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Title: Guided Self-Help to Reduce Psychological Distress in South Sudanese Female Refugees in Uganda: A Cluster Randomized Trial

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Methods: We conducted a cluster randomized trial in rural refugee settlements in northern Uganda. Participants were female South Sudanese refugees with at least moderate levels of psychological distress (cut-off ≥ 5 on the Kessler 6). Intervention comprised access to usual care and five 2-hour audio-recorded stress management workshops (20-30 refugees) led by briefly-trained lay facilitators, accompanied by an illustrated self-help book. Villages were randomized on a 1:1 basis. Within 14 villages, randomly selected households were approached. Screening of women in households continued until 20-30 eligible participants were identified. The primary outcome was individual psychological distress, assessed using the Kessler 6 one-week before, one-week after, and three-months after intervention. Secondary outcomes included: personally-identified problems; posttraumatic stress; depression symptoms; feelings of anger; social interactions with other ethnic groups; functional impairment; and subjective wellbeing. Assessors were masked to allocation.

Findings: Of 694 eligible participants (331 SH+, 363 EUC), 613 (88.3%) completed all assessments. We found stronger improvements for SH+ on psychological distress three months post-intervention ($\Delta = -1.20$; $p = 0.04$; 95% CI = -2.33, -.08, $d = -0.26$). We also found larger improvements for SH+ three months post-intervention for five of eight secondary outcomes (effect size range $d = -0.30$ to $d = -0.36$). Refugees with different trauma exposure, length of time in settlements, and initial psychological distress benefitted similarly.

Interpretation: An innovative guided self-help intervention that can be rapidly deployed to large numbers of participants resulted in meaningful

reductions in psychological distress at three months among South Sudanese female refugees.

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Research in context

Evidence before this study: A meta-analysis of studies with populations affected by humanitarian crises in low- and middle-income countries highlighted the potential that psychological therapies offer for reducing symptoms of posttraumatic stress disorder (standardized mean difference [SMD] -1.07, 95% Confidence Interval [CI] -1.34, -0.79, n=1272; 16 trials; low-quality evidence), depression (SMD -0.86, 95% CI -1.06, -0.67; n=1254; 14 trials; low-quality evidence), and anxiety (SMD -0.74, 95% CI -0.98, -0.49; n=694; five studies; low-quality evidence).

Added value of this study: There is an opportunity to scale up currently existing evidence-based psychological therapies in humanitarian settings in low- and middle-income countries by adapting them in innovative ways. This is the first randomized controlled trial evaluating the effectiveness of an innovative, guided self-help intervention. The intervention (Self Help Plus, SH+) can be rapidly trained to lay providers, is delivered to large groups of people in workshops through audio recordings and an illustrated self-help book. We found that SH+ was associated with higher levels of improvements on psychological distress, functioning, and wellbeing outcomes at three months after the intervention.

Implications of all the available evidence

Guided self-help appears to be a promising firstline strategy, that can be delivered rapidly to large groups of people in low-resource humanitarian settings.

Summary

Background: Innovative solutions are required to provide mental health support at scale in low-resource humanitarian contexts. We aimed to assess the effectiveness of a guided self-help intervention (Self-Help Plus; SH+) to reduce psychological distress in female refugees.

Methods: We conducted a cluster randomized trial in rural refugee settlements in northern Uganda. Participants were female South Sudanese refugees with at least moderate levels of psychological distress (cut-off ≥ 5 on the Kessler 6). Intervention comprised access to usual care and five 2-hour audio-recorded stress management workshops (20-30 refugees) led by briefly-trained lay facilitators, accompanied by an illustrated self-help book. Villages were randomized on a 1:1 basis. Within 14 villages, randomly selected households were approached. Screening of women in households continued until 20-30 eligible participants were identified. The primary outcome was individual psychological distress, assessed using the Kessler 6 one-week before, one-week after, and three-months after intervention. Secondary outcomes included: personally-identified problems; posttraumatic stress; depression symptoms; feelings of anger; social interactions with other ethnic groups; functional impairment; and subjective wellbeing. Assessors were masked to allocation.

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Funding: This study was funded by the Research for Health in Humanitarian Crises (R2HC) Program, managed by Elhra (grant#12934).

Trial registration: Prospectively registered at ISRCTN50148022

Data sharing: Deidentified data and a data dictionary will be made available for individual patient data meta-analyses with publication of the trial after approval of a proposal and signed data access agreement (wtol@jhu.edu, vanommerenm@who.int).

Introduction

Conflict-affected populations are at elevated risk of psychological distress and a range of mental disorders.¹ Over the last two decades, research has identified psychological treatments that are effective among conflict-affected populations (e.g., cognitive behavioral interventions and interpersonal therapy).² Although evidence of the effectiveness of these interventions is promising,³ they are challenging to scale-up in low-resource humanitarian settings.

First, such treatments require a substantial clinical workforce not typically available in disrupted, under-resourced health systems.⁴ Although task sharing to non-specialists is a key strategy,⁵ non-specialists offering psychological interventions need to be well-trained and supervised, a challenging requirement in insecure contexts. Secondly, current evidence-based interventions commonly target single mental disorders. However, not only mental disorders but also subsyndromal psychological distress are common in conflict-affected populations.

Psychological distress poses risk for subsequent mental disorders and causes marked impairment.⁶ Thirdly, although non-specialist-delivered interventions reduce psychological symptoms with moderate to large effect sizes, they typically only reach individuals or small groups of people at a time.

Many other areas of public health promote interventions with small individual health effects (e.g., tobacco or injury messaging) that, at scale, add up to large population health effects.⁷ WHO has been seeking to apply such a public health approach to address vast mental health needs and has developed a multi-media (audio-recordings and book), guided self-help intervention called Self-Help Plus (SH+).⁸ The intervention's format was selected informed by meta-analyses showing promising results for bibliotherapy, group-based pre-recorded psychoeducational self-help interventions and guided self-help in general.⁹⁻¹¹

Following formative research,^{12,13} this study aimed to evaluate the effectiveness of SH+ in a cluster randomized controlled trial (cRCT) with South Sudanese female refugees living in Uganda. We hypothesized that SH+ would result in larger improvements on indicators of psychological distress and functioning at the 3-month follow-up compared to controls.

