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Effectiveness of an intervention to reduce suicidal ideation in adolescents

Submission date
11/11/2025

Recruitment status
Not yet recruiting

Registration date
20/11/2025

Overall study status
Ongoing

Last Edited
20/11/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Delivering school-based prevention programs could reduce suicidal ideation (SI) in adolescents, an important risk factor for suicide in this population. However, the evidence regarding its effectiveness and duration of the effects on SI is unclear. We adapted an eight-session digital intervention (Reframe-IT) and created five face-to-face sessions to reinforce some of its contents. In Chilean schools, the adapted program (Reframe-IT+) was acceptable, feasible, and significantly reduced SI, depressive and anxiety symptoms, and hopelessness at post-intervention. The four-month follow-up showed non-significant reductions in SI, but significant effects in depressive and anxiety symptoms and psychotic experiences. This fits with the literature encouraging the enhancement of the maintenance of the effects on SI. This could be achieved through adding an intervention involving parents/caregivers (parents). We will test if a prevention intervention of SI involving parents of adolescents with SI can be implemented in schools settings (are acceptable and feasible).

The study has a general objective to develop an intervention to improve parental skills and to test its acceptability and feasibility among parents of adolescents with SI from secondary schools in Chile and explore its impact on reducing SI in adolescents when delivered in conjunction with Reframe-IT+. The primary objectives will assess participant acceptability and satisfaction with the intervention, and to evaluate feasibility in terms of recruitment, questionnaire response, attendance, retention, and data collection during and after the programme. Secondary objectives will measure the intervention's impact on caregiver skills (such as parental self-efficacy, family functioning, and problem-solving) and to compare changes in SI, depression, anxiety, hopelessness, emotional regulation, problem-solving, and perceived parental support among adolescents in intervention versus control schools.

Who can participate?
Learner/student aged 13-18 years attending to 9-11 Grades with SI and their parents.

What does the study involve?
The study will compare two interventions:
1. Adolescent-only condition (Reframe-IT+).13 modules (8 internet-based models and 5 face-to-face modules). The topics covered by the eight internet-based modules are: engagement and

problem identification, emotional recognition and distress tolerance, identification of automatic negative thinking, behavioral activation-help seeking, behavioral activation—activity scheduling (including relaxation techniques), problem-solving, and cognitive restructuring and a wrap-up session. The face-to-face component consists of five based sessions delivered by school psychologists previously trained and will help the students in three aspects: i) close support and monitoring in case of an increase of symptomatology; ii) motivation to persist with the intervention; and iii) support the interaction between the students and and the whole program. The intervention aims to reduce SI, depressive and anxiety symptoms, hopelessness, and to improve emotional regulation and problem-solving skills, and perceived parental support.

2. Adolescent + caregiver condition (Reframe-IT+ plus parental component). Adolescents will receive Reframe-IT+ . Parents will recei ve a training program aimed to enhance their skills in supporting their children with SI. It comprises five online and three face-to-face sessions, with an emphasis on empathy, communication, and joint problem resolution between caregivers and adolescents.
We will test its acceptability and feasibility among parents as primary outcome and explore its impact on secondary outcomes when delivered in conjunction with Reframe-IT+. Secondary outcomes for caregivers are communication and problem-solving skills and perceived parental self-efficacy.

What are the possible benefits and risk for participants?
1. Adolescents will learn skills useful to cope difficult and stressful thoughts and emotions.
2. Parents/caregivers will develop skills (empathy, communication, and joint problem resolution) to support their children in coping mental health issues.

The interventions does no involve any risk for participants.

Where is the study run from?
The Universidad de Talca, Chile.

When is the study starting and how long is it expected to run for?
March 2026 to November 2026.

Who is funding the study?
The Chilean National Agency for Research and Development (ANID)

Who is the main contact?
Daniel Núñez, dnunez@utalca.cl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

ANID, FONDECYT Regular grant number
1250325

Study information

Scientific Title
Testing the acceptability and feasibility of an intervention to improve parental skills in caregivers of adolescents from secondary schools with suicidal ideation: A protocol for a cluster randomized controlled pilot study

Acronym
PIRASI

Study objectives
General objective
To develop an intervention to improve parental skills and to test its acceptability and feasibility among caregivers of adolescents with SI from secondary schools in Chile and explore its impact on reducing SI in adolescents when delivered in conjunction with Reframe-IT+

Specific primary objectives
1. To determine participant acceptability and satisfaction with the intervention using the Client Satisfaction Questionnaire (CSQ-8) and in-depth interviews.
2. To determine the feasibility of recruiting study subjects, the level of response to questionnaires and attendance at interviews and sessions, participant retention, and data collection during and after the program.

