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Prevention and promotion effects of Self Help Plus: secondary analysis of cluster randomised controlled trial data among South Sudanese refugee women in Uganda

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ABSTRACT

Introduction Evidence-based and scalable prevention and promotion focused mental health and psychosocial support interventions are needed for conflict-affected populations in humanitarian settings. This study retrospectively assessed whether participation in Self Help Plus (SH+) versus enhanced usual care (EUC) resulted in reduced incidence of probable mental disorder and increased positive mental health and well-being post-intervention among South Sudanese refugee women in Uganda.

Methods This study used secondary data from treatment-oriented pilot (n=50) and fully-powered cluster randomised controlled trials (cRCT)s (n=694) of SH+ versus EUC. Data from baseline and post-intervention assessments were combined. A composite latent indicator for mental health problems was generated using mental health and well-being measures included in both cRCTs. In order to assess incidence, a binary variable approximating probable mental disorder was created to exclude those with probable mental disorder from the analysis sample and as the primary prevention outcome. The promotive effects of SH+ relative to EUC were examined in the same sample by assessing subjective well-being and psychological flexibility scale scores.

Results A single factor for mental health problems was identified with all factor loadings >0.30 and acceptable internal consistency (α=0.70). We excluded 161 women who met criteria for probable mental disorder at baseline. Among those with at least moderate psychological distress but without probable mental disorder at baseline and with follow-up data (n=538), the incidence of probable mental disorder at post-intervention was lower among those who participated in SH+ relative to EUC (Risk ratio =0.16, 95% CI: 0.05 to 0.53). Participation in SH+ versus EUC was also associated with increased subjective well-being (β =2.62, 95% CI: 1.63 to 3.60) and psychological flexibility (β=4.55, 95% CI: 2.92 to 6.18) at post-intervention assessment.

Conclusions These results support the use and further testing of SH+ as a selective and indicated prevention and promotion focused psychosocial intervention in humanitarian settings.

Trial registration number ISRCTN50148022.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A latent variable for mental health problems and thresholds for probable mental disorder were retrospectively generated using pilot and fully powered cluster randomised controlled trial (cRCT) data.
⇒ Innovative secondary data analysis techniques were used to maximise data efficiency and contribute to evidence on focused prevention and promotion interventions.
⇒ While the scales used to create the probable mental disorder variable were translated into Juba Arabic and adapted for use in the pilot and cRCT studies, the mental health problems variable was not validated within these samples.

INTRODUCTION

Exposure to potentially traumatic events alongside ongoing stressors contributes to a high burden of psychological distress, mental health and substance use problems among refugees and other populations affected by humanitarian crises.[1–3] These mental health and psychosocial impacts affect day-to-day functioning amidst ongoing adversity. Many mental health and psychosocial problems that are associated with significant functional impairment are likely preventable.[4 5] Despite increasing calls for prioritising prevention focused research and practice, which form part of efforts to meet the third Sustainable Development Goal of 'Good Health and Well-Being', there remains little rigorous research on mental health and psychosocial

interventions for prevention of mental disorders in humanitarian settings.[6–8]

Both treatment and prevention of mental disorders are pursued under the common goal of reducing the burden of mental health problems.[9] A third, but related concept of mental health promotion refers to strengthening positive aspects of mental health and well-being without an explicit focus on mental disorders.[8] In contrast to treatment efforts to reduce symptoms and functional impairment among those living with mental disorder, prevention efforts focus on ensuring that mental disorders do not occur or worsen.[8] Prevention efforts can be further divided into universal, selective and indicated depending on whether a programme is targeted toward the whole population, a subpopulation at increased risk of disorder or a population that demonstrates early signs or symptoms of disorder.[9]

Scalable, evidence-based, prevention focused mental health and psychosocial interventions, alongside treatment and promotion focused interventions and interventions that address the social and environmental determinants of mental health, are needed to improve mental health in humanitarian settings.[7] Current approaches to mental health and psychosocial service provision (both treatment and prevention focused) are insufficient for meeting vast mental health needs due to their limited reach and high resource requirements. This issue is closely related to a research-practice gap wherein the most commonly implemented mental health and psychosocial interventions have received minimal research attention and have a limited evidence-base while evidence-based interventions are not widely implemented in practice.[10 11] By design, mental health and psychosocial interventions with the strongest evidence base, such as cognitive behavioural interventions and interpersonal therapy, are challenging to bring to scale in low-resource settings with limited access and mental health infrastructure and capacity.[10 12–14]

