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Reframe-IT+, an indicated preventive school-based intervention, reduces suicidal ideation among adolescents in vulnerable contexts in Chile

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Abstract

Background Suicide prevention programs delivered in school settings have been shown to reduce suicide attempts and ideation among adolescents. School-based digital interventions targeting at-risk youth are a promising avenue for suicide prevention, and some evidence has shown that blending digital and face-to-face components may improve the effectiveness. However, further evidence is needed, especially in Latin America, where mental health support is limited. We tested the effectiveness of the Reframe-IT+, a blended cognitive behavioral indicated intervention to reduce suicidal ideation, designed to be delivered in school settings. It includes 13 sessions, combining eight internet-based sessions and five face-to-face sessions.

Methods We conducted a cluster RCT and delivered the Reframe-IT+ among secondary students attending Years 9–11. We recruited 21 schools that were randomized into two groups: (1) Intervention Reframe-IT+ Group (IG) ($n=863$) and (2) Control Group (CG) ($n=683$). All consented students completed online screening self-reported questionnaires at baseline. The primary outcome was suicidal ideation. Additionally, we tested the impact of the intervention on depressive and anxiety symptoms, hopelessness, and emotion regulatory strategies, including social solving-problems skills, behavioral activation, cognitive reappraisal, and emotion suppression. A total of 303 students (IG, $n=164$; CG, $n=139$) were identified as at risk and eligible for inclusion in the study. From those, 224 students (IG, $n=123$; CG, $n=101$) and their caregivers were interviewed to confirm inclusion and exclusion criteria. Finally, 48 and 47 students were allocated to control and intervention groups, respectively, and answered the online questionnaires at post-intervention. We performed an intention-to-treat analysis using repetitive measures and multilevel regression analyses.

Results We found a significant reduction in suicidal ideation ($b=-6.7$, $p=0.015$, Cohen's $d=0.49$), depressive ($b=-3.1$, $p=0.002$, Cohen's $d=0.81$) and anxiety ($b=-2.60$, $p<0.001$, Cohen's $d=0.72$) symptoms, and hopelessness ($b=-3.7$, $p<0.001$, Cohen's $d=0.70$) in the intervention group compared to the control group at post-intervention. We also found improvement in solving-problems skills ($b=-1.6$, $p=0.002$, Cohen's $d=0.58$), behavioral activation ($b=2.8$, $p=0.019$, Cohen's $d=0.47$), and cognitive reappraisal ($b=2.2$, $p=0.029$, Cohen's $d=0.53$). In the exploration of the

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intervention mechanisms concerning suicidal ideation, the total indirect effect of the intervention ($b = -5.727923$; $p = 0.008$) was significant, whereas the direct effect ($b = -0.03195473$, $p = 0.903$) was not significant (Suppl 2, Table 1). Problem-solving skill ($b = -2.84$, $p = 0.016$) was a significant mediator of intervention effects on suicidal ideation (Path a*b).

Conclusions This is the first clustered RCT evaluation of the effectiveness of a blended indicated intervention to prevent suicidality in school settings in Latin America. This is the first step to informing policymakers to scale up an effective intervention for an important public health problem.

Trial registration Clinical Trials NCT05229302. Registered on January 27th, 2022.

Introduction

Suicide-related behaviors (SRB) are prevalent in young people [1, 2]. A recent meta-analysis showed a worldwide suicidal ideation prevalence of 15.4–18.4% among individuals aged 14 to 21, and it was associated with an increased risk for suicide [3, 4]. On the other hand, studies show that direct interventions could be more effective in reducing suicidal ideation and behaviors than interventions targeting other outcomes such as depression or anxiety [5, 6]. On the other hand, suicide prevention strategies have called for delivering and testing prevention interventions in educational settings [7–11] and using internet-based interventions [6, 12, 13]. These kinds of interventions are mainly based on cognitive behavioral therapy (iCBT), showing promising results in reducing SI and repetition of self-harm in adolescents [12–16]. Nevertheless, conclusions about its effectiveness are not definitive [17], and several issues have arisen from the currently available studies. For instance, small to medium effect sizes, low adherence levels, and the lack of understanding of the effect of moderating and mediating variables require further research [18].

Some experiences show that including interactive exercises and monitoring the advancement in the sessions can improve adolescents' involvement. For example, these added-on features, such as therapeutic support, either synchronous or asynchronous, delivered by a professional or a paraprofessional included in interventions to prevent depression, have improved the effect size and adherence of participants when compared with self-guided interventions [19]. Additionally, combining digital interventions with human support could also improve the effectiveness of iCBTs, as shown by recent systematic reviews of interventions focused on depression and anxiety symptoms [20, 21]. However, studies testing blended interventions to reduce SI are very scant and conducted with adult populations. For example, using a quasi-experimental design, Büscher et al. (2023) examined the feasibility of a blended treatment combining video therapy with self-help online modules, concluding that the program was feasible and safe [22]. The only RCT available was conducted by King et al. (2023) among construction workers [23]. Using a smartphone suicide prevention

intervention combined with face-to-face was shown to be effective in improving help-seeking intentions.

