

STUDY PROTOCOL

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Evaluation of the effectiveness of SOM-RIU, a multifaceted, school-based, suicide prevention intervention targeted to Spanish adolescents: study protocol for a cluster-randomised controlled trial

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Abstract

Background Adolescent suicide is a major public health concern and the third leading cause of death among young people worldwide. Schools are widely recognized as effective settings for universal mental health promotion and suicide prevention. This study aims to evaluate the effectiveness of SOM-RIU, a multifaceted school-based intervention involving pupils and gatekeepers (teachers and parents) in preventing suicidal behaviour and promoting adolescent mental health.

Methods We will conduct a six-month, two-arm, cluster-randomised controlled trial. We will recruit 2,280 pupils from 114 classrooms in 38 secondary schools across the Balearic Islands (Spain). Eligible pupils will be aged 12–16 and enrolled in the 2nd and 3rd years of compulsory secondary education. Schools will be randomly assigned (1:1) to either the intervention or control group. Schools in the intervention group will implement the SOM-RIU programme, which includes four weekly psychoeducational sessions for pupils, delivered by trained educational psychologists. These sessions focus on mental health literacy, emotional regulation, suicide risk detection and management, and help-seeking strategies. In parallel, gatekeepers (teachers and parents) will receive a digital educational co-intervention consisting in four multimedia modules to strengthen their role in suicide prevention. Schools in the control group will receive a minimal intervention consisting of educational posters on mental health and suicide prevention displayed within school premises. The primary outcome will be suicidal ideation (Paykel Suicide

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Scale). Secondary outcomes will include suicide attempts, depression symptoms, well-being, self-harm, substance use, internet addiction, bullying, and cognitive disconnection. Teachers and parents will report on suicide-related knowledge, self-efficacy, and student referrals. Data will be collected at baseline and six-month follow-up. Analyses will be conducted using generalized linear mixed models to account for clustering, and multiple imputation will be used for missing data. A qualitative process evaluation will explore implementation, acceptability, and perceived impact of the intervention, while also examining contextual factors and potential mechanisms of action that may have influenced the outcomes.

Discussion This trial will generate evidence on the effectiveness of multifaceted, school-based suicide prevention interventions for adolescents. If effective, the SOM-RIU programme could serve as a practical model for enhancing mental health support within educational settings in Spain.

Trial registration NCT06996054 (clinicaltrials.gov). Registration date: 2025-05-30.

Keywords Multifaceted intervention, Suicide prevention, Mental health, Adolescents, Randomized controlled trial, School-based intervention, Health literacy

Background

Suicide is a major public health issue with a significant impact on individuals, families and the community. According to the World Health Organization, every year, 720,000 people take their own lives, making suicide the third leading cause of death among individuals aged 15 to 29 [1]. This complex issue involves various individual attributes (e.g., sex, race, socioeconomic status, gender identity, and sexual orientation) intersecting with social contexts [2].

In Spain, suicide has been the leading external cause of death since 2008 [3]. According to The National Statistics Institute, a growing trend in deaths by suicide was observed during the 2018–2022 period, with 2022 recording the highest suicide ratings in its history (a mortality rate of 8.85 per 100,000 population) [3]. In the following year, 2023, although the overall suicide rate decreased, it continued to rise among the 15 to 29 age group, reflecting a higher risk in this population.

Notably, international evidence shows that suicidal ideation during adolescence is strongly linked to suicidal behaviour in adulthood [4, 5]. Research consistently indicates that these behaviours often begin in early to mid-adolescence, well before a suicide is consummated [6]. These findings underscore the need for preventive action before late adolescence.

Given that most adolescents regularly attend to school, the development of universal school-based interventions for suicide prevention has been positioned as promising due to their potential reach [7] and their capacity to mitigate suicidal risk in adolescents [8]. Schools can be considered an ideal environment for guiding suicide prevention efforts and enhancing adolescents' mental health for different reasons: (a) most risk and protective factors for suicidal behaviour have their onset before the age of 25 [9]; (b) adolescents respond favourably to the promotion of actions regarding health, emotional well-being, and behavioural problem prevention [10], so additional

mental health improvements can be achieved [11]; (c) schools are an excellent intervention setting for psychologists, as they allow for direct therapeutic work [12, 13]; and (d) interventions in schools help reduce barriers to adolescents' access to mental health services and create a safe socio-emotional school environment [14, 15].

School-based interventions for suicide prevention can target either students directly or other key actors (i.e., gatekeepers such as educators and family members) [16]. The main distinction lies in the potential for direct intervention: while psychoeducational programmes empower students to recognize risk in themselves or their peers and seek help, gatekeeper training equips adults with the skills to identify and support at-risk youth. To establish a more integrated system of care, it has been recommended to involve not only the school but also families and the broader community, as their participation expands the network of potential gatekeepers and strengthens the overall system of care.

Previous literature has demonstrated that psychoeducational interventions can lead to significant reductions in both suicidal ideation and suicide attempts [17, 18]. Some programmes have shown effectiveness in decreasing severe suicidal ideation and reducing the incidence of suicide attempts across different countries [17, 19]. Others have been successful in addressing broader mental health issues, such as externalising and internalising problems, improving mental health literacy, and reducing stigma [20]. However, further research on school-based mental health programmes is still needed to assess their long-term effects and their impact on diverse mental health outcomes [21], as a recent systematic review has highlighted the very low certainty of evidence for universal interventions [22].

