Title:

Owning Rights and Protection: GBV Prevention, Mitigation, and Response in Colombia (2023-2025)

Date: April 30, 2024

NCT: NCT06312592

Statistical Analysis Plan (SAP)

Study Title: Evaluating the Impact of the Entrepreneurship School with Gender Lens (ESGL) on Self-Reliance and Wellbeing among Forcibly Displaced Women in Colombia

Study Type: Pilot Randomized Controlled Trial (RCT)

Version: April 2024

1. Objectives

- To assess the impact of the ESGL intervention on household self-reliance, depressive symptoms, and resilience.
- 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.

2. Primary Outcomes

• Self-reliance: Total and domain-specific scores from the Self-Reliance Index (SRI), with scores ranging from 1 to 5 (except health status domain: 1–3).

• Depression: Patient Health Questionnaire-9 (PHQ-9), scores range 0–27; higher scores indicate more severe depressive symptoms.

• Resilience: Brief Resilient Coping Scale (BRCS), scores range 4–20; higher scores indicate greater coping ability.

3. Study Sample

Participants were randomized within each of three cities to the treatment or control group. Inclusion was restricted to women scoring between 2.0 and 4.25 on the SRI at baseline. Additional inclusion criteria included: being a woman at least 18 years of age; at risk of or had ever experienced gender-based violence; Colombian or Venezuelan (with a Temporary Protection Permit); resided in Colombia for at least six months; and had an entrepreneur profile assessed through HIAS' profile scanning process.

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 Universidad de los Andes IRB (Approval #1863).