To our knowledge, Reframe-IT [15] is the only iCBT program tailored to be delivered in school environments. It contains eight CBT internet-based modules delivered over ten weeks by school wellbeing staff, supervised and monitored by a mental health professional during the same period [24, 25]. Preliminary evidence suggests that this intervention is acceptable and feasible [24], and although it showed some reduction in suicidal ideation, depression, and hopelessness among adolescents [25], none of them at a significant level [15]. No RCT studies have tested the effectiveness of blended interventions among adolescents in school settings. To fill this relevant gap, in the context of the well-recognized need to personalize interventions targeting SI [26], and the potential benefits of delivering preventive interventions in educational environments [8–10], we have created additional face-to-face modules to be delivered and added to the guided online school-based program Reframe-IT (Reframe-IT+). Throughout this blended intervention, we wanted to reinforce and provide more opportunities for students to understand and practice specific preventive skills such as emotion identification and regulation, relaxation strategies, the awareness of the relationship between thoughts, emotions, and behaviors, problem-solving, and cognitive restructuring. See the protocol [27] for more details on the intervention. Additionally, there is evidence that depression, anxiety, and hopelessness are closely related to suicidal ideation and potential mediators in the causal pathway [28]. Moreover, social problem-solving skills [29], behavioral activation [30], cognitive reappraisal [31] and restructuring [29, 32], and emotional suppression [31] seem to be good candidates to be included in preventive interventions to reduce common mental disorders and suicide-related behaviors. Therefore, due to the poor understanding of the mechanisms behind the effectiveness of these interventions among adolescents [29, 33], it is important to explore potential mediators associated with the strategies delivered by an intervention such as Reframe-IT+.

This study aimed to test the effectiveness of a blended intervention (Reframe-IT+) to reduce suicidal ideation

among adolescents attending vulnerable schools in Chile. Additionally, we tested if the intervention reduced depressive and anxiety symptoms and hopelessness and improved social problem-solving skills, behavioral activation, cognitive reappraisal and restructuring, and emotional suppression. Finally, we explored the mediation mechanisms explaining the effectiveness of the intervention.

Methods

Study design, setting, participants, and eligibility criteria

This was a cluster randomized controlled trial. Municipal and subsidized schools provide education for most low-income students in the Region of Maule. Our sampling frame comprised all municipal and subsidized secondary, mixed-sex schools, with two or more 1°-3° Medio grades (equivalent to 9th -11th grade in the United States) in the Region of Maule. All invited schools were informed about the study's aims and methodology. Twenty-one out of 41 eligible schools accepted the invitation to participate. After being granted authorization from the school's principals, the research team participated in parent meetings at the beginning of the academic year to inform them about the study and to ask for written and informed consent for their children's participation. After receiving the signed consent, the schools were randomly allocated to groups: (1) Reframe-IT+group and (2) Control group. The randomization was carried out by an independent statistician using the Microsoft Excel function RAND in a 1:1 proportion. Due to an uneven number of schools consented, more schools were allocated to the control group for practical reasons, reducing the costs associated with implementing the whole intervention. After allocation, research assistants blinded to the school condition supported the baseline assessment using an online survey through the schools' computer labs. Students also provided written assent to participate and answered the questionnaires. The primary inclusion criterion was scoring ≥ 3 points on the Columbia-Suicide Severity Rating Scale (C-SSRS) [34], validated as a self-report in Chile [35]. Exclusion criteria were: (1) PHQ-8 score > 19 ; (2) One or more suicidal attempts in the last 30 days; (3) Presence of perceptual anomalies (auditory and visual hallucinations); and (4) Intellectual disability or communication difficulties due to language. For the PHQ-8, it was used the cut-off score of 19 for Severe depression as the scoring threshold used for the PHQ-9, based on the evidence that both scales (PHQ-8 and PHQ-9) had a similar likelihood of any depressive disorder at each level of depression severity level [36]. The exclusion of subjects with PHQ-8 score > 19 was based on the indicated preventive nature of the intervention, reducing the risk of including students with clearly severe depressive symptoms who required more complex and evidence-based

treatments. All eligible students were invited to participate with their parents in clinical interviews to confirm the exclusion criteria and determine their motivation to participate in the study. Additionally, all adolescents who scored ≥ 3 points on the C-SSRS and > 19 points on the PHQ-9 were invited to an interview with their caregivers to inform these results and support referral to health centers.

