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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a randomized controlled pilot trial.

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ABSTRACT

Introduction: Spirituality is a dynamic and essential dimension of human beings through which meaning and transcendence are sought and should, therefore, be a necessary element of health care. Spiritual care (SC) has been recognized as a quality aspect for critically ill patients, and its incorporation in health care could improve long-term clinical outcomes.

Methods and analysis: This is a single-site, pilot, randomized controlled trial of a spiritual care intervention compared with usual care. The primary aim is to assess the feasibility and acceptability of the spiritual care strategy in critically ill patients. Secondary aims include evaluating the differences in anxiety and depression symptoms and post-traumatic stress disorder between the spiritual care group and the usual care control group.

Ethics and dissemination: Ethical approval was obtained from the Ethics Committee for Medical Sciences of the Pontificia Universidad Católica de Chile (#220111005) and by the Ethics Committee of the Servicio de Salud Metropolitano Sur Oriente. The study has been funded by Pontificia Universidad Católica de Chile (project number #105699/DPCC2021). Study findings will be disseminated widely in peer-reviewed publications, academic conferences, local community-based presentations, partner organizations, and the Chilean Intensive Care Society.

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Article Summary

Strengths and limitations of this study

- This is the first randomized study in Chile to examine the feasibility, acceptance, and efficacy of a program of systematic and periodic spiritual care and accompaniment in the prevention of post-ICU syndrome in surviving critically ill patients.
- The proposed intervention is innovative, as trained volunteers provide spiritual care and accompaniment telematically. Additionally, it is systematic and standardized, allowing it to be reproducible in other clinical settings.
- In this trial, the comparison is standard care, so participants and the practitioner will not be blinded, and complete blinding of the evaluator may be difficult due to self-reported outcome measurement.
- Participants may be heterogeneous due to the wide age range and possible comorbidities with other diseases.
- The sample size of this pilot study is too small to examine the effectiveness of systematic and periodic spiritual care and companionship programs in the prevention of post-ICU syndrome in surviving critically ill patients.

Introduction

Many patients who survive a critical illness suffer physical, psychological, and cognitive problems, which have been termed Post-ICU Syndrome (PICS)(1). Some studies have reported a residual effect several months after discharge from the Intensive Care Unit (ICU), affecting people's quality of life and functionality (2). Psychological symptoms of PICS include symptoms of depression, anxiety, and post-traumatic stress disorder (PTSD) (3). The reported prevalence of anxiety ranges from 12 to 43%, depressive symptoms from 10 to 30%, and PTSD from 5 to 64% (4)(5)(6). It is estimated that at least 50% of ICU survivors will present psychological symptoms of PICS at discharge, and other studies report that a quarter of survivors present with PTSD symptoms one year after discharge from the ICU (7)(8)(9). These statistics suggest that it is a prevalent problem in patients who receive ICU care and may be explained by the immediate psychological impact of critical illness on patients, which numerous studies have reported. Although interventions aimed at preventing PICS have been proposed, the studies that evaluate them show low effectiveness; very few have used standardized instruments to assess results, and an even smaller number have used an experimental design (10)(11). In addition, most of the interventions are pharmacological, focused on the physical rehabilitation of patients, and less on intervening in the mental health symptoms and/or psychological distress experienced by the patient at an early stage (4)(9)(12).

Spirituality is a dynamic and intrinsic aspect of humanity through which persons seek ultimate meaning, purpose, and transcendence and experience relationships to self, family, others, community, society, nature, and the significant or sacred. Spirituality is expressed through beliefs, values, traditions, and practices (13). Admission into an ICU is an experience that involves stressful suffering; in this context, most patients and family members feel vulnerable and, therefore, require not only physical healing but also emotional and spiritual attention (14)(15). Spirituality is important to most patients with severe illness and their relatives and can influence medical decision-making. Moreover, patients with serious illnesses frequently desire spiritual care. Still, the spiritual needs of these patients are frequently unaddressed within medical care, especially since spiritual care is infrequent in the care of such patients (16).

Spiritual care (SC) recognizes and pays attention to spirituality within health care. Spiritual care relies on a multidisciplinary team (e.g., chaplains, physicians, nurses, and social workers) and requires standard inclusion of a spiritual history as part of a comprehensive medical history (13). SC has been recognized as a quality aspect for critical patients (17)(18)(19). Complementarily, in studies on patients with chronic diseases, spiritual practices have been associated with hope, meaning, and peace, causing essential relief among them (20). Furthermore, ICU professionals have recognized SC as positive, contributing to the psychological well-being and satisfaction of patients and their families (21). However, spiritual care and accompaniment are frequently not part of the care patients receive in the ICU and many other hospital areas because clinicians do not have time, do not consider attention to spiritual needs as their responsibility, or are uncomfortable discussing spirituality with patients (22). Because spiritual care training is one of the strongest predictors of subsequent provision of spiritual care, it suggests that all multidisciplinary care team members should receive training in spiritual care provision. Studies indicate that training interventions could help standardize spiritual care (16)(23).