Self Help Plus (SH+) was developed by the World Health Organization (WHO) and is based on evidence supporting guided self-help interventions and evidence-based stress management techniques. SH+ was devised as a potentially scalable alternative to more resource-intensive evidence-based interventions.[15] Pre-developed materials are used in SH+ with the aim of reducing the training and supervision load. The primary role of the facilitator is to manage the group following a highly scripted approach and to ensure safety of participants. Following extensive adaptation and piloting, SH+ was prospectively shown to reduce psychological distress and other mental health problems in a cluster randomised controlled trial (cRCT) among South Sudanese refugee women in Uganda.[16–18]

This secondary data analysis used data from pilot and fully powered cRCTs of SH+ among South Sudanese in northern Uganda.[16 18] The original cRCT was designed to assess if SH+ would result in greater reductions in psychological distress and improve secondary outcomes at post-treatment and after 3 months of follow-up compared with a treatment as usual condition (ie, a treatment aim).[16] However, the trial unexpectedly screened in over 98% of participants based on an inclusion criterion of at least moderate psychological distress. Because of this near universal inclusion, we were curious to understand if SH+ may have had preventive effects among participants who were distressed at baseline, but who did not meet criteria for probable mental disorder at baseline.

The overall goal of this secondary analysis was to retrospectively assess SH+ as an indicated preventive intervention among South Sudanese refugee women in Uganda by approximating a prevention framework through data analysis. We were interested in exploring whether participation in SH+ was associated with reduced incidence of probable mental disorder relative to enhanced usual care (EUC). The first aim of this analysis was to generate a composite latent indicator using a variety of mental health and well-being measures included in the cRCTs and to identify thresholds on that indicator corresponding to level of probable mental disorder at baseline. The second aim of this analysis was to assess the proportion of participants who later crossed the threshold on the composite latent indicator and met criteria for at least mild probable mental disorder between baseline and follow-up in the SH+ versus EUC groups. A secondary analysis examined the extent to which SH+ promoted aspects of positive mental health, indicated by increased subjective well-being and psychological flexibility at follow-up, among those without probable mental disorder at baseline.

METHODS

A protocol for this secondary data analysis was published on the Open Science Framework in March 2020.[19] The design and results of the original trials, which built on work to adapt and pilot SH+ with South Sudanese refugees in northern Uganda, are detailed in previous reports.[16–18] Briefly, two villages in the 2016 pilot trial and 14 villages in the 2017 fully powered cRCT within a northern Ugandan refugee settlement were randomised to SH+ or EUC. The primary aim of the fully powered cRCT was to understand whether SH+ was associated with reductions in psychological distress, regardless of presence of probable mental disorder. Women were randomly selected within villages by spinning a bottle on the ground and approaching the first household in the direction that the bottle pointed to and then every fifth household thereafter. A total of 50 women in the pilot trial and 694 women in the fully powered trial were enrolled after having met inclusion criteria: they were 18 years of age or older, spoke Juba Arabic, received a score of 5 or more on the Kessler-6 (K6) indicating at least moderate psychological distress,[20 21] were not at immediate risk of suicide or showing symptoms of severe mental disorder and were able to understand basic instructions. In the original pilot or fully powered cRCTs, the presence of a common mental disorder at baseline was not assessed using diagnostic interviews and was not an exclusion criterion.

Women randomly allocated to SH+ (n=356) were invited to participate in one group session (up to 2 hours) led by a pair of lay facilitators each week for 5 weeks. During SH+ sessions, facilitators were responsible for turning the audio recording on and off, answering questions, directing individual exercises and small group discussions in a highly scripted manner and ensuring participant safety (eg, responding to any risk-related issues). All participants (those in villages allocated and not allocated to SH+) were offered EUC. EUC consisted of a single 30 minute psychoeducation session delivered by a community health worker with content focused on overthinking and strategies for self-management. Through EUC, participants were provided with information on available mental health services and basic psychosocial support delivered by community health workers.

