**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

**NCT number:** NCT06078124

**Date:** July 20, 2024

# Statistical Analysis Plan (SAP)

Study 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

Study Type: Pilot Randomized Controlled Trial (RCT)

Version: July 2024

## 1. Objectives

- To assess the impact of the SSAGE intervention on adolescent girls' anxiety and depressive symptoms, self-esteem, family functioning, gender equitable household task sharing, and coping skills
- To estimate both the intent-to-treat (ITT) and the local average treatment effect (LATE) of the intervention using instrumental variable analysis.
- To explore the role of participant characteristics in loss to follow-up and outcome changes.

## 2a. Primary Outcomes

- DSM-V cross-cutting youth: Respondents will be asked to indicate the frequency of 19 symptoms in the previous two weeks, selecting from the following response options: 0-Never; 1- Rarely (1 or 2 days); 2- Slightly (between 3 and 6 days); 3- Moderately (more than 7 days of the last two weeks); and 4-Severely (Every day in the last two weeks). Respondents will also report whether they have engaged in each of five behaviors related to drug and alcohol use, self-harm and suicide ideation (answering yes or no) in the last two weeks and whether they have ever attempted suicide in their lifetime (yes or no). The included symptoms are meant to represent 12 domains of mental disorders: somatic symptoms, sleep problems, inattention, depression, ange, irritability, mania, anxiety, psychosis, repetitive thoughts and behaviors, substance use, and suicide ideation/attempts. A respondent will be flagged as requiring further inquiry for a given domain if they answer '2' or higher on at least one of the symptoms in each respective domain. As such, this outcome will be operationalized as 12 dichotomous variables reflecting the 12 domains.
- Depression and anxiety symptomology: Will be measured using the Revised Children's Anxiety and Depression Scale (RCADS-25). The RCADS-25 asks respondents to indicate how frequently they have experienced each of 25 symptoms. Possible responses include 0-Never; 1-Sometimes; 2-Frequently; and 3-Always. An overall RCADS-25 score will be created by adding the responses across all 25 items and looking up the corresponding T-score from a previously created T-score chart based on gender and grade.

## 2b. Secondary Outcomes

- Family functioning: A modified version of the Family Attachment Changeability Index 8 (FACI-8) will be used to measure family functioning. This version includes 12 items (some are reverse scored) and asks respondents to indicate how common each item is on a 4-point likert scale from "never" to "always." Scores may assume a value from 12 to 48, with higher scores signaling greater family functioning.
- Self-esteem: captured using the Rosenberg Self-Esteem Scale (RSES). The RSES asks respondents to indicate their level of agreement with ten statements on a 4-point likert scale ranging from "totally disagree" to "totally agree". After reverse scoring five of the ten items, the final score represents the sum of all items. Scores may assume a value from 10 to 40 where higher values reflect greater self-esteem.
- Coping: A modified version of KidCOPE will be used to assess the use of 15 healthy and unhealth coping strategies in the last two weeks. For each coping strategy, respondents will be able to indicate how often the strategy was employed in the last two weeks using a 4-point likert scale ranging from "never" to "almost all of the time." Each coping strategy will be examined separately.

## 3. Study Sample

Eligibility criteria included adolescent girls who had migrated from Venezuela or who were born in Colombia and had previously emigrated to Venezuela for at least five years and recently returned to Colombia. In order to minimize community tensions between migrant and host populations, a few adolescent girls from internally displaced or host families who met all other inclusion criteria were included in the study. Other eligibility criteria included being 13-19 years old, being available to participate, along with their family members, to participate in the SSAGE intervention for twelve weeks, and being available for endline data collection immediately following the completion of SSAGE.

## 4. Descriptive and Baseline Analysis

• Baseline Balance: Descriptive statistics will be computed separately by study arm. Mean comparisons will be conducted using independent samples t-tests.

• Imbalance Adjustment: Outcomes found to differ significantly at baseline between groups will be included as controls in regression models of change scores.

## 5. Estimating Treatment Effects

### 5.1. Intent-to-Treat (ITT) Analysis

OLS regression models will estimate the average treatment effect of assignment to the treatment group on changes in each outcome.

Models:

1. Bivariate association between treatment assignment and outcome change.

2. Model 1 + controls for baseline value of outcome.

3. Model 2 + controls for baseline covariates associated with outcome of interest at baseline.

### 5.2. Instrumental Variable (IV) Analysis

Participants are considered to have adhered to the intervention if they received both a completion certificate and seed capital.

Two-stage least squares (2SLS) using `ivregress 2sls` in Stata.

Stage 1: Predict adherence using treatment assignment as an instrument.

Stage 2: Estimate the causal effect of adherence on outcome changes.

## 6. Handling Attrition

• Attrition Analysis: Logistic regression will assess whether loss to follow-up is associated with baseline characteristics.

## 7. Sensitivity Analyses

Compare results using:

• Change scores vs. endline-only models controlling for baseline values.

## 8. Software

All analyses will be conducted in Stata (version 16), using appropriate packages for regression, 2SLS, and multiple imputation.

## 9. Ethical Considerations

All study protocols and procedures were approved by the Washington University in St. Louis IRB (Approval #202407174).