Specific secondary outcomes
1. To determine the effects of the parental intervention on caregiver skills (perceived parental self-efficacy, family functioning, and problem-solving skills).
2. To identify and compare changes in suicidal ideation, depressive and anxiety symptoms, hopelessness, emotional regulation, and problem-solving skills, and perceived parental support among adolescents in the intervention group schools and the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/05/2025, Comité Ético Científico, Universidad de Talca (Casilla 747, Talca, 34600000, Chile; 56-712203065; dnunez@utalca.cl), ref: 14/2025

Primary study design

Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Single

Purpose
Prevention

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Suicidal ideation in adolescents

Interventions
This is a double-blind, two-arm, cluster randomized controlled pilot trial using an add-on design.

Participants. Schools with secondary education (Grades 9-12), mixed sex, located in three different cities in the South of Chile, with three classes per year. Schools will be randomized (1:1) to one of two active conditions:
a. Adolescent-only condition (Reframe-IT+), in which only adolescents receive the program.
b. Adolescent + parent condition (Reframe-IT+ plus parental component), in which caregivers also participate in a collaborative skills training program.

This add-on design enables assessment of the feasibility and acceptability of integrating a parental component into an existing evidence-based school intervention, ensuring that all participants receive indicated mental health care.
Sample size. Recommendations for feasibility studies propose a minimum of 30 participants per arm to estimate the parameters for future sample size calculations. We will select 6 schools. Prior studies showed that the expected prevalence of SI is around 10%. With an average participation of 40 students per class, we hope to recruit 12 students per school (4 from each grade). Each arm of the study should have a total of 36 students for a total of 72 students, just above the expected sample size calculated.

Recruitment. Our sample framework includes secondary schools with a vulnerability index (School Vulnerability Index - National Equity Allocation System (IVE-SINAE) ≥ 75%.

Enrollment Strategy. This project will be disseminated after the approval of the Scientific Ethics Committee. At the beginning of the academic year, a letter with information about the study and the written consent will be sent to all parents/caregivers. To select the participants, students attending to 9-11 Grades will be invited to participate, and the students will be asked for a written assent. All consented/assented students will be surveyed with the following

screening questionnaires during the second month of the academic year: Columbia Suicide Severity Rating Scale (C-SSRS); Patient Health Questionnaire (PHQ-9); Community Assessment of Psychic Experiences–Positive (CAPE-P-15). Those reporting suicidal ideation (score of 3 or higher on the C-SSRS) will be invited to an interview with a psychologist from the research team, regardless of whether or not they meet the exclusion criteria. The interview will take place at the school, and the students and their caregivers will be invited to attend to provide feedback on the results, offer information about how to access mental health care, and, if necessary, make a referral to the health centers with which the schools are networked. For this purpose, the guidelines and protocols contained in the document "Recommendations for the Prevention of Suicidal Behavior in Educational Establishments" (MINSAL, 2019), will be followed. It defines the roles and responsibilities of schools to ensure that students at risk receive timely interventions. In these interviews, parents/caregivers will also be invited to participate in the pilot study.

Informed consent will be requested from students. The students of the selected schools will be invited to participate in informative talks about the study. Once the study, inclusion and exclusion criteria have been explained, a description of the screening instruments, their importance, and the selection process will be provided to interested parties. The informed consent will be sent to those accepting participate by emails and signed digitally through Qualtrics, a platform allowing information to be collected online, with high-security standards, and that also can facilitate the digital signature through a cell phone or tablet (using the finger) or through a computer (with a mouse). This platform will collect data of mentioned screening instruments. These data will be used for the study eligibility analysis.

Evaluation procedure. Primary outcomes. We will assess acceptability by examining how caregivers receive the intervention. They will be given a questionnaire at the end of the intervention to gather their opinions on various aspects of the program. This data will be supplemented with in-depth interviews conducted with a random sample of participants. These data will be complemented by in-depth interviews with a random sample of participants to collect qualitative information about their experience in the program. This information will help improve the intervention and make the program more appealing to users.

We will assess feasibility by recording several implementation aspects:
(a) Recruitment rate: Proportion of eligible adolescents and their caregivers who consent to participate; (b) Retention rate: Proportion of participants who complete the intervention, (c) Session attendance: Average attendance per session, (d) Completion rate: Proportion of participants who complete the post-intervention assessment.