The primary outcome for both trials was psychological distress assessed using the K6 and secondary outcomes included personally identified problems assessed using the Psychological Outcomes Profiles Instrument,[22] functional impairment using the WHO Disability Assessment Schedule (WHODAS),[23] post-traumatic stress symptoms using the PTSD Checklist Civilian 6-item version (PCL-6),[24] depression symptoms using the Patient Health Questionnaire-9 (PHQ-9),[25] feelings of anger using two dichotomous items indicating explosive anger attacks,[26] questions on social interactions with other ethnic groups using three items developed for the studies, subjective well-being using the WHO-5 Well-Being Index (WHO-5)[27] and psychological flexibility using the Acceptance and Action Questionnaire (AAQ-II).[28] Among these measures, this secondary analysis used only the K6, WHODAS, PCL-6, PHQ-9, WHO-5 and AAQ-II. Assessors were blinded to intervention allocation. Primary and secondary outcome assessments were carried out 1 week pre-intervention and 1 week post-intervention for the pilot trial and 1 week pre-intervention, 1 week post-intervention and 3 months post-intervention in the fully powered trial. This secondary analysis used only baseline and 1 week post-intervention time points for consistency within the combined sample.

Patient and public involvement

South Sudanese refugees, including members of a community advisory board, were involved in informing the design and implementation of the original trials, including through a needs assessment, the adaptation and piloting of SH+, the feasibility trial which tested study procedures and use of assessment tools, and the fully powered cRCT.[17 18 29] Process evaluations following SH+ piloting and the fully powered cRCT assessed the burden of the intervention on participants. Dissemination meetings were conducted to share results of the trials with participants and community leaders. There was no specific participant or public involvement in the development of this manuscript.

Statistical analysis

Construction of latent factor and identification of thresholds

A latent factor representing mental health problems was constructed using the baseline values of mean scores for scales of psychological distress (K6), functional impairment (WHODAS), symptoms of depression (PHQ-9) and post-traumatic stress (PCL-6), subjective well-being (WHO-5) and psychological flexibility (AAQ-II). Item level data was not used to construct the latent factor. The number of factors to extract from the indicator set was determined using parallel analysis to compare eigenvalues from the observed correlation matrix with those of a random data set generated using 1000 simulations.[30] An exploratory factor analysis was performed using the principal factor method to estimate a single continuous underlying factor from a correlation matrix generated by the set of continuous indicators. The strength of loadings (≥0.30) was examined to assess if items should be retained.[31 32] Cronbach's alpha (α) was calculated for the factor to assess internal consistency and an overall $\alpha \geq 0.60$ was considered adequate. A standardised sum score was also calculated by standardising the score for each scale and summing these scores and the correlation between the standardised sum score and the factor score was assessed. Cases with one or more missing values within the indicator set were excluded from all analyses.

Thresholds indicative of probable mental disorder on the 'mental health problems' factor were then identified using percentiles corresponding to the distribution of factor scores within the analysis sample. Thresholds were selected based on recent prevalence estimates for probable mental disorder among adults in conflict-affected settings (point prevalence of 22.1% (95% Confidence Interval (CI): 18.8% to 25.7%)).[3] Participants with scores on the 'mental health problems' factor at or above the 22.1st percentile of factor scores at baseline were considered to have probable mental disorder. In order to assess potential preventive effects of SH+, participants with probable mental disorder at baseline were excluded from the analysis. The prevention analysis sample included only those without probable mental disorder at baseline. The factor score corresponding to the 22.1st percentile of the distribution of factor scores was retained to generate a dichotomous outcome variable representing probable mental disorder versus no probable mental disorder. Factor scores corresponding to the 18.8th and 25.7th percentiles of the factor score distribution in the broader sample were also retained to generate dichotomous variables representing the lower and upper bounds of the CI for the prevalence estimate that was used as the basis for the probable mental disorder threshold. Dichotomous variables corresponding to the 18.8th and 25.7th percentiles of the factor score distribution were used in sensitivity analyses. Before excluding participants who met criteria for probable mental disorder at baseline to generate the prevention and promotion analysis sample, the proportion with probable mental disorder in each of the intervention groups was examined.

