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Brief psychological intervention for suicide prevention based on problem-solving applied in different formats to people over 50 years old: protocol for a randomized controlled trial

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Abstract

Background Suicide is a major public health problem, especially among individuals over 50 years old. Despite the suitability of this life stage for prevention, research on the efficacy of psychological interventions is scarce and methodologically limited, affecting their clinical utility and efficacy. Brief, flexible interventions that can be applied both in-person and remotely are needed. This study aims to evaluate the efficacy of a brief problem-solving-based suicide prevention program applied through various modalities to individuals over 50 years old.

Methods A randomized controlled trial will be conducted. A sample of 212 adults aged 50 or older with suicidal ideation will be randomly assigned to a problem-solving-based psychological intervention administered face-to-face (PSPI-P; $n=53$), by telephone multiconference (PSPI-M; $n=53$), via a smartphone app (PSPI-A; $n=53$), or to a usual care control group (UCCG; $n=53$). The intervention will be delivered in 7 sessions or modules of 90 min each. Blind trained evaluators will conduct assessments at pre-intervention, post-intervention, and follow-ups at 3, 6, and 12 months. The primary outcome will be suicidal ideation evaluated using the Suicidal Ideation Scale (SSI) and the Columbia Suicide Severity Rating Scale (C-SSRS). Secondary outcomes will include hopelessness, anxiety and depression symptoms, reasons for living, impulsivity, problem-solving skills, social support, anger syndrome, gratitude, personality, dropouts, treatment adherence, and satisfaction with the intervention.

Discussion This study will provide evidence of the efficacy of a brief problem-solving-based intervention for suicide prevention in individuals over 50 years old, administered face-to-face, by telephone multiconference, and via a smartphone app. If results are favorable, it will indicate that an effective, accessible, clinically and socially useful suicide prevention intervention has been developed for affected individuals, families, and communities.

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Keywords Over 50 years old, Problem-solving, Prevention, Suicide, Suicidal ideation, Protocol

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Background

Suicidal behavior is a complex, multifaceted phenomenon manifesting through a spectrum of self-destructive thoughts and behaviors, ranging from suicidal ideation to the consummation of the act, including planning and attempting suicide [1].

This phenomenon represents a serious public health issue, accounting for more than 700,000 annual deaths worldwide [2]. It is estimated that for every completed suicide, 20 people attempt suicide [1], and about 11.3% of the general population experiences suicidal ideation each year [3]. Furthermore, each suicide affects an average of six people, including family and close friends [1], constituting a tragedy with lasting impacts on families and communities.

One of the most vulnerable populations globally is individuals over 50 years old [4, 5]. In 2021, the suicide mortality rates for people aged 50 to 74 and those over 75 were 14.7 and 29.0 per 100,000 inhabitants, respectively [4]. These figures exceed the global average (9 per 100,000) and the rates observed in younger age groups [4]. Factors frequently contributing to these suicide rates in this age group include major depressive disorder (MDD) and depressive symptoms, specific life stressors (e.g., medical conditions, functional disability, bereavement, or legal and financial issues), and social disconnection, which are well-supported by research in their relation to suicidal behaviors [6–11].

Additionally, people in these age groups show fewer warning signs and choose more lethal methods of suicide [12, 13]. Furthermore, it is anticipated that these data will worsen in the coming years as the number of individuals in this age range increases due to population aging [14]. On the other hand, from the age of 50 onwards, a stage of life opens up that is ideal for preventive actions, since, according to Levinson [15], there is a transition in adult life that represents an important opportunity to modify and improve life structure.

Therefore, it is necessary to develop strategies to prevent suicide risk in this population. Previous studies evaluating the efficacy of psychological interventions for suicide prevention in this age group through randomized controlled trials (RCTs) have shown positive results. For instance, Kiosses et al. [16] compared the efficacy of problem-adaptation therapy and supportive therapy in 39 older adults with MDD and cognitive impairment, finding comparable reductions in suicidal ideation over 12 weeks following both interventions. Zhang et al. [17] evaluated the efficacy of a resilience-focused program in 68 institutionalized older adults with suicidal ideation against a waitlist control group, noting a decrease in suicidal thoughts post-intervention and at one-month follow-up.

Despite these promising results, the amount of research in this field is insufficient and methodologically and clinically limited. The interventions were not developed based on a theoretical model; were applied to small, specific samples limiting external validity; and did not include long-term follow-ups. Additionally, treatments were delivered individually in person, requiring substantial resources and time, increasing costs and limiting efficiency, utility, and accessibility. One potential solution could be implementing interventions using information and communication technologies (ICTs). The use of ICTs (e.g., telephone multiconferencing, apps) increases the possibilities for dissemination and access to populations in need. Bringing interventions to these age groups through ICTs could reduce accessibility barriers (e.g., lack of services in rural areas, transportation issues, or stigmatization).

