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

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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, facilitator-guided group-based self-help intervention. The intervention (Self-Help Plus, SH+) can be rapidly taught to lay providers, is delivered to large groups of people in workshops through audio recordings and an illustrated self-help book. Compared to controls, 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 facilitator-guided, group-based 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). The 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 per site. 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. Compared to controls, we found stronger improvements for SH+ on psychological distress three months post-intervention (β= -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, facilitator-guided, group-based 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.

*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 and innovative strategies have been tested, important challenges to providing mental health and psychosocial support interventions at scale in low-resource humanitarian settings remain.

First, current evidence-based treatments generally require a substantial clinical workforce not typically available in disrupted, under-resourced health systems.4 Task sharing with non-specialists has been a key strategy, also in humanitarian settings.5-7 At the same time, non-specialists offering psychological interventions need to be well-trained and supervised, a challenging requirement in insecure contexts.8

Secondly, current evidence-based interventions commonly target single mental disorders, whereas comorbidity is highly prevalent in humanitarian settings.9 Training providers in multiple evidence-based therapies for multiple disorders is resource-prohibitive. Recent efforts have focused on developing and testing transdiagnostic approaches in humanitarian settings, i.e. interventions that can address symptoms across a range of mental disorders. For example, interventions such as the Common Elements Treatment Approach,10 Problem Management Plus,11 and Youth Readiness Intervention12 have combined elements from disorder-specific evidence-based treatments to target (signs and symptoms of) multiple mental disorders.

Thirdly, studies on mental health interventions in humanitarian settings have predominantly focused on people scoring above cut-offs on symptom checklists associated with particular mental disorders (notably PTSD and depression). However, subsyndromal psychological distress is also highly prevalent in conflict-affected populations.8 Psychological distress poses risk for subsequent mental disorders and causes marked impairment13,14.

Fourthly, 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. In settings of armed conflict, large groups of women are survivors of gender-based violence and experience gendered stressors.15 Although previous studies have evaluated effective treatment strategies with conflict-affected women and girls,5,16 there remains a paucity of knowledge on how to bring mental health supports to the required scale.17

Against these challenges, it is clear that addressing the substantive mental health needs in humanitarian settings will require further innovation. 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.18 The World Health Organization (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+).19 The intervention’s format was informed by meta-analyses showing promising results for bibliotherapy, group-based pre-recorded psychoeducational self-help interventions and guided self-help in general.20,21 The intervention builds on existing innovations in delivery of mental health interventions in humanitarian settings by relying on task sharing and addressing a broader range of mental health difficulties. At the same time, the intervention was designed to address challenges related to scale and access, by (1) further reducing the burden and demand on a workforce of non-specialists through delivery in the form of a preformatted multi-media package; and (2) more quickly reaching larger numbers of people because the intervention can be delivered in workshops with 20-30 people. In addition, the intervention’s focus on psychological distress broadly (by teaching stress management skills that may be applied across a range of difficulties) may further reduce needs for detailed diagnostic procedures, thus enhancing potential for scale-up.

Following formative research,22,23 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 cRCT from April to October 2017 (Figure 1). The trial protocol was published previously,24 and no changes were made to design after the trial started. A cluster design was chosen to avoid contamination of intervention materials within villages, because participants may share self-help materials (e.g., the book) with their neighbors. 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, and were interested in detecting an effect size of at least 0.20.20,25 We used the PowerUp! Tool to estimate sample size, using an average cluster size of 42 individuals, 14 clusters (equal assumed), intracluster 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.