Finally, we will assess safety using a scale completed by adolescents immediately before and after each Reframe-IT+ module, rating suicidal ideation (SI) on a scale from 0 to 3 (0 = no SI, 1 = SI without plan or intention, 2 = moderate SI with some level of intention and vague plan, 3 = severe SI with clear plan and intention). The school wellbeing staff will be informed of these assessments and will be available to act in accordance with the school's established safety protocols.
Participant satisfaction will be measured using a satisfaction instrument administered at each session to beneficiaries, along with a summary survey covering the overall experience at the end of the program.

Monitoring and implementation fidelity: The program will include real-time monitoring indicators, as well as tools to quantify implementation fidelity, all to be completed by program implementers. This will allow for early identification of the need to make adjustments to program delivery, which must be approved by the Ethics Committee.

Secondary outcomes. They will be evaluated in adolescents and caregivers. All adolescents included in the study, will answer self-report questionnaires assessing secondary outcomes, administered at baseline (one week before the start of the intervention) and at post-intervention.

All caregivers included in the study will answer self-report questionnaires assessing parental self-efficacy, family functioning, problem-solving, and mental health aspects such as depression and anxiety, administered at baseline (one week before the start of the intervention) and at post-intervention.

Randomization. Schools will be randomly assigned to either group with a 1:1 allocation as per a computer-generated randomization. An independent statistician will perform the randomization. All consented/assented students will be surveyed with the mentioned screening questionnaires. Those reporting SI during the previous month in the C-SSRS will be invited to participate in the following step of the study. The two arms will be balanced for school size.

Blind condition: By the nature of the intervention, the participants are not blind with respect to the group allocation (intervention or control group). The evaluations will be carried out through self-report questionnaires sent in electronic format, and their evaluation will be automatic, without human action. In data analysis, the statistician will be blind to the intervention group of participants.

Study duration. From its recruitment and enrollment phase to the last evaluations (post-test), the study will last approximately 12 months.

Intervention conditions. This trial comprises two active intervention conditions within an add-on design, ensuring that all participants receive appropriate mental health care according to national guidelines. In both conditions, adolescents will participate in the Reframe-IT+ program, a blended cognitive-behavioral intervention delivered in schools by trained psychologists.

Adolescent-only condition (Reframe-IT+). In this condition, adolescents with suicidal ideation will receive the Reframe-IT+ program, described elsewhere. It consists of 13 modules (8 internet-based models and 5 face-to-face modules). The topics covered by the eight internet-based modules are: engagement and problem identification, emotional recognition and distress tolerance, identification of automatic negative thinking, behavioral activation-help seeking, behavioral activation—activity scheduling (including relaxation techniques), problem-solving, and cognitive restructuring and a wrap-up session. The face-to-face component consists of five psychotherapeutic CBT-based sessions (45-min) conducted by school psychologists previously trained and will help the students in three aspects:
i) close support and monitoring in case of an increase of symptomatology; ii) motivation to persist with the intervention;
and iii) support the interaction between the students and CBT.

In addition to the program, all adolescents and their caregivers will be referred to mental-health services for standard clinical care (see below).

Adolescent + caregiver condition (Reframe-IT+ plus parental component).In this condition, caregivers of participating
adolescents will receive a complementary intervention designed to strengthen parental skills to support adolescents experiencing suicidal ideation. The caregiver component consists of five

online and three face-to-face sessions addressing engagement and family safety planning, understanding adolescent development, communication and emotional validation, and collaborative problem-solving skills based on CBT and the Collaborative Problem Solving model.

The program will be administered at schools by trained school psychologists (one psychologist per school). The authors will deliver the training of the program. Each participant will have access to their personalized web page accessed via secure login. Each module will be completed in the psychologist's presence and participants will also be able to access it at home 24 h a day.

Standard Mental Health Care (Treatment As Usual) Because all participating adolescents present suicidal ideation, every participant—regardless of study condition—will be referred to public or private primary care mental health services in accordance with the national protocol for the management of suicidal behavior established by the Chilean Ministry of Health (MINSAL, 2019).

In primary-care clinics, trained psychologists assess symptom severity andpropose a course of action ranging from initiation of individual cognitive-behavioral psychotherapy (typically four to eight sessions delivered twice per month) to referral to a general practitioner for pharmacological evaluation. When indicated, general practitioners may prescribe antidepressant medication, most commonly selective-serotonin reuptake inhibitors (SSRIs) such as fluoxetine or sertraline. Patients are medically reviewed monthly or bimonthly. To minimize performance bias, all adolescents who require care in public health centers will receive comparable treatment because these centers operate under standardized national guidelines and similar resource levels. The research team will record and quantify all clinical interventions delivered by health-care providers to assess potential between-site variability.