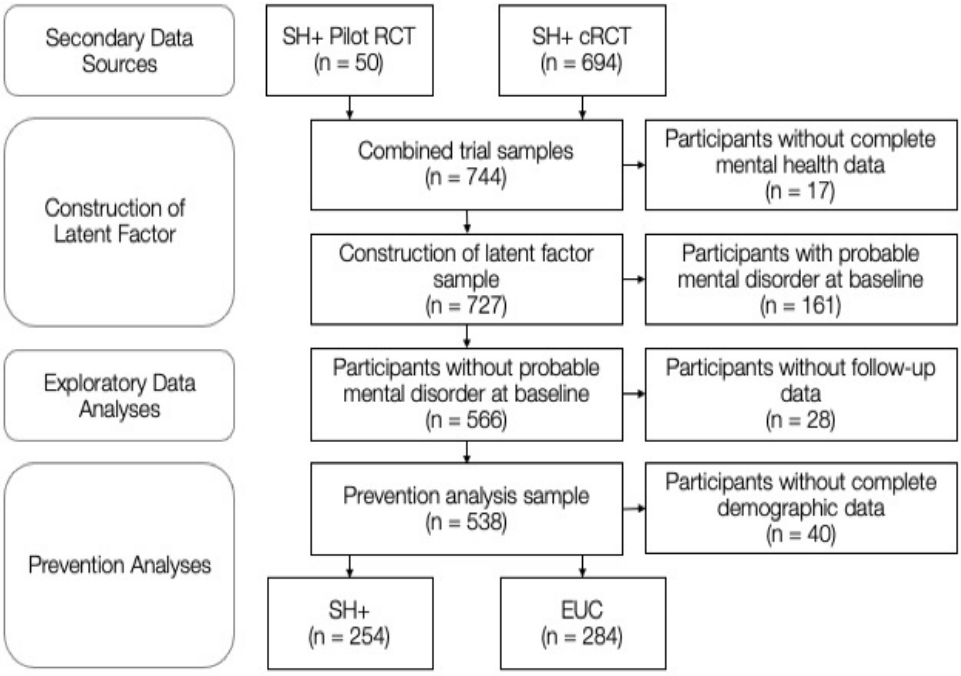

Figure 1 Study flow diagram. cRCT, cluster randomised controlled trial; EUC, enhanced usual care; RCT, randomised controlled trial; SH+, Self Help Plus.

Socio-demographic characteristics of women without probable mental disorder at baseline

Descriptive statistics were calculated for demographic variables among women without probable mental disorder at baseline, including: the means and Standard Deviations (SD) for age and length of stay in the settlement at baseline; and the number and percentage of women identifying with each ethnicity category, highest education level completed category, marital status category and occupation category at baseline. Balance on demographic characteristics between the SH+ and EUC conditions was checked using a standardised mean difference above 0.1 in absolute value as the threshold.

Prevention and promotion analyses

To assess SH+ as an indicated preventive intervention among South Sudanese refugee women in Uganda, the proportion of participants who were classified as having probable mental disorder at follow-up was compared between those who received SH+ versus EUC. An unadjusted log-binomial regression model was used to estimate the relative risk of being classified as having probable mental disorder at follow-up between those in the SH+ versus EUC groups. In sensitivity analyses this model was replicated using main trial data only (excluding the pilot trial data). The 'number needed to treat' (ie, the average number of women who would need to be 'treated' (ie, receive SH+) to prevent one woman from being classified as having probable mental disorder) was calculated as the inverse of the risk difference, with results rounded to the nearest upper integer.[33]

Propensity score weighting was used to address imbalance between intervention groups in the analysis sample. The Augmented Inverse Propensity Weighted (AIPW) estimator was then used to estimate the proportion of people with probable mental disorder if the entire analysis sample had received SH+ and the proportion of people with probable mental disorder if the entire analysis sample had received only EUC.[34] The propensity score was estimated using a logistic regression model to weight observations based on baseline demographic characteristics. These models included covariates for age, ethnicity, length of stay in the refugee settlement, highest education level, work status and marital status.