Considering all these issues, developing brief, simple interventions applicable practically and flexibly in both face-to-face and remote modalities is essential. Problem-solving therapy (PST) [18], based on the problem-solving model of D'Zurilla and Nezu [19], stands out among these. It has been described as pragmatic, transdiagnostic, effective, and easy to learn [20] and has proven effective in numerous contexts and with various problems [18, 20], including suicide [21–23]. In relation to this issue, Gustavson et al. [22] conducted an RCT to evaluate the efficacy of PST compared to supportive therapy in reducing suicidal ideation in adults with MDD and executive dysfunction. Participants receiving PST showed significantly greater reductions in suicidal ideation post-intervention and at 36-week follow-up. Unützer et al. [23] conducted an RCT to examine the long-term effects of the IMPACT program, which included PST, on suicidal ideation in older adults with MDD, finding it effective in reducing suicidal thoughts during, after the intervention, and at 18 and 24-month follow-ups. Choi et al. [21] introduced the use of ICTs in PST implementation by conducting an RCT to evaluate the efficacy of PST delivered in person and via videoconference compared to telephone support in homebound low-income older adults with depressive symptoms. Results showed that videoconference PST was more effective than in-person PST and telephone support in reducing suicidal ideation at 36-week follow-up. However, the three studies were designed with the aim of reducing depressive symptoms, with suicidal ideation being a secondary outcome evaluated through a single item. Additionally, the applicability of these results is limited by the characteristics of the samples used [21, 22] or by the nonspecific role of PST within the intervention [23].

Another significant limitation is that among existing prevention levels, indicated prevention is crucial to

address this phenomenon. According to the US Institute of Medicine [IOM] [24], indicated prevention strategies target individuals who already show signs and symptoms indicating a predisposition to develop a mental disorder but do not yet meet diagnostic criteria (for suicide, individuals showing signs of suicidal behavior or a condition placing them at very high risk, such as a recent suicide attempt) [1]. Despite its importance, only Zhang et al. [17] used an indicated prevention perspective among all reviewed studies [16, 17, 21–23].

This study aims to: (1) evaluate the efficacy of a brief problem-solving-based psychological intervention for indicated suicide risk prevention administered face-to-face, by telephone multiconference, or via a smartphone app to individuals aged 50 or older compared to a usual care control group; and (2) examine the mediators and moderators of change in suicidal ideation. The main hypothesis is that the three experimental conditions, compared to the usual care control condition, will significantly reduce suicidal ideation at post-intervention and 3, 6, and 12-month follow-ups. Additionally, it is expected that other clinical variables (hopelessness, anxiety and depression symptoms, impulsivity, anger, gratitude) will improve. We also anticipate that problem-solving skills will mediate the relationship between treatment and the reduction in suicidal ideation; and that sociodemographic, family-related variables, personal history, suicide risk factors, reasons for living, social support, personality, adherence, and satisfaction with the intervention will moderate treatment effects.

Methods

Design

A randomized controlled trial (RCT) will be conducted. The present trial protocol follows the recommendations for clinical trial protocols from the SPIRIT Declaration [25] (see checklist in Additional file 1) and its update [26]. The RCT will adhere to the CONSORT guidelines extension for psychological and social interventions CONSORT-SPI 2018 [27]. Participants will be assigned to four groups: (a) a problem-solving-based psychological intervention administered in-person (PSPI-P; experimental group 1); (b) a problem-solving-based psychological intervention administered via telephone multiconference (PSPI-M; experimental group 2); (c) a problem-solving-based psychological intervention administered via a smartphone app (PSPI-A; experimental group 3); or (d) a control group receiving usual care (UCCG; usual care control group).

The study stages are shown in Fig. 1. There will be five measurement points across the four groups: pre-intervention (T1), post-intervention (T2), and follow-ups at 3, 6, and 12 months (T3, T4, and T5, respectively). After baseline evaluation (pre-intervention), eligible subjects will be selected, and interventions administered. Post-intervention evaluation and three follow-ups (at 3, 6, and 12 months) will be conducted. To minimize participant loss and optimize protocol compliance and follow-up, recommended strategies will be employed [28], such as making the intervention simple, scheduling comfortable and pleasant sessions, conducting non-invasive, useful, and interesting evaluations, encouraging participants to continue with the trial, and recovering lost participants during follow-up.

Participants

Recruitment

Participants will be recruited by the Research Group on Mental Health and Psychopathology (GRISAMP) at the University of Santiago de Compostela (USC) from individuals over 50 years old attending health centers of the Galician Health Service (SERGAS) in the Autonomous Community of Galicia, Spain. Galicia is a region in northwest Spain covering an area of 29,575 km^2 with a population of 2,693,451 [29] and is the second most aged community in Spain [30].

After referral by health professionals, potential participants will be contacted by phone to schedule the initial evaluation (T1). During the in-person evaluation session at USC facilities, project details will be explained, and those interested in continuing will be asked to sign an informed consent form. Evaluators will then collect sociodemographic data, conduct a clinical interview, and assess suicidal ideation to ensure eligibility criteria are met. Participants meeting these criteria will complete the remaining questionnaires.

Eligibility criteria

Inclusion criteria include: (a) being at least 50 years old; (b) residing in the Autonomous Community of Galicia; and (c) presenting suicidal ideation as indicated by scores above 6 on the Suicidal Ideation Scale (SSI) [31]. Exclusion criteria include: (a) severe mental or medical disorders (e.g., severe major depressive disorder, bipolar disorder, schizophrenia, severe cognitive impairment, dissociative disorders, substance dependence, acute suicide risk); (b) having started psychological or psychopharmacological treatment in the two months prior to the study or participating in another suicide prevention-related study; (c) lacking an appropriate device to participate (smartphone with internet connection), sufficient Spanish language proficiency, or having sensory or physical problems preventing participation; or (d) planning to move out of the Autonomous Community of Galicia in the next 18 months.