In relation to gatekeeper training, further evidence is required to determine its effectiveness. While some studies have indicated that gatekeeper training for teachers not only enhances their knowledge of suicide but also

improves their self-efficacy in recognising signs of suicide risk and increases their willingness to intervene [23, 24], other findings have shown a non-significant benefits [19]. Thus, the lack of available scientific evidence on the effectiveness of these programmes highlights the need to conduct more methodologically rigorous clinical trials [25, 26].

Building on this, recent literature has explored the potential of delivering gatekeeper interventions in digital formats, particularly for teachers and parents, as a way to increase their reach and uptake. Digital delivery may offer a cost-effective and sustainable strategy, and its potential to prevent and reduce depression, anxiety, and suicidal ideation has been supported by emerging evidence [27–29]. Nonetheless, although digital interventions to gatekeepers have shown promise in reducing these symptoms, it remains unclear whether these reductions are clinically significant [25, 26].

Aim of the study

To develop and evaluate the effectiveness of a multifaceted, school-based intervention aimed at preventing suicidal behaviour and promoting mental health among adolescents in Spain.

Hypothesis

A multifaceted, school-based intervention —combining a psychoeducational component for students and a digital educational programme for parents and teachers— will

lead to a significant reduction in severe suicidal ideation among Spanish adolescents. Specifically, based on results from the largest prior randomised controlled trial (RCT) in this field [18], we expect a reduction of at least 40% in episodes of severe suicidal ideation at six-month follow-up.

Methods

Study design

We will conduct a six-month, two-arm, cluster-randomized controlled trial (Fig. 1). Schools will serve as the unit of randomization to minimize contamination between study arms. Eligible schools will be randomly allocated in a 1:1 ratio to either the intervention group, which will receive the SOM-RIU multifaceted programme (described below), or the control group, which will receive a minimal intervention consisting of six educational posters displayed within the school premises (Fig. 2).

Intervention programme: SOM-RIU

SOM-RIU is a multifaceted school-based intervention designed to prevent suicidal behaviour and promote mental health among adolescents through a combination of classroom-based psychoeducational sessions and a digital co-intervention for parents and school personnel. All materials are available in Spanish and Catalan to ensure inclusivity and accessibility.

