Title: Sibling-Support for Adolescent Girls (SSAGE): A study protocol for a pilot randomized-controlled trial of a whole-family, gender transformative approach to preventing mental illness among forcibly displaced adolescent girls

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Sibling-Support for Adolescent Girls (SSAGE): A study protocol for a pilot randomized-controlled trial of a whole-family, gender transformative approach to preventing mental illness among forcibly displaced adolescent girls

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Abstract

Forcibly displaced adolescents, especially girls, are at increased risks for mental illness and distress, with adolescent girls disproportionately affected in part due to the heightened gender inequity that often accompanies forced displacement. Although the family unit has the potential to prevent mental illness and promote healthy development in adolescents, few family interventions have employed a gender transformative approach or included male siblings in an effort to maximize benefits for adolescent girls.

This study will assess an innovative whole-family and gender transformative intervention—Sibling Support for Adolescent Girls in Emergencies (SSAGE)—to prevent mental health disorders among adolescent girls in Colombia who were recently and forcibly displaced from Venezuela. The study will employ a hybrid type 1 effectiveness-implementation pilot randomized control trial (RCT) to test the program's effectiveness and mechanistic pathways as well as to explore determinants of implementation in order to establish the feasibility, acceptability, and fidelity of SSAGE.

To address these aims, we will enroll 180 recently arrived, forcibly displaced adolescent girls in an RCT and examine the program's effectiveness on the prevention of mental illness (through reduction in anxiety, depression, interpersonal sensitivity, and somatization symptoms) one-month post-intervention. We will use contextually adapted and piloted measures to collect additional data on the hypothesized mechanistic pathways, including family attachment, gender equitable family functioning, self-esteem, and coping strategies. The implementation evaluation will employ mixed methods to assess the program's feasibility, acceptability, fidelity and barriers and facilitators to successful implementation. Potential findings can support humanitarian program implementation, as well as inform policy to support adolescent girls' mental health and to prevent the myriad disorders that can arise as a result of exposure to displacement, conflict, and inequitable gender norms in their households and communities.

Background and Rationale

Forcibly displaced children and adolescents face heightened levels of mental distress and illness (1–3). Evidence demonstrates that many experiences surrounding the forced migration process—such as exposure to conflict and violence, family loss or separation, and other adverse events—serve as risk factors for mental distress among displaced adolescents (2). Adolescent girls face additional gendered exposures in humanitarian settings, including intimate partner and non-partner physical and sexual violence, early marriage, and sexual exploitation, which may serve to exacerbate mental distress and health (2,4). Mental illness among forcibly displaced girls most often manifests through internalizing behaviors and symptoms, such as anxiety, depression, and psychosomatic symptomology (2,4,5).

The mental well-being of adolescent girls may be further impacted by gender inequitable attitudes and norms, which are often exacerbated in humanitarian settings (6–8). Previous research from low-income country and refugee settings reveals a strong relationship between gender inequitable norms at the community level and lowered self-esteem and well-being at the individual level for adolescent girls (7,9). Girls who internalize norms that marginalize and devalue their role within the family and community, may experience lowered self-esteem, perceived agency and resilience (7,10,11). Inequitable

household gender norms rooted in patriarchal systems rely not only on strict father-daughter interactions, but also on inequitable sibling relationships wherein adolescent male relatives such as brothers or cousins engage in disciplining girls for transgressing gender norms (12). Further, fathers and brothers' strategies for keeping girls safe in humanitarian settings often include limiting girls' mobility, which can erode healthy coping and attachment and consequently increase vulnerability to mental health disorders when experiencing stressors (13,14).

Conversely, evidence shows that household environments characterized by high levels of family functioning, supportive relationships, and healthy caregiving practices, can promote resilience in children and adolescents (3,14,15). For example, family connectedness was found to be inversely associated with internalized mental health symptoms among conflict-affected children and adolescents in Chechnya; and, in Gaza, supportive parenting practices were linked to reduced symptoms of depression, aggression, and other antisocial behavior among adolescents (15–17). As such, family-level interventions have become an in increasingly employed approach for bolstering resilience and mental health among adolescents affected by conflict or experiencing forced displacement. The majority of literature supporting the utility of whole-family interventions in improving adolescent mental health derives from high-income countries, though a small body of evidence points to the promise of such interventions in low-income and humanitarian settings. A family-level psychosocial intervention implemented in the Democratic Republic of Congo, for example, reduce post-traumatic stress symptoms for youth or adolescents who had previously been abducted or had a family member who had been abducted (18)(19). However, a recent scoping review of whole-family interventions in humanitarian settings found only two programs employed a gender-transformative approach, and limited evidence speaks to the impact of no whole-family interventions in these settings incorporate gender-transformative approaches and limited evidence speaks to the potential consider gender-transformative considerations of whole-family interventions in these settings, nor considers , rigorous evidence is also lacking on effective family-based interventions that employ a gender-transformative approach to ensure positive impacts for adolescent girls, in particular (20).