Methods

Design and sample size calculations

We conducted a single-blind, parallel group, superiority cRCT from April to October 2017 (Figure 1). The trial protocol was published previously,¹⁴ and no changes were made to design after the trial started. A cluster design was chosen to avoid contamination of intervention materials within villages. The trial focused on female refugees because a needs assessment¹⁵ and formative work¹² showed acute needs and acceptability of SH+ in this target group. The project was approved by the MildMay Uganda Research Ethics Committee, the Uganda National Council for Science and Technology, and the WHO Ethical Review Committee and all participants provided informed consent.

We predicted small-to-medium effect sizes at the 3-month follow-up, based on meta-analyses of similar self-help, psycho-educational interventions.⁹ We used the PowerUp! Tool to estimate sample size, using an average cluster size of 42 individuals, 14 clusters (equal assumed), intraclass correlation of .012, 20% attrition, 80% power, an α of .05, and a two-tailed test. Under these assumptions the minimum detectable effect size is 0.219 with a total sample of $n=588$. We did not plan interim analyses: trial participation ended after at least three attempts were made to locate all participants for follow-up assessment.

Setting

Rhino Camp settlement is located in northwestern Uganda, and hosts >250,000 mainly South Sudanese refugees. Renewed armed conflict in South Sudan has instigated the third largest refugee crisis in the world.¹⁶

Randomization and masking

Randomization was performed by an independent epidemiologist at Johns Hopkins University. A simple random allocation sequence was generated using Stata 14,¹⁷ and villages were allocated to intervention with enhanced usual care (EUC) or EUC alone, without applying stratification or matching, on 1:1 basis. All settlement villages listed by the Office of the Prime Minister at commencement of the study were eligible for randomization, except for villages involved in prior formative research. The allocation sequence was hidden from assessors. SH+ facilitators were given names of SH+ villages immediately prior to implementation. To maintain masking, assessors worked in a separate office and visited the settlement on different days from SH+ facilitators, who were strictly instructed not to disclose allocation.

Within villages, we randomly selected households by spinning a bottle and approaching the first household in the direction pointed to by the bottle and, then repeating this, every fifth household thereafter. We asked whether any Juba Arabic-speaking women were residing in each household. If only one Juba Arabic-speaking female adult lived in the household we approached her for consent. If there were multiple eligible women we randomly selected one by drawing slips. We administered the Kessler 6 (K6) to assess psychological distress, applying a cut-off of ≥ 5 for moderate-level psychological distress.¹⁸ Participants were excluded if they were (1) at

imminent risk of suicide (assessed with structured questionnaire); (2) showing observable signs of severe mental disorder (e.g., psychosis); or (3) not able to understand basic instructions. Both (2) and (3) were assessed with observation checklists. Screening continued until we could form two groups of 20-30 participants in each village. In smaller villages screening stopped after every household in the village had been approached.

Procedures

The local project coordinator (MRL) approached village leaders to explain the study and ask for permission the day before data collection. Interviewers sought informed consent for baseline assessment the day following initial screening. Participants at imminent risk of suicide were immediately assisted by a trained clinical team. All questionnaires were administered in interview-format. Assessors were Ugandan nationals residing in the camp area, proficient in Juba Arabic and English, with at least an undergraduate diploma. Training of assessors took place in a 1-week course that emphasized skills-based learning through role-playing.

Intervention

SH+ is based on acceptance and commitment therapy (ACT), a modern variant of cognitive behavioral therapy focused on enhancing psychological flexibility. Rather than suppressing or avoiding difficult thoughts and feelings, ACT aims to teach alternative strategies primarily through mindfulness techniques. ACT also focuses on guiding participants to live in ways consistent with their personal values.¹⁹

SH+ comprises a pre-recorded psychoeducational audio-course of five weekly 2-hour sessions, delivered in workshops with 20-30 participants. The sessions focus on management of

psychological distress through ‘grounding’ (slow breathing, present moment awareness - session 1); ‘unhooking’ (noticing and naming overwhelming feelings and refocusing on present activities – session 2); identifying personal values and living in consistence with these values (session 3); being kind to oneself and others (session 4); and ‘making room’ (strengthening the ability to accommodate strong feelings without being overwhelmed by them – session 5). An illustration-based self-help book with limited text (to enhance use by participants with limited literacy skills) covers key points from audio sessions. To enhance scalability, SH+ aims to reduce psychological distress arising in the context of diverse stressors (e.g., interpersonal violence, chronic poverty) across a broad range of mental health conditions, regardless of whether people meet diagnostic criteria for particular disorders. Given that content is mainly delivered through audio-recorded materials, it can be delivered by non-specialists with brief training. SH+ is not intended for people with complex mental health problems (such as psychosis) or those at imminent risk of suicide.

SH+ was deemed a good fit for this setting after an initial needs assessment indicated the ubiquity of “overthinking”,¹⁵ a local idiom of psychological distress and a target of ACT. An uncontrolled pilot evaluation¹² and feasibility cRCT¹³ found SH+ to be relevant, acceptable, and feasible among female South Sudanese refugees.

SH+ was delivered in pairs by eight female facilitators: seven Ugandans residing in the area, and one South Sudanese refugee. All finished secondary education, had experience working in the settlement, and were proficient in Juba Arabic and English. None had formal mental health training or work experience. Four of the facilitators were trained before the uncontrolled pilot trial (5 days)¹² and feasibility trial (4 days)¹³ by master trainers (FB, KC). Four new facilitators were trained, by (1) listening through the audio, taking part in practice SH+ sessions (led by

intervention team leader) (4 days); and (2) training in SH+ facilitation skills (4 days). The facilitators' role was limited, focusing on playing the audio-recording, responding to questions and disruptions and facilitating highly scripted individual exercises and small group discussions.

One facilitator functioned as intervention team leader and led post-session technical debriefs. Intervention supervision was provided by a Ugandan social worker, who was available for questions, attended the debriefs, and provided supervision every two weeks. Additional supervision was requested from the SH+ master trainer if necessary (amounting to <2 hour per month). We checked fidelity through adherence forms completed by facilitators. The intervention supervisor observed 10% of the sessions and completed an adherence form.

Enhanced Usual Care

EUC was provided to participants in both study arms. After screening, all participants met with a trained community health worker who provided psycho-education using a structured script covering “overthinking” and strategies for self-management. In addition, participants were provided information on where to access existing mental health services, which comprised of (1) weekly visits to the four government primary health care centers by a multi-disciplinary mental health team based at the regional hospital, providing psychosocial and pharmacological interventions; (2) a network of trained South Sudanese refugee community health workers providing basic psychosocial support.