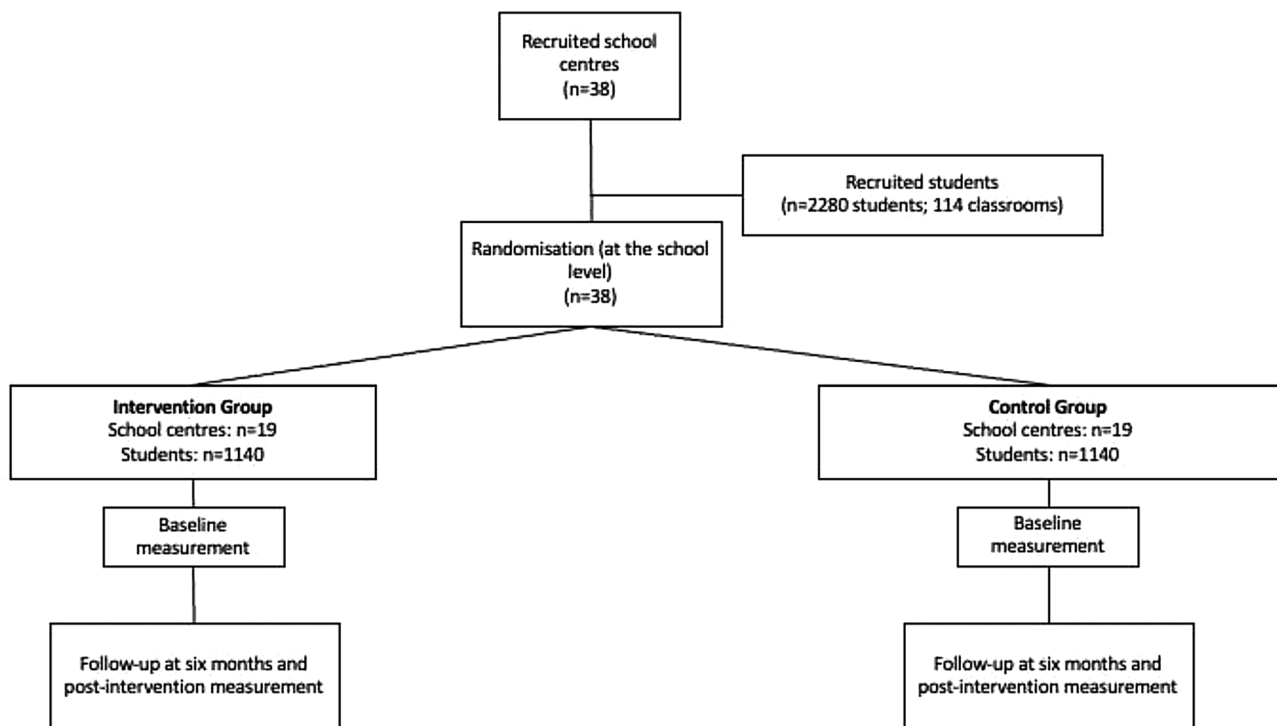


Fig. 1 Consort flowchart

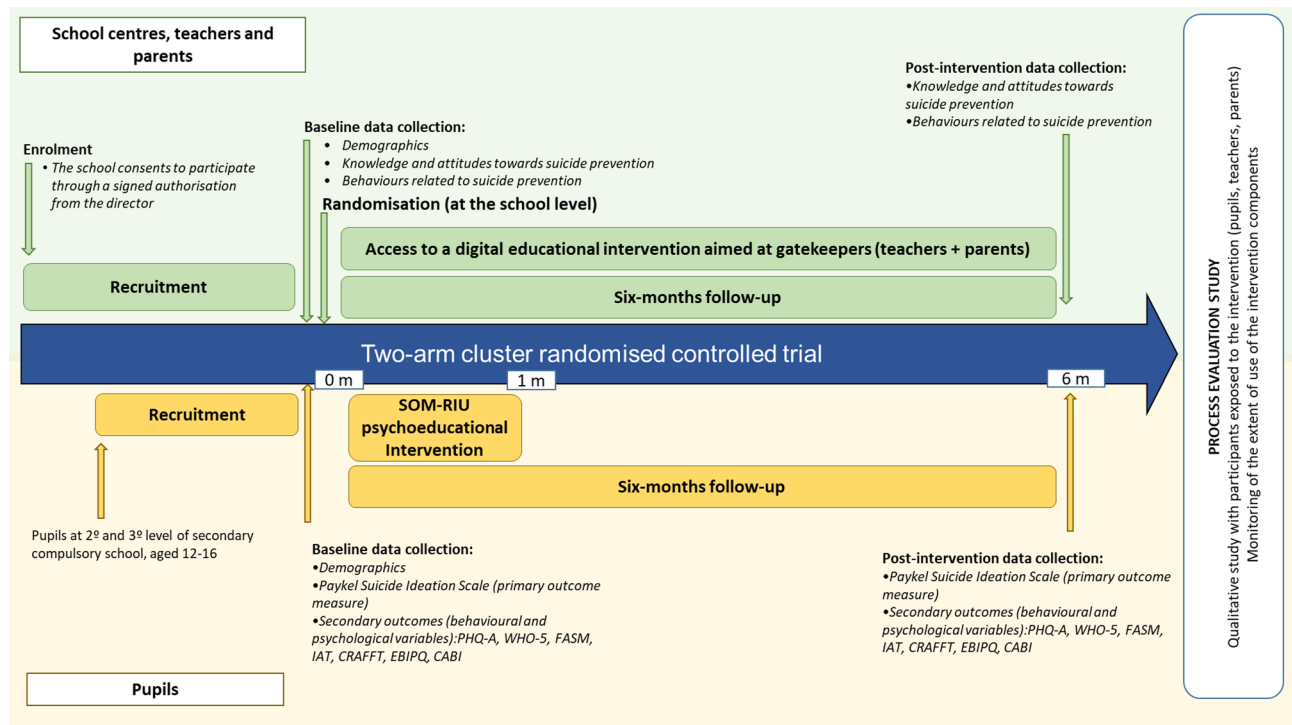


Fig. 2 Schedule of the randomised controlled trial

SESSION 1: “WE LEARN”		SESSION 2: “WE LIVE”	
Objective	To improve mental health literacy and reduce stigma	Objective	To focus on the individual’s experience of distress
Components	<ul style="list-style-type: none"> • Definition of mental health • Identification of stigma and mistaken beliefs • Raising awareness about risk and protective factors • Promotion of a safe space 	Components	<ul style="list-style-type: none"> • Development of emotion regulation skills • Promotion of cognitive flexibility • Enhancement of self-knowledge and emotional awareness • Importance of social support
SESSION 3: “WE OVERCOME”		SESSION 4: “WE FACE”	
Objective	To prevent suicidal behaviour	Objective	To consolidate interpersonal skills and strengthen protective factors
Components	<ul style="list-style-type: none"> • Identification of warning signs • Promotion of communication and help-seeking • Acquisition of coping strategies for crisis situations • Establishment of response protocols • Address misconceptions about suicide 	Components	<ul style="list-style-type: none"> • Reflection on coping skills • Reinforcement of interpersonal skills • Recognition of barriers and promotion of help-seeking • Integration of learning from previous sessions

Fig. 3 Content of the intervention targeted to adolescents

Classroom-based intervention for adolescents

The student component consists of four weekly sessions, each lasting 1.5 h, delivered during school hours by trained educational psychologists (Fig. 3). The sessions are based on a comprehensive adolescent suicide prevention model integrating mental health literacy [30],

emotional regulation and coping skills [31, 32], early crisis detection [33], and help-seeking strategies [34].

Each session combines theoretical content with dynamic group activities to foster engagement and experiential learning. Sessions begin with a 5–10-minute mindfulness exercise adapted to adolescents, aimed at promoting focus and a calm emotional climate [35].

- Session 1: Establishing a safe and supportive classroom environment, introducing mental health concepts, addressing myths and stigma, and exploring risk and protective factors for self-harm and suicidal behaviour.
- Session 2: Recognising personal experiences of emotional distress, practising basic emotion regulation strategies, and reflecting on the role of social support in managing difficult emotions.
- Session 3: Identifying warning signs of self-harm, suicidal ideation, and emotional crisis in oneself and others, challenging misconceptions about suicide, and introducing help-seeking strategies and action protocols.
- Session 4: Consolidating coping and interpersonal skills, reinforcing protective factors such as peer support, emotional expression, and proactive help-seeking.

To complement the face-to-face sessions, students have access to digital materials (via QR code) throughout the six-month follow-up period. These resources reinforce session content and provide additional tools for emotional well-being.

A predefined emotional safety protocol will be in place [36]: if a student experiences discomfort or wishes to leave a session, they will be accompanied by a staff member, and the school counselling team will be notified for further support and referral if needed.