	STUDY PERIOD				
TIMEPOINT	*Pre-intervention* (t_1)	*Post-intervention* (t_2)	*3 months follow-up* (t_3)	*6 months follow-up* (t_4)	*12 months follow-up* (t_5)
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation	X				
PILOT STUDY:	X	X	X	X	X
INTERVENTIONS:					
PSPI-P	←	→			
PSPI-M	←	→			
PSPI-A	←	→			
UCCG	←	→			
ASSESSMENTS:					
Sociodemographic characteristics	X				
Diagnostic Interview	X				
Suicidal Ideation	X	X	X	X	X
Severity of suicidal behaviour	X	X	X	X	X
Hopelessness	X	X	X	X	X
Anxiety and depression	X	X	X	X	X
Reasons for living	X	X	X	X	X
Impulsivity	X	X	X	X	X
Problem-Solving skills	X	X	X	X	X
Social support	X	X	X	X	X
Syndrome of clinical anger	X	X	X	X	X
Gratitude	X	X	X	X	X
Personality	X	X	X	X	X
Satisfaction with the intervention		X			
Treatment adherence and dropouts	←	→			

Fig. 1 SPIRIT Figure. Phases of a randomized controlled trial

Randomization

Eligible patients will be randomly assigned with equal probability (1:1; random allocation) to one of the four study conditions after initial evaluation (T1). The Spanish version of the automated OxMaR system [32] will be used for randomization, allowing group assignment and ensuring concealment of the randomization sequence. This will be communicated to researchers through sealed envelopes numbered per participant with instructions for use in numerical order. Due to the nature of the interventions, blinding participants to their assigned group will not be possible.

Sample size

Given the heterogeneity of the types of interventions and the results of existing studies, a conservative estimation of the sample size is necessary. In two previous works [22, 33], according to the procedure for interpreting the magnitude of Odds Ratios described by Chen et al. [34], moderate to large effect sizes were reported for suicidal ideation, suicidal orientation, and depressive symptoms for the problem-solving groups compared to the comparison groups. Taking a moderate effect size (Cohen's $d = 0.50$) as a reference, assuming a two-tailed test, an α of 0.05, and a power ($1-\beta$) of 0.80, a sample size of 42 participants per group is required. Additionally, anticipating a sample loss of approximately 25%, similar to that reported by Fox et al. [35], it is necessary to recruit a minimum of 53 participants in each group, resulting in a final sample of 212 subjects.

Ethics

The trial will comply with the principles of the Declaration of Helsinki and the Spanish Organic Law 3/2018 on the Protection of Personal Data and guarantee of digital rights [36]. It has been approved by the Bioethics Committee of the University of Santiago de Compostela (Code USC 52/2023). Participation will be entirely voluntary without financial or other incentives, and all participants must provide written informed consent.

If a therapist detects an acute suicide risk in a participant, they will be immediately referred to the appropriate health services for psychological and psychiatric treatment for ethical reasons. This participant will exit the intervention due to the initiation of new psychiatric or psychological treatment (exclusion criterion b); their data will be retained for statistical analysis.

Interventions

A standardized intervention protocol for each experimental condition will be developed to increase internal validity. Participants in the PSPI-P group will receive the intervention in person at USC facilities; those in the PSPI-M group will receive it via telephone multiconference; and those in the PSPI-A group will receive it via a smartphone app. The UCCG group will receive usual care.

The three experimental conditions will consist of 7 sessions/modules, each lasting 90 min, conducted once a week, and will include between-session tasks to practice skills in real life. Task completion will be recorded by therapists in the PSPI-P and PSPI-M groups, and by the participants themselves through the app in the PSPI-A group.

In the PSPI-P and PSPI-M groups, the intervention will be administered by psychologists (with master's or doctoral training) who will be previously trained through approximately 60 h of theoretical-practical seminars and role-playing exercises by three professionals with 20 to 35 years of experience in cognitive-behavioral therapies. To control for therapist effects on treatment outcomes in this study, as the same therapy is used across the different experimental groups, varying only in the delivery format, a "crossed therapist" design will be used: the three therapists will participate in the administration of the therapy.

Following the training and prior to conducting the randomized controlled trial, a pilot study will be carried out in which each therapist will apply the intervention to approximately 15 subjects to review the acceptability of the material and refine the intervention. The concordance of the scores among therapists will be checked by calculating kappa indices. Once the pilot experience has been analyzed, the sample recruitment for the randomized controlled trial will be conducted, following the already described procedure. In the PSPI-P and PSPI-M groups, sessions will be recorded, and the professionals responsible for training the therapists will supervise their work weekly, evaluate their adherence to the intervention manuals, their application skills, and also provide weekly supervision to the therapists.

Problem-Solving-Based Psychological Intervention Administered In-Person (PSPI-P)

This group will receive a problem-solving-based psychological intervention developed from the problem-solving model [19]. The main component of the intervention will focus on teaching participants problem-solving skills to effectively cope with adverse circumstances currently in their lives. The program will also include other empirically supported techniques derived from cognitive-behavioral therapies [37] and positive psychology [38].

On the other hand, previous research by the research team will also be taken as a reference (e.g., with people of similar ages to those in the present study, the application of therapies in both face-to-face and remote modalities, or problem-solving therapy); in particular, the indicated

depression prevention program in group format [39], which has demonstrated its effectiveness in non-professional caregivers with subclinical depression in reducing depressive symptoms, emotional distress, burden, and preventing the onset of new episodes of clinical depression both in the short term [40] and long term [41], with the results on depressive symptoms maintained at the 8-year follow-up [42]; and also the indicated suicide prevention group intervention using problem-solving, developed by our research group, which has demonstrated its effectiveness in adolescents in Brazil [33].

The intervention will be delivered in a group format across 7 sessions, each lasting approximately 90 min, once a week. All sessions will have a similar structure: beginning with a recap of the previous session and review of homework (from the second session), followed by the introduction of key concepts, training in various skills and techniques, and the assignment of homework (see Table 1). If a participant misses a session or does not progress as expected, an individual phone call will be made to inquire about their situation, discuss reasons for lack of progress, and encourage continuation without active intervention.