*Randomization and masking*

Randomization was performed by an independent epidemiologist at Johns Hopkins University. A simple random allocation sequence was generated using Stata 14,26 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. The independent assessors administered the Kessler 6 (K6) to assess psychological distress, applying a cut-off of ≥5 for moderate-level psychological distress.14 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, and participants showing observable signs of severe mental disorder (e.g., psychosis) were referred to a standby psychiatric 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. More detailed information about session content can be found in the **Supplementary Material 1**. ACT builds on the cognitive behavioural therapy tradition and includes some common elements (such as engagement and psychoeducation). However, ACT uses specific techniques (e.g. cognitive defusion, mindfulness exercises, values clarification exercises) to help promote psychological flexibility - the ability to contact the present moment more fully and to maintain or change behavior so that the person behaves in a way that is consistent with their subjectively identified values.27 SH+ incorporates many of these factors, with a strong focus on mindful practices and grounding, values clarification, and compassion (being kind to self and others), with the latter also encouraging a social support element through the practice of acts of kindness towards others outside of sessions. ACT is a-diagnostic in that it is not a syndrome- or symptom-based approach. Instead it aims to support people in finding more functional ways of coping with difficult life experiences given their self-identified values. A recent systematic review of ACT mediation studies found that of the five studies that examined this question, four showed psychological flexibility to mediate treatment outcomes.28 Although ACT focuses on promoting values-based living, rather than attempting to directly control or reduce symptoms, there is nonetheless a substantial evidence base linking ACT with reductions in anxiety, depression, and stress,29 and there is an emerging evidence for mindfulness based-approaches and ACT25 in self-help formats. In this study, we therefore expected to find stronger improvements in the intervention condition on all symptom measures. ‘Third-wave’ approaches (such as ACT and mindfulness-based approaches) have been piloted previously in humanitarian settings,30-32 but this is – to the best of our knowledge – the first randomized trial. SH+ comprises a pre-recorded psychoeducational audio-course of five weekly 2-hour sessions, delivered in workshops with 20-30 participants. 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”,33 a local idiom of psychological distress and a target of ACT. Initial piloting with one group of male and female refugees each identified challenges with engagement and participation of male refugees.22 We subsequently decided to focus further piloting and the current trial on female refugees, and engage in a separate trajectory to adapt and test the intervention with male refugees. A feasibility cRCT23 found SH+ to be relevant, acceptable, and feasible among female South Sudanese refugees. The population in the Rhino Camp refugee settlement consists in large majority of women and children. Female refugees have been exposed to high levels of gender-based violence. We were interested in testing an intervention that could reduce distress in this particular population, and SH+ materials briefly mention gender-based violence as a potential cause of psychological distress. At the same time, we were interested in testing an intervention that could strengthen skills to manage distress arising from a broader range of stressors in both men and women, in order to (1) avoid potential stigma resulting from specifically targeting gender-based violence survivors, and (2) enhance potential scale-up through keeping content more broadly applicable.

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)22 and feasibility trial (4 days)23 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). Fidelity was checked by the intervention supervisor through adherence forms completed by facilitators. In addition, 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 once for 30 minutes 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 (1) psychosocial and pharmacological interventions, offered by a multi-disciplinary mental health team that visited the four government primary health care centers weekly; (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 a structured procedure including: (1) initial translation from English to Juba Arabic by a bi-lingual team, with immediate back-translation to English to ensure appropriate translation by the study team; (2) review by an independent South Sudanese mental health expert to assess translations for clinical validity; and (3) several rounds of piloting in which we checked item functioning and consulted with a bilingual team and the community advisory board about comprehensibility, acceptability and other response set issues, relevance, and completeness.34 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. We selected the K6, as opposed to e.g. a symptom checklist associated with a particular disorder, because it matched well with: (1) the idiom of ‘overthinking’ identified in previous qualitative research,33 thus measuring a psychological construct of local salience; (2) the broader stress management aims of SH+. 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).35 The K6 has been widely applied with good psychometric properties in a range of socio-cultural settings.35 We applied the standard cut-off for moderate levels of psychological distress (≥5)14 with internal consistency (Cronbach Alpha; α) of 0.65.

*Secondary Outcomes*

Personally identified problems were examined with the Psychological Outcome Profiles instrument (PSYCHLOPS),36 which asks participants to describe two problems from their own perspective and rate problem severity on a 6-point scale (range 0-18, α=0.65). PTSD symptoms were assessed with the PTSD Checklist-Civilian 6-item version (PCL-6), using a 5-point scale (range 6-30, α=0.72).37 We measured depression symptoms with the Patient Health Questionnaire, 9-item version (PHQ-9), which has a 4-point scale (range 0-27, α=0.67). Anger was assessed using two dichotomous questions asking about explosive anger attacks.38 Based on formative research22 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, α=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)39 (seven items on a 7-point scale, range 7-49, α=0.77).