Digital co-intervention for parents and school personnel

Parents and school staff (including teachers and other personnel) participate in a digital co-intervention delivered through a custom-designed platform. This component runs in parallel with the student programme and remains accessible for six months.

The digital intervention consists of four multimedia modules aligned with the student sessions, covering mental health literacy, emotional regulation, suicide risk detection, and help-seeking strategies. Each module includes videos, podcasts, and additional resources to strengthen the role of parents and school staff as gatekeepers. Adherence is monitored through a combination of self-reported module completion and automated tracking of video visualization within the platform.

Development process

The SOM-RIU intervention was developed through a rigorous, multi-phase process, which involved:

- Evidence Review: A comprehensive review of scientific and grey literature on school-based suicide prevention and mental health promotion informed the theoretical framework and content.
- Stakeholder Consultation: Structured meetings were held with key stakeholders, including representatives from the educational community, health service professionals, school-based psychologists, and university pedagogy experts, to ensure contextual relevance and feasibility.
- Pilot Workshops with Adolescents: Four workshops were conducted in secondary school classrooms to explore students' needs and preferences, which guided the adaptation of content and delivery strategies.
- Specialist Input: A psychologist specialised in group facilitation designed interactive activities for classroom sessions and developed training materials for the educational psychologists delivering the intervention.

This collaborative and iterative process ensured that the intervention is evidence-based, culturally adapted, and feasible for large-scale implementation.

Control group

Schools allocated to the control group will receive a minimal intervention consisting of six educational posters displayed within the school premises. This comparator was chosen because it represents the current standard practice in many schools, where suicide prevention efforts are often limited to passive educational materials. Using posters as a minimal intervention ensures that all participants receive at least some information on mental health and suicide prevention, while avoiding contamination of active components of the SOM-RIU programme. Additionally, this approach allows us to isolate the added value of the multifaceted intervention compared to a low-intensity strategy that is feasible and ethically acceptable in the school setting.

Participants and sample size

Participants will be recruited from school centres in the Balearic Islands, Spain. Eligibility criteria for schools' centres will include: (a) centres with no more than 75% of students of a single gender; and (b) agreement of participation from the school authority (i.e., school principal). Student eligibility criteria will include: (a) enrolment in either the second or third year of compulsory secondary education during the 2026–2027 school year; (b) provision of informed consent from both the parents and the students; and (c) being aged 12 to 16 years.

The sample size is estimated to be of 2,280 high-school students from 114 classrooms across 38 school centres. It was calculated using the GRANMO sample size calculator. This will allow us to detect a relative reduction of at least 40% in the prevalence of severe suicidal ideation — the primary outcome— with a 95% confidence level and

Table 1 Participant timeline

Time point	Pre-intervention			Intervention period						Post-inter- vention
	-12 M/ -3 M	-3 M/ -1 day	0	1	2	3	4	5	6	7/8 M
Enrolment:										
Enrolment of schools (informed consent signed)	X									
Enrolment of pupils and gatekeepers (informed consent signed)		X								
Randomization (school level):										
Intervention delivery:										
Face-to-face intervention targeted to pupils				X						
Digital intervention targeted to gatekeepers				X	X	X	X	X	X	
Assessments in pupils (face-to-face, at school):										
Demographics	X	X								
Suicidal ideation (primary outcome): Paykel Scale	X	X								X
Suicide attempts: individual item from Paykel scale	X	X								X
Depression symptoms: PHQ-A		X								X
Well-being: WHO-5	X	X								X
Self-Harm: FASM	X	X								X
Internet addiction: IAT	X	X								X
Substance abuse: CRAFFT	X	X								X
School bullying: EBIPQ		X								
Cognitive Disconnection Syndrome: CABI 2.0		X								
Assessments in gatekeepers (remotely, digitally delivered):										
Demographics		X								X
Suicide knowledge: LOSS-SF		X								X
Self-efficacy in intervening in suicide-risk situations: spanish adaptation of the GKSES		X								
Qualitative process evaluation:										
Pupil interviews										X
Gatekeepers interviews										X

M, month, PHQ-A, Patient Health Questionnaire-9; WHO-5, World Health Organisation's Well-Being Scale; FASM, Functional Assessment of Self-Mutilation Scale; IAT, Internet Addiction Test; CRAFFT, CRAFFT Substance Abuse Screening Test; EBIPQ, European Bullying Intervention Project Questionnaire; CABI 2.0, Child and Adolescent Behavior Inventory; LOSS-SF, Literacy of Suicide Scale – Short Form

80% statistical power. The calculation assumes a baseline prevalence of 10% for severe suicidal ideation (based on regional epidemiological data), a 20% drop-out rate, an intra-cluster correlation coefficient (ICC) of 0.007, and a design effect of 1.69 due to cluster randomisation.

Recruitment strategy

To ensure adequate participant enrolment and reach the target sample size, a structured recruitment strategy will be implemented in collaboration with the Balearic Islands' Department of Education, which has formally endorsed the study. Eligible schools will be invited to participate through an initial phone call, followed by an email containing the participant information sheet tailored for school administrators. If a school expresses interest, a follow-up meeting—either in person or via videoconference—will be arranged with members of the research team to explain the study in detail and address any questions. Upon agreement to participate, recruitment of students, their parents or legal guardians, and school staff will be conducted through the school's

internal communication channels. Specifically, the school's educational psychologist will distribute a circular with the participant information sheet to families of students in 2nd and 3rd year of compulsory secondary education (ESO). Parents will have the opportunity to consult with the psychologist or the research team before providing informed consent for their own and their child's participation in the trial.