In secondary analyses to assess whether SH+ promoted positive subjective well-being and psychological flexibility, WHO-5 and AAQ-II scores were compared between the SH+ and EUC groups at follow-up. These analyses were first performed using linear regressions, adjusting for baseline scale values, to predict subjective well-being

Table 1 Factor loadings for the mental health problems factor

Indicator	Factor loading
Psychological distress (K6)	0.37
Functional impairment (WHODAS)	0.59
Depression symptoms (PHQ-9)	0.63
Post-traumatic stress symptoms (PCL-6)	0.70
Subjective well-being (WHO-5)	−0.41
Psychological flexibility (AAQ-II)	−0.56

AAQ-II, Acceptance and Action Questionnaire; K6, Kessler-6; PCL-6, PTSD Checklist Civilian six-item version; PHQ-9, Patient Health Questionnaire-9; WHO-5, WHO-5 Well-Being Index; WHODAS, WHO Disability Assessment Schedule.

Table 2 Evaluation of balance between the SH+ and enhanced usual care groups in the analysis sample on demographic variables

Demographic variables	SH+ (n=271)	EUC (n=295)	Total	Standardised mean difference
Age (mean, SD)	30.4 (10.0)	30.7 (11.1)	30.6 (10.6)	−0.02
Ethnicity (No., %)				
Kakwa	119 (47.6)	153 (55.4)	272 (51.7)	**−0.11**
Dinka	48 (19.2)	3 (1.1)	51 (9.7)	**0.44**
Nuer	19 (7.6)	16 (5.8)	35 (6.7)	0.05
Muru	1 (0.4)	21 (7.6)	22 (4.2)	**−0.26**
Pojulu	30 (12.0)	33 (12.0)	63 (12.0)	0.00
Other	33 (13.2)	50 (18.1)	83 (15.8)	−0.10
Length of stay (No., %)				
<6 months	118 (47.2)	75 (27.1)	193 (36.6)	**0.30**
6 months to 1 year	62 (24.8)	92 (33.2)	154 (29.2)	**−0.13**
>1 year	70 (28.0)	110 (39.7)	180 (34.2)	**−0.18**
Highest education level (No., %)				
No schooling	81 (29.9)	88 (29.9)	169 (29.9)	−0.00
Primary school	140 (51.7)	150 (51.0)	290 (51.3)	0.01
At least high school	50 (18.5)	56 (19.0)	106 (18.8)	−0.01
Work status (No., %)				
No income	218 (80.4)	242 (82.0)	460 (81.3)	−0.03
Paid labour	53 (19.6)	53 (18.0)	106 (18.7)	0.03
Marital status (No., %)				
Single or unmarried	99 (36.5)	113 (38.3)	212 (37.5)	−0.03
Married or cohabitating	172 (63.5)	182 (61.7)	354 (62.5)	0.03

Standardised mean difference values above 0.1 or below −0.1 are marked in bold. Forty values were missing for ethnicity, 39 for length of stay and 1 for highest education level.
EUC, enhanced usual care; SH+, Self Help Plus.

and psychological flexibility scores at follow-up. A similar propensity score weighting procedure to that employed in primary analyses was then used for secondary analyses. The AIPW was used and propensity scores were estimated, controlling for demographic characteristics (age, ethnicity, length of stay in the refugee settlement, highest education level, work status and marital status) and baseline scale values.

To describe effect sizes, standardised coefficients and their Standard Errors (SE) were calculated for all models. Cohen's D and its SE for the adjusted mean difference of post-treatment values between the two treatment arms was also calculated for linear regressions predicting subjective well-being and psychological flexibility using the 'esizereg' Stata command.[35 36] All analyses were performed using Stata V.15.1.[37]

RESULTS

Construction of latent factor and identification of thresholds

Among the combined pilot trial (n=50) and cRCT samples (n=694) at baseline, complete data on psychological distress (K6), functional impairment (WHODAS), symptoms of depression (PHQ-9) and post-traumatic stress (PCL-6), subjective well-being (WHO-5) and psychological flexibility (AAQ-II) were available from 727 women (figure 1). There were 17 cases with incomplete baseline data that were excluded from analyses to create the latent factor, representing less than 3% of the combined pilot trial and cRCT samples. Mean scale scores and SDs for indicators of psychological distress, functional impairment, depression symptoms, post-traumatic stress symptoms, subjective well-being and psychological flexibility at baseline are shown in online supplemental table 1, along with standardised sum scores.