All participants in both groups were referred to primary care centers, where a protocol for managing suicidal ideation defined by the Chilean Ministry of Health was applied [37] when possible. The procedure includes CBT-based psychological and pharmacological interventions when needed. This was considered treatment as usual (TAU). Further procedure details can be found in the RCT protocol [27].

The recruitment of schools was extended from September 26th, 2022, to March 8th, 2023. The recruitment of students was from July 25th, 2023, to September 21st, 2023. The baseline assessment was from July 25th, 2023, to October 2nd, 2023, and the post-intervention assessment was from October 24th, 2023, to December 27th, 2023.

Ethical issues

Data were collected following the Declaration of Helsinki. This study was approved by the ethics committee of Universidad de Talca, Folio 02-2021 (May 12th, 2021). To assess the safety of participants, we put in place close monitoring and supervision of suicidal ideation and attempts weekly, during sessions, and daily in between sessions. None of the participants reported suicidal attempts during the trial.

Sample size

This sample size considers a loss at follow-up of 55% of the students from eligible ones (C-SSRS score ≥ 3), a harmonic mean of 8 students recruited by the school, and the following mean (SD) scores of SIQ after intervention obtained in a pilot study under review: Control group (mean=51.9; SD=21.4); Intervention group (mean=41; SD=18.6). We expected to recruit at least 18 schools. We used the "clustersampsi" command in Stata Software to estimate the number of clusters in two arms, using the following command: clustersampsi, samplesize mu1(X1) mu2(X2) sd1(Y1) sd2(Y2) m(Z) rho(R). Where X1=mean in arm 1; X2=mean in arm 2; Y1=standard deviation (SD) in arm 1; Y2=SD in arm 2; Z=number of children per school on average (harmonic mean) ($n=10$); and R=intracluster correlation ($R=0.023$). The two arms were balanced for the school's size.

Intervention and control groups

Intervention group. Reframe-IT+ is a blended intervention described elsewhere [27]. The *online component* comprises eight ~20-minute video-based modules of CBT and is administered at schools by trained psychologists (one psychologist per school). Each participant has access to their personalized web page accessed via secure login. Each module is completed in the psychologist's presence, and participants can also access it at home 24 h a day. Additionally, the student finds a series of fact sheets covering various related topics, including managing SI, plus downloadable relaxation MP3s [15, 24]. The *face-to-face component* comprises five CBT sessions to (1) build a safety plan, (2) reinforce emotion recognition and practice relaxation exercises, (3) understand the relationships among emotions, thoughts, and behavior, (4) develop problem-solving skills, and (5) promote thinking restructuring. The first face-to-face session consists of building an individualized safety plan to provide students with a toolkit of strategies to help them cope with psychological distress and suicidal ideation [38, 39]. The other face-to-face sessions followed two online sessions to ensure the content was complementary. These face-to-face sessions used brief videos (1–2 min), activities, and mood checking. Each session lasted about 30 min.

Control group. Students in this group were referred to primary care clinics and received the TAU defined by the Chilean Ministry of Health for this population. TAU consists of identification and assisted referral to a primary care clinic, where trained psychologists will assess the symptomatology and propose a course of actions, from psychotherapy to a general practitioner to initiate medication if needed. Based on the Cognitive-Behavioral Model, psychotherapy in primary care clinics consists of 4–8 sessions twice a month. General practitioners may also suggest using medications, which generally are SSRI antidepressants (e.g., Fluoxetine, Sertraline). A medical check-up is conducted every month or every two months.

Outcome measures

The primary outcome measure was the Suicidal Ideation Questionnaire (SIQ) [40], which provided a continuous score measured after the intervention. The SIQ is a 15-item self-report measure designed to assess SI in adolescents. It has high levels of internal consistency ($\alpha=0.93$) and test-retest reliability over four weeks ($\kappa=0.72$) [41]. We used a Spanish version previously validated in adolescents in Chile [42]. In our sample at baseline, Cronbach's α was 0.95, and McDonald's ω was 0.96.

The secondary outcome measure was the PHQ-8, which consists of eight of the nine criteria on which the DSM-5 diagnosis of depressive disorders is based [43], with responses ranging from 0 (not at all) to 3 (nearly

every day). The ninth question in the DSM-5 assesses suicidal or self-injurious thoughts. It was omitted because suicidal ideation was assessed with the C-SSRS for the inclusion criteria and with SIQ as the primary outcome. We wanted to have a measure of depression severity and avoid collinearity in the analyses. Total scores can range from 0 to 24 [44]. In Chilean adolescents, Borghero et al. [45] observed the following psychometric properties for the PHQ-9: internal consistency= 0.78 ; sensitivity= 86.2% , specificity= 82.9% . In our sample, the PHQ-8 had a Cronbach's α (α) of 0.86, and McDonald's Omega Coefficient (ω) was 0.86 at baseline.