Primary Outcome

All outcomes were measured at the individual (not cluster) level. Measures were translated using standard procedures, including blind back-translation and initial piloting.²⁰ Psychological distress

was assessed using the K6, first as a screener, and then re-administered at immediate post-treatment and 3-month follow-up assessment. The K6 asks six questions about sadness, nervousness, restlessness, hopelessness, feeling everything is an effort, and worthlessness in the last 30 days on a 5-point response scale (range 0-24).²¹ We applied the standard cut-off for moderate levels of psychological distress (≥ 5)¹⁸ with internal consistency (Cronbach Alpha; α) of 0.60.

Secondary Outcomes

Personally identified problems were examined with the Psychological Outcome Profiles instrument (PSYCHLOPS),²² which asks participants to describe two problems from their own perspective and rate problem severity on a 6-point scale (range 0-18, $\alpha=0.65$). PTSD symptoms were assessed with the PTSD Checklist-Civilian 6-item version (PCL-6), using a 5-point scale (range 6-30, $\alpha=0.72$).²³ We measured depression symptoms with the Patient Health Questionnaire, 9-item version (PHQ-9), which has a 4-point scale (range 0-27, $\alpha=0.67$). Anger was assessed using two dichotomous questions asking about explosive anger attacks.²⁴ Based on formative research¹² we included three questions concerning positive interactions between ethnic groups (greeting, conversing with, and meeting with people from other ethnic groups) (scored on a 4-point scale, range 0-12, $\alpha=0.74$). Hazardous alcohol use was assessed but not included in analyses since only four participants reported using alcohol at baseline. We assessed psychological flexibility (both as outcome and putative mediator) using the Acceptance and Action Questionnaire (AAQ-II)²⁵ (seven items on a 7-point scale, range 7-49, $\alpha=0.77$).

Functional impairment and subjective wellbeing were assessed with the WHO Disability Assessment Schedule 2.0 (WHODAS)²⁶ and the WHO-5 Wellbeing Index (WHO-5).²⁷ We used

the 12-item version of the WHODAS, which uses a 5-point scale (range 12-60, $\alpha=0.78$). The WHO-5 contains five questions using a 6-point scale (range 0-25, $\alpha=0.78$). In addition, we assessed several moderators (exposure to different levels of traumatic events, session attendance) and cost-effectiveness indicators (use and cost of health services, earnings), and the results from the latter assessments will be presented elsewhere.

Statistical Analysis

A statistical analysis plan was finalized and signed before data analysis. We followed an intent-to-treat approach; we analyzed all participants randomized to either study arm, regardless of level of intervention participation. For participants lost at follow-up, we used listwise deletion (or complete case analysis), an acceptable approach when the level of missing data is minimal. Preliminary analyses included a comparison of baseline characteristics to ensure randomization was successful. We used linear mixed-effects models to evaluate the impact of SH+ and to accommodate the hierarchical structure of the data using the lme4 package in R²⁸ with village as a random effect. We present adjusted odds ratios (AORs), and 95% confidence intervals (CIs) using individual data matching baseline-, post-, and follow-up (0, 6, 18 weeks) assessments. Demographics such as ethnicity, work status, marital status and initial psychological distress were included as covariates in the random effect model. We explored moderation effects of initial severity at baseline, gender-based violence exposure, exposure to trauma, and length of stay in the refugee camp. These moderation analyses involved inclusion of interaction terms (intervention status x moderator variable) in linear mixed effects models.

Role of the funding source

The funders did not have a role in the research design; collection, analysis, or interpretation of data; writing the report; nor the decision to submit for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

After screening, 694 participants met inclusion criteria and not exclusion criteria (**Figure 1**). Only five participants (0.7%) were excluded for not meeting the moderate psychological distress inclusion criterion. Eight participants (1.1%) met exclusion criteria and five declined to participate in screening. We could not interview 34 participants (4.9%) at the immediate post-intervention assessment and 36 participants (5.2%) at the 3-month post-intervention assessment. Most participants were lost to follow-up because they moved location. Participants lost to follow-up were similar in number across study arms, and attrition was not significantly related to study condition, marital status, work status, or education.

Table 1 shows socio-demographic characteristics. Study conditions were largely similar with regard to socio-demographics and baseline scores on outcomes, with the exception of ethnicity and length of time in refugee settlement. We included both as covariates in effectiveness analyses. Mean participant age was 31 years (SD 10.9). Close to two-thirds (60.2%) were married, for almost half primary school was the highest received level of education (45.8%), and half of the sample (48.6%) were of Kakwa ethnicity. Most women were either homemakers (45.8%) or unemployed (35.3%).

Table 2 presents differences between study conditions on trajectories of the outcome measures. With regard to the primary outcome, SH+ led to significantly greater reductions in

psychological distress immediately after intervention ($\beta=-3.25$; $p<0.0001$; 95% CI=-4.31,-2.19, $d=-0.72$) and three months after intervention relative to the EUC ($\beta=-1.20$; $p=0.04$; 95% CI=-2.33,-.08, $d=-0.26$). The 3-month effect (our primary endpoint of interest) was not moderated by gender-based violence exposure, exposure to trauma, length of stay in settlement, or levels of initial psychological distress (**Supplementary Materials**).

SH+, relative to EUC, was also associated with larger improvements three months after intervention for the secondary outcomes of posttraumatic stress and depression symptoms, explosive anger, functional impairment, and subjective wellbeing, with effect sizes ranging between $d=-0.30$ and $d=-0.36$. For two secondary outcomes (personally identified problems, psychological flexibility), significant intervention benefits were identified immediately after intervention, but not three months after intervention. There were no differences in interethnic relations (secondary outcome) either immediately after or three months after intervention.

None of the intervention effects at three months were moderated by violence exposure, length in settlement, or baseline levels of psychological distress (**Supplementary Materials**).

Assessment of over 10% of SH+ sessions showed near-perfect fidelity: two minor mistakes across all eight groups were identified (a delay in re-starting the audio; taking more time for smaller group discussion than allotted in the manual). Participation in the intervention was consistently high. Of the 331 individuals randomized to SH+, 293 participated in the first session (88.5%). Participation dropped slightly at the second session, but remained stable and high: session 2, $n=267$ (80.7%); session 3, $n=272$ (82.2%); session 4, $n=279$ (84.3%); session 5, $n=265$ (80.1%). We did not find evidence that blinding of assessors was compromised: assessors correctly guessed the study condition of clusters 34% of the time. Semi-structured interviews

with 52 participants after the 3-month follow-up did not indicate exposure to intervention materials in control villages.