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability and feasibility of intervention measured using self-report questionnaires answered by caregivers to assess their opinion about the intervention (perceived usefulness, satisfaction levels, contents, safety) at baseline (one week before the start of the intervention) and at post-intervention

2. Viability will be assessed by computing (a) Recruitment rate: Proportion of eligible adolescents and their guardians who consent to participate; (b) Retention rate: Proportion of participants who complete the intervention; (c) Session attendance: Average attendance at sessions; (d) Completion rate: Proportion of participants who complete the post-intervention assessment measured using data collected from study records at one timepoint

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Key secondary outcome(s))
1. Perception of parental efficacy measured using the Brief Parental Self-Efficacy Scale (BPSES) for parenting interventions at baseline and post-intervention

2. Family functioning measured using The Family Adaptability and Cohesion Rating Scale at baseline and post-intervention

3. Family problem-solving measured using McMaster Family Assessment Device-General Functioning Subscale (FAD-GF) at baseline and post-intervention

4. Depressive symptoms measured using the Patient Health Questionnaire at baseline and at post-intervention

5. Anxiety symptoms measured using the Generalized Anxiety Disorder-7 (GAD-7) scale at baseline and at post-intervention

6. Suicide ideation measured using The Suicidal Ideation Questionnaire (SIQ) at baseline and post-intervention

7. Suicide attempt measured using two questions assessing whether participants had attempted suicide; if yes, how many attempts at baseline and post-intervention

8. Hopelessness measured using the Beck Hopelessness Scale at baseline and post-intervention

9. Emotional regulation measured using the Emotion Regulation Questionnaire for Children and Adolescents (ERQ-CA) at baseline and post-intervention

10. Cognitive-behavioral skills measured using The Cognitive-Behavioural Therapy Skills Questionnaire (CBTS) at baseline and post-intervention

11. Social problem solving measured using The Short Form of the Social Problem-Solving Inventory Revised (SPSI-R Short Form) at baseline and post-intervention

12. Perception of parental support measured using the subscale of the Multidimensional Adolescent Functioning Scale (MAFS) at baseline and post-intervention

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Completion date
01/11/2026

Eligibility

Key inclusion criteria
Students (age range= 13-18 years) attending to 9-11 Grades with suicidal ideation (score of 3 or higher on the C-SSRS) and their parents/caregivers.

Participant type(s)
Carer, Learner/student

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
13 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Students with intellectual disabilities and communication difficulties due to language.
2. Students with one or more suicide attempts during the last month.
3. Students endorsing psychotic symptoms (>1.50 in the CAPE-P-15).

All these students will be referred to Primary Care Centers.

Date of first enrolment
01/03/2026

Date of final enrolment
30/05/2026

Locations

Countries of recruitment
Chile

Study participating centre
Liceo Bicentenario San Miguel Arcancel del Linares
Colo Colo 392
Linares
Chile
3580000

Study participating centre
Liceo Bicentenario de Molina
Avenida Presidente 1865
Molina
Chile
3380004

Study participating centre
Instituto Regional del Maule
Balmaceda 2120

San Javier
Chile
3600000

Study participating centre
Liceo Sagrados Corazones
Miraflores 1645
San Javier
Chile
3600000

Study participating centre
Liceo Juan Ignacio Molina
Avenida Ignacio Carrera Pinto 0490
Talca
Chile
3460000

Study participating centre
Liceo de la Cultura y Difusión Artística
6 Sur 2 Oriente
TALCA (ZONA URBANA)
Chile
34600000

Sponsor information

Organisation
University of Talca

ROR
https://ror.org/01s4gpq44

Organisation
University of Talca

ROR
https://ror.org/01s4gpq44

Organisation
Universidad de Los Andes

ROR
https://ror.org/04pqpvr75

Funder(s)

Funder type
Not defined

Funder Name
Agencia Nacional de Investigación y Desarrollo

Alternative Name(s)
Agencia Nacional de Investigación y Desarrollo de Chile, National Agency for Research and Development, Government of Chile, Chilean National Agency for Research and Development, Agencia Nacional de Investigación y Desarrollo de Chile (ANID), ANID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Daniel Nunez, dnunez@utalca.cl.
• The type of data that will be shared: All of the individual participant data collected during the trial, after deidentification.
• Timing for availability: Immediately following publication: No end date.
• Whether consent from participants was required and obtained: Informed consent will be obtained. It states that anonymized data can be shared.
• Comments on data anonymization: Questionnaires will be administered digitally through Qualtrics software (https://www.qualtrics.com/security-statement/). All collected data will be password-protected and encrypted. Only the Principal Investigators can access to the data through a protected password.
• Any ethical or legal restrictions: There is no ethical or legal restriction to share anonymized data
• Any additional comments: There are no additional comments

IPD sharing plan summary

Available on request