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:

Ethics Approval Documentation

Version:

Version 1.0

Document Date:

April 2025

VALPARAÍSO – SAN ANTONIO HEALTH SERVICE

SCIENTIFIC ETHICS COMMITTEE
Accredited by the Health Authority on 24.12.2014, R.E. N° 2940
Re-accredited on 13.11.2023, R.E. N° 2305136096

ORD. N° 842 – 15.05.2025

FROM: Acting Director of the Valparaíso – San Antonio Health Service
TO: As per Distribution List
SUBJECT: Approval of Multicenter Study
REF.: Hospital del Salvador Study / LMG / INT. N° 26 / 2025

Regarding the research study titled:
"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"**),

I am pleased to inform you that the Scientific Ethics Committee of the Valparaíso – San Antonio Health Service conducted its ethical–scientific evaluation and **granted approval in the session held on April 30, 2025**, in accordance with the legal regulations in force for scientific research involving human beings. The following is detailed:

LOCAL PRINCIPAL INVESTIGATORS:
- Dr. **Fanny Leyton Álvarez**
- Dr. **Rubén Alvarado**

CO-INVESTIGATORS:
- Dr. **Roberto Garnham Parra**
- Dr. **Alexies Dagnino**
- Dr. **Nicolás López**
- Psychologist **Rocío Barrientos**
- Prof. **Ximena Velasco**
- Dr. **Marcela Horwitz**

RESEARCH SITES:
- Hospital del Salvador de Valparaíso
- Escuela Joaquín Edwards Bello
- Escuela Cirujano Videla

EVALUATING ETHICS COMMITTEE:

Scientific Ethics Committee of the Valparaíso – San Antonio Health Service (SSVSA)

DATE OF FAVORABLE DECISION:

April 30, 2025

Committee Requirements

1. Authorization from the Director of the Establishment

Before initiating the study, the Principal Investigator must request **explicit authorization** from the Director of the Establishment where the research will take place.
The Director must respond **within a period not exceeding 20 working days** from the date of the Committee's favorable evaluation (Article 10 bis of the Regulation of Law 20.120).
A refusal of authorization must be **duly justified**.

2. Confidentiality and Protection of Clinical Records

The Director of the Establishment, as guarantor of clinical records, must ensure:

- confidentiality of the participant's identity,
- protection of personal information,
- protection of medical, genetic, and other sensitive data.

Therefore, the necessary measures must be taken to ensure that the investigator and collaborators who access this information protect it and use it **exclusively for the purposes for which it was requested**.

3. Compliance with the Legal Framework

Upon authorizing the execution of the research protocol, the Director is responsible for ensuring that the study is conducted **within the current legal framework**.

The investigator is obligated to disseminate the research results in academic meetings or scientific events, according to the research protocols established by the institution.

4. Progress Report and Final Closing Report

The Principal Investigator must submit:

- a **Progress Report at 6 months**, and
- a **Closing Letter together with the Final Report** to the CEC-SSVSA and to the Research Unit of the institution where the study is conducted.

If re-approval is needed, it must be requested **3 months prior** to the expiration date of the current approval.

Failure to comply with the submission of progress or closing reports will render the investigator **ineligible to submit future studies** to the CEC-SSVSA, as established in the SSVSA Ethics Committee Regulations.

VALPARAÍSO – SAN ANTONIO HEALTH SERVICE

SCIENTIFIC ETHICS COMMITTEE
Accredited by the Health Authority on 24.12.2014, R.E. N° 2940
Re-accredited on 13.11.2023, R.E. N° 2305136096

MINUTES N° 26 OF APPROVAL / 2025

LOCAL PRINCIPAL INVESTIGATORS:

– Dr. **Fanny Leyton Álvarez**
– Dr. **Rubén Alvarado**

CO-INVESTIGATORS:

– Dr. **Roberto Garnham Parra**
– Dr. **Alexies Dagnino**
– Dr. **Nicolás López**
– Psychologist **Rocío Barrientos**
– Prof. **Ximena Velasco**
– Dr. **Marcela Horwitz**

RESEARCH SITES:

– Hospital del Salvador de Valparaíso
– Escuela Joaquín Edwards Bello
– Escuela Cirujano Videla

EVALUATING ETHICS COMMITTEE:

Scientific Ethics Committee, Valparaíso – San Antonio Health Service

DATE OF FAVORABLE REPORT:

Approval granted on April 30, 2025

The favorable approval is valid for one year from the date of approval issued by the CEC-SSVSA.

The Scientific Ethics Committee of the Valparaíso – San Antonio Health Service certifies that it has reviewed the documents submitted for the research protocol titled:

“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”**).

This work is a study led by the University of Valparaíso, with the support of the Department of Pediatrics, the Child Psychiatry Section, and Hospital del Salvador de Valparaíso. The study is intended to be presented in academic settings and in national/international scientific journals.