Posthoc analyses

Our aim in this study was to assess the impact of a highly scalable intervention that has the potential to be rapidly reach larger groups of people in settings of mass adversity. To aid interpretability and ability to compare study results with evidence from past studies evaluating more resource-intensive psychotherapeutic interventions, we conducted the following post-hoc (non-specified) analyses (**Supplementary Material**).

First, we were interested in understanding intervention impacts on participants with severe psychological distress (i.e., scoring 13 or higher on the K6, which in studies in other settings¹⁸ indicates a high likelihood of having a serious mental disorder causing functional limitations requiring treatment) as opposed to moderate levels of psychological distress (5 or higher). We found that the majority of participants in this study met criteria for severe psychological distress (83.9%). Immediately post-intervention, 57.6% of the control condition compared to 33.2% in the SH+ condition continued to score ≥ 13 . This difference was also observed at the 3-month assessment, although it became smaller (47.9% vs 39.3%, respectively) respectively.

Second, we calculated the minimally important difference by comparing the proportions of participants in both study conditions showing positive changes of more than 0.5 standard deviation.²⁹ We found a statistically significant difference between study conditions in favour of SH+ with regard to the proportion of participants achieving a minimally important difference between baseline and 3-month follow-up (Pearson $\chi^2(3) = 9.63$, $p = 0.022$). For primary outcome

psychological distress, this appears to be mainly a function of a larger group of people who deteriorate in the control condition (16.0%) vs. SH+ condition (9.1%). We also found statistically significant differences in minimally important difference in favor of the SH+ condition for posttraumatic stress (Pearson $\chi^2(3) = 26.58, p < .0001$) and depression symptoms (Pearson $\chi^2(3) = 10.47, p = 0.015$). For posttraumatic stress symptoms, the difference appeared to be driven by a larger proportion of SH+ condition participants who improved (61.3% vs. 50.1%) and a smaller group of participants in the SH+ condition who deteriorated (10.6% vs. 20.9%). For depression, the difference appeared to be associated with a smaller group of participants who deteriorated in the SH+ condition (14.5% vs 20.4%).

Discussion

We evaluated an intervention designed to overcome major obstacles to providing evidence-based mental health support at scale for conflict-affected populations. In low-resource settings, rapidly reaching large groups of people with evidence-based psychotherapies is inhibited by: the resources required to train and adequately supervise a clinical workforce; challenges in maintaining fidelity to intervention manuals; the need to address psychological distress experienced by people with and without diagnosable mental disorders; and size of the affected population⁴. The intervention attempted to meet these challenges by decreasing requirements for training and supervision while delivering excellent intervention fidelity through use of audio-recordings and a self-help book; targeting psychological distress regardless of whether people meet criteria for diagnosable mental disorders; and tripling the number of participants reached per session. To the best of our knowledge, this study is the first RCT of a guided self-help intervention in a low-resource humanitarian setting.

In line with our hypotheses, we found larger improvements at the 3-month post-intervention assessment in the SH+ arm for primary outcome psychological distress and five of eight secondary outcomes. Identified effects were robust, i.e. not moderated by trauma and GBV exposure, length of time in settlement, or baseline levels of distress. Identified effect sizes were similar to psychoeducational courses evaluated in adversity-affected populations living in high-income countries (e.g., the *Coping with Depression* course has a pooled effect size of $d=0.28$).⁹ Screening for moderate psychological distress resulted in negligible exclusion and *de facto* implementation of SH+ as a universal intervention. Because of the diversity of mental health conditions in universally-targeted populations, such interventions commonly have smaller effect sizes, but have greater feasibility and reach. Post-hoc analyses identified that the large majority of participants scored above the cut-off for severe psychological distress at baseline, and that a larger percentage of participants in the SH+ condition were below this level compared to the control condition at 3-months post-intervention. Moreover, we found a pattern of larger minimally significant deterioration in the control condition compared to the SH+ condition for psychological distress, posttraumatic stress, and depression symptoms at 3-months post-intervention. This is interesting to note, given the high level of continued stressors experienced by South Sudanese refugees in northern Uganda, including continued political instability in South Sudan, restrictions in access to basic needs, and gender-based violence (e.g., intimate partner violence).

We note several limitations of the study. First, follow-up assessment was conducted 3-months after intervention. Longer-term assessments would be helpful to understand benefits over time. Nonetheless, alleviation of suffering is a widely accepted objective of humanitarian action, and SH+ offers sizeable immediate effects. Second, our psychological distress measure had an

internal consistency of 0.60, indicating it may tap into multiple types of mental health phenomena rather than one unified concept. Third, our study focused on female refugees, but testing SH+ with male participants is important as well.

Taken together, our findings indicate that SH+ may be well suited as a first-line intervention for large populations exposed to major stressors in low-resource settings. Where feasible, this intervention should be implemented within a stepped care framework where those for whom SH+ is not sufficient are offered a more potent intervention. Following WHO's model of the optimal mix of mental health services,³⁰ SH+ would fill an important role to strengthen self-care and informal community care. The moderation results suggest that the intervention benefits populations similarly across different trauma histories and levels of distress. Given these positive results, WHO will make the Juba Arabic version of SH+ publicly available, and will make the English version available after replication of this study.

Our findings raise several questions for future research. First, as with resource-intensive psychological treatments in humanitarian settings,³ it is important to understand why effect sizes reduce over time. A Cochrane review of psychological treatments – mostly consisting of relatively higher resource-intensive interventions - in humanitarian settings in low-and middle-income countries found a drop in effect size for posttraumatic stress disorder symptoms from -1.07 posttreatment (16 studies), to -0.49 at 1-3 months after intervention (18 studies), and -0.37 at six months after intervention (five studies).³ Studies could explore whether booster sessions or integration within humanitarian programming aimed at addressing critical stressors (e.g., poverty, gender-based violence) may assist in maintaining benefits. Additional questions concern: whether SH+ may be an effective indicated preventive intervention; cost-effectiveness of SH+ compared to established evidence-based psychotherapies, which tend to have higher

effect sizes, but are more resource-intensive; how SH+ delivery may be optimized to perform at larger scale in low-resource contexts (e.g, integration with primary health care, specialized mental health services, or stepped care models).

