR outcomes due to study design, and the absence of an independent rater for fidelity monitoring.

We successfully implemented an EBI to improve mental health and psychosocial functioning integrated into an ENTR for youth, demonstrating that this approach is feasible and acceptable and that a workforce without specialized training in MHPSS could deliver the EBI with competence and fidelity. The CTA was also able to facilitate cross-site learning and led to moderate to high ratings of intervention feasibility. These findings have important implications for scaling-out mental health EBIs via alternative delivery platforms, which are informative to government and development actor decision making regarding promoting MHPSS access in conflict-affected settings.¹³⁻¹⁸ To achieve further scaling-out and sustainment of EBIs, enabling environments characterized by systems strengthening related to appropriate policies, workforce, financing, and technical leadership to ensure mental

health services implementation and sustainment will be necessary. Leveraging investments in development programs by integrating EBIs into youth livelihood programs in conflict-affected settings is an innovation that can help to expand reach with quality and build capacity to address the mental health treatment gap globally.

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