Additional measures and their reliability coefficients at baseline are described below. The Generalized Anxiety Disorder Scale [46] is a 7-item questionnaire to assess the severity of anxiety symptoms ($\alpha=0.87$; $\omega=0.87$). The Beck Hopelessness Scale [47] is a 20-item scale aiming to assess feelings of hopelessness ($\alpha=0.88$; $\omega=0.88$). The Short Form of the Social Problem-Solving Inventory-Revised (SPSI-R Short Form) [48] is a 25-item scale evaluating several social problem-solving skills ($\alpha=0.88$; $\omega=0.87$). The Emotion Regulation Questionnaire for Children and Adolescents (ERQ-CA) [49] is a 10-item self-report scale assessing two emotional regulation styles: Cognitive Reappraisal (CR), which consists of redefining a potential emotion-eliciting situation in such a way that its emotional impact is changed ($\alpha=0.83$; $\omega=0.83$); Expressive Suppression (ES), which consists of the inhibition of ongoing emotion-expressive behavior. It has been validated in adolescents from Chile [50] ($\alpha=0.67$; $\omega=0.68$). The Cognitive-behavioral Therapy Skills Questionnaire (CBT-SQ) [51] is a 16-item scale assessing two skills: cognitive restructuring (CR) ($\alpha=0.84$; $\omega=0.84$) and behavioral activation (BA) ($\alpha=0.83$; $\omega=0.83$) (i.e., changes in avoidance/behavioral control and changes in cognitive style).

Statistical analyses

Firstly, we used descriptive statistics to assess balance across arms at baseline. The primary between-group analysis was carried out on an intention-to-treat basis for post-intervention SIQ scores. We used linear mixed-effects model analysis to compare the intervention and control groups regarding the change in outcome measures from baseline to post-intervention. Schools were included as a random factor for each outcome measure to account for possible school effects. We repeated the analyses with secondary and additional outcomes.

Finally, we explored mediation effects using seemingly unrelated regression modeling to explain the effectiveness of the intervention with the command "sureg" in Stata 17. We calculated the intervention effect for each mediator, the effect of each mediator on the primary outcome (suicidal ideation), and the intervention effect

that was mediated by each mediator. For each model, we computed the total indirect effects of the intervention (i.e., the total effect of intervention mediated by the sum of the mediating factors) and the single indirect effect for each mediator as suggested by Preacher and Hayes [52], adjusting by sex, age, and baseline scores for each variable. Moreover, we calculated the program's direct effect (i.e., the effect not explained by the hypothesized mediators). The randomization occurred at the school level; therefore, we entered the school as the second level and individuals as the first level. To control for variability across schools, we used multilevel modeling.

Results

Demographic features

There were 41 schools in the sampling frame, 21 of which participated in the trial. A total of 95 secondary school students participated. Figure 1 shows the flow of schools and students in the study. The number of students enrolled in both groups was comparable. However, participation in the baseline survey was lower in the control group. After the interview, a higher proportion of students/caregivers rejected participation in the study, which resulted in both groups having a similar number of students (IG=51; CG=49). Primary outcome data after intervention were available for 98% ($n=48$) of participants in the control group and 92% ($n=47$) in the intervention group.

The trial arms were well balanced at baseline (Suppl 1, Table 1) regarding age, symptomatology, and psychological skills.

Regarding students who entered the trial, there were more girls than boys in the control group ($p=0.049$), and the mean age was similar (15.4 years in the CG, and 15.3 years in the IG). (See Table 1). More CG students received psychological or psychiatric treatment at baseline than IC students. The history of suicide attempts in the family was similar in both groups (30.6% in CG and 29.4% in the IG); however, the history of suicide in the family was slightly higher in the control group. Symptomatology and psychological skills seem to be similar in both groups.

Intervention effectiveness

There was clear evidence of a reduction in suicide ideation in the intervention group over the control group after controlling by sex, age, and baseline scores (Adjusted Mean Difference [AMD] = -5.6, 95%CI: -10.7 to -0.4; $P=0.037$). See Table 2.

Among the secondary outcomes considered, the intervention had a beneficial effect on depression (AMD= -2.8, 95%CI: -4.9 to -0.8; $P=0.009$), anxiety (AMD= -2.6, 95%CI: -4.1 to -1.1; $P=0.002$), and hopelessness (AMD=-3.3,

95%CI: -4.8 to -1.8; $P<0.0001$) after the intervention. See Table 3.

No harm or unintended effects were reported in each group.

