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:
Study Protocol

Version:
Version 1.0

Document Date:
April 2025

Full 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
(Fantasy name: *Raíces para la Vida Project: Strengthening Mental Health in School Communities*)

Protocol Version and Date
Version 1.0 — April 2025

Study Type
Pilot quasi-experimental study with intervention and control schools

Sponsor Institution
University of Valparaíso, Chile

Countries of Recruitment
Chile and Ecuador

Trial Phase
Not applicable (behavioral intervention)

Estimated Study Duration
13 months

Funding
This study is sponsored by the **University of Valparaíso, Chile**.

Study Sites
The study will be conducted in primary schools in **Chile and Ecuador**.

Chile:

Chiloé Province (Los Lagos Region)

- Liceo Insular de Achao — Achao
- Liceo Ramón Freire — Achao
- Liceo Alfredo del Carmen Barría Oyarzún — Curaco de Vélez

Valparaíso Region

- Escuela Joaquín Edwards Bello — Valparaíso
- Escuela Cirujano Videla — Valparaíso

Ecuador:

Guayas Province — Daule

- Unidad Educativa Victoria Torres de Neira — Daule
- Unidad Educativa José Joaquín de Olmedo — Daule

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Trial Registration
ClinicalTrials.gov — registration in progress (NCT ID not yet assigned) at time of protocol finalization.

Confidentiality Notice
This document is confidential and intended only for research governance and ethics oversight.

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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

Fantasy name: Raíces para la Vida Project: Strengthening Mental Health in School Communities

PROTOCOL VERSION AND DATE

Version: 1.0
Date: April of 2025

SPONSOR / INSTITUTIONS

Department of Pediatrics, Child and Adolescent Psychiatry Unit and Department of Public Health School of Medicine, Universidad de Valparaíso, Chile

PRINCIPAL INVESTIGATORS

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Dr. Rubén Alvarado – Public Health, University of Valparaíso, Chile

COUNTRIES OF RECRUITMENT

Chile and Ecuador

STUDY PHASE

Pilot behavioral intervention study

ETHICS APPROVAL

This study was reviewed and approved by the Scientific Ethics Committee of the Valparaíso–San Antonio Health Service (CEC-SSVSA), an ethics committee accredited by the Chilean Health Authority. Approval for the study *"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"* was granted in the session of 30 April 2025, as recorded in Approval Minutes No. 26/2025 and Official Letter (ORD.) No. 842 dated 15 May 2025. Approval is valid for one year from the decision date.

The Committee approved the Study Protocol and the Informed Consent Form (Version April 2025) and confirmed compliance with the Declaration of Helsinki, Good Clinical Practice, and applicable

Chilean regulations. Institutional authorization from participating centers will be obtained prior to implementation.

BACKGROUND AND RATIONALE

Child mental health (CMH) is the foundation upon which mental, physical, and social health develop in adulthood (1–4). Prevention and early intervention for problems identified during this developmental phase are valuable strategies in the field of Public Health. In the pediatric population, mental health (MH) disorders generate a high burden of disease, both in children aged 1 to 9 years (30.3%) and in adolescents aged 10 to 19 years (38.3%) (5), with an estimated prevalence of 22.5% for child–adolescent mental health disorders (6), and a treatment gap greater than 70% (1–4). Addressing this issue requires an effective intersectoral approach and comprehensive actions in promotion, prevention, and early intervention.

In consideration of this problem, the literature reports various barriers to improving MH indicators. Among the factors associated with these barriers are the capacity of parents to recognize or identify their children's MH problems (7), parental beliefs and attitudes toward mental health services (8), perceived availability of care services, waiting lists, and satisfaction with previous experiences, among others (9). Among adolescents, lower help-seeking behavior is reported when there is a higher perception of difficulty accessing specialized centers (10), and greater help-seeking when parents are sensitive to their children's MH problems (11). Likewise, international and national evidence shows that the largest percentage of help-seeking requests in mental health originate from schoolteachers (between 21.9% and 36.0%), with the main problems being school-disruptive behavior and emotional problems (50% and 17%, respectively) (12). In Chile, evidence indicates that only 41.6% of children and adolescents with a psychiatric disorder associated with social disability consulted any type of health service in the past year, and a large proportion did not receive specialized care (13).

Given that the school environment, with its various actors, constitutes the primary source of referral to MH services for children and adolescents, it has been a privileged setting for identifying emotional and behavioral problems (13). However, school communities rarely possess the necessary knowledge to identify problematic emotions and behaviors that require professional attention and to differentiate which problems can be addressed at the primary care level and which require specialized mental health professionals (14). Additionally, the school system does not have a coordinated and functional intersectoral network to connect children and adolescents who require care with appropriate services.

Continuing with this, international evidence highlights the importance of a community that is literate in mental health (15), defined as a set of knowledge and beliefs regarding mental health, including etiology, protective and risk factors, treatments, their availability and access pathways, as well as a set of skills to conduct timely identification and implement effective self-help and first-aid strategies for others, promoting favorable beliefs and attitudes to reduce stigma (15,16,17).