Regarding the session content, in Session 1, an approach will be taken to the concept of suicidal ideation and behavior, their prevalence, and associated factors. In this line, the relationship between suicidal ideation and behaviors and adverse events as a precipitating factor will be presented, as well as coping strategies and problem-solving skills as protective factors. Additionally, the problem-solving model that underpins the main component of the intervention will be explained. Participants will be asked to identify their main current problems. A behavioral contract will also be drawn up, and participants will be trained in mood monitoring techniques, deep breathing, and self-reinforcement. Session 2 will focus on developing a personalized crisis response plan, which will include identifying symptoms and warning signs, cognitive and behavioral emotional regulation strategies, emergency contacts, and arguments against suicidal thoughts. Moreover, cognitive reframing will be conducted to promote active problem-solving. In Session 3, starting from the problems identified by the patients, this session will delve into problem definition, goal setting, and generating alternative solutions. Also, a plan for enjoyable activities will be proposed. During Session 4, decision-making and planning the implementation of the chosen solution will be addressed. In addition, a guided mindfulness practice will be included as a complementary activity. In Session 5, the consequences of implementing the chosen solution will be evaluated, identifying possible obstacles and benefits, and the problem-solving process will be repeated with another problem. Furthermore, participants will be instructed in the identification and reformulation of irrational thoughts. In Session 6, the results obtained after applying the second solution will be evaluated, the process will be repeated with a third problem, and participants will be instructed in a gratitude practice. Finally, in Session 7, the effects of implementing the third chosen solution will be evaluated, and all the skills and techniques learned throughout the intervention will be compiled. To prevent potential relapses, participants will be guided in creating a life project, identifying goals, obstacles, and available resources for coping.

Problem-Solving-Based Psychological Intervention Administered via Telephone Multiconference (PSPI-M)

Participants in this group will receive the previously described intervention in a telephone multiconference group format with the same duration, content, and structure. Adaptations will include small adjustments related to switching from in-person to telephone multiconference format: managing a telephone waiting system, using telephone communication skills (e.g., smiling at the beginning of the call, greeting and identifying oneself, especially courteous speaking, speaking slowly and clearly) [43]; adding a group rule for participants to state their name each time they speak; abbreviating explanations related to program content; and providing written support materials (a summary brochure for each session with key content and tasks to complete between sessions) by email or postal mail to participants' homes.

Problem-Solving-Based Psychological Intervention Administered via Smartphone App (PSPI-A)

Participants in this group will receive the intervention described earlier, adapted for delivery via a smartphone app with equivalent duration, content, and structure. All intervention components will be maintained, although the program will be adapted for intuitive design and usability. Content will be summarized and simplified for easy comprehension and engagement, using attractive animations and transitions combined with a pleasant and colorful design, enriched with videos and audios to explain the techniques. The app will include a feedback mechanism allowing users to record tasks and receive information on their progress.

Usual Care Control Group (UCCG)

Participants in the control group will receive usual care. Standard care will include individual and/or group psychotherapy and/or psychiatric medication as determined by the health professionals participants are attending at the time of the study, whether in public or private settings. Choosing usual care as the control group allows for comparison of the interventions in the experimental

Table 1 Contents of the intervention based on the problem-solving model

Session/ Module	Techniques and Strategies	Materials	Homework
1	Information about suicidal behaviors and associated risk factors Discussion of the vicious cycle between life events, problems, emotional distress, and coping strategies Overview of the theoretical foundations of the problem-solving model Creation of a behavioral contract Identification and listing of current personal problems Training in self-observation and mood monitoring Guided deep breathing training Self-reinforcement training	Group norms Intervention program summary brochure Therapeutic contract List of problems Mood thermometer Guided deep breathing audio Deep breathing self-record	Complete the mood thermometer daily Practice deep breathing technique daily for at least 15–20 min and complete the self-record Self-reinforce daily
2	Review of the previous session Review of homework Knowledge and skills for identifying warning signs in oneself Training in crisis situation strategies Creation of a crisis response plan Review of current problem list Positive orientation towards problems Guided deep breathing training Homework	My crisis response plan Positive self-affirmations	Complete the mood thermometer daily Practice deep breathing technique daily for at least 15–20 min and complete the self-record Self-reinforce daily Reread and complete all elements of the crisis plan. Place the crisis plan in an accessible location and refer to it if needed Reread, complete, and place the list of positive thoughts about problem-solving ability in an accessible location
3	Review of the previous session Review of homework Information on problem-solving styles and their effectiveness Definition of problems Decomposition and refocusing of problems Goal setting Generation of alternative solutions Planning enjoyable activities Guided deep breathing training Homework	My problem-solving worksheet Pros and cons list for solving the problem My activities list My activity plan	Complete the mood thermometer daily Practice deep breathing technique daily for at least 15–20 min and complete the self-record Self-reinforce daily Perform at least three enjoyable activities until the next session, one involving physical activity or social interaction. Refer to the crisis plan if needed
4	Review of the previous session Review of homework Training in a systematic and rational method for decision-making Decision making Planning the execution of the chosen solution Planning enjoyable activities Instruction and guided practice of breathing-focused meditation Homework	Aspects to consider in cost–benefit analysis of a solution My problem-solving worksheet from the previous session My activity plan Guided breathing-focused meditation audio Mindfulness self-record	Complete the mood thermometer regularly Self-reinforce daily Perform at least four enjoyable activities until the next session, two involving physical activity or social interaction Implement the plan designed for the chosen problem solution and evaluate the results Practice breathing mindfulness daily for at least 10 min and complete the self-record Practice deep relaxation and refer to the crisis plan if needed