To generate evidence on what works to prevent mental illness among forcibly displaced adolescent girls, Washington University in St. Louis, Universidad de Los Andes, Women's Refugee Commission, and Mercy Corps are conducting a hybrid type 1 effectiveness-implementation pilot randomized-controlled trial (RCT) of Sibling Support for Adolescent Girls in Emergencies (SSAGE). SSAGE is a whole-family and gender-transformative mental health intervention that aims to foster more secure family attachments, improve girls' self-esteem, and strengthen healthy coping skills on the path to improved mental health for forcibly displaced adolescent girls. The objectives of this hybrid type 1 pilot RCT are twofold. First, the study aims to examine the preliminary effectiveness and mechanistic pathways of SSAGE to prevent mental health disorders among recently arrived, forcibly displaced adolescent girls in Colombia; and second, the study seeks to assess the feasibility, acceptability and fidelity of the SSAGE intervention and identify determinants of successful implementation.

Study objective

- Primary Objective: The study aims to assess the effectiveness of the SSAGE intervention in preventing mental health disorders among recently displaced adolescent girls in Colombia, particularly focusing on reducing symptoms of anxiety, depression, interpersonal sensitivity, and somatization.

- Secondary Objective: The study seeks to explore the mechanistic pathways through which SSAGE operates, including its impact on family attachment, gender equitable family functioning, self-esteem, and coping strategies.
- Implementation Evaluation: Additionally, the study will evaluate the feasibility, acceptability, and fidelity of implementing SSAGE, including identifying barriers and facilitators to successful implementation at endline.

Methodology

We will undertake a hybrid type 1 effectiveness-implementation pilot RCT to test the effectiveness and mediators of SSAGE while simultaneously using a concurrent, convergent mixed methods design to examine the acceptability, feasibility, and fidelity of the intervention.

Screening for Eligibility: Inclusion Criteria

Recruitment for this study will draw from families who fled Venezuela and relocated to Colombia within the last year. Included among this population are families originally born in Colombia who had previously emigrated to Venezuela for at least five years and subsequently returned to Colombia. Eligibility requirements include adolescent girls aged 13-19 years old who: live with a male and female caregiver and an adolescent male sibling or relative; immigrated to Colombia within the last year; are available, along with their family members, to participate in the SSAGE intervention for three months; and are available to participate in survey questionnaires immediately before and one month after the intervention (please see Figure 1 for a study schedule). We will recruit 180 adolescent girls from 180 families. Study participants will be recruited by Mercy Corps and consented and enrolled in the study by Los Andes University.

Figure 1. Schedule of enrolment, interventions, and assessments

	2024					2025							
TIMEPOINT	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**
Eligibility screen	X												
Informed consent	X												
Allocation	X												
INTERVENTIONS:													
Treatment: SSAGE		X	X	X									
Control: Care as usual		X	X	X									
DATA COLLECTION:													
Baseline survey data collection	X												
Endline survey data collection				X									
Qualitative data collection for implementation outcomes				X	X								

DATA ANALYSIS AND DISSEMINATION													
Analysis						X	X	X	X	X	X		
Write-up of findings										X	X	X	X
Dissemination												X	X

Subject Recruitment, enrollment, treatment assignment and sample size

Following confirmation of eligibility criteria, the study team will obtain informed parental consent and direct assent from potential adolescent girl participants. Every adolescent girl recruited to the study will be assigned a unique study identification number to enable tracking survey responses across points of data collection.

Sample size and power analysis: To detect a medium effect size in our primary outcomes of interest of d=0.5, assuming statistical power of 80% and a one-sided alpha of 0.05, we need a sample size of 63 adolescent girls in each study arm. We expect approximately 20% attrition from baseline to T2 either through: (1) declining to participate in subsequent rounds of data collection or (2) data collectors' inability to locate the participant. Additionally, when estimating the effect of SSAGE on the four outcomes of interest, we will exclude adolescent girls already exhibiting above-threshold scores on the four-dimension measure of mental health symptoms at baseline as it would not be possible to 'prevent' mental health disorders in this subgroup. We expect this to result in the loss of an additional 10% of the initial sample. As such, we require a sample size of 90 girls for each study arm.