The educational context constitutes a privileged opportunity to implement mental health literacy (MHL) programs in children and adolescents, both because of the amount of time students spend in school (allowing early visibility of mental health problems) and because it is the first point of entry

for help-seeking by children and their families (6). Most MHL programs available internationally are directed toward secondary school students (92.3%), with only 7% aimed at primary education (18); unfortunately, even though MHL and other preventive measures are considered cost-effective, most of these programs are implemented in developed countries (18).

This study is the next step of the "Chilean National Fund for Health Research and Development" (FONIS) Project SA21I0143 "Participatory Construction and Feasibility of a Multicomponent Intervention to Improve the Well-being of Primary School Children after the COVID-19 Pandemic," which began in 2022 and concluded in March 2024. One of its main objectives was to evaluate the effect and feasibility of a Mental Health Literacy intervention for public primary school teachers, based on a 6-session program of 2 hours each, with group activities, delivery of information, and sharing of experiences among participants (see details below and in Annex No. 1). Preliminary results are positive: teachers in the intervention group acquired greater knowledge in child MH, decreased their depressive symptoms (measured with the PHQ-9 scale, where the intervention group reduced its score from 7.4 to 6.6, while the control group increased from 10.9 to 11.3), and reduced one of the indicators of burnout (measured with the MBI questionnaire, where the intervention group decreased its emotional exhaustion score from 21.6 to 15.6, while the control group did so only slightly, from 29.0 to 28.8).

Our current project builds on the previous one and is an extension of it, as it uses the same intervention (MHL for teachers) but adds a similar intervention aimed at parents and guardians. In turn, this project expands the previous one in three important aspects:

1. It is implemented in different contexts (different regions of Chile and in Ecuador);
2. It evaluates effectiveness at the level of children, who are the final beneficiaries of this type of intervention; and
3. It seeks to construct an explanatory model to understand the effects of the intervention, with mediating and moderating variables operating at different levels (child, family, neighborhood, and school).

Given that child MH problems are a global priority—as stated by WHO and PAHO—and that our team collaborates with other research groups, we have integrated a team of researchers in Guayaquil into this study, aiming to move toward a proposal that can later be extended to other countries and contexts in Latin America through progressive scaling, contributing to guidelines issued by these multilateral organizations.

RESEARCH QUESTION

What is the preliminary effectiveness and feasibility of a mental health literacy intervention for teachers and parents/guardians in improving the mental health of boys and girls in 3rd to 5th grade in socially vulnerable schools in Chile and Ecuador?

OBJECTIVES

Primary Objective

Evaluate the preliminary effectiveness of an MHL intervention for teachers and parents/guardians on the mental health of boys and girls in 3rd to 5th grade.

Secondary Objectives

1. Evaluate whether the intervention improves mental health literacy among teachers and parents/guardians.
2. Assess whether improvements in adult mental health literacy mediate changes in child mental health.
3. Analyze moderating or mediating effects of family, school, and neighborhood-level variables on child outcomes.
4. Assess feasibility and acceptability of the intervention.

STUDY DESIGN

This is a **quasi-experimental cluster-assigned pilot study** with **pre- and post-intervention evaluations**.

- **Clusters:** Schools
- **Participants:** children in 3rd–5th grade, their parents/guardians, and teachers
- **Groups:** intervention vs. control (wait-list)
- **Blinding:** none (open-label)

Control schools receive the intervention only **after post-intervention data collection**.

STUDY SETTING

Public and subsidized primary schools located in socially vulnerable areas of:

- Chile (Valparaíso Region and Chiloé Province)
- Ecuador (Guayaquil)

STUDY POPULATION

Children (Primary Outcome Population): Boys and girls enrolled in **3rd–5th grade** in selected schools.
Teachers: Teachers responsible for primary-level classes.
Parents / Guardians: Parents or legal guardians of participating children.

INCLUSION AND EXCLUSION CRITERIA

CHILDREN

Inclusion

- Enrolled in 3rd–5th grade
- Parent/guardian has provided written informed consent
- Child has provided assent for biological sample collection

Exclusion: Severe sensory or physical disability preventing questionnaire completion

TEACHERS

Inclusion: Teachers in public or subsidized private schools teaching primary levels

Exclusion

- Non-teaching staff
- Declines participation

PARENTS / GUARDIANS

Inclusion: Parent/guardian of a child in 3rd–5th grade under 12 years old

Exclusion

- Parent/guardian of a child ≥12 years old
- Declines participation

SAMPLE SIZE

Based on an expected effect size of 0.40, $\alpha = 0.05$, and 80% power, **98 children per group** are required with complete assessments. Allowing for 15% attrition, **115 per group (total 230)** are required. Current school enrollments make this feasible.