Table 1 (continued)

Session/ Module	Techniques and Strategies	Materials	Homework
5	Review of the previous session Review of homework Evaluation of the achieved solution and identification of invested efforts, encountered obstacles, and obtained benefits Identification and reformulation of irrational thoughts Repetition of the problem-solving process with another problem Planning enjoyable activities Instruction and guided practice of breathing-focused mindfulness Homework	Reformulation of my irrational thoughts My problem-solving worksheet My activity plan Mindfulness self-record	Complete the mood thermometer regularly Self-reinforce daily Perform at least five enjoyable activities until the next session, three involving physical activity or social interaction Practice breathing mindfulness daily for at least 10 min and complete the self-record Reformulate another irrational thought Implement the plan with the chosen solution for the problem and evaluate the results Practice deep relaxation and refer to the crisis plan if needed
6	Review of the previous session Review of homework Evaluation of the achieved solution and identification of invested efforts, encountered obstacles, and obtained benefits Introduction to the concept and practice of gratitude Repetition of the problem-solving process with another problem Planning enjoyable activities Instruction and guided practice of breathing-focused mindfulness Homework	Gratitude journal My problem-solving worksheet My activity plan Mindfulness self-record	Complete the mood thermometer regularly Self-reinforce daily Perform at least six enjoyable activities until the next session, four involving physical activity or social interaction Practice breathing mindfulness daily for at least 10 min and complete the self-record Reformulate another irrational thought Implement the plan with the chosen solution for the problem and evaluate the results Complete the gratitude journal daily Practice deep relaxation and refer to the crisis plan if needed
7	Review of the previous session Review of homework Evaluation of the chosen solution in the previous session and identification of invested efforts, encountered obstacles, and obtained benefits Review of what has been learned and the changes made Final evaluation, farewell, and closure	My learned tools and skills My changes with therapy My plan to prioritize mental health Recommendations for maintaining mental health	

groups PSPI-P, PSPI-M, and PSPI-A with the current standard of treatment, ensuring clinical relevance, ethics, and generalization of the results.

Outcome measures

Participants will be evaluated at pre-intervention (T1), post-intervention (T2), and at follow-ups at 3 (T3), 6 (T4), and 12 months (T5) with the instruments listed in Table 2. Evaluations will be conducted in-person by independent psychologists who are trained and blind to the study's objectives, hypotheses, interventions, and participants' group assignments. Evaluators' training will be provided by two experts with 30 years of experience in assessment, consisting of 35 h of theoretical-practical seminars and role-playing on the assessment instruments used.

Sociodemographic and clinical characteristics

To collect information on sociodemographic variables, family-related factors, personal history, and current suicide risk following the criteria recommended in the Clinical Practice Guideline for the Prevention and Treatment of Suicidal Behavior [44], a structured interviewer-administered questionnaire will be used. It will include information on sex, age, marital status, living arrangements, rural/urban setting, educational level, main activity, monthly family income, characteristics of suicidal ideation (e.g., possible plans, access to lethal methods, intent to die, previous suicide attempts); present/past risk factors (e.g., risk factors related to psychological and psychiatric problems, family history of suicidal behavior and mental disorders, history of physical abuse or sexual abuse); and health and psychosocial stressors (e.g., presence of chronic illness, financial problems).

Table 2 Variables, measurement instruments, and administration format

Instruments	Format
Participant profile	
Sociodemographic and clinical characteristics	Interviewer-administered
Presence of mental disorders	
MINI Diagnostic Interview	Interviewer-administered
Primary outcomes	
Suicidal ideation: SSI	Interviewer-administered
Columbia Scale: C-SSRS	Interviewer-administered
Secondary outcomes	
Problem-solving skills: SPSI-R	Self-administered
Hopelessness: HS	Self-administered
Anxiety and depression symptoms: GHQ-12	Self-administered
Reasons for living: RFL	Self-administered
Impulsivity: BIS-11	Self-administered
Social support: DUKE-UNC-11	Self-administered
Clinical anger syndrome: CAS	Self-administered
Gratitude: GQ	Self-administered
Personality: BFI-10	Self-administered
Dropouts	Recorded by investigator
Treatment adherence	Recorded by investigator
Satisfaction with the intervention: CSQ-8	Self-administered
Adverse events	Recorded by investigator

MINI Mini International Neuropsychiatric Interview, *SSI* Suicidal Ideation Scale, *C-SSRS* Columbia Suicide Severity Rating Scale, *HS* Hopelessness Scale, *GHQ-12* General Health Questionnaire, *RFL* Reasons for Living Inventory, *BIS-11* Barrat Impulsiveness Scale, *SPSI-R* Revised Social Problem-Solving Inventory, *DUKE-UNC-11* DUKE-UNC Functional Social Support Questionnaire, *CAS* Clinical Anger Scale, *GQ* The Gratitude Questionnaire, *BFI-10* Big Five Inventory (short form with 10 items), *CSQ-8* Client Satisfaction Questionnaire

Presence of mental disorders

To detect mental disorders in subjects, the MINI International Neuropsychiatric Interview [45] version 7.0.2 will be used. This structured interview with 120 questions explores the main mental disorders of Axis 1 of DSM-5, showing adequate reliability ($k = 0.50–0.90$), sensitivity between 17%-92%, and specificity between 75%-100%.

