

## **STUDY DOCUMENT COVER PAGE**

### **Official Title:**

Pilot Study of a Mental Health Literacy–Based Intervention for Parents and Teachers to Improve the Mental Health of Children in 3rd to 5th Grade of Primary Education in Chile and Ecuador

### **Brief Title:**

Roots for Life Project: Strengthening Mental Health in School Communities

### **ClinicalTrials.gov Identifier:**

Not yet assigned

### **Unique Protocol ID:**

ORD842

### **Document Type:**

Statistical Analysis Plan

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Version 1.0

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April 2025

## **Statistical Analysis Plan**

Version 1.0 – April 2025

### **Study Design and Analysis Overview**

This study uses a quasi-experimental design with intervention and control schools, with pre- and post-intervention assessments. Analyses will estimate the preliminary effectiveness and feasibility of a mental health literacy intervention directed at teachers and parents/guardians, and its impact on children's mental health. Analyses are primarily exploratory given the pilot nature of the study. Any hypothesis testing will be interpreted as preliminary.

### **Analysis Populations**

#### **Intention-to-Treat (ITT) Population**

The ITT population includes all children, parents/guardians, and teachers who provided informed consent and completed baseline assessments. Participants will be analyzed according to the intervention assignment of their school, regardless of level of participation or adherence.

#### **Per-Protocol (PP) Population**

The PP population includes participants with complete pre- and post-intervention data and who met minimum participation criteria (attendance and completion of assessments, where applicable). PP analyses will be conducted as sensitivity analyses only.

### **Sample Size Determination**

The minimum sample size was calculated assuming a standardized effect size of 0.40, with a two-sided significance level of 0.05 and 80% statistical power. Under these assumptions, 98 children per group (intervention and control) are required, for a total of 196 participants with complete pre- and post-intervention assessments.

To account for an estimated attrition rate of 15%, the target sample size was increased to 115 children per group, resulting in a total planned sample of 230 boys and girls distributed across the participating schools. This sample size is considered feasible based on school enrollment data and is appropriate for a pilot effectiveness study.

### **Primary Outcome Analysis**

#### **Primary Outcome**

Children's mental health, measured using the Total Difficulties Score (TDS) of the Strengths and Difficulties Questionnaire (SDQ), based on parent and teacher reports, assessed at baseline and post-intervention.

## **Primary Analysis Method**

Within each group (intervention and control), pre- to post-intervention changes in SDQ TDS will be assessed using paired-sample statistical tests:

- Paired t-tests for approximately normally distributed outcomes.
- Wilcoxon signed-rank tests for non-normal distributions.

The primary effectiveness estimate will be based on the comparison of change scores (post minus pre) between the intervention and control groups:

- Independent-sample t-tests will be used for normally distributed change scores.
- Mann–Whitney U tests will be used if distributional assumptions are not met.

Effect sizes will be reported using Cohen’s d with 95% confidence intervals.

Given the cluster-assigned design, additional analyses using regression models accounting for clustering at the school level may be conducted as sensitivity analyses.

## **Secondary Outcome Analyses**

Secondary outcomes include:

- Mental health literacy scores among teachers and parents/guardians.
- Mental health symptoms in teachers and parents/guardians measured by GHQ-12.
- Children’s stress reactivity measured by nail cortisol concentration (pg/mg).

Each secondary outcome will be analyzed using the same analytical framework as the primary outcome, including within-group pre–post comparisons and between-group comparisons of change scores.

Nail cortisol data will be examined for skewness and outliers. If distributions are markedly skewed, log-transformation will be applied prior to analysis.

## **Covariate-Adjusted Analyses**

Multivariable regression models will be used to adjust for baseline characteristics and potential confounders. Linear regression models will be preferred to preserve the continuous nature of outcome variables.

Baseline values of the outcome will be included as covariates. Additional covariates may include child age and sex, adverse childhood experiences, parental mental health, locality, and country, as collected at baseline.

## **Mediation Analyses**

Exploratory mediation analyses will be conducted to examine whether changes in mental health literacy among teachers and parents/guardians mediate changes in children’s mental health outcomes. Regression-based mediation models with bootstrapped confidence intervals for indirect effects will be used. Results will be interpreted cautiously due to the pilot design.

## **Moderation Analyses**

Moderation analyses will be performed by including interaction terms between intervention status and selected baseline variables (e.g., adverse childhood experiences, baseline symptom severity, locality, or country). Significant interactions will be explored using stratified analyses or marginal effects as appropriate.

## **Feasibility Analyses**

Feasibility outcomes will be analyzed descriptively and will include:

- Recruitment rates.
- Retention and completion rates.
- Attendance and adherence to intervention sessions.
- Participant satisfaction scores from Likert-type items.
- Qualitative analysis of barriers and facilitators identified through focus groups and open-ended survey responses.

No formal hypothesis testing will be conducted for feasibility outcomes.

## **Missing Data Handling**

The extent and patterns of missing data will be described by outcome and study group. If the proportion of missing data is low, complete-case analyses will be performed. If missingness is substantial, sensitivity analyses using multiple imputation under a missing-at-random assumption may be conducted.

## **Multiplicity and Statistical Significance**

All statistical tests will be two-sided with a nominal significance level of 0.05. Given the pilot nature of the study and the multiple outcomes assessed, no formal adjustment for multiple comparisons will be applied. Results will be interpreted as exploratory, with emphasis on effect sizes, confidence intervals, and consistency of findings across outcomes rather than on statistical significance alone.

## **Assumption Checking**

Statistical assumptions for each analysis will be evaluated using graphical and analytical methods, including assessment of distributional properties, residual diagnostics, and influence measures. Any deviations from assumptions and corrective actions taken will be documented.

## **Deviations from the Statistical Analysis Plan**

Any deviations from this Statistical Analysis Plan will be documented, justified, and reported prior to data analysis or at the time of reporting results.