Conclusions

Among South Sudanese female refugees, a self-help intervention with EUC resulted in larger improvements in psychological distress, PTSD and depression symptoms, explosive anger, functional impairment, and subjective wellbeing at 3-months post intervention compared to EUC.

Disclaimer

The opinions expressed in this paper are those of the authors and do not necessarily represent the decisions, policies, or views of the WHO.

Author contributions

WAT, FLB, and MVO designed the study with inputs from KC, JA, RAB, CGM, PV, and RGW. MRL coordinated data collection, with support from DPL, AA, and WAT. AA provided clinical backstopping. RJM and DPL conducted statistical analyses. All authors assisted in interpretation of results. WT wrote a first draft of the manuscript. All authors contributed significantly to revising the manuscript and approved submission. The authors alone are responsible for the views expressed in this article and they do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated.

Declaration of interests

None of the authors have conflicts of interests to disclose.

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Figure 1. Flow diagram of Progress through Phases of a Cluster Randomized Controlled Trial Comparing a Guided Self-Help Intervention vs Enhanced Usual Care Among South Sudanese Women Residing in a Refugee Settlement in Uganda

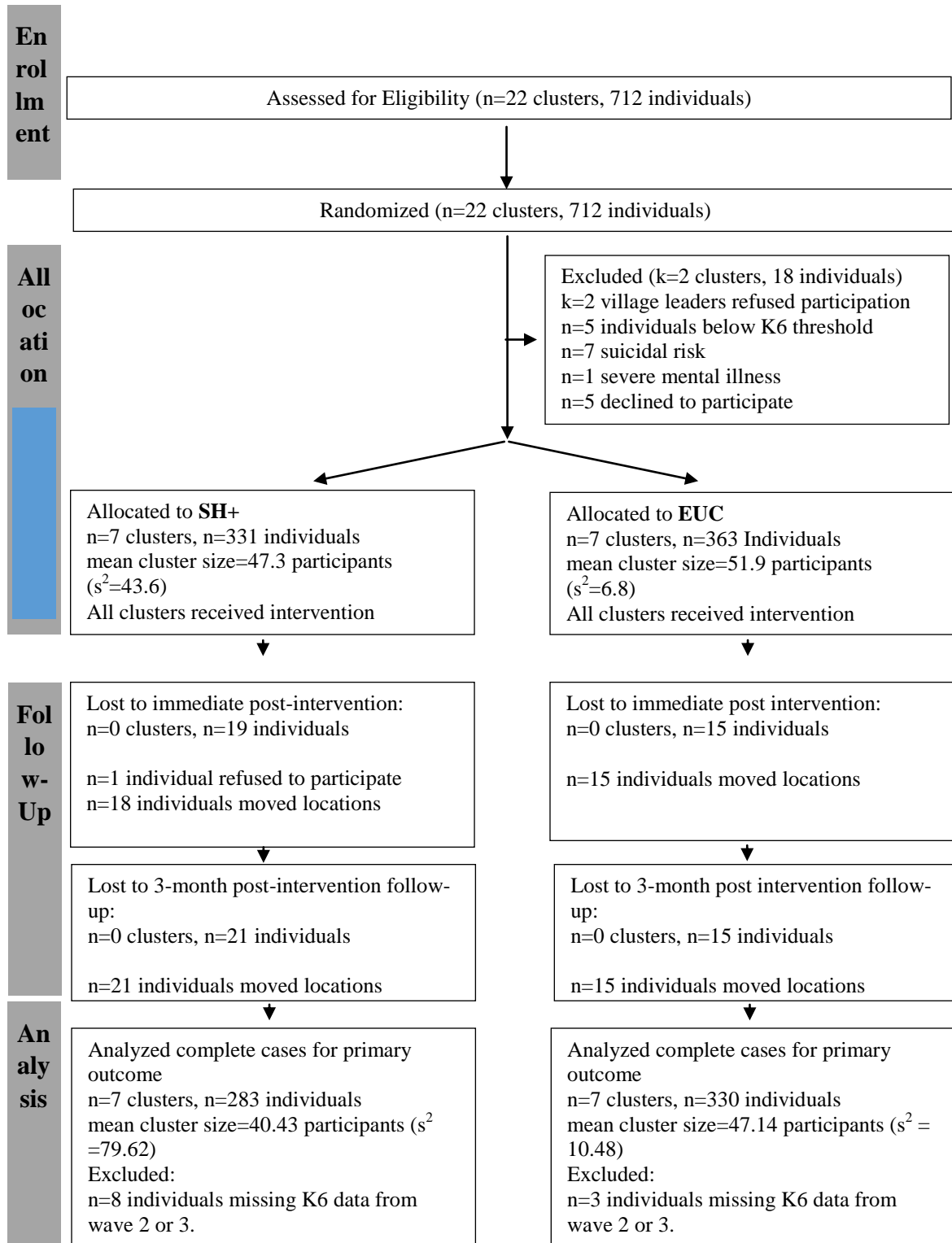


Table 1. Demographic characteristics

Variable	Total (N=694)	Study Condition	
		Intervention (n=331)	Enhanced Usual Care (n=363)
Age, mean (SD)	30.9 (10.9)	30.9 (10.3)	31.0 (11.4)
Education			
No schooling, <i>n</i> (%)	205 (29.5)	98 (29.6)	107 (29.4)
Primary school, <i>n</i> (%)	338 (48.7)	158 (47.7)	180 (49.6)
Secondary and higher, <i>n</i> (%)	134 (19.3)	62 (18.7)	72 (19.8)
Missing, <i>n</i> (%)	17 (2.5)	13(3.9)	4(1.1)
Ethnicity			
Kakwa, <i>n</i> (%)	337 (48.6)	151 (45.6)	186 (51.2)
Dinka, <i>n</i> (%)	68 (9.8)	65 (19.6) †	3 (.8) †
Nuer, <i>n</i> (%)	43 (6.2)	20 (6.0)	23 (6.3)
Other, <i>n</i> (%)	227 (32.7)	81 (24.6) †	146 (40.3) †
Missing	19 (2.7)	14 (4.2)	5 (1.4)
Marital status			
Single/Never Married, <i>n</i> (%)	260 (37.5)	121 (36.6)	139 (38.3)
Married/Living as Married, <i>n</i> (%)	418 (60.2)	197 (59.5)	221 (60.9)
Missing <i>n</i> (%)	16 (2.3)	13(3.9)	3(.8)
Occupation			