Primary outcomes

Suicidal ideation will be the primary outcome of the study. The Suicidal Ideation Scale (SSI) [31], a 19-item semi-structured scale with internal consistency (Kuder-Richardson 20 [KR-20]) of 0.89 and inter-rater reliability (k) of 0.83, will be used. Complementarily, the Columbia Suicide Severity Rating Scale (C-SSRS) [46], a semi-structured interview assessing the severity of suicidal ideation and behavior over the past month, will be administered. It has good convergent and discriminant validity and high sensitivity (100.0%) and specificity (99.4%) for classifying suicidal behavior; the ideation intensity subscale showed a Cronbach's alpha of 0.73-0.95.

Secondary outcomes

Hopelessness Hopelessness will be assessed with the Beck Hopelessness Scale (HS) [47], a 20-item self-administered instrument with an internal consistency (KR-20) of 0.93.

Anxiety and depression symptoms The presence of anxiety and depressive symptoms will be assessed with the General Health Questionnaire (GHQ-12) [48], a 12-item self-administered questionnaire for screening psychiatric morbidity (non-psychotic) with an internal consistency (Cronbach's alpha) of 0.86 for those under 65 years old and 0.90 for those 65 and older.

Reasons for not attempting suicide Deterrent reasons for suicidal thoughts will be assessed through the Reasons for Living Inventory (RFL) [49]. This is a 48-item self-administered instrument with six subscales, with internal consistencies (Cronbach's alphas) ranging from 0.72 to 0.89.

Impulsivity The Barratt Impulsiveness Scale (BIS-11) [50] will be used to assess impulsivity. This 30-item self-administered instrument has internal consistencies (Cronbach's alphas) ranging from 0.79 to 0.82.

Problem-solving skills Coping and problem-solving skills will be assessed with the Revised Social Problem-Solving Inventory (SPSI-R) [51], a 52-item inventory with internal consistencies (Cronbach's alpha) ranging from 0.68 to 0.92.

Social support The Duke-UNC Functional Social Support Questionnaire (Duke-UNC-11) [52] will be used to assess perceived social support. This is an 11-item questionnaire with an internal consistency (Cronbach's alpha) of 0.90.

Anger syndrome Anger syndrome will be assessed with the Clinical Anger Scale (CAS) [53], a 21-item self-administered instrument with an internal consistency (Cronbach's alpha) of 0.94.

Gratitude Gratitude will be assessed with the Gratitude Questionnaire [54], a 6-item self-administered instrument with an internal consistency of 0.82.

Personality Personality will be assessed with the 10-item short version of the Big Five Inventory (BFI-10) [55], a self-administered instrument with internal consistencies ranging from 0.70 to 0.90.

Dropouts and treatment adherence Throughout the study, information on dropouts will be recorded. Treatment adherence will be evaluated by recording the number of sessions attended/modules completed by each participant (in the app), and the number of between-session tasks completed.

Satisfaction with the intervention The Client Satisfaction Questionnaire (CSQ-8) [56] will be used to assess participants' satisfaction with the intervention. This scale consists of 8 self-administered items and has an internal consistency (Cronbach's alpha) of 0.80.

Data management

Personal and clinical data of the participants will be coded and stored separately. Participants' files will be organized numerically and kept for 5 years after the study concludes. Data will be entered into a database without including personally identifiable information. Range and consistency checks will be performed with the data already recorded in the database. All information related to the study data will be stored in locked cabinets. Only the researchers will have access to the study data through a password system. A backup of the original database will be made every 15 days. All study reports and publications will be written in a way that ensures no participant can be identified.

Data analysis

The statistical package SPSS for Windows (version 29.0) and R (version 4.4.1) [57] will be used for data analysis. All analyses will be conducted according to the intention-to-treat principle. If participants drop out of the study or there are missing data for other reasons (e.g., incomplete questionnaires), the missing values will be imputed using multiple imputation [58]. The imputation will be based on predictors of the outcome, including auxiliary variables (sex, age, marital status, living arrangements, rural/urban setting, education level, main activity, monthly family income, characteristics of suicidal ideation, present/past risk factors, health and psychosocial stressors, hopelessness, anxiety and depression symptoms, reasons for living, impulsivity, problem-solving skills, social support, anger, gratitude, and personality), using 10 imputations through chained equations.

To analyze the effect of the intervention on the primary outcome variable (suicidal ideation) and secondary outcomes (hopelessness, anxiety and depression symptoms, impulsivity, anger syndrome, gratitude, and personality) at post-intervention and follow-ups at 3, 6, and 12 months, Linear Mixed Models [59] will be used. In the post hoc comparisons, Bonferroni correction will be applied (comparisons between times, between groups, and for the time x group interaction). The effect size will be calculated using Cohen's d, interpreting values $d < 0.5$ as small, $d = 0.5–0.79$ as medium, and $d \geq 0.8$ as large [60].

For the evaluation of the clinical significance of the effects of the three interventions, the JT method [61] will be followed, which involves two complementary procedures: calculating the Reliable Change Index (RCI) and analyzing the clinical significance of these changes. The RCI will be calculated using the formula RCI = post – pre / SEdiff. The index SEdiff = standard error of the difference, obtained from the formula: SEdiff = SD1$\sqrt{2}\sqrt{1}$-r, where: SD1 = standard deviation (group or individual);

r = reliability index of the measurement instrument (Cronbach's alpha). An RCI > 1.96 is defined as a positive reliable change; RCI < -1.96 is a negative reliable change; and RCI values between -1.96 and 1.96 are defined as no change. The clinical significance criterion is operationally defined as a cutoff point (c) beyond which the post-intervention score of the subject falls within the distribution of the functional population, and therefore closer to the mean of the functional population than the dysfunctional one. It is calculated using the formula: c = (*SD0 M1* + *SD1 M0*) / *SD0* + *SD1*, where: *SD0* = *SD1* = pre-intervention standard deviation (experimental or control group) or the general population; *M0* = mean of the functional general population; *M1* = pre-intervention mean (experimental and control group).