Mediating analyses results (suppl. 2)

Concerning suicidal ideation, the total indirect effect of the intervention ($b = -5.727923$; $p=0.008$) was significant, whereas the direct effect ($b=-0.03195473$, $p=0.903$) was not significant (Suppl 2, Table 1). Social problem-solving skills ($b=-2.84$, $p=0.016$) were a significant mediator of intervention effects on suicidal ideation (Path a*b). Regarding depression, the total indirect effect of the intervention ($b = -1.704665$; $p=0.005$) was significant, whereas the direct effect ($b = -1.088063$, $p=0.089$) was marginally significant (Suppl 2, Table 2). Social problem-solving skills ($b=-0.99$, $p=0.035$) were a significant mediator of intervention effects on depression (Path a*b), whereas the mediating effect of behavioral activation was only marginally significant ($b=-0.60$; $p=0.055$). Concerning anxiety, the total indirect effect of the intervention ($b = -1.635282$; $p=0.008$) was significant, whereas the direct effect ($b = -1.024881$, $p=0.079$) was marginally significant (Suppl 2, Table 3). Social problem-solving skills ($b=-1.06$, $p=0.018$) were a significant mediator of intervention effects on anxiety (Path a*b), whereas the mediating effect of cognitive reappraisal was only marginally significant ($b=-0.44$; $p=0.083$). And finally, concerning hopelessness, the total indirect effect of the intervention ($b = -1.721213$; $p=0.009$) was significant, whereas the direct effect ($b = -1.566542$, $p=0.016$) was significant (Suppl 2, Table 3). Behavioral activation ($b=-0.44$, $p=0.067$) and cognitive reappraisal ($b=-0.90$; $p=0.087$) were significant mediators of intervention effects on hopelessness. (Path a*b).

Discussion

This is the first study examining the effects of a blended CBT-based indicated intervention to reduce suicidal ideation among adolescents in school settings. We found a significant reduction in suicidal ideation at post-intervention, which fits with prior evidence [6, 18]. We additionally observed reductions in depressive and anxiety symptoms and hopelessness, as reported in previous studies [15, 53–55]. Finally, in the exploratory analyses, we found that social solving-problem skills were the main mediator of the reduction in SI, depressive, and anxiety symptoms.

Our results support literature revealing that indicated iCBT-based programs can effectively reduce SI [6, 18] and that blended interventions could improve its effectiveness [22]. However, only two iCBT interventions to reduce SI have been targeted at adolescents. The self-guided community-based program by Hill and Pettit

