

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:

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INFORMED CONSENT FORM FOR RESEARCH STUDY

Information for Teachers

The purpose of this document is to invite you to participate in the “*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 in Chile and Ecuador*” (also known as “*Raíces para la Vida Project: Strengthening mental health in school communities*”).

You have been invited because you are a teacher at one of the primary schools selected to participate in this study, and your role is essential in identifying and providing an initial response to mental health problems in children. Your participation is key, as this study aims to evaluate the impact of a mental health literacy intervention directed at adults responsible for the care and education of children.

The principal investigators are Dr. Fanny Leyton from the Child and Adolescent Psychiatry Unit of Hospital Psiquiátrico del Salvador in Valparaíso, and Dr. Rubén Alvarado, along with co-investigators Dr. Roberto Garnham, Psychologist Rocío Barrientos, Dr. Marcela Horwitz, Dr. Nicolás López, Dr. Alexies Dagnino, and Professor Ximena Velasco.

The study is sponsored by the Interdisciplinary Center for Health Studies (CIESAL) of the University of Valparaíso and the Subdepartment of Mental Health and Reparations of the Valparaíso–San Antonio Health Service.

Your participation is voluntary, and in order for you to make an informed decision, we explain below the procedures involved in the research and what your participation will entail:

Where and When the Research Will Take Place

The study will be conducted in primary schools located in Valparaíso, Achao, and Curaco de Vélez in Chile, as well as in the Daule area in Ecuador. It will take place over a period of 13 months, beginning in the first semester of 2025 and ending in the first semester of 2026.

Motivation and Purpose of the Study

Child mental health is essential for their integral development, influencing their emotional wellbeing, ability to relate to others, and academic performance. However, many mental health problems go unnoticed or are not addressed in a timely manner, either due to lack of access to specialized services or because adults responsible for children do not know how to identify them.

Teachers and parents play a fundamental role in the early detection of emotional difficulties in children, but they often lack mental health knowledge or do not know how to act when faced with warning signs. Evidence indicates that improving the *mental health literacy* of adults surrounding children can facilitate the identification of problems and improve access to appropriate support.

This study seeks to evaluate whether an educational intervention focused on mental health literacy for teachers and parents in primary schools in Chile and Ecuador can help improve the detection and management of emotional difficulties in childhood. In simple terms, we want to know whether

providing concrete tools to adults in contact with children can make a difference in their psychological wellbeing and access to support when needed.

What Your Participation Involves

Your participation in this study is entirely voluntary, meaning that you may decide whether or not you wish to participate, and you may withdraw at any time without consequences for you or your educational community.

If you decide to participate, you will attend a mental health literacy workshop aimed at teachers, which will be delivered at your school in person. The workshop consists of 6 sessions where tools will be provided for the early identification of emotional problems in childhood and their management within the school environment.

Additionally, you will be asked to complete questionnaires before and after the workshop to assess changes in your level of mental health literacy and perception of the school climate. These questionnaires will take approximately 20 minutes each time.

A subgroup of participants will also be invited to participate in focus groups to explore experiences related to the mental health of students in the school context. These sessions will last between 45 minutes and 1 hour, will be recorded for analysis, and will be conducted with a minimum of 4 participants per group. If invited, you may voluntarily choose not to attend.

The study will last a total of 13 months, but your personal participation will occur only during the activities mentioned.

Risks

This study does not involve physical risks for you. However, some individuals may feel uncomfortable answering questions about mental health or reflecting on personal topics.

If you experience emotional discomfort during the questionnaires or the intervention, a support team trained in psychological first aid will be available to offer guidance and emotional support (Responsible professional: Psychologist Rocío Barrientos).

Benefits

This research may not provide direct individual benefits to participants; however, it may contribute to improvements in mental health literacy and support systems in school communities.

Costs and Payments

Participation in this study is completely free and does not involve any cost to you.

It is important to note that this study does not include payments or reimbursements for participants. No money will be given for attending the sessions or completing the questionnaires. Likewise, the researchers will not receive any financial compensation for conducting this study.