Moderation and mediation analyses will be conducted for the IPSP-P, IPSP-M, and IPSP-A groups. To improve interpretation, variables may be centered, according to the recommendations of Kraemer and Blasey [62]. The impact of potential moderators on the change in suicidal ideation between pre and post-intervention and between pre-intervention and the 12-month follow-up will be analyzed using linear regression analysis. To evaluate the effect of the potential moderator, the model proposed by Baron and Kenny [63] will be applied, whose general formulation, adapted to the case of a treatment variable with four categories, can be expressed as:

$$Y = iY + b1T1 + b2T2 + b3T3 + b4W + b5T1W + b6T2W + b7T3W + eY$$

This formulation considers the effect on suicidal ideation (Y) of the different treatment forms X (represented by the comparison of each group Ti against the control) depending on the level of the moderator variable (W). Each term TiW represents the interaction between treatment and the moderator variable. Potential moderators are baseline values of sociodemographic, family-related variables, personal history, current suicide risk factors, reasons for living, social support, personality, adherence, and satisfaction with the intervention. If any of the regression coefficients for the TiW products is significantly different from zero, it implies that the effect of X on Y depends on W [64].

To analyze whether problem-solving skills act as mediating variables for changes in suicidal ideation, the differences in suicidal ideation between pre and post-intervention will be used as the dependent variable (Y), the intervention as the independent variable (X), and the difference in problem-solving skills between pre and post-intervention as a potential mediator (M). A simple mediation analysis will be performed without covariates and without interaction. The direct effect (c'i) and the total effect (ci) of the treatment levels (Ti) on suicidal ideation (Y) through the change in problem-solving skills (M) will be estimated. The primary interest will be in the indirect effect, represented as aib, equivalent to the difference between the total relative effect of each treatment and the direct relative effect: aib = ci − c'i. An equation expressing the effect ai of each treatment level and the effect b is:

$M = iM + a1T1 + a2T2 + a3T3 + eM$ (association between the independent variable and the mediating variable, ai);

$Y = iY + c'1T1 + c'2T2 + c'3T3 + bM + eY$ (association between the mediating variable and the dependent variable controlling for the independent variable, b).

The direct effect would be expressed as $Y = iY + c1T1 + c2T2 + c3T3 + eY$ (association between the independent variable and the dependent variable, c).

Inference on these effects will be made by calculating 95% confidence intervals using the bootstrap method, based on a minimum of 5000 samples [65]. Mediation will be considered present when any of the indirect relative effects is significantly different from zero [66].

Acceptability and satisfaction with the interventions will be described through frequency distributions. The percentage of participants who drop out of the study will be considered. Adherence to the interventions will be studied through the number of sessions attended/modules completed and the record of tasks performed between sessions. Additionally, the level of satisfaction with each intervention (measured with CSQ-8) will be described through frequency analysis and descriptive statistics. Supervised classification/regression trees will be used to identify which variables and to what extent they help predict dropout, adherence, and satisfaction level.

Monitoring

An independent Data Monitoring Committee (DMC) will be established, separate from the study organizers. The steering committee, led by the principal investigator, will adhere to the principles of good clinical practice, including quality control of the clinical protocol, data management, and organization of team meetings. An annual report will be provided in strict confidentiality to the DMC on the progress of the trial.

A pilot study will be conducted to evaluate the feasibility of the protocol, interventions, and instruments. Any significant modification of the protocol that may impact the study's execution, potential benefit, or patient safety, including significant changes in study design, patient population, sample sizes, or study procedures, will require a formal amendment to the protocol. This

amendment will be approved by the Bioethics Committee before implementation.

Additionally, an interim analysis will be conducted after the pilot study and on the primary objective when 50% of the patients have been randomized and completed follow-ups. The interim analysis will be performed by an independent statistician. The statistician will report to the independent DMC, which will have unblinded access to all data and will discuss the interim analysis results with the steering committee in a joint meeting. The steering committee will decide on the continuation of the trial and report to the Bioethics Committee.

Exit strategy

An exit plan will be established for two specific scenarios: first, if a participant decides to leave the trial early, a voluntary phone call will be made to gather their reasons using a questionnaire. The project team will ensure that the exit is managed appropriately and that the participant feels satisfied with the conclusion. Second, at the end of the study period, which includes up to 14 weeks of intervention and 12 months of follow-up, participants will be clearly informed about the transition and closure of the study.

Discussion

In this study, the efficacy of a brief psychological intervention administered face-to-face, via telephone multiconference, and through a smartphone app for the indicated prevention of suicide in people aged 50 and over will be evaluated. The main component of the intervention will be adapted from the problem-solving model by D'Zurilla and Nezu [19]. Considering the results of previous studies that evaluated the efficacy of problem-solving therapy (PST), both in face-to-face format [22, 23] and remote format [21], and the available evidence on digital cognitive-behavioral interventions [67], we expect to find a significant reduction in suicidal ideation in the three intervention groups compared to the control group.