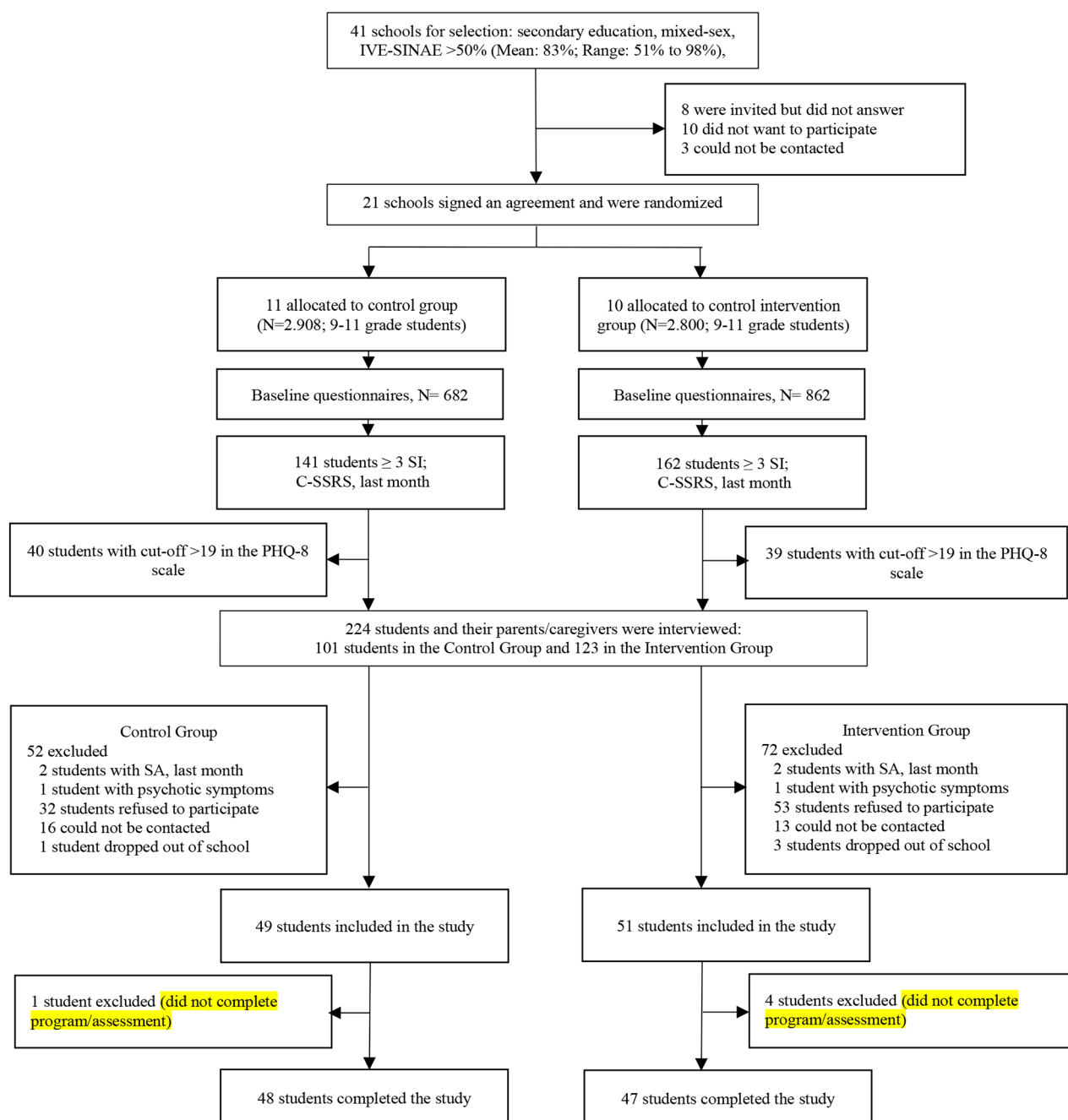


Fig. 1 Recruitment and follow-up of schools and students. Notes: IVE-SINAE = for initials in Spanish of “Índice de Vulnerabilidad Escolar - Sistema Nacional de Asignación con Equidad” (School vulnerability index - National Allocation System with Equity); SI = Suicidal Ideation; C-SSRS = Columbia–Suicide Severity Rating Scale; PHQ-9 = Patient Health Questionnaire-9; SA = Suicide Attempt

(2019) showed significant effects on perceived burden-someness, thwarted belongingness, and depressive symptoms but not on SI [56]. On the other hand, the guided school-based program by Hetrick et al. (2017) yielded positive but not significant effects on SI, depressive symptoms, hopelessness, and problem-solving skills [15]. Additionally, other differences may arise when comparing

or studying with other interventions. For instance, we observed a slightly larger effect size and adherence to the intervention than reported by recent meta-analyses [12, 18] on iCBT interventions. Despite some similarities between our program and those by Hill & Petit (2019) [56] and Hetrick et al. (2017) [15] (e.g., sample size, iCBT-based interventions), direct comparisons must

Table 1 Demographics with all students at risk included in the trial

Variables	Control (n = 49)		Intervention (n = 51)		p-value
Sex	n	%	n	%	
Male	12	24.5	22	43.1	0.049
Female	37	75.5	29	56.9	
Psychological/psychiatric treatment					
Never	14	28.6	20	39.2	0.512
In the past	18	36.7	17	33.3	
Currently	17	34.7	14	27.5	
Psychological/psychiatric treatment in family					0.544
Never	4	8.2	8	15.7	
In the past	17	34.7	13	25.5	
Currently	13	26.5	12	23.5	0.484
I do not know	15	30.6	18	35.3	
History of suicide attempts in family					
No	7	14.3	12	23.5	0.133
Yes	15	30.6	15	29.4	
I do not know	27	55.1	24	47.1	
History of suicide in family					0.627
No	19	38.8	30	58.8	
Yes	11	22.5	8	15.7	
I do not know	19	38.8	13	25.5	0.245
Age	n	Mean (SD)	n	Mean (SD)	
SIQ	49	15.4 (1.0)	51	15.3 (1.1)	
CSSRS	49	51.4 (16.9)	51	47.4 (17.5)	0.071
PHQ-8	49	5 (1.5)	51	4.5 (1.3)	
GAD-7	49	13.9 (2.9)	51	13.0 (2.8)	
SPSI-R: S	49	13.2 (4.5)	51	12.0 (3.6)	0.108
BHS	49	47.2 (7.8)	51	45 (11.8)	
CBT Questionnaire	49	7.4 (4.4)	51	8.2 (4.6)	
Behavioral activation	49	18.5 (5.8)	51	18.4 (5.9)	0.433
Cognitive restructuring	49	21.8 (5.7)	51	20.5 (5.5)	
ERQ-CA	49	18.9 (3.7)	51	18.6 (4.6)	
Cognitive reappraisal	49	14.2 (2.9)	51	13.9 (3.4)	0.767
Expressive suppression	49		51		
	49		51		