Functional impairment and subjective wellbeing were assessed with the WHO Disability Assessment Schedule 2.0 (WHODAS)40 and the WHO-5 Wellbeing Index (WHO-5).41 We used the 12-item version of the WHODAS, which uses a 5-point scale (range 12-60, α=0.78. The WHO-5 contains five questions using a 6-point scale (range 0-25, α=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).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 R 42 with village as a random effect. We present adjusted odds ratios (AORs), and 95% confidence intervals (CIs) using data from the same individual for 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 psychological distress 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**

This study was funded by Elrha’s Research for Health in Humanitarian Crises (R2HC) Programme, which aims to improve health outcomes by strengthening the evidence base for public health interventions in humanitarian crises. The R2HC programme is funded by the UK Government (DFID), the Wellcome Trust, and the UK National Institute for Health Research (NIHR). 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 (seven for being at imminent risk of suicide and one for potential psychosis) 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 of these 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 30.9 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%). The most commonly mentioned adversities from the HTQ were (1) lack of food or clean water (n = 643, 92.7%), lacking shelter (n = 609, 87.8%), and losing a family member to violence (n = 580, 83.6%). In this sample, 182 women (26.2%) reported lifetime physical violence perpetrated by an intimate partner, 70 reported sexual violence by an intimate partner (10.1%), 167 women reported physical violence by someone other than their partner (24.1%), and 46 reported sexual violence by someone other than their partner (6.6%). The primary outcome psychological distress correlated as expected with other variables, indicating discriminant and convergent validity (**Supplementary Material 2**). With regard to safety considerations, the independent Data Safety Management Board responded to 6 adverse events, and none were evaluated to be concerns in response to the intervention.

**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 (β=-3.25; *p*<0.0001; 95% CI=-4.31,-2.19, *d*=-0.72) and three months after intervention relative to the EUC (β=-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 Material 3**).

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 Material 3**).

Assessment of over 10% of SH+ sessions showed near-perfect fidelity: two minor mistakes across all eight observed 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 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 4**).

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 conducted in other settings14 indicates a high likelihood of having a serious mental disorder causing functional limitations requiring treatment) as opposed to moderate levels of psychological distress (5-12). 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.

Secondly, 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.43 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 χ2(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 χ2(3) = 26.58, p<.0001) and depression symptoms (Pearson χ2(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 population 4. The intervention attempted to meet these challenges by further innovation in the area of task sharing and intervention delivery (i.e., 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, compared to the control arm, we found larger improvements at the 3-month post-intervention assessment in the SH+ arm for the primary outcome of 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),20 and some transdiagnostic interventions in conflict-affected low-resource settings (e.g.12). Screening for moderate psychological distress resulted in neglible exclusion and *de facto* implementation of SH+ as a universal intervention in these refugee settlements. 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 a lower than acceptable internal consistency of 0.65, indicating it may tap into multiple types of mental health phenomena rather than one unified concept, which may hamper consistent interpretation of change over time. Third, we did not control for frequency of contact with service providers between study conditions. Fourth, we randomized a limited number of clusters. Although we did not identify differences between study conditions at baseline, it is possible that clusters differed on unmeasured variables. Fifth, our study focused on female refugees, which has important implications for generalizability. Women are an important group in conflict-affected settings given their high exposure to systematic and gendered adversities, but it will also be critical to understand how male mental health needs may be addressed.

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,44 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 Currently, there is limited knowledge on whether these drops in effect sizes are due to intervention-related processes (e.g., a loss of gained skills over time, a return to previous behavior patterns), or context-related processes (e.g., new or continued adversities associated with renewed psychological distress). 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. Second, a related question concerns how SH+ may have achieved its effects, i.e. the mechanisms of change. Research on this topic would also assist in situating this ‘third wave’ intervention vis a vis cognitive behavioral treatment elements more commonly tested in humanitarian settings. Such research could consist of detailed mediation analyses, as well as an effort to understand participants’ own perspectives regarding identified benefits. Third, future research should address 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). An important question for all psychological interventions tested in controlled research settings concerns how quality of implementation and monitoring of safety concerns can be guaranteed as part of routine service delivery. Additional questions concern: whether SH+ may be an effective preventive intervention, and cost-effectiveness of SH+ compared to established evidence-based psychotherapies.