Paid work <i>n</i> (%)	10 (1.4)	6 (1.8)	4 (1.1)
Self-employed <i>n</i> (%)	43 (6.2)	23 (7)	20 (5.5)
Farming <i>n</i> (%)	46 (6.6)	23 (7)	23 (6.3)
Student <i>n</i> (%)	5 (.7)	2 (.6)	3 (.8)
Homemaker <i>n</i> (%)	318 (45.8)	149 (45)	169 (46.6)
Retired <i>n</i> (%)	1 (.1)	1 (.3)	-
Unemployed <i>n</i> (%)	245 (35.3)	111 (33.5)	134 (36.9)
Other <i>n</i> (%)	10 (1.4)	3 (.9)	7 (1.9)
Missing, <i>n</i> (%)	16 (2.3)	13(3.9)	3(.8)
Time in refugee settlement			
Less than 6 months	237 (34.2)	153 (46.2)	84 (23.1%)
6mos – 1 Year	196 (28.2)	76 (23) †	120 (33.1) †
More than 1 Year	261 (37.6)	102 (30.8) †	159 (43.8) †

† indicates a significant *p*-value for a χ^2 test of significant difference between study conditions

Table 2. Summary statistics and results from linear mixed-effects models

	Intervention	Enhanced usual care	Mixed-model analysis		
Outcomes and assessment time-point	Mean (SD)	Mean (SD)	Regression coefficients (95% CI)	P value	Effect size
Primary outcome					
K6 score					
Baseline	16.5 (4.1)	16.8 (4.2)			
Post-treatment	10.4 (4.9)	13.5 (4.8)	-3.25 (-4.31, -2.19)	<.0001	-.72
Follow-up	10.5 (4.5)	12.0 (4.9)	-1.20 (-2.33, -.08)	.04	-.26
Secondary outcomes					
PSYCHLOPS score					
Baseline	17.2 (2.8)	16.9 (3.4)			
Post-treatment	12.2 (5.2)	14.7 (4.6)	-2.79 (-4.07, 1.51)	<.0001	-.58
Follow-up	12.1 (4.9)	13.1 (4.8)	-1.17 (-2.37, .04)	.06	-.25
PCL-6 score					
Baseline	22.1 (4.7)	21.7 (5.0)			
Post-treatment	16.1 (5.5)	19.2 (5.5)	-3.53 (-4.67, -2.38)	<.0001	-.68
Follow-up	16.1 (4.9)	17.7 (5.8)	-1.55 (-2.87, -.24)	.02	-.30
PHQ-9 score					
Baseline	15.1 (4.7)	15.1 (4.8)			
Post-treatment	9.7 (5.4)	12.8 (5.3)	-3.78 (-5.39, -2.17)	.0003	-.75
Follow-up	9.5 (4.2)	10.8 (5.1)	-1.46 (-2.77, -.15)	.03	-.31
Explosive anger ^a					
Baseline	79 (25.0)	97 (27.1)			
Post-treatment	49 (15.8)	99 (28.5)	.50 (.32, .50)	.002	.50
Follow-up	42 (14.4)	83 (24.9)	.63 (.40, 1.0)	.04	.63
Interethnic relationship score					
Baseline	7.5 (2.6)	7.7 (2.3)			
Post-treatment	7.2 (2.6)	7.5 (2.3)	-.14 (-.47, .19)	.37	-.06
Follow-up	6.6 (3.0)	7.2 (2.8)	-.19 (-.56, .19)	.30	-.07
AAQ-II score					
Baseline	21.0 (9.6)	20.6 (8.2)			
Post-treatment	27.8 (12.0)	23.9 (10.6)	4.49 (.90, 8.09)	.02	.42
Follow-up	24.5 (14.6)	24.8 (11.4)	1.11 (-4.26, 6.48)	.66	.09
WHODAS 2.0					
Baseline	23.9 (8.7)	23.8 (8.4)			
Post-treatment	15.3 (8.5)	20.7 (9.6)	-6.10 (-7.86, -4.34)	<.0001	-.77
Follow-up	15.0 (7.8)	17.3 (9.0)	-2.52 (-5.01, -.03)	.05	-.30

WHO-5					
Baseline	7.3 (5.1)	7.9 (5.3)			
Post-treatment	11.9 (6.1)	9.5 (5.7)	2.89 (1.52, 4.27)	.0006	.51
Follow-up	11.9 (5.7)	10.4 (5.4)	1.94 (.81, 3.06)	.0028	.36

^a Presence or not of explosive anger attacks, reported as Odds Ratio

Supplementary Materials

Moderator analyses

Primary outcome: Psychological distress (K6)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
Post-intervention ^a	Gender-based violence exposure ^b	-1.50	0.11
	Trauma exposure ^b	-0.15	0.15
	Length of stay in refugee settlement	0.001	0.97
	Initial psychological distress (continuous)	0.13	0.14
	Initial psychological distress (dichotomous) ^c	-1.03	0.31
Follow-up ^d	Gender-based violence exposure ^b	-0.38	0.68
	Trauma exposure ^b	-0.09	0.41
	Length of stay in refugee settlement	0.008	0.75
	Initial psychological distress (continuous)	-0.17	0.06
	Initial psychological distress (dichotomous) ^c	-2.04	0.05

^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Secondary outcome: Personally identified problems (PSYCHLOPS)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
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Post-intervention ^a	Gender-based violence exposure ^b	-2.10	0.07
	Trauma exposure ^b	-0.15	0.15
	Length of stay in refugee settlement	0.001	0.97
	Initial psychological distress (continuous)	-0.15	0.22
	Initial psychological distress (dichotomous) ^c	-1.12	0.40
Follow-up ^d	Gender-based violence exposure ^b	-0.38	0.68
	Trauma exposure ^b	-0.12	0.35
	Length of stay in refugee settlement	-0.02	0.51
	Initial psychological distress (continuous)	-0.04	0.75
	Initial psychological distress (dichotomous) ^c	-1.15	0.38