Table 2 Analysis of SIQ scores at post-intervention

Variable	Control mean (SD)	Intervention mean (SD)	Adjusted Mean Difference (95% CI)*	p-value	Cohen d (95% CI)
Post intervention	39.7 (18.1)	32.0 (13.0)	-5.6 (-10.7 to -0.4)	0.037	0.49 (0.08 to 0.90)
	No. 48	No. 47			

Note: *This was adjusted, including baseline measures, sex and age, and clustering by school

SIQ=The Suicidal Ideation Questionnaire assesses the frequency of suicidal ideation

be cautiously done. Reframe-IT+ is a blended intervention with a *face-to-face component* to reinforce specific themes (emotion recognition, understanding relationships between emotions, thoughts and behaviors, social problem-solving skills, and cognitive restructuring), highlighted as relevant aspects of traditional CBT interventions [57]. Aligned with prior findings on depression and anxiety [20, 21], we hypothesized that reinforcing iCBT contents using a guided approach with adding the face-to-face component might explain our better results.

However, this interpretation needs further research with a larger sample size.

A significant impact of Reframe-IT+ in our study was also found on depressive and anxiety symptoms and hopelessness. By contrast, a recent meta-analysis by Sander et al. (2023) [58] of iCBT suicide preventive interventions only found significant effects on depression outcomes but inconsistent effects on anxiety and no effects on hopelessness, and the authors suggested that the revised interventions needed additional components for

Table 3 Secondary outcomes at post-intervention

Variable	Control mean (SD)	Intervention mean (SD)	Adjusted Mean Difference (95% CI)*	p-value	Cohen d (95% CI)
PHQ-8 scores	10.8 (4.6)	7.3 (4.2)	-2.8 (-4.9 to -0.8)	0.009	0.80 (0.39 to 1.22)
GAD-7 scores	10.6 (5.3)	7.2 (4.2)	-2.6 (-4.1 to -1.1)	0.002	0.71 (0.30 to 1.13)
BHS score	6.9 (4.6)	3.8 (4.2)	-3.3 (-4.8 to -1.8)	< 0.001	0.69 (0.27 to 1.10)
SPSI-R: S scores	43.4 (13.7)	41.0 (11.7)	-0.9 (-6.3 to 4.5)	0.721	0.18 (-0.22 to 0.59)
CBT Questionnaire					
Behavioral activation	18.6 (6.2)	21.4 (5.3)	2.3 (-0.05 to 4.7)	0.054	-0.49 (-0.90 to -0.08)
Cognitive restructuring	21.0 (4.9)	21.2 (5.9)	0.6 (-1.8 to 3.0)	0.620	-0.04 (-0.44 to 0.37)
ERQ-CA					
Cognitive reappraisal	19.9 (4.5)	22.1 (4.0)	1.9 (-0.2 to 3.9)	0.078	-0.52 (-0.92 to -0.11)
Expressive suppression	13.7 (3.2)	13.0 (3.3)	-0.6 (-1.8 to 0.5)	0.266	0.21 (-0.20 to 0.61)

Note: *This was adjusted, including baseline measures, sex and age, and clustering by school

PHQ-8= The Patient Health Questionnaire-9 measures depressive symptoms

GAD-7= Generalized Anxiety Disorder Scale-7

BHS= Beck Hopelessness Scale measures several aspects of hopelessness

SPSI-R: S= Social Problem-solving Inventory - Revised Short Form assesses problem-solving skills

CBT-Q= Cognitive Behavioral Therapy Questionnaire measures CBT skills

ERQ-CA= The Emotion Regulation Questionnaire for Children and Adolescents measures different aspects of emotion regulation

managing anxiety symptoms and hopelessness. Reframe-IT+ has several components to help students develop social problem-solving skills, behavioral activation, and cognitive reappraisal; each could have a different role in improving outcomes beyond suicide ideation. Very few studies have explored the potential mediators of preventive interventions to understand better the mechanisms of change [59] on suicidal ideation.

To our knowledge, this is the first study providing evidence about the role of potential mediators in explaining the effectiveness of an iCBT blended intervention to reduce SI among adolescents at schools, which is highly relevant to developing evidence-based treatment decision models [12, 13]. Our exploratory mediation analyses yielded that social-problem skills fully mediated the effect of the intervention on SI. Other studies have highlighted that enhancing problem-solving skills may act as a protective factor over SI [33, 60, 61]. Our findings are similar to those reported by Xavier et al. (2019) [62] among adolescents and young people in Brazil, studying the effectiveness of a group and face-to-face intervention to reduce suicide ideation. Moreover, as we previously mentioned, Reframe-IT+ was also effective in reducing depressive and anxiety symptoms by improving social problem-solving skills. A recent systematic review concluded that problem-solving skills seem to be the active ingredient in indicated prevention interventions for young people [63], especially in reducing depressive symptoms. The authors proposed that problem-solving skills help adolescents improve mechanisms such as cognitive appraisal, self-efficacy, and optimism [63]. Specifically, social problem-solving skills may help adolescents create meaningful social relationships, find support from others, improve other cognitive skills such

as inhibitory control [64], and manage depressive and anxiety symptoms using a proactive strategy to regulate these symptoms [65]. More research is needed to explain the underlying pathways of how social problem-solving reduces SI and depressive and anxiety symptoms and also to understand the specific effect on these and other outcomes.