**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.

**Autthor 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. KC and TA conducted SH+ training and provided intervention-related technical backstopping. 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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**

*Table 1. Demographic characteristics*

|  |  |  |
| --- | --- | --- |
|  |  | **Study Condition** |
| **Variable** | **Total (N=694)** | **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, *n* (%) | 205 (29.5) | 98 (29.6) | 107 (29.4) |
| Primary school, *n* (%) | 338 (48.7) | 158 (47.7) | 180 (49.6) |
| Secondary and higher, *n* (%) | 134 (19.3) | 62 (18.7) | 72 (19.8) |
| Missing, n (%) | 17 (2.5) | 13(3.9) | 4(1.1) |
| Ethnicity |
| Kakwa, *n* (%) | 337 (48.6) | 151 (45.6) | 186 (51.2) |
| Dinka, *n* (%) | 68 (9.8) | 65 (19.6) † | 3 (.8) † |
| Nuer, *n* (%) | 43 (6.2) | 20 (6.0) | 23 (6.3) |
| Other, *n* (%) | 227 (32.7) | 81 (24.6) † | 146 (40.3) † |
| Missing | 19 (2.7) | 14 (4.2) | 5 (1.4) |
| Marital status |  |
| Single/Never Married, *n* (%) | 260 (37.5) | 121 (36.6) | 139 (38.3) |
| Married/Living as Married, *n* (%) | 418 (60.2) | 197 (59.5) | 221 (60.9) |
| Missing *n* (%) | 16 (2.3) | 13(3.9)  | 3(.8)  |
| Occupation |  |
| Paid work *n* (%) | 10 (1.4) | 6 (1.8) | 4 (1.1) |
| Self-employed *n* (%) | 43 (6.2) | 23 (7) | 20 (5.5) |
| Farming *n* (%) | 46 (6.6) | 23 (7) | 23 (6.3) |
| Student *n* (%) | 5 (.7) | 2 (.6) | 3 (.8) |
| Homemaker *n* (%) | 318 (45.8) | 149 (45) | 169 (46.6) |
| Retired *n* (%) | 1 (.1) | 1 (.3) | - |
| Unemployed *n* (%) | 245 (35.3) | 111 (33.5) | 134 (36.9) |
| Other *n* (%) | 10 (1.4) | 3 (.9) | 7 (1.9) |
| Missing, *n* (%) | 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 𝝌2 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 (0 - 24) |  |  |  |  |  |
| 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 (0 - 20) |  |  |  |  |  |
| 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 (6 – 30) |  |  |  |  |  |
| Baseline | 22.0 (4.7) | 21.8 (4.8) |  |  |  |
| 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 (0 - 27) |  |  |  |  |  |
| 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 angera (4 - 16) |  |  |  |  |  |
| 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 (3 - 12) |  |  |  |  |  |
| 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 (7 - 49) |  |  |  |  |  |
| Baseline | 21.9 (8.8) | 20.9 (7.9) |  |  |  |
| Post-treatment | 29.6 (10.1) | 25.0 (9.6) | 4.49 (.90, 8.09) | .02 | .42 |
| Follow-up | 30.2 (9.4) | 27.1 (9.0) | 1.11 (-4.26, 6.48) | .66 | .09 |
| WHODAS 2.0 (0 - 48) |  |  |  |  |  |
| 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 (0 - 25) |  |  |  |  |  |
| 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 Material 1: Overview of Self Help Plus (SH+)**