Participant Rights

Right to Ask Questions and Express Concerns

You have the right to express any doubts or concerns about the study at any time. You may contact the principal investigator, Dr. Fanny Leyton, for more information or clarification regarding your participation.

If you have questions before, during, or after the study, you may contact the research team at:

- **Email:** fanny.leyton@uv.cl
- **Email:** proyectoraicesparalavida@gmail.com
- **Phone:** +56 9 3438 1048

Right to Voluntary Participation, to Know Alternatives, and to Withdraw Consent

Your participation in this study is completely voluntary, meaning that you may decide whether or not to participate. Furthermore, at any moment during the study, you may withdraw without having to justify your decision; you only need to notify the principal investigator or a member of the research team.

If you choose not to participate or decide to withdraw, this will not affect your access to health services, education, or any other benefit to which you are entitled. Your wellbeing is our priority.

Right to Attention and Timely Referral

This study has been designed to minimize any risk or discomfort for participants. However, if you or your students experience emotional discomfort during the study, a team trained in psychological first aid will be available to offer support and guidance.

If during the research it is detected that any child under your responsibility may require mental health attention, you will be informed confidentially and guided on how to access professional care. Referral will be made through the corresponding CESFAM or the school mental health unit. In the event of an unexpected adverse event related to the study, access to appropriate care will be ensured.

Right to Receive Relevant Information From the Study

You have the right to receive any new information that arises during the study and that may be relevant to your participation. Likewise, once the research is completed, general results will be shared with participants and the educational community. This will allow schools, teachers, and parents to understand the main findings and apply them for the benefit of children's wellbeing.

If you wish to receive a summary of the final results of the study, you may request it from the research team using the contact information provided.

Confidentiality

Confidentiality of Participant Identity

Participant identity will remain strictly confidential, and your name will never be disclosed in study results. To ensure privacy, each participant will be identified with a unique code, and the data will be stored in secure databases with restricted access to the research team.

Privacy of Personal and Sensitive Data

All information obtained in this study will be handled with strict confidentiality. Personal and sensitive data provided by participants will be accessible only to the research team and will not be shared with third parties without your authorization.

The data will be stored in password-protected digital files located on a secure computer in a research team office. Physical documents will be stored in a locked filing cabinet with restricted access to the responsible investigators.

Once the study is completed, data will be retained for five years and then securely destroyed to prevent any misuse.

Dissemination and Delivery of Results

The results of the study will be disseminated without compromising participant identity. Findings will be presented in scientific publications, conferences, and academic seminars, as well as in meetings with educational and health institutions that may benefit from the information obtained.

Likewise, general results will be shared with the participating schools and their educational communities, so they may understand the main findings and apply the conclusions in daily practice.

The collected data may be used in future research as long as it remains within the scope of the objectives of this study and does not deviate from its original purpose. Any additional use will be evaluated by the research team, and new consent will be requested if necessary.

If you wish to receive a summary of the final results, you may request it from the research team.

Ethical and Scientific Evaluation

This research has been reviewed and approved by the Scientific Ethical Committee of the Valparaíso–San Antonio Health Service. If you have concerns regarding your rights as a participant, you may contact:

Phone: 32–257 6581

Email: octavio.guzman@redsalud.gob.cl

Informed Consent Act – Teachers

I, _____,

RUN: _____,

declare that the principal investigator, Dr. Fanny Leyton Álvarez, has invited me to participate in the *“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 in Chile and Ecuador,”* which will be conducted in _____.

I have fully read the information provided in this document and understand what my participation will entail.

I have been clearly informed and had explained to me the study procedures to which I will be subjected.

I have had the opportunity to ask questions and resolve all my doubts with the investigator.

I understand that I have the right to revoke my consent and that doing so will not cause any harm or negative consequences.

By signing this document, I voluntarily accept my participation in this research.

I will receive a complete, signed copy of this document.

Participant Signature

Date:

Name and Signature of Responsible Investigator

Date:

Name and Signature of School Director or Delegate

Date:

Valparaíso–San Antonio Health Service

Phone: (32) 2576581 / MINSAL Extension: 326581

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