Following the recruitment of 180 girls from 180 families, 90 adolescent girls each will be randomized to the treatment and control arm using a random number generator. Randomization will not be blinded.

Consent

Prior to data collection, participants and their caregivers (for those under 18 years of age) will be informed about the study's purpose, procedures, potential risks, and safeguards, including confidentiality and referrals for services. They'll learn that participation in the SSAGE intervention is random but not being selected won't affect access to future programs. Participation is voluntary, and participants won't face penalties for declining. They can withdraw at any time and refuse to answer questions. Participants will be informed about data usage. Researchers will ensure genuine informed consent by providing thorough explanations, multiple opportunities for questions, and avoiding coercion. Staff will be trained accordingly. The appendix contains the informed consent document that requires participant signature or parent/guardian signature for participants under the age of 18 years.

Data Collection

To measure effectiveness of the intervention, all 180 adolescent girls in the study (both treatment and control arms) will complete a survey questionnaire through an enumerator-facilitated interview using computer-assisted personal interview (CAPI) software immediately prior to the onset of the intervention. These same participants will be visited one month following the completion of the 12-week intervention (T2) to take the same survey using CAPI. The survey questionnaire is expected to take approximately 60 to 90 minutes to complete. Study participants' study identification will be used to link their survey responses between baseline and T2.

Study Outcome Measures and Ascertainment

The primary outcome measures include mental illness, anxiety and depression. A full list of primary and secondary outcomes, corresponding sources of measurement, and hypothesized directions of change can be found in Table 1. Relevant socio-demographic variables will also be collected, including age, education status, caregiver employment status, current living situation and household composition, relationship status, time in Colombia, country of birth, stressful life events, and other support services being received by the household. Survey tools will be translated into Spanish and back-translated.

Before each participant leaves the data collection site, their data will be reviewed by a data collector for completion. All data will be incrementally backed up each day on a secure data system and a full back-up will be performed weekly. The research team at Washington University in St. Louis will be responsible for weekly data checks to ensure data quality; errors will be reported to the local field team and rectified. Only selected, authorized WRC, Mercy Corps, University of Los Andes, and Washington University staff will have access to the password-protected data.

Table 1. Primary and secondary outcomes and hypothesized direction of change

Construct as presented in Figure 1	Source of measure	Hypothesized direction of change
Primary outcomes of interest		
Mental illness	DSM-V cross-cutting youth (35)	Decrease
Anxiety and depression	Revised Child Anxiety and Depression Scale-25 (36)	Decrease
Secondary outcomes/mediators		
Gender equitable family functioning	Gendered responsibilities scale (37)	Increase
Family attachment	Family Attachment and Changeability Index (FACI8) (38)	Increase

Improved self-esteem	Rosenberg Self-Esteem Scale (RSES) (39)	Increase
High instrumental coping skills	Kidcope (40)	Increase

Ethical Considerations:

Participants will be fully informed about the research study's ethical guidelines to ensure their rights and welfare are protected. Prior to data collection, participants will be asked to provide informed consent, ensuring they understand the purpose, procedures, risks, and benefits of participation. Furthermore, all research procedures will undergo review and approval by the Institutional Review Board to uphold ethical standards.

Risks and Benefits:

Participants will be informed about the potential risks involved in the study, such as discomfort or emotional unease when answering personal questions. However, participants will be assured that measures will be taken to minimize these risks, including the availability of support services if needed. While there may be no direct benefits to individual participants, they will be informed that their involvement could contribute valuable insights to benefit communities in humanitarian contexts, including Colombia, in the future.

Safety and Adverse Events:

To prioritize participant safety, support services will be readily accessible to participants through Mercy Corps and other local resources if they experience any adverse events or discomfort during participation. Confidentiality measures will also be implemented to protect participant privacy and ensure the security of personal information. Participants will be reassured of their right to withdraw from the study at any time without facing any negative consequences.