Based on parallel analysis results (online supplemental figure 1), one factor representing 'mental health problems' was extracted from the data. Factor loadings were greater than 0.30 for all indicators (table 1). Cronbach's alpha for the 'mental health problems' factor was satisfactory (α=0.70). The 'mental health problems' factor was highly correlated with the sum of standardised scale scores (r=0.98). The 'mental health problems' factor score was highly correlated with all indicators at follow-up, ranging from 0.62 in the case of subjective well-being to 0.88 in the

Table 3 Proportion of women meeting the threshold for probable mental disorder in primary and sensitivity analyses among the analysis sample

Estimated preventive effects of SH+ versus EUC using log-binomial regression models (N=538)					
Percentile thresholds for probable mental disorder	**Probable mental disorder among SH+ group (No., %)**	**Probable mental disorder among EUC group (No., %)**	**Risk difference**	**Risk ratio (p value)**	**95% CI**
22.1%	3/254 (1.18)	21/284 (7.39)	−6.21%	0.16 (0.003)	(0.05 to 0.53)
18.8%	2/262 (0.76)	20/298 (6.71)	−5.95%	0.11 (0.003)	(0.03 to 0.48)
25.7%	3/243 (1.23)	20/270 (7.41)	−6.17%	0.17 (0.003)	(0.05 to 0.55)
Estimated preventive effects of SH+ versus EUC using the AIPW estimator* (N=498)					
Percentile thresholds for probable mental disorder	**Estimated percentage of probable mental disorder among SH+ group**	**Estimated percentage of probable mental disorder among EUC group**	**Risk difference**	**Risk ratio (p value)**	**95% CI**
22.1%	1.24	9.56	−8.31%	0.13 (0.002)	(0.04 to 0.47)
18.8%	0.42	9.04	−8.62%	0.05 (<0.001)	(0.01 to 0.20)
25.7%	1.54	10.60	−9.07%	0.15 (0.003)	(0.04 to 0.51)

*Proportion of women meeting the threshold for probable mental disorder in primary and sensitivity analyses among the analysis sample when using propensity scores to correct for imbalance between groups.
AIPW, Augmented Inverse Propensity Weighted; CI, Confidence Interval; EUC, enhanced usual care; SH+, Self Help Plus.

case of post-traumatic stress (in absolute value, and always in the expected direction, ie, a negative correlation was identified with subjective well-being and psychological flexibility scores and a positive correlation was identified for all other scales).

A factor score of 0.61 corresponding to the 22.1st percentile of factor scores at baseline was used to identify participants with scores on the 'mental health problems' factor indicative of probable mental disorder. A total of 161 women met the criteria for probable mental disorder at baseline, 72 (21.0%) in the SH+ group and 89 (23.2%) in the EUC group. For sensitivity analyses, factor scores corresponding to the outer bounds of the CI at the 18.8th and 25.7th percentiles (around the 22.1st percentile)[3] were 0.73 and 0.52, corresponding to 137 and 187 women who met the criteria for probable mental disorder as indicated by the CI, respectively.

Socio-demographic characteristics of women without probable mental disorder at baseline

After excluding participants who met criteria for probable mental disorder at baseline, the analysis sample included 566 women (figure 1). Within this sample, 271 (47.9%) received SH+ and 295 (52.1%) received EUC. Across the intervention groups, a strong balance with similar variable values and p values consistently above 0.50 was identified for age, educational level, marital status and working condition (table 2). Imbalance between the SH+ and EUC groups in the analysis sample was identified for ethnicity and length of stay in the camp, indicated by values of the standardised mean difference above 0.1 in absolute value.

Prevention and promotion analyses

Follow-up data were missing for less than 5% of the analysis sample (n=28/566). The primary prevention analysis sample therefore included 538 women (figure 1). The proportion of women who met criteria for probable mental disorder at post-intervention assessment was 1.18% in the SH+ group and 7.39% in the EUC group when using the 22.1st percentile cut-off (table 3). The relative risk of being classified as having probable mental disorder at follow-up between those in the SH+ versus EUC group was 0.16 (95% CI: 0.05 to 0.53), indicating a strong protective effect of SH+. Very similar results were identified in sensitivity analyses using only the main trial data (excluding the pilot trial data) (risk difference=6.58%, risk ratio=0.16, p value=0.003, 95% CI: 0.05 to 0.54). The average number of women who would need to be 'treated' (ie, receive SH+) to prevent one woman from being classified as having probable mental disorder was estimated to be 17. A similar protective effect for SH+ was observed in sensitivity analyses when using thresholds for probable mental disorder at the 18.8th and 25.7th percentiles.