The development of this intervention follows the clinical practice guidelines of NICE [68], which recommend the use of structured, person-centered psychological interventions based on cognitive-behavioral therapy; as well as the collaborative development of a safety plan in an accessible format. The adaptability and ease of learning of PST confer it the potential to overcome barriers identified in the implementation of suicide prevention interventions, such as the lack of adequacy to participants' needs and resources or perceived complexity [69].

Additionally, this study proposes the implementation of ICTs in its administration, through telephone multiconference and a smartphone application. According to the World Health Assembly Resolution on Digital Health [70], digital health interventions have the capacity to contribute to advancing universal health coverage, one of the Sustainable Development Goals (SDGs). They allow addressing challenges in health systems such as geographic inaccessibility, delays in service delivery, or patient costs; improving coverage, quality, and affordability of care, and facilitating progress towards universal coverage [71]. The use of ICTs in the implementation of our intervention entails the intrinsic advantages of digitalization, such as anonymity, increased accessibility, or cost-efficiency [71, 72]. Furthermore, administration through group telephone multiconference facilitates social interaction with people going through similar experiences and has the potential to create communities and support networks. On the other hand, the use of an application adds additional benefits such as dissemination at any time and place (without waiting or appointments), the possibility of reviewing materials at the patient's own pace, and personalizing the content or accessing psychological tools [73]. Additionally, given the importance of user engagement to achieve therapeutic outcomes in this format [74], strategies to improve adherence are proposed, such as support, personalized feedback, or reminders [75, 76].

The strengths of this clinical trial include the specification of the prevention level and the corresponding selection of participants, the prior estimation of sample size, a randomized controlled design with allocation concealment, and the implementation of an intervention based on a theoretical model that has demonstrated its efficacy in previous research [21–23]. Additionally, the intervention will be manualized, therapist adherence to the protocol will be evaluated, and the results will be analyzed by trained professionals who will be blinded to the study conditions, with a follow-up period of 12 months. Validated instruments will be used to evaluate the outcomes. The prevalence of suicidal ideation will be measured using the Suicidal Ideation Scale (SSI) [31] and the risk of suicide using the Columbia-Suicide Severity Rating Scale (C-SSRS) [46]; both tools have demonstrated high correlation and concurrent validity [77], ensuring consistency and accuracy in the assessment of suicidality. The use of these internationally recognized and validated instruments increases the methodological robustness of our research and facilitates the comparison of our results. Moreover, the study will be conducted in a community context, ensuring a high generalizability of the findings.

In conclusion, this research is pioneering in developing a brief, versatile, and efficient intervention, applied in innovative formats that increase its accessibility, to prevent suicide in at-risk individuals over 50 years old. Its efficacy will be evaluated through a randomized

controlled trial, addressing the methodological limitations observed in the literature. Its novelty and methodological quality could have a significant scientific impact. Furthermore, given the relevance of the issue under study, if its efficacy is proven, it would have enormous clinical utility and social impact, helping to mitigate the psychological, social, and economic repercussions on affected individuals, families, and communities.

Status of the trial

Active, not recruiting.

Abbreviations

BFI-10	Big Five Inventory (short form with 10 items)
BIS-11	Barrat Impulsiveness Scale
CAS	Clinical Anger Scale
CONSORT	Consolidated Standars of Reporting Trials
CSQ-8	Client Satisfaction Questionnaire
C-SSRS	Columbia Suicide Severity Rating Scale
DUKE-UNC-11	DUKE-UNC Functional Social Support Questionnaire
RCT	Randomized controlled trial
UCCG	Usual care control group
GHQ-12	General Health Questionnaire
GQ	The Gratitude Questionnaire
HS	Hopelessness Scale
IHME	Institute for Health Metrics and Evaluation
IMPACT	Improving Mood Promoting Access to Collaborative Care Treatment
PSPI-A	Problem-solving-based psychological intervention administered via smartphone app
PSPI-M	Problem-solving-based psychological intervention administered via telephone multiconference
PSPI-P	Problem-solving-based psychological intervention administered in-person
MINI	Mini International Neuropsychiatric Interview
WHO	World Health Organization
RFL	Reasons for Living Inventory
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SPSI-R	Revised Social Problem-Solving Inventory
SSI	Suicidal Ideation Scale
MDD	Major depressive disorder
ICTs	Information and Communication Technologies
PST	Problem Solving Therapy
GRISAMP	Research Group on Mental Health and Psychopathology
SERGAS	Galician Health Service
INE	Instituto Nacional de Estadística [National Statistics Institute]
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
RCI	Reliable Change Index
DMC	Data Monitoring Committee

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12888-024-06076-5.

Additional file 1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

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Authors' contributions

FV: Conceptualization, Funding acquisition, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. AT: Conceptualization, Funding acquisition, Project administration, Writing – review & editing. VB: Conceptualization, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. QB: Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. EA: Conceptualization, Formal analysis, Methodology, Writing – review & editing. PO: Conceptualization, Investigation, Methodology, Writing – review & editing. MS: Conceptualization, Writing – review & editing. AB: Conceptualization, Writing –review & editing. MA: Conceptualization, Writing – review & editing. MP: Conceptualization, Writing – review & editing. AF: Writing – review & editing.

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Availability of data and materials

The results of the study will be communicated through publications, which will include data supporting the findings. The dataset used will be available upon prior request to the principal author.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Human rights and the dignity of the study participants will be ensured in accordance with the principles of the Declaration of Helsinki. The study procedures have received approval from the Bioethics Committee of the University of Santiago de Compostela (Spain). Confidentiality for all participants will be guaranteed, and they will be required to provide written informed consent to participate in the study, according to the form approved by the Bioethics Committee of the University of Santiago de Compostela (Spain). Reference number: 52/2023.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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