Other studies have found that behavioral activation [30], cognitive reappraisal [66], and restructuring [32] are potential mediators of CBT interventions. The evidence is somehow mixed regarding the role of emotional suppression [31] in depression and suicidality. Considering this, we were careful that all content promoting these and problem-solving skills were promoted among subjects. However, given that the cognitive, behavioral, and affective emotional regulation strategies are complex, especially in their possible interaction and person- and context-dependent [29, 67, 68], different doses are likely required to develop these skills. This is especially relevant for suicidal-related behaviors [29]. A study with a larger sample and testing the effectiveness of differentiated components could help elucidate this question.

Limitations

This study has some limitations. First, although we met the sample size requirements regarding the number of schools, the recruitment rate of students was low, as found in other studies [15, 69]. One explanation for the lower recruitment rate in the control arm might be related to the reduced interest of parents or main caregivers in participating due to the little incentive, knowing that the control schools will not receive the intervention but the usual care [70, 71]. Second, during the interview, to confirm inclusion and exclusion criteria, more

students and parents in the Intervention Group refused to participate in the study than in the Control Group. Sometimes, there could be less interest in participating in the intervention group in a clinical trial setting due to various concerns and barriers. Participants might perceive higher risks or discomfort associated with the intervention, such as potential side effects or inconvenience [70]. Even though the interviewer was trained to communicate the objectives of the study clearly, a lack of understanding of the benefits and purpose of the intervention can also reduce interest [70]. Trust issues with researchers, the intervention itself, and previous negative experiences can further discourage participation [72]. Additionally, participants may be less inclined to engage if they do not see immediate benefits or have other competing health or personal priorities [72]. Social influence and skepticism from family can also significantly diminish interest in the intervention group. Third, we used self-report questionnaires. This may overestimate the prevalence of symptoms and influence the responses due to memory biases. However, we used valid and reliable measures, and the scores of the outcomes and mediating factors were similar between groups at baseline, reducing the measuring bias effect. Fourth, we only recruited participants from public schools. Therefore, the results might not apply to adolescents from higher socioeconomic backgrounds who usually attend private schools. Fifth, we excluded subjects with severe depressive symptoms (PHQ-8 score > 19), which also would negatively impact the generalizability of our results. Sixth, our pre-post-test analyses without a follow-up have limitations on knowing the duration of the effect of this kind of intervention. The impact of psychological interventions in the school setting can diminish and disappear over time due to several factors, including the lack of continuous reinforcement, changes in the school environment, loss of student interest or motivation, and transitions to new educational levels. Additionally, external influences such as family or social issues and the need to integrate the intervention into the school curriculum can further reduce its effectiveness. We need to explore the results with the follow-up undertaken during this year. Finally, regarding the sustainability and potential scaling up of this intervention, the fact that we used an external health professional to implement the intervention with the students in the school may have limitations. While young people see school welfare staff as an acceptable source of help, there are some reasons why these professionals might not feel confident working with at-risk students. On the one hand, there is a lack of training on mental health issues among school staff, which reduces the possibility of working effectively with the students. On the other hand, school welfare staff already have a heavy

workload, which reduces the chances of having the time to work with these students.

Conclusions

This is the first clustered RCT evaluation of the effectiveness of a blended indicated intervention to prevent suicidality in school settings in Latin America. This is the first step to informing policymakers to scale up an effective intervention for an important public health problem. Reframe-IT + reduced suicidal ideation, depressive and anxiety symptoms, and helplessness. The intervention seems to be effective through the improvement of problem-solving skills.

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

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Author contributions

DN, JR and JG conceived the study. DN and JG supervised the whole project. DM, JA were in charge of data collection. DN and JG wrote the manuscript draft, analyzed the data, and edited the final version. JR edited the final version of the manuscript.

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Data availability

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request. Codes for sample size and statistical analyses are provided in the corresponding section.

Declarations

Ethics approval and consent to participate

This study was approved by the ethical committee of Universidad de Talca (Folio 02-2012, May 12th, 2021). Informed consents were obtained from all subjects and their legal guardians. The authors confirm that all methods were performed in accordance with the declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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