^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Secondary outcome: Posttraumatic stress symptoms (PCL-6)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
Post-intervention ^a	Gender-based violence exposure ^b	-1.80	0.15
	Trauma exposure ^b	-0.06	0.65
	Length of stay in refugee settlement	0.02	0.50
	Initial psychological distress (continuous)	-0.009	0.99
	Initial psychological distress	-1.02	0.39

	(dichotomous) ^c		
Follow-up ^d	Gender-based violence exposure ^b	-0.58	0.63
	Trauma exposure ^b	-0.09	0.51
	Length of stay in refugee settlement	-0.004	0.90
	Initial psychological distress (continuous)	-0.07	0.56
	Initial psychological distress (dichotomous) ^c	-1.57	0.20

^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Secondary outcome: Depression symptoms (PHQ-9)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
Post-intervention ^a	Gender-based violence exposure ^b	-0.30	0.80
	Trauma exposure ^b	-0.07	0.62
	Length of stay in refugee settlement	0.002	0.95
	Initial psychological distress (continuous)	-0.11	0.29
	Initial psychological distress (dichotomous) ^c	-1.27	0.26
Follow-up ^d	Gender-based violence exposure ^b	-0.58	0.63
	Trauma exposure ^b	-0.04	0.76
	Length of stay in refugee settlement	-0.009	0.75
	Initial psychological distress (continuous)	-0.02	0.81

	Initial psychological distress (dichotomous) ^c	-1.97	0.07
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^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Secondary outcome: Feelings of anger (explosive anger index)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
Post-intervention ^a	Gender-based violence exposure ^b	0.39	0.40
	Trauma exposure ^b	0.01	0.79
	Length of stay in refugee settlement	0.03	0.15
	Initial psychological distress (continuous)	-0.05	0.35
	Initial psychological distress (dichotomous) ^c	-0.93	0.12
Follow-up ^d	Gender-based violence exposure ^b	0.05	0.92
	Trauma exposure ^b	0.02	0.75
	Length of stay in refugee settlement	-0.02	0.88
	Initial psychological distress (continuous)	-0.02	0.68
	Initial psychological distress (dichotomous) ^c	-1.00	0.26

^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Secondary outcome: Interethnic group relations (locally developed measure)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
Post-intervention ^a	Gender-based violence exposure ^b	-0.20	0.50
	Trauma exposure ^b	0.08	0.02*
	Length of stay in refugee settlement	0.003	0.75
	Initial psychological distress (continuous)	-0.01	0.81
	Initial psychological distress (dichotomous) ^c	0.22	0.54
Follow-up ^d	Gender-based violence exposure ^b	0.08	0.81
	Trauma exposure ^b	0.01	0.70
	Length of stay in refugee settlement	-0.01	0.29
	Initial psychological distress (continuous)	-0.06	0.10
	Initial psychological distress (dichotomous) ^c	-0.30	0.43

^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Secondary outcome: Psychological flexibility (AAQ-II)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
Post-intervention ^a	Gender-based violence exposure ^b	4.1	0.06
	Trauma exposure ^b	0.28	0.26

	Length of stay in refugee settlement	0.05	0.38
	Initial psychological distress (continuous)	0.51	0.02*
	Initial psychological distress (dichotomous) ^c	3.84	0.10
Follow-up ^d	Gender-based violence exposure ^b	-2.12	0.32
	Trauma exposure ^b	0.30	0.23
	Length of stay in refugee settlement	-0.002	0.98
	Initial psychological distress (continuous)	0.35	0.13
	Initial psychological distress (dichotomous) ^c	3.74	0.15

^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Secondary outcome: Functional impairment (WHODAS 2.0, 12-item)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
Post-intervention ^a	Gender-based violence exposure ^b	-1.6	0.35
	Trauma exposure ^b	-0.34	0.08
	Length of stay in refugee settlement	0.01	0.80
	Initial psychological distress (continuous)	-0.22	0.20
	Initial psychological distress (dichotomous) ^c	-1.96	0.28
Follow-up ^d	Gender-based violence exposure ^b	0.93	0.53

	Trauma exposure ^b	-0.09	0.61
	Length of stay in refugee settlement	0.02	0.69
	Initial psychological distress (continuous)	0.04	0.79
	Initial psychological distress (dichotomous) ^c	0.18	0.92

^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Secondary outcome: Subjective wellbeing (WHO-5)

<i>Assessment time-point</i>	<i>Moderator</i>	<i>B</i>	<i>P-value</i>
Post-intervention ^a	Gender-based violence exposure ^b	3.5	0.003**
	Trauma exposure ^b	0.16	0.22
	Length of stay in refugee settlement	-0.02	0.60
	Initial psychological distress (continuous)	0.20	0.07
	Initial psychological distress (dichotomous) ^c	1.69	0.16
Follow-up ^d	Gender-based violence exposure ^b	-0.21	0.85
	Trauma exposure ^b	0.20	0.11
	Length of stay in refugee settlement	-0.02	0.37
	Initial psychological distress (continuous)	-0.05	0.66
	Initial psychological distress (dichotomous) ^c	-0.33	0.78

^a 6-week post-baseline (1 week after intervention) ^b Total number of types of lifetime exposure events; ^c Dichotomized as moderate psychological distress (5-12) and severe psychological distress (≥ 13) ^d 18-week post-baseline (3 months after intervention)

Post-hoc analyses

Impacts on participants with severe psychological distress

Proportion of participants with K6 scores ≥ 13

	SH+ condition N(%)	Control condition N(%)	Total N(%)
Baseline	277 (83.7%)	305 (84.0%)	582 (83.9%)
Post-intervention	110 (33.2%)	209 (57.6%)	319 (46.0%)
Follow-up	130 (39.3%)	174 (47.9%)	304 (43.8%)

Minimally important difference

Percentage of participants achieving MID (0.5 SD change) on psychological distress between baseline and 3-month follow-up

	SH+ condition N(%)	Control condition N(%)	Total N(%) ^a
No MID change	54 (16.3)	63 (17.4)	117 (16.9)
Positive MID change	207 (62.5)	212 (58.4)	419 (60.4)
Detrimental MID change	30 (9.1)	58 (16.0)	88 (12.7)
Missing ^b	40 (12.1)	30 (8.3)	70 (10.1)
Total	331 (100.0)	363 (100.0)	694 (100.0)

a: Pearson $\chi^2(3) = 9.6346$, $p = 0.022$; b: These are raw calculations, not applying any imputation methods for people who were lost to follow-up at either baseline or 3-month follow-up