Using propensity score weighting to correct for imbalance between intervention groups in the analysis sample (n=498 with complete demographic data) (figure 1), the proportion of women who met criteria for probable mental disorder at post-assessment was 1.24% in the SH+ group and 9.56% in the EUC group when using the 22.1st percentile cut-off (table 3). The relative risk of being classified as having probable mental disorder at follow-up between those in the SH+ versus EUC groups was 0.13 (95% CI: 0.04 to 0.47), indicating a strong protective effect of SH+. The average number of women who would need to be treated (ie, receive SH+) to prevent one woman from being classified as having probable mental disorder was estimated to be 13. A similar protective effect for SH+ was observed in sensitivity analyses when using thresholds for probable mental disorder at the 18.8th and 25.7th percentiles.

Table 4 Pre–post changes in positive mental health outcomes between SH+ and enhanced usual care groups among the prevention analysis sample

Positive mental health outcomes	SH+	EUC
Subjective well-being	(N=255)	(N=284)
Baseline, mean (SE)	8.35 (0.31)	8.99 (0.30)
Follow-up, mean (SE)	12.96 (0.38)	10.47 (0.34)
Pre–post change	4.61 (0.48)	1.48 (0.39)
Effect estimated through linear regression (β,95% CI)	2.62 (1.63 to 3.60)	–
Effect estimated through AIPW (β,95% CI)	2.62 (1.58 to 3.66)	–
Standardised coefficient (SE)*	0.17 (0.04)	–
Cohen's D*	0.45 (0.09)	
Psychological flexibility	(N=254)	(N=284)
Baseline, mean (SE)	24.11 (0.51)	22.26 (0.45)
Follow-up, mean (SE)	30.96 (0.61)	26.18 (0.56)
Pre–post change	6.86 (0.76)	3.92 (0.67)
Effect estimated through linear regression (β,95% CI)	4.55 (2.92 to 6.18)	–
Effect estimated through AIPW (β,95% CI)	4.42 (2.64 to 6.20)	–
Standardised coefficient (SE)*	0.10 (0.04)	–
Cohen's D*	0.47 (0.09)	

Participants with both baseline and post-assessment data were included in analyses.
*Based on linear regression.
AIPW, Augmented Inverse Propensity Weighted; EUC, enhanced usual care; SH+, Self Help Plus.

Secondary analyses to assess whether SH+ promoted enhanced subjective well-being and psychological flexibility, relative to EUC, at follow-up demonstrated small to moderate significant promotive effects (table 4). Participants in the SH+ group experienced an average increase of 2.62 points (95% CI: 1.63 to 3.60) on the WHO-5 total score and 4.55 points (95% CI: 2.92 to 6.18) on the AAQ-II total score relative to those in the EUC group at follow-up as estimated in linear regression models adjusting for baseline scale values. Results using the AIPW model with regression adjustment to correct for imbalance between intervention groups at baseline were largely similar (table 4).

DISCUSSION

This study approximated a prevention framework through a novel secondary data analysis approach using data from trials comparing SH+ to EUC among South Sudanese refugee women in Uganda. Primary results suggest that within a sample of women with at least moderate psychological distress but without probable mental disorder at baseline, those who received SH+ were significantly less likely to meet criteria for probable mental disorder immediately post-intervention relative to those who received EUC. This finding was maintained in sensitivity analyses that addressed imbalance across intervention groups in the analysis sample. Secondary results suggest that SH+ promoted positive mental health and well-being, as indicated by larger increases in subjective well-being and psychological flexibility scores with small to medium effect sizes among those who received SH+ relative to those who received EUC. This study is among the first to assess the preventive and promotive effects of SH+ in a humanitarian context.[38 39]

High quality evidence on the preventive capacity of mental health and psychosocial support interventions in humanitarian settings is generally lacking. A recent systematic review and meta-analysis identified seven randomised controlled trials examining the preventive effects of psychological and social interventions in humanitarian settings, among which only two were conducted among adults.[6] Many studies that aim to assess prevention do not systematically exclude participants with probable mental disorder at baseline and do not assess for the development of probable mental disorder at follow-up, as such they cannot assess change in incidence. Indeed, a Cochrane review on mental health in humanitarian settings found no prevention studies that evaluated changes in incidence.[6]