Randomisation procedure, allocation concealment and blinding

Randomisation of centres to the intervention or control group will take place only after baseline data collection has been fully completed (Table 1). Stratified randomisation will be performed using a computer programme (Research Electronic Data Capture – REDCap), considering the size of the school centre and its type (i.e., public or private). This timing ensures allocation concealment, as neither the schools nor the research team involved in recruitment and data collection will be aware of group assignments during these initial phases. The random

allocation sequence will be generated centrally by a member of the research team not involved in recruitment, using REDCap's secure randomisation module. Once baseline assessments are finalised, school centres will be informed of the group to which they have been assigned, but the assignment will remain blinded to the statistical research staff during the intervention trial and for the data analysis.

Due to the nature of the intervention, blinding of participants, educational psychologists, and school staff is not feasible. However, outcome assessors and data analysts will remain blinded to group allocation throughout the trial to minimise bias in data interpretation and statistical analysis. Given that the SOM-RIU intervention is psychoeducational, non-pharmacological, and low-risk, and because the personnel delivering the intervention (educational psychologists) are not blinded, the need for emergency unblinding for immediate clinical management of a participant is not anticipated. If, for administrative or regulatory purposes (e.g., at the request of the Ethics Committee or the study steering team for a critical review of safety data), unblinding of the data analysts were necessary, the allocation sequence will only be revealed by the central member of the research team not involved in data analysis (responsible for randomization), upon justified and documented request.

Data collection

Data will be collected at two time points: baseline (prior to randomisation) and six-month follow-up (Fig. 2). For students, data collection will be conducted in person within school facilities by trained psychotherapists, who will administer self-report questionnaires in a standardized format. These professionals will receive prior training to ensure consistency and minimize measurement bias. For teachers and parents, data will be collected online via secure survey links sent through school communication channels.

To ensure data quality, surveys will be reviewed for completeness at the time of administration, and digital data will be subject to range checks and consistency validation. Any missing or inconsistent responses will be flagged for follow-up. All data collection procedures will follow a standardized protocol, and instruments will be available in both Spanish and Catalan to ensure accessibility.

Data management

All collected data will be entered into a secure, password-protected database hosted on REDCap, with access restricted to authorized members of the research team. Data entry will be performed using electronic forms with built-in validation rules to minimize entry errors. Regular data audits will be conducted to identify inconsistencies

or missing values. Personal identifiers will be removed during data processing to ensure confidentiality, and all datasets will be anonymized prior to analysis. Backups will be performed regularly, and data will be stored in compliance with institutional and national data protection regulations.

Retention and follow-up strategies

To promote participant retention and ensure complete follow-up, especially among gatekeepers completing online surveys, several strategies will be implemented. First, reminder messages will be sent via the school's internal communication channels at regular intervals during the follow-up period, encouraging completion of the post-intervention questionnaires. These reminders will be personalized and, when possible, reinforced by the school's educational psychologist. Second, the digital platform will include automated notifications and progress tracking to motivate users to complete all modules and associated surveys. Third, participants will be informed at the outset about the importance of completing both baseline and follow-up assessments, and the estimated time required, to foster commitment. Finally, the research team will remain available to resolve technical issues or respond to questions throughout the follow-up period.

For students, in-person data collection within the school setting will help ensure high response rates. Any students absent during scheduled sessions will be offered alternative dates to complete the assessments. All these procedures aim to minimize attrition and ensure the integrity of outcome data.

Assessment instruments for students

Sociodemographic characteristics of both students (i.e., age, sex, nationality, familiar structure, and socioeconomic level) and schools (i.e., number of teachers, students, students for teachers' ratio, social privation-MEDEA index- and dropout rate) will be measured.

Students will complete measures on suicidal ideation (primary outcome measure), as well as suicide attempts, depression symptoms, well-being, self-harm, internet addiction, substance abuse, and school bullying (secondary outcome measures). These secondary outcomes, although more indirectly related to the primary outcome, have been associated with increased suicide risk and may serve as relevant covariates to better understand the mechanisms and moderating factors of the intervention's effectiveness.

Suicidal ideation

Suicidal ideation (primary outcome) will be measured with the Suicidal Paykel Scale [37], applying the Spanish adaptation validated by Fonseca-Pedrero et al. for

adolescent populations [38]. This scale assesses the severity of suicidal ideation during the previous three months, with items ranked in increasing severity. Participants will respond to a 5-item questionnaire with dichotomous answers (0 = no; 1 = yes). The cut points are as follows: no suicidal ideation (total score of zero), thoughts of death (positive score in items one or two) and suicidal ideation (positive score on items three, four and/or five). Thus, the higher the score, the greater the presence of suicidal ideation. Internal consistency indices of this scale have indicated adequate reliability in adolescents (Alpha de Cronbach = 0.799).

Suicide attempts

Suicide attempts will be assessed using the Suicidal Paykel Scale item “Have you ever tried to end your life?” (0 = no; 1 = yes) [37].

Depression symptoms

The severity of depression symptoms will be measured using the Patient Health Questionnaire-9 (PHQ-A) modified [39] aged from 12 to 17 years. This self-report scale consists of 9 items that reflect the diagnostic criteria for depression according to the DSM-IV, evaluating symptoms experienced over the past two weeks. Each item is rated on a 4-point Likert scale ranging from 0 (“not at all”) to 3 (“nearly every day”), with total scores ranging from 0 to 27.