Percentage of participants achieving MID (0.5 SD change) on posttraumatic stress symptoms between baseline and 3-month follow-up

	SH+ condition N(%)	Control condition N(%)	Total N(%)^a
No MID change	43 (13.0)	73 (20.1)	116 (16.7)
Positive MID change	203 (61.3)	182 (50.1)	385 (55.5)
Detrimental MID change	35 (10.6)	76 (20.9)	111 (16.0)
Missing ^b	50 (15.1)	32 (8.8)	82 (11.8)
Total	331 (100.0)	363 (100.0)	694 (100.0)

a: Pearson $\chi^2(3) = 26.58, p < .0001$; b: These are raw calculations, not applying any imputation methods for people who were lost to follow-up at either baseline or 3-month follow-up

Percentage of participants achieving MID (0.5 SD change) on depression symptoms between baseline and 3-month follow-up

	SH+ condition N(%)	Control condition N(%)	Total N(%)^a
No MID change	38 (11.5)	52 (14.3)	90 (13.0)
Positive MID change	195 (58.9)	205 (56.5)	400 (57.6)
Detrimental MID change	48 (14.5)	74 (20.4)	122 (17.6)
Missing ^b	50 (15.1)	32 (8.8)	82 (11.8)

	331 (100.0)	363 (100.0)	694 (100.0)
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a: Pearson $\chi^2(3) = 10.4667$, $p = 0.015$; b: These are raw calculations, not applying any imputation methods for people who were lost to follow-up at either baseline or 3-month follow-up

CONSORT checklist

[Click here to download Necessary Additional Data: SH+ cRCT paper LGH CONSORT checklist 2019-05-27.docx](#)

Statistical Protocol

[Click here to download Necessary Additional Data: SH+ cRCT Uganda Statistical Protocol.docx](#)



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May 27, 2019

Dear Dr Mullan,

We are excited to submit our work for publication in the *Lancet Global Health*. We completed a state-of-the-art cluster randomized trial (n=694) of an innovative multi-media self-help intervention with refugees in a low-resource humanitarian setting. To the best of our knowledge, this is the first trial of a self-help intervention, and the largest mental health trial ever conducted with refugees.

We believe the paper would be of interest to readers of the *Lancet Global Health* for at least three reasons.

First, the **mental health of refugees is a critical global public health concern**. Several influential papers published in the *Lancet* family of journals have demonstrated the ubiquity of psychological distress, mental disorders, and their impact on functioning in conflict-affected populations over the last decades (1-6). This issue is currently particularly urgent, since the world is experiencing the highest ever-recorded number of refugees (>65 million). However, most conflict-affected and displaced populations live in low- and middle-income countries, where resources to meet this vast crisis are sorely insufficient.

Important progress has been made in strengthening evidence for psychological interventions with conflict-affected populations in low-resource settings. The *Lancet* continues to be at the forefront of publishing randomized controlled trials for such populations and contexts (7). Collectively, evaluations have shown that lay practitioners can reduce symptoms of mental disorders in low-resource settings with moderate to large effect sizes (5, 8). WHO guidance accordingly recommends such interventions (9, 10).

However, **there are major challenges with bringing evidence-based psychotherapies to the scale required to meet the needs of the world's record number of refugees**. Scaling up evidence-based psychotherapies in low-resource settings is inhibited by the significant resources required to train and adequately supervise a clinical workforce. Although task shifting to non-specialists is a key strategy, non-specialists offering psychological interventions need to be well-trained and supervised - a highly challenging requirement in insecure contexts. Maintaining fidelity to intervention manuals is a major obstacle in real-world humanitarian settings. In addition, many refugees suffer from subsyndromal psychological distress, which poses risk for subsequent mental disorders and is associated with marked impairment. Such distress is not cost-efficiently addressed by resource-intensive psychotherapies focused on particular disorders.

Finally, although non-specialist-delivered interventions effectively reduce psychological symptoms they typically reach individuals or small groups of people at a time.

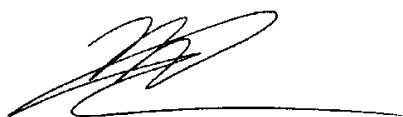
The WHO developed an innovative, brief, guided self-help intervention called Self Help Plus (SH+) to address these challenges. SH+ consists of audio-recorded materials and an illustrated self-help book, which is delivered by briefly trained facilitators over five workshops with 20-30 people. SH+ addresses above-noted challenges by decreasing requirements for training and supervision while ensuring fidelity through use of audio-recordings and a self-help book; targeting psychological distress regardless of whether people meet criteria for diagnosable mental disorders; and tripling the number of participants reached per session.

Second, we believe we have completed a **state-of-the-art trial in difficult circumstances**. We were able to conduct a study adhering to cluster CONSORT guidelines in a remote and dynamic refugee settlement in northwestern Uganda. We completed a sufficiently-powered study after substantive formative work (11, 12). Our trial was registered prior to data collection (13); we applied well-tested instruments; did not find evidence of contamination; were able to blind assessors to study condition; had high levels of participation in the intervention; and – due to intensive tracking – lost few people at follow-assessments (4.9% at the immediate post-intervention assessment, 5.2% at 3-month post-intervention assessment).

Third, we found **promising results for an innovative intervention with high potential for scale-up**. Screening using the Kessler 6, based on moderate psychological distress (≥ 5), resulted in the *de facto* implementation of SH+ as a universal intervention. Given the variety of mental health conditions in universal interventions these tend to have smaller effect sizes, but this is outweighed by their greater feasibility and reach. We found a moderately large effect size on the primary outcome immediately after the intervention (psychological distress, $d=0.72$), which was reduced at the 3-month post-intervention assessment ($d=0.26$). Three months after intervention we also found meaningful effect sizes on five of eight secondary outcomes (effect size range $d=0.30-0.36$). These results compare favorably to evaluations of psycho-education, audio-recorded self-help interventions with adversity-affected populations in high-income settings (e.g., the Coping with Depression Course's meta-analysis effect size of $d=0.28$) (14). Analysis of moderators showed that SH+ benefits were experienced similarly across participants with different trauma histories, initial distress levels, and length of stay in refugee settlements.

Our findings show that SH+ may be a safe, applicable, feasible, and effective first-line intervention to reduce psychological distress in large populations exposed to major stressors.

Sincerely, on behalf of the author team,



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