Conducting rigorous health (including mental health and psychosocial support) prevention research in humanitarian settings is challenging due to a range of factors, such as acute needs requiring rapid intervention, security risks, resource and logistics constraints and limited funding.[40] In all settings, but in humanitarian settings in particular, upholding ethical principles for intervention research is paramount.[40 41] Among these, not duplicating existing research or over-researching a given population are essential for reducing already high demands placed on populations in humanitarian settings.[41] In light of the dearth of mental health and psychosocial support prevention research in humanitarian settings and the feasibility and ethical complexities of conducting research in humanitarian settings, novel methodological approaches that harness existing data hold promise for maximising efficiency and building evidence.

This study used novel analytical tools to approximate a prevention and promotion framework. A latent variable representing mental health problems was constructed using multiple mental health and well-being measures used in both the original pilot and cRCT. A threshold representing probable mental disorder on this indicator was then identified and used to generate the prevention and promotion analysis sample. This binary indicator was also used as the primary outcome. Such an approach may represent an innovative method for maximising secondary data efficiency, particularly in situations where prevention research is difficult to conduct, such as in humanitarian settings and with hard to reach populations.

The primary limitation of this study is the reliance on secondary data as neither the pilot nor cRCT studies were specifically designed to assess preventive or promotive

effects. Further, the latent variable for mental health problems and the threshold for probable mental disorder were retrospectively generated. While the scales used to create this variable were translated into Juba Arabic and adapted for use in the pilot and cRCT studies,[17 18] the mental health problems variable was not validated within these samples. The probable mental disorder construct could therefore also be interpreted as reflecting more severe mental health problems. Other limitations include a lack of combined data at 3 months follow-up which limits our understanding of whether or not preventive and promotive effects were maintained over time. The interval between baseline and follow-up was relatively short (approximately 6–7 weeks) and those in the SH+ group were actively engaging in the intervention for most of this period (5 weeks). The results of these analyses do not provide meaningful information on carry over effects. Further, the difference in intensity of intervention (ie, the amount of time the intervention and control groups were participating in SH+ and EUC conditions, respectively) could have contributed to the differences in outcomes reported here and in the original studies. The generalisability of these results is also limited as men were excluded from both the pilot and cRCT studies.

Findings from this study along with those from the treatment-focused cRCT highlight the promise of SH+ as a scalable mental health and psychosocial support intervention in humanitarian settings.[16] Given that 98% of potential participants met criteria for at least moderate psychological distress in the fully powered cRCT, results from this study could be interpreted as suggesting that SH+ may be suitable for both the indicated and selective prevention of probable mental disorder and promotion of positive mental health and well-being. Characteristics of SH+ implementation, such as its delivery through pre-recorded audio sessions by a minimally trained facilitator and large group format, may enhance its potential for scale-up.[15] When delivered as an independent primary mental health and psychosocial support intervention or as a first line intervention within a stepped-care model of mental health service provision, prevention focused SH+ could potentially contribute substantially to reducing the mental health burden in humanitarian settings if brought to scale.[16 42 43] Due to its flexible format, SH+ could also be integrated with non-mental health and psychosocial support interventions in order to holistically address both mental health and well-being outcomes and their social and environmental determinants.[4 7] Holistic efforts such as these are urgently needed as without them, the utility of mental health and psychosocial support interventions may be reduced to that of temporary solutions for the mental health impacts of much deeper, pervasive and chronic problems.[44]

CONCLUSION

The results of this secondary data analysis offer preliminary support for the use of SH+ as a selective and indicated prevention and promotion focused mental health and psychosocial support intervention among South Sudanese women refugees in northern Uganda. Prospectively collected data is needed to confirm the effectiveness of SH+ in a prevention and promotion framework and to explore its use in other contexts. This study also demonstrated the feasibility of using innovative approaches to analyse existing cRCT data in order to generate evidence on mental health and psychosocial support prevention and promotion interventions in humanitarian settings. Taken together, these findings support the potential use of prevention and promotion focused SH+ and highlight its utility for reducing the burden of mental health problems in humanitarian settings if brought to scale.

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