Data Analysis

Statistical methods

To assess the effectiveness of SSAGE in preventing mental health disorders, we will test the null hypothesis that adolescent girls who participate in SSAGE exhibit the same or greater levels of mental health symptoms as compared to girls who receive care as usual. We will test this hypothesis using both an intent-to-treat and per protocol analytical approach (41,42). We will employ generalized linear regression models to estimate the effect of the intervention on the primary outcomes, controlling for covariates not balanced between the two study arms at

baseline; given that treatment assignment is random, we expect that we will not need to control for many covariates. Per protocol analysis will also be conducted, leveraging attendance data from all participating family members. The threshold for meeting program adherence will be defined alongside program implementers prior to program implementation.

As a secondary, exploratory analysis, we will examine the effect of SSAGE on gender equitable family functioning, family attachment, self-esteem and coping strategies (see mechanistic pathways in Figure 1); and, we will assess if the effect of SSAGE on each of the primary outcomes of interest is mediated by these four secondary measures. The effect of SSAGE on each secondary outcome will be assessed using linear regression models (as described above). Mediation analysis will be conducted using structural equation modeling to estimate the degree to which each secondary measure mediates the impact of SSAGE on the prevention of mental health disorders. To avoid a reduction in statistical power and potentially biased results, we will employ iterative Monte Carlo Markov Chain (MCMC) multiple imputation to handle missing data in Stata. We will first generate 50-100 imputed datasets using expectation-maximization algorithm as estimates on which we will employ the MCM procedure. All statistical inferences will then be made using the combined results across all complete datasets

Implementation evaluation

Qualitative implementation evaluation data–including key informant interviews with program staff and mentors (n=8) (43) and semi-structured in-depth interviews with a subset of individuals in the treatment arm (n=24)–will be conducted immediately following the end of the intervention to assess program acceptability, feasibility, and fidelity, and to identify implementation determinants (i.e., barriers and facilitators) that may influence the quality of program delivery.(44,45) Program participants will be purposively sampled in order to ensure representation from all cohorts (male caregivers, female caregivers, adolescent boys, and adolescent girls) as well as levels of adherence to the treatment protocol including number and length of sessions delivered as well as attendance. By also including participants with low attendance, we will be able to explore fidelity as well as potential barriers to acceptance and feasibility. Program mentors and staff will also be purposively sampled to ensure representation across target cohorts and levels of oversight, respectively, in order to inform an exploration of implementation determinants. Interview guides will be guided by the Exploration, Preparation, Implementation, and Sustainment (EPIS) Framework(46,47) and Implementation Outcomes Framework(48) and will focus on the facilitators of and barriers to program implementation as well as the acceptability, feasibility, and fidelity of SSAGE. Interviews will be recorded, translated, transcribed, and cleaned for analysis.

SSAGE's acceptability and feasibility will also be measured through administration of the acceptability and feasibility sub-scales of the Mental Health Implementation Science Tools (mhIST). These two scales will be administered to all treatment participants (n=90) at T2, as part

of the quantitative survey.(49) The mhIST was developed specifically for use in low-resource settings and the tool has been validated in multiple low- and middle-income countries, including in Colombia.(49) Each scale includes 15 questions that are answered by the respondent using a Likert scale.

Descriptive statistics for the mhIST items and scales will first be estimated to identify perceptions of program acceptability and feasibility. Qualitative data will be imported into a qualitative data analysis software and analyzed using qualitative content analysis, a theory-driven approach that will involve both deductive and inductive coding.(50,51) Deductive codes will be derived from guiding conceptual frameworks.(46,48,52) Mixed methods analyses will involve merging the quantitative and qualitative data in joint displays to examine the extent to which the two types of data converge. These results will inform further refinements of SSAGE and the identification of implementation strategies that may be needed to address identified determinants and ensure that the intervention is routinely delivered with high quality.

Data Handling, Confidentiality and Security

U.S. government representatives, including the Office for Human Research Protections, may access records pertaining to this research to fulfill federal or state responsibilities. Representatives from the National Institute of Mental Health, the University, and the Institutional Review Board (IRB) oversee the conduct of this study. All identifiers will be removed from data, which will be stored in a separate locked file cabinet. Once entered into computer files, data will be password protected, with access restricted to the research team. Data shared with others will be stripped of identifiers and coded for anonymity. This research is covered by a Certificate of Confidentiality from the federal U.S. government, allowing researchers to refuse to disclose information that may identify participants in legal proceedings or to unauthorized individuals. Participants have the right to control the disclosure of their information and involvement in the study, including granting permission for the research team to disclose their information to third parties.

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