Well-being

The well-being will be examined using the Spanish version of the World Health Organisation’s Well-Being Scale (WHO-5) [40]. Participants will respond to a total of five items on a 7-point Likert scale (0 = Never, 6 = All the time) to indicate how frequently they experienced each statement over the past two weeks. A score below 13 indicates poor wellbeing.

Self-Harm

The presence of self-injurious behaviours, including method, frequency, motivation, and contextual factors, will be assessed using the Functional Assessment of Self-Mutilation (FASM) scale [41]. The FASM is a self-report instrument developed to evaluate both the frequency and functions of non-suicidal self-injury in adolescents. It includes a checklist of self-injurious behaviours and a set of items assessing the reasons for engaging in these behaviours, grouped into intrapersonal and interpersonal functions. The FASM has been widely used in adolescent populations and has demonstrated good psychometric properties across diverse cultural contexts, including Spanish-speaking samples [42].

Internet addiction

Internet addiction will be measured using the Spanish version of the Internet Addiction Test (IAT) [43, 44]. This test assesses the impact of Internet use on social interactions, as well as its influence on daily life through 20 items on a 5-point Likert Scale (1 = Rarely, 5 = Always). Total scores range from 20 to 100, indicating Controlled Internet use (scores between 20 and 49), Frequent problems due to Internet use (scores between 50 and 79), and Significant life problems caused by Internet use (scores above 80).

Substance abuse

High-risk alcohol and drug risk consumption will be assessed through the Spanish version of the CRAFFT Substance Abuse Screening Test [45, 46], which has been widely used across different countries. The CRAFFT Substance Abuse Screening Test is a 9-item questionnaire (6 items in addition to 3 previous screening items) with dichotomous answers (0 = no; 1 = yes), with scores ranging from 0 to 6. A score above two serves as the cut-off point to determine risk consumption.

School bullying

School bullying will be assessed using the European Bullying Intervention Project Questionnaire (EBIPQ) [47]. This self-report instrument consists of 14 items, with 7 items assessing victimization and 7 items assessing perpetration. The items refer to specific bullying behaviours such as hitting, insulting, threatening, stealing, name-calling, exclusion, and spreading rumours. Each item is rated on a 5-point Likert scale ranging from 0 (“never”) to 4 (“always”), based on the frequency of experiences over the past two months. The EBIPQ has been validated in Spanish-speaking adolescent populations and has shown adequate psychometric properties for identifying both victims and aggressors in school settings [48].

Cognitive disconnection syndrome

Will be assessed using the corresponding subscale from the Child and Adolescent Behaviour Inventory – Parent Version 2.0 (CABI 2.0) [49]. This self-report instrument includes 15 items that evaluate symptoms associated with sluggish cognitive tempo, such as daydreaming, mental confusion, slow thinking, low activity levels, and difficulty expressing thoughts. Parents will complete the scale by rating the frequency of each behaviour observed in their child over the past month using a 6-point Likert scale ranging from 0 (“almost never”) to 5 (“almost always”). The Spanish parent version has been validated in Spanish-speaking populations, whereas the adolescent self-report version is still under development and has not yet been validated.

Assessment instruments for teachers and parents

Teachers and parents will complete measures on suicide knowledge and self-efficacy in intervening in suicide-risk situations. In addition, teachers will also report the number of times they asked students about suicide and number of referrals of at-risk students to mental health services.

Suicide knowledge

Parental knowledge about suicide will be assessed using the Spanish version of the Literacy of Suicide Scale – Short Form (LOSS-SF). This 12-item self-report questionnaire evaluates suicide literacy across four domains: signs and symptoms, risk factors, causes, and prevention/treatment. Each item is answered as “true,” “false,” or “don’t know,” with higher scores indicating greater knowledge about suicide. The LOSS-SF has been validated in Spanish-speaking populations [50].

Self-efficacy in intervening in suicide-risk situations

As no validated Spanish questionnaire currently exists to assess self-efficacy in suicide prevention skills, we developed an ad hoc translation of the Suicide Prevention Gatekeeper Self-Efficacy Scale (GKSES). This 9-item self-report questionnaire evaluates laypersons’ perceived self-efficacy in performing gatekeeper functions, such as identifying individuals at risk, engaging in supportive dialogue, and facilitating access to professional help. Each item is rated on a Likert scale from 0 (“not at all”) to 7 (“extremely”), with higher scores indicating greater confidence in gatekeeper abilities. The GKSES has demonstrated good internal consistency and construct validity in its original validation study with a Japanese sample [51].

Assessment of harms

Potential adverse effects related to the intervention will be systematically monitored. For the adolescent component, the educational psychologist delivering the sessions will maintain a structured log of any students reporting psychological distress during or immediately after the sessions. A predefined emotional safety protocol—on which all educational psychologists have been trained—will guide the response to such cases, including immediate support and referral to school counselling services if needed. In addition, an ad hoc self-report questionnaire will be administered to students at follow-up to capture any perceived harm or negative experiences associated with participation. For gatekeepers (teachers and parents), a similar ad hoc questionnaire will be used to assess any unintended negative effects of the digital co-intervention. All reported adverse events will be documented and reviewed by the research team to ensure appropriate follow-up and mitigation.