Note: SH+ undergoes a rigorous cultural adaptation, where terms and concepts are modified as required. The table below describes SH+ using terminology from the generic English language version.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Session 1** | **Session 2** | **Session 3** | **Session 4** | **Session 5** |
| **Overall Theme** | **Grounding** | **Unhooking** | **Values** | **Being Kind** | **Making Room** |
| **Main goals** | * Engage participants
* Practice present-centered awareness during an everyday activity (e.g. awareness of drinking)
* Practice grounding, as a way to respond effectively to stress
 | * Practice noticing and naming difficult thoughts and feelings to further unhook from them
 | * Participants clarify their own personal values
* Learn to engage in values-guided actions
 | * Identify ways to act kindly towards oneself and towards others
* Learn to engage in values-guided actions during difficult situations
 | * Learn to accept difficult thoughts and feelings, rather than struggling with them
 |
| **Encouragemnt of practice** | In each session, there is suggestion to practice one or more exercises (e.g. grounding, practicing notice and naming), as well as a discussion on experiences from practice. |
| **Engagement** | * Included reviewing ground rules, instilling hope of change, brief self-reflection on reasons for attending the group, validation and self-acknowledgement of participants' effort and motivation to attend group
 |
| **Psychoeducation** | * Normalize and validate experiencing stress
* Introduce concepts of getting "hooked" by difficult thoughts and feelings when stressed, and getting lost in "emotional storms", which often leads people to do things distractedly or behave in ways that move them away from who they would like to be
 | * Provide information on the different ways that people often try to get rid of difficult thoughts and feelings (e.g., isolating, using drugs or alcohol), and how these actions are largely ineffective and often create additional problems
 | * Introduce concept of values as one's deepest desires for who they would like to be as a person
* Introduce concept of acting in accordance with one's values
 | * Normalize the tendency for people to treat themselves unkindly and present rationale for self-kindness
* Provide examples of acting in kind and caring ways, even in difficult situations
* Introduce values-based problem solving (i.e., acting in line with values in the midst of difficult situations)
 | * Provide rationale for accepting difficult thoughts and feelings, rather than trying to get rid of them
 |
| **Experiential Exercises** | * **Awareness of drinking**: Practice "paying attention with curiosity" by using the five senses to observe and drink water/tea.
* **Grounding**: Breathe slowly, focus on the breath, and then refocus attention on the external world using the five senses.
 | *Repeat from last session:** **Grounding**

*New exercises:** **Awareness exercise:** Identify difficult physical sensations and thoughts
* **Hands as thoughts and feelings**: Imagining that the person’s hands represent their difficult thoughts and feelings, participants experience getting "hooked" vs "unhooking" from them.
* **Notice and Name**: Unhook from difficult thoughts and feelings by noticing them, naming them, and then refocusing on the external world in the present.
* **Mindfulness of Sounds**: Mindfully pay attention to sounds, while noticing the difference between the sounds and one's thoughts about those sounds
 | *Repeat from last session:** **Hands as thoughts and feelings**
* **Notice and name**
* **Grounding**

*New exercises:** **Values clarification:** Identify 2-3 values that are most personally important
* **Committed actions:** Make a plan to engage in values-guided actions over the next week
 | *Repeat from last session:** **Notice and name**
* **Grounding**

*New exercises:** **Unkind judgments:** Identify unkind self-judgments and practice grounding
* **Befriending others:** Identify kind words and actions and imagine using these with others.
* **Befriending yourself**: Practice self-compassion with kind words and touch.
* **Values-guided problem-solving:** Make a plan to engage in values-guided actions when faced with a difficult situation over the next week
 | *Repeat from last session:** **Notice and name**
* **Grounding**
* Brief self-kindness practice

*New exercises:** **Pushing paper:** Participants imagine that all their difficult thoughts and feelings are on a piece of paper. They experience pushing away vs accepting their thoughts and feelings.
* **Making room**: Participants practice noticing, naming, and making room for difficult thoughts and feelings, rather than trying to get rid of painful internal experiences.
 |
| **Core components** | The following components are included in one or more sessions during the SH+ course as both psychoeducation and practice.a) Contact with the present moment, b) Acceptance, c) Defusion, d) Values, e) Committed Action, f) Compassion towards self and others,  |

**Supplementary Material 2: Additional details regarding psychometric functioning of the primary outcome Kessler 6 (K6)**

**Bivariate correlations at baseline**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | K6 | WHODAS | PSYCHLOPS | PHQ9 | PCL6 | WHO5 | HTQA |
| K6 | 1.00 |  |  |  |  |  |  |
| WHODAS | **0.23\*** | 1.00 |  |  |  |  |  |
| PSYCHLOPS | **0.28\*** | 0.30\* | 1.00 |  |  |  |  |
| PHQ9 | **0.21\*** | 0.50\* | 0.32\* | 1.00 |  |  |  |
| PCL6 | **0.26\*** | 0.48\* | 0.30\* | 0.52\* | 1.00 |  |  |
| WHO5 | **-0.23\*** | -0.22\* | -0.29\* | -0.16\* | -0.29\* | 1.00 |  |
| HTQA | **0.20\*** | 0.22\* | 0.21\* | 0.27\* | 0.31\* | -0.05 | 1.00 |