The favorable opinion was granted in the session held on April 30, 2025, and in accordance with the legal regulations governing scientific research involving human beings:

a) It possesses scientific validity and social value.
b) The risk/benefit ratio was deemed favorable.
c) It presents an Informed Consent Form that has been reviewed and authorized by the members, ensuring respect for participants and protection of privacy and the confidentiality of collected records.
d) The academic background of the Principal Investigator demonstrates sufficient qualifications to conduct this study within the ethical and legal framework, and there is a commitment to submit a 6-month progress report and final results once the study is completed.
e) The ethical–scientific evaluation was performed independently, and prior conflict-of-interest declarations were submitted by all CEC members.

It is recorded that all members of the Committee submitted their conflict-of-interest declarations before the evaluation. In accordance with current legal regulations for scientific research involving human beings, the study was approved in the ordinary session held on April 30, 2025, by all members present:

– **Elizabeth Hellman Sepúlveda**
– **Mariana Torres Brito**
– **Mariana Cubillos Gómez**
– **Octavio Guzmán Aguilera**
– **Fernando Moreno Astorga**

APPROVED DOCUMENTATION

Approved: Protocol titled
“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”**)
Version April 2025.

Approved: Informed Consent Form for the study titled
"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")
Version April 2025.

DECLARATION OF COMPLIANCE WITH GOOD CLINICAL PRACTICE

This Scientific Ethics Committee of the Valparaíso – San Antonio Health Service is organized, operates, and issues its decisions in full accordance with:

– The Declaration of Helsinki (1964 and its amendments of 1975, 1983, 1989, 1996, 2000, 2002, 2004, and 2008)
– Good Clinical Practice (GCP) Guidelines established by the World Health Organization (WHO, 1996)
– The Harmonized Tripartite Guidelines for Good Clinical Practice (1996)
– The International Ethical Guidelines for Biomedical Research Involving Human Subjects (PAHO/CIOMS, 1996)
– Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO, 2000)
– National Regulations (Technical Standard N° 57, June 4, 2001, Ministry of Health of the Government of Chile: Regulation of the execution of clinical trials using pharmaceutical products in human subject.

Respectfully,

OCTAVIO ATILIO GUZMÁN AGUILERA
Executive Secretary
Scientific Ethics Committee (CEC)
Valparaíso – San Antonio Health Service

INFORMED CONSENT FORM FOR RESEARCH STUDY

Information for: Participant / Parents or Legal Guardians of Minors

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

You have been invited because you are the father, mother or legal guardian of a boy or girl enrolled in 3rd to 5th grade in one of the primary schools selected to participate in this study. Your participation is key, as the study seeks 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**, Psychiatrist and faculty member at the University of Valparaíso in the Child and Adolescent Psychiatry Unit of Hospital Psiquiátrico del Salvador, Valparaíso, and Dr. **Rubén Alvarado**, together with co-investigators Dr. **Roberto Garnham**, Psychologist **Rocío Barrientos**, Dr. **Marcela Horwitz**, Dr. **Nicolás López**, Dr. **Alexies Dagnino** and Prof. **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 research will be carried out in primary schools located in **Valparaíso, Achao and Curaco de Vélez** in Chile, as well as in the **Daule** area in Ecuador. It will be conducted over a period of **13 months**, starting in the first semester of 2025 and ending in the first semester of 2026.

Motivation and purpose of the study

Child mental health is key to the integral development of boys and girls, as it influences their emotional wellbeing, their ability to relate to others, and their school performance. However, in communities with high levels of social vulnerability, 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 the adults responsible do not know how to identify them.

Teachers and parents/guardians play a fundamental role in the early detection of emotional difficulties in children, but they often lack information about mental health or do not know how to act in the face of certain warning signs. Evidence indicates that improving the mental health literacy of adults

surrounding children can facilitate the identification of problems and promote access to appropriate support.

This study seeks to evaluate whether an educational intervention focused on mental health literacy for teachers and parents/guardians 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 the adults who are in contact with children can make a difference in their psychological wellbeing and in their access to support when they need it.

What your participation involves

Your participation in this study is completely voluntary, which means that you may decide whether or not you wish to participate, and at any time you may withdraw without consequences for you or your child.

If you decide to participate, you will attend mental health literacy sessions, which will be conducted at your school or in person at a location designated by the research team. These sessions are directed at teachers and parents/guardians and aim to provide tools to identify and manage emotional problems in childhood.

In addition, you will be asked to complete questionnaires **before and after** the intervention, in order to evaluate changes in your level of knowledge about mental health. These questionnaires will take approximately **15 minutes** to complete on each occasion. If your child is also part of the study, their emotional wellbeing will be assessed through a validated questionnaire (**SDQ**), which you will complete.

A subgroup of participants will also be invited to take part in **focus groups**, both with parents and with children, to explore experiences related to mental health and possible situations of stigma. These sessions will last between **45 minutes and 1 hour**, will be audio-recorded for analysis, and will be conducted with a minimum of **4 people per group**.

You will also be asked to complete a questionnaire regarding your child's emotional and behavioral status. In addition, we will measure a hormone called **cortisol**, which will allow us to evaluate stress in your child, through a **fingernail sample** collected before and after the intervention. This is a simple and non-invasive procedure. You and/or your child may decide to complete only the questionnaires and not provide the nail sample. If you agree to provide the nail sample, you will be trained by one of the researchers to carry out the procedure.