Process evaluation

A qualitative process evaluation will be conducted following the UK Medical Research Council (MRC) guidance for process evaluations of complex interventions [52]. We will carry out approximately 25 semi-structured interviews with students, teachers, and parents after the six-month follow-up period, in school settings or via secure online platforms to ensure flexibility and accessibility. Separate interview guides will be developed for each participant group, aligned with common objectives: to explore implementation fidelity, acceptability, perceived impact, and contextual factors influencing outcomes. All interviews will be audio-recorded, transcribed verbatim, and analysed using thematic analysis [53]. Two independent researchers will code the data inductively to identify recurring themes, resolving discrepancies through discussion or consultation with a third researcher. NVivo software will be used to support systematic coding and enhance analytical rigor.

Data analysis

The trial results will be presented as comparative summary statistics (differences in proportions or means) with 95% confidence intervals. All statistical tests will be two-sided and conducted at a 5% significance level. The study findings will be reported in accordance with the CONSORT 2025 guidelines [54]. To analyze differences between the intervention and control groups at follow-up, generalized linear mixed models (GLMM) will be used, including a random effect to account for clustering of students within schools. For the primary and secondary outcomes, statistical significance will be determined based on adjusted coefficients, and 95% confidence intervals for the experimental intervention group compared to the control group at six months.

Multiple imputation procedures will be used to handle missing data [55]. Interaction terms will be included to assess the effectiveness of the intervention across specific subgroups: age, gender, family income level, use of psychotropic medication, engagement in psychotherapy, and previous suicide attempts. The primary statistical analysis will follow the intention-to-treat principle [56].

Data monitoring committee (DMC)

A formal, independent Data Monitoring Committee (DMC) will not be established for this study. This decision is based on the nature of the SOM-RIU intervention, which is psychoeducational and non-pharmacological, classifying the trial as low to moderate risk to participants. Safety oversight and data integrity monitoring will be managed directly by the principal investigators and the Institutional Review Board (CEI-IB). The research team will conduct regular data audits and will strictly adhere

to the predefined emotional safety protocol for managing and documenting all reported potential adverse effects.

Discussion

Suicide is a preventable cause of death, and timely, evidence-based, and often low-cost interventions can play a key role in its prevention. In line with the World Health Organization's recommendations [57] there is an urgent need to prioritize the development and evaluation of suicide prevention programmes, particularly those aimed at young people. This study protocol describes a multifaceted, school-based intervention designed to protect adolescent mental health and prevent suicidal behaviour through direct engagement with students and the involvement of parents and teachers via a digital co-intervention.

This study aims to contribute significantly to the existing scientific knowledge on suicide prevention by implementing a large-scale, methodologically rigorous cluster RCT in Spain. Evidence on school-based interventions targeting adolescent mental health remains limited in Spain [58], and findings from this trial may offer valuable insights into effective strategies to reduce suicide rates and improve adolescent mental health within the school setting.

Importantly, the intervention adopts a holistic approach by addressing multiple levels of the adolescent environment: the individual (students), the family (parents or legal guardian), and the educational context (teachers). This systems-level intervention is expected to strengthen existing support structures for adolescents, promote help-seeking behaviours, and reduce stigma surrounding mental health. Furthermore, the integration of digital technology for the gatekeeper training modules enhances accessibility, scalability, and sustainability, aligning with contemporary public health approaches.

The expected benefits extend beyond the reduction of suicidal ideation and behaviour, aiming also at improving related mental health outcomes such as depression, anxiety, and experiences of school bullying. Addressing these underlying factors may not only help prevent immediate suicidal crises but also contribute to the prevention of mental disorders later in adulthood, thus reducing the long-term societal burden of mental illness.

Strengths and limitations of the study

This study presents several strengths. First, it addresses a pressing public health need by targeting adolescent mental health and suicide prevention through a school-based, multifaceted intervention. Second, the intervention design is grounded in a comprehensive evidence base, incorporating findings from both scientific and grey literature, active consultation with key stakeholders, and pilot workshops conducted with adolescents. This strong

coordination with local health authorities, schools, mental health services, and community organizations creates optimal conditions for the effective implementation of this prevention program. Third, the inclusion of parents and teachers through a digital co-intervention extends the intervention's reach beyond the classroom, reinforcing a systemic approach to mental health promotion. The use of a cluster RCT design minimizes contamination bias between intervention and control groups, while the large sample size ensures adequate statistical power to detect meaningful effects. Additionally, the incorporation of both quantitative and qualitative data collection methods allows for a comprehensive evaluation of both outcomes and implementation processes.

However, several limitations must be acknowledged. First, while randomising at the school level helps prevent contamination between study arms, the relatively small number of clusters means that randomisation may not fully balance important school-level characteristics (e.g., socioeconomic context, teacher-student ratios, mental health resources) between intervention and control groups. This limitation is inherent to cluster designs and persists even when stratified randomisation is applied, unlike individual-level randomisation where larger sample sizes improve balance. Second, adherence to the digital co-intervention among parents and teachers may vary, potentially limiting its impact; although monitoring systems will be used, self-reported adherence measures might be subject to reporting bias. Third, while the intervention content is evidence-based and culturally adapted, the generalisability of the findings may be limited to similar socio-educational contexts within Spain. Finally, the follow-up period of six months may not be sufficient to capture the long-term sustainability of intervention effects on suicidal ideation and mental health outcomes. A longer follow-up (e.g., 12 months) was considered; however, logistical constraints related to project timelines and the academic calendar made this unfeasible. Extending the follow-up would coincide with students changing grade levels—and in some cases schools—substantially increasing the risk of attrition and compromising data completeness.