K6: Kessler 6 (psychological distress); WHODAS: World Health Organization Disability Assessment Schedule 2.0, 12-item interviewer administered version (functional impairment); PSYCHLOPS: Psychological Outcome Profiles instrument (personally identified problems); PHQ9: Patient Health Questionnaire, 9-item version (depression symptoms); PCL6: PTSD Checklist-Civilian 6-item version; WHO5: WHO-5 Wellbeing Index (subjective wellbeing): HTQ: Harvard Trauma Questionnaire section A adapted (exposure to potentially traumatic events); \*: correlation coefficients significant at p ≤ .05.

**High psychological distress (≥13) and potentially traumatic events (HTQ-A) (χ2-tests)**

Potentially traumatic events (HTQ-A): participants reporting K6≥13 are more likely to report losing a family member to violence (χ2 = 6.26, p = .012), experiencing physical violence by someone other than a partner (χ2 = 8.60, p = .003); witnessing sexual abuse or rape (χ2 = 3.59, p = .06) being beaten by a current or previous partner (χ2 = 3.17, p = .08) were marginally significant

**High psychological distress (≥13) and functional impairment (WHODAS) (between-groups t-test)**

Women with higher K6 scores had a significantly higher mean disability score (Mean = 24.56) compared to women with lower K6 scores (Mean = 20.04, t = -5.17, p <.0001).

**Supplementary Material 3: Moderator analyses**

*Primary outcome: Psychological distress (K6)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | -1.50 | 0.11 |
|  | Trauma exposureb | -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-upd | Gender-based violence exposureb | -0.38 | 0.68 |
|  | Trauma exposureb | -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)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | -2.10 | 0.07 |
|  | Trauma exposureb | -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-upd | Gender-based violence exposureb | -0.38 | 0.68 |
|  | Trauma exposureb | -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)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | -1.80 | 0.15 |
|  | Trauma exposureb | -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 (dichotomous)c | -1.02 | 0.39 |
| Follow-upd | Gender-based violence exposureb | -0.58 | 0.63 |
|  | Trauma exposureb | -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)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | -0.30 | 0.80 |
|  | Trauma exposureb | -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-upd | Gender-based violence exposureb | -0.58 | 0.63 |
|  | Trauma exposureb | -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 |

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)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | 0.39 | 0.40 |
|  | Trauma exposureb | 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-upd | Gender-based violence exposureb | 0.05 | 0.92 |
|  | Trauma exposureb | 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)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | -0.20 | 0.50 |
|  | Trauma exposureb | 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-upd | Gender-based violence exposureb | 0.08 | 0.81 |
|  | Trauma exposureb | 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)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | 4.1 | 0.06 |
|  | Trauma exposureb | 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-upd | Gender-based violence exposureb | -2.12 | 0.32 |
|  | Trauma exposureb | 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)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | -1.6 | 0.35 |
|  | Trauma exposureb | -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-upd | Gender-based violence exposureb | 0.93 | 0.53 |
|  | Trauma exposureb | -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)*

|  |  |  |  |
| --- | --- | --- | --- |
| *Assessment time-point* | *Moderator* | *B* | *P-value* |
| Post-interventiona | Gender-based violence exposureb | 3.5 | 0.003\*\* |
|  | Trauma exposureb | 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-upd | Gender-based violence exposureb | -0.21 | 0.85 |
|  | Trauma exposureb | 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)

**Supplementary Material 4: 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) |
| Missingb | 40 (12.1) | 30 (8.3) | 70 (10.1) |
| **Total** | 331 (100.0) | 363 (100.0) | 694 (100.0) |

a: Pearson chi2(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) |
| Missingb | 50 (15.1) | 32 (8.8) | 82 (11.8) |
| **Total** | 331 (100.0) | 363 (100.0) | 694 (100.0) |

a: Pearson chi2(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) |
| Missingb | 50 (15.1) | 32 (8.8) | 82 (11.8) |
|  | 331 (100.0) | 363 (100.0) | 694 (100.0) |

a: Pearson chi2(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