The study will have a total duration of **13 months**, from March 2025 to April 2026, but your personal participation will be limited to the specific activities described above.

Risks

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

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

In addition, if the questionnaires suggest that your child may need mental health care, you will be informed and guided regarding the steps to follow for a potential referral to your **CESFAM** or corresponding health service. In exceptional cases where a high risk is detected (such as severe symptoms of anxiety or depression), or moderate risk together with elevated cortisol levels in the collected samples, school psychosocial teams or the associated health center will be contacted, ensuring that the child can receive appropriate care.

Benefits

This research may not provide direct individual benefits; however, it may contribute to improved mental health literacy and support systems for children and families.

Costs and payments

Participation in this study is completely free and does not entail 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 for answering the questionnaires. Likewise, the researchers will not receive any financial remuneration for conducting this research.

Participant rights

Right to ask questions and raise 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 her by mobile phone or through the following emails:

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

Right to voluntary participation, to know alternatives, and to withdraw consent
Your participation in this study is completely voluntary, which means that you may decide whether or not you wish to participate. Furthermore, at any time during the study you may withdraw without

needing to justify your decision; you only need to inform the principal investigator or a member of the research team.

If you decide not to participate or to withdraw from the study, this will have no consequences and will in no way affect your access to health services, education, or any other benefit to which you are entitled. Your wellbeing and that of your child are our priority.

Right to timely care and referral
This study has been designed to minimize any risk or discomfort for participants. However, if you or your child experience any emotional distress during the study, there will be a support team trained in psychological first aid to provide containment and guidance.

If during the research it is detected that your child may need mental health care, you will be informed confidentially and guided on how to access professional care. Referral will be made through your CESFAM or the corresponding school mental health unit, where your child may be assessed by a specialist in child mental health. If any unexpected adverse event related to the study occurs, access to appropriate care will be guaranteed.

Right to receive relevant information arising from the research
You have the right to receive any new information that may arise during the study and that is relevant to your participation. Likewise, once the research has been completed, **general results** will be shared with participants and the educational community. This will allow schools, teachers and parents/guardians to become familiar with 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 details provided.

Confidentiality

Protection of participant identity
The identity of the participants will be strictly confidential. At no time will your name or that of your child be revealed in the study results or in any report derived from the research. To ensure your privacy, each participant will be identified by a **unique code**, which will allow the information collected to remain anonymous.

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

Data will be stored in password-protected digital files with restricted access, located on a secure computer in an office belonging to the research team. In addition, any physical documents will be kept in a locked filing cabinet with access limited only to the investigators responsible for the study.

Once the research has been completed and after a period of **five years**, the data will be securely destroyed to prevent any misuse.

Dissemination and delivery of results

The results of this study will be disseminated without compromising the identity of participants. The 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 participating schools and their educational communities so that they may become familiar with the main findings and apply the conclusions in daily practice.

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

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

Ethical and scientific evaluation

This research has been reviewed and approved by the **Scientific Ethics Committee of the Valparaíso–San Antonio Health Service**. If you have any questions about your rights as a participant, you may contact:

- Phone: **32–257 65 81**
- Email: **octavio.guzman@redsalud.gob.cl**

Informed Consent Act
(Participant / Parent or Legal Guardian of the Minor)

I, _____ (Full name),
ID/RUT: _____ (Numeric digits),
_____ (Legal representative – specify relationship to the child, e.g. father, mother or legal guardian), of _____ (Full name of the minor),

1. Declare that the Principal Investigator, **Dra. Fanny Leyton**, together with **Dr.**, **Dr. Rubén Alvarado**, **Dr. Roberto Garnham, Psychologist Rocío Barrientos** and **Dr. Marcela Horwitz** from the Department of Public Health; **Dr. Nicolás López** and **Prof. Ximena Velasco** from the Department of Pediatrics, Child and Adolescent Psychiatry Section; and **Dr. Alexies Dagnino** from the Institute of Physiology of the Faculty of Sciences, all from the University of Valparaíso, have invited me to participate in 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," which will be carried out in two regions of the country: **Valparaíso** and **Los Lagos**.

2. I have fully read the information provided in this document about the study and what my participation (or that of the minor) will involve.
3. I have been clearly informed and had explained to me the study procedures to which I (or my son/daughter or the minor I represent) will be subjected.
4. I have had the opportunity to ask questions and clarify all my doubts with the investigator.
5. I understand that I have the right to revoke my consent and that this decision will not cause any harm or negative consequences.
6. In accordance with what I have stated in this document, I sign to accept my voluntary participation (or that of my son/daughter or ward) in this research.
7. I will receive a complete and signed copy of this document.

Participant / Parent or Legal Guardian of the Minor
Name and Signature: _____
Date: _____

Responsible Investigator
Name and Signature: _____
Date: _____

Director of the Establishment or Delegate
Name and Signature: _____
Date: _____