Conclusion

In conclusion, this multifaceted school-based intervention has the potential to be a cost-effective, feasible, and scalable strategy for promoting adolescent mental health and preventing suicidal behaviour. If proven effective, the programme could be implemented across schools in the Balearic Islands and other Spanish regions, producing a positive health impact by reducing suicide rates, improving mental health outcomes, and fostering greater acceptance and understanding of mental disorders among young people. By targeting both direct and indirect

contributors to suicidal ideation and promoting stronger support systems, the intervention may also contribute to long-term mental health improvements and reduce future mental health burden at the population level.

Abbreviations

CABI 2.0	Child and Adolescent Behavior Inventory
CEI-IB	Institutional Review Board of the Balearic Islands Health Service Research Ethics
CIBER	Centre for Biomedical Research Network
CIBERESP	CIBER in Epidemiology and Public Health
CONSORT	Guideline for reporting randomised trials (referring to the CONSORT 2025 guidelines)
CRAFFT	CRAFFT Substance Abuse Screening Test
DMC	Data Monitoring Committee
EBIPQ	European Bullying Intervention Project Questionnaire
FASM	Functional Assessment of Self-Mutilation Scale
GKSES	Suicide Prevention Gatekeeper Self-Efficacy Scale
GLMM	Generalized Linear Mixed Models
IAT	Internet Addiction Test
IDISBa	Health Research Institute of the Balearic Islands
IUNICS	Research Institute of Health Sciences
LOSS-SF	Literacy of Suicide Scale – Short Form
M	Month
MRC	Medical Research Council
PHQ-A	Patient Health Questionnaire-9
RCT	Randomised Controlled Trial
REDCap	Research Electronic Data Capture
RICAPPS	Network for Research on Chronicity, Primary Care, and Health Promotion
SOM-RIU	Multifaceted, School-Based, Suicide Prevention Intervention
UIB	University of the Balearic Islands
WHO	World Health Organization
WHO-5	World Health Organisation's Well-Being Scale

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12888-025-07570-0>.

Supplementary Material 1

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Author contributions

IRC, MAFR, and MJSR conceived the study. IRC and MAFR drafted the study protocol. The intervention design was carried out by PRS, MJSR, PGP, MBV, AMYJ, MGP, MGT, CSQ, MBC, EGG, XGG, MEGB, and MWBP. The study methodology and statistical analysis were developed by IRC, MAFR, AMYJ, and ALR. IRC and MWBP contributed to the drafting of the manuscript. All authors critically reviewed and approved the final version of the manuscript. PRS and MGP participated in the coordination of the study and contributed to the clinical and educational aspects of the intervention. All authors read and approved the final manuscript.

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Data availability

Upon completion of the trial and publication of the main results, de-identified individual participant data, including the data dictionary and statistical code used for analysis, will be made available upon reasonable request to the corresponding authors. Access will be granted for research purposes following approval by the study team and in compliance with data protection regulations.

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of the Balearic Islands Health Service Research Ethics (CEI-IB Ref No: IB 4837/22 PI) and follows the Declaration of Helsinki ethical standards. Written consent from all participants will be obtained, and all data collected will be kept anonymous and confidential. Participants will be able to voluntarily withdraw their informed consent at any time during the study.

Ancillary and post-trial care and compensation

Compensation for Harm: Given the low-to-moderate risk, non-pharmacological nature of the SOM-RIU intervention, the study is covered by the standard institutional liability insurance of the Health Research Institute of the Balearic Islands (IDISBa) for all participants. Post-Trial Care: All participants identified as requiring support due to suicidal ideation or related distress during the trial will receive immediate support via the predefined emotional safety protocol and subsequent referral to the school counselling team. These referrals ensure linkage to the public mental health services network, guaranteeing continuity of care beyond the six-month follow-up period of the trial. Post-Trial Availability and Sustainability: If the results of this cluster-RCT demonstrate the effectiveness of the SOM-RIU program in reducing suicidal ideation and improving mental health outcomes, the intervention materials, curriculum, and training resources will be made available for use by all educational centres in the Balearic Islands that wish to adopt the program. Future large-scale implementation will be coordinated through established collaboration channels and will be subject to the formal approval and authorization of the Balearic Islands Department of Education (Conselleria d'Educació de les Illes Balears), ensuring the sustainable integration of the intervention into the regional educational system.

Dissemination policy

The definitive results of the trial will be submitted for publication in a peer-reviewed academic journal, reporting findings in accordance with the CONSORT 2025 guidelines. To ensure that the findings are accessible to all stakeholders, a plain-language summary of the results will be developed in both Spanish and Catalan. This summary will be actively disseminated through our collaborators, including the Balearic Islands Department of Education, and via all participating school networks (through newsletters, circulars, or dedicated public meetings) to reach students, parents, and teachers directly. Furthermore, results will be presented at relevant professional conferences and communicated directly to policymakers and the funding body to inform future public health planning and potential large-scale implementation.

Protocol amendments

Any major modifications to the protocol that affect the study design, participant eligibility criteria, interventions, outcomes, or statistical analysis

plan will be formally documented. These important protocol modifications will be promptly communicated to the Institutional Review Board of the Balearic Islands Health Service Research Ethics (CEI-IB) for formal approval. Once approved, the trial registration (NCT06996054) on clinicaltrials.gov will be updated accordingly. Researchers and participating school staff will be notified of any changes relevant to the conduct of the trial, and participants will be informed if the amendments directly affect their rights, well-being, or willingness to continue participation.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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