INTERVENTION

TEACHER MENTAL HEALTH LITERACY PROGRAM

- Six modules
- 120 minutes each (total 12 hours)
- Participatory learning with case-based discussions, audiovisuals, role-play, theoretical content

Topics include
self-care, healthy development, anxiety, depression, suicidal spectrum, ADHD, conduct disorder, ODD, ASD, child maltreatment.

Delivered in-person at schools.

PARENT / GUARDIAN MENTAL HEALTH LITERACY PROGRAM

- Three 90-minute modules
- Case discussions and reflective dialogue
- Topics include stigma, healthy development, warning signs, emotional support, and available help-seeking pathways

CONTROL GROUP

Wait-list: receives the full intervention after post-assessment.

OUTCOMES

Primary Outcome: Change in **child mental health symptoms** (SDQ Total Difficulties Score) from baseline to post-intervention. The primary analysis time point is immediately after completion of the intervention.

Secondary Outcomes

- SDQ internalizing and externalizing subscales
- Parent GHQ-12
- Teacher GHQ-12
- Mental Health Literacy Scale (teachers & parents)
- Nail cortisol concentration (biomarker of chronic stress)
- Feasibility indicators:
    - interest / participation rates
    - retention
    - satisfaction
    - reported barriers & facilitators

STUDY PROCEDURES AND SCHEDULE

Assessments will occur before intervention (April 2025) and after intervention (early second semester 2025).

Level	Variable	Instrument	Respondent			Aplication		Duration
			Child	Parents / Guardians	Teachers	Pre intervention	Post intervention	
Child	Child MH problems	SDQ	-	X	X	X	X	15’
Child	Stress reactivity	Nail cortisol	X	-	-	X	-	2’
Child	Adverse events	NSCH-ACEs	-	X	-	X	-	5’
Parents	Parental MH problems	GHQ-12	-	X	-	X	X	6’
Parents	MH literacy	MHL Scale	-	X	-	X	X	5’
School	MH literacy	MHL Scale	-	-	X	X	X	5’
School	Emotional well-being (teachers)	GHQ-12	-	-	X	X	X	5’

CONSENT AND ASSENT

- **Parents/guardians provide written consent**
- **Teachers provide written consent**
- **Children provide assent for cortisol sampling**

Participation is voluntary and withdrawal carries no consequences.

RISK MANAGEMENT AND SAFETY

This is a **minimal-risk behavioral study**. If SDQ results suggest mental health need, referrals will be made to the child’s local primary health service following school protocols. A structured emotional

crisis-response plan is in place for distressed parents/teachers. No DSMB is required due to minimal risk.

For the purpose of this study, an adverse event (AE) is defined as any psychological deterioration, distress, or safety concern identified during participation that may reasonably be associated with study procedures.

CONFIDENTIALITY AND DATA MANAGEMENT

Participants will be assigned study codes.
Personal identifiers and coded data will be stored separately in secure systems.

Data retention: **5 years** after study completion.
Nail samples: stored at controlled temperature and destroyed after analysis.

Access is restricted to authorized study personnel.

STATISTICAL CONSIDERATIONS (SUMMARY ONLY)

A separate SAP will provide full details. In summary:

- Descriptive statistics will summarize baseline characteristics.
- Pre-post change scores will be calculated.
- **Primary analysis:** comparison of change in SDQ Total Difficulties Score between intervention and control groups using regression/mixed-effects models accounting for clustering at school level.
- Effect sizes will be reported.
- Analyses will follow a pragmatic intention-to-treat approach where feasible.
- Missing data will be handled using appropriate modern methods (e.g., multiple imputation) depending on pattern and extent.

Qualitative data will be analyzed thematically.

DATA ACCESS AND QUALITY ASSURANCE

Periodic internal monitoring will verify consent documentation, secure storage, and data entry accuracy. Only authorized investigators will access identifiable data.

DISSEMINATION PLAN

Results will be shared with:

- Participating schools and families (aggregate form)
- Ministries/Departments of Health and Education
- Scientific community via publications and conferences

- Missing data will be examined for patterns and handled using multiple imputation where appropriate, with complete-case analyses conducted as sensitivity analyses.

No identifiable information will be disclosed.

EXPECTED BENEFITS

Potential benefits include:

- improved recognition and response to child mental health needs
- improved mental health literacy among adults
- better family–school–health system coordination

There is no financial compensation for participation.

STUDY DURATION AND TIMELINE

Total duration: **13 months (2025–2026)**

1. Preparation & baseline assessment
2. Intervention delivery
3. Post-intervention assessment & analysis

ROLES AND RESPONSIBILITIES

The PI team is responsible for scientific oversight, ethical compliance, training, monitoring, data security, and dissemination.

COMPLIANCE

This research complies with:

- Declaration of Helsinki
- Good Clinical Practice principles
- Chilean and Ecuadorian research regulations
- Institutional ethics requirements

This document corresponds to Protocol Version 1.0. Any future amendments will be documented with version and date, together with a description and rationale, and submitted for prior approval by the relevant Ethics Committees.

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