Considering that, the proposed study aims to evaluate the feasibility of implementing a spiritual accompaniment intervention for patients who received care in the ICU. The study will provide information regarding the feasibility of implementing an intervention of this type in this context and will permit the obtaining of some preliminary results of the effect of the intervention. Showing spiritual care's impact on individuals' health outcomes through studies such as this one may contribute to a paradigm shift from a biomedical perspective to a holistic view of ICU patients. Although the technological and advanced life support offered by the ICU is essential for critical patients, survival of a severe disease without a good quality of life makes it necessary to seek strategies to improve this problem, which undoubtedly requires a comprehensive approach to the person, through medical-physiological care and spiritual care. The study protocol is described below, with emphasis on the proposed intervention.

Methods and analysis

Design and study setting

This protocol is described as required by the 2013 SPIRIT guidelines to ensure consistent reporting of clinical trials. The trial is a single-site pilot feasibility randomized controlled trial designed to evaluate the feasibility of implementing a

spiritual accompaniment and care and to evaluate the effects of the intervention on psychological disorders (anxiety, depression, and PTSD) in critically ill patients. A total of 30 patients will be enrolled, and 15 subjects will be randomized to each arm.

The study is aimed at the patients hospitalized in the ICU of the Complejo Asistencial Dr. Sótero del Río (CASR) in Santiago, Chile. The CASR is a highly complex public hospital with an assigned population of approximately 1.5 million inhabitants (24). The ICU has 36 beds, and complicated procedures such as ECMO (extracorporeal membrane oxygenation), multimodal neuromonitoring, invasive hemodynamic monitoring, etc., can be performed. The ICU has a staff of professionals (physicians, nurses, kinesiologists, speech therapists, occupational therapists, clinical pharmacologists, etc.) trained in intensive care medicine.

Once the Informed Consent is signed, the patients will be randomized to receive a program of accompaniment and systematic and periodic spiritual care or standard care (control group). The randomization sequence will be generated by the Informatics Unit of the Faculty of Medicine of the Pontificia Universidad Católica de Chile through a computer program, and it will be carried out by random blocks of 5, with a 1:1 allocation. The allocation concealment will be achieved through a centralized randomization in RedCAP and implemented by our institution's informatics unit. The research staff will perform randomization. Due to the type of intervention under study, the patient and the research team cannot be blinded to group assignment. However, the statisticians, researchers responsible for data analysis, and those performing the long-term outcome evaluations will be blinded to group assignment.

Participants

Critically ill patients are eligible for participation based on the following inclusion and exclusion criteria:

Inclusion Criteria

1. Adult patients (≥ 18 years)
2. Patients who have had at least 72 hours of Invasive Mechanical Ventilation (IMV)
3. Patient is currently in the ICU
4. Glasgow 15 at the moment of the screening

Exclusion Criteria:

1. Presence of mental or intellectual disability before hospitalization or communication/language barriers
2. Patient with primary neurological or neurosurgical disease
3. Patient who required IMV in another episode of hospitalization in the two months before screening
4. Pre-existing comorbidity with a life expectancy not exceeding six months (e.g., metastatic cancer)
5. Readmission to the ICU (patients will be included if they are on their first ICU admission to the present hospitalization)
6. No fixed address for follow-up
7. Patients with moderate to severe visual or hearing impairment
8. Early limitation of therapeutic effort

Intervention

Enrolled participants included in the intervention phase will receive a program of systematic and periodic spiritual accompaniment and care based on using the FICA instrument and consider at least three sessions to be carried out telematically, via Zoom or video call, by volunteers trained explicitly for the intervention. The SC that will be delivered does not correspond to any particular creed, constituting a trans-religious intervention.

The intervention on accompaniment and SC proposed in this study has three distinctive characteristics: (1) it is systematic and periodic, which is achieved through a standardized schedule of 3 accompaniment sessions based on the FICA instrument (see below); (2) care is delivered by volunteers trained for the intervention (see Appendix 1), which is fundamental to ensure that the intervention is systematic and standardized; (3) it is delivered telematically, via Zoom or video call. This makes it easier to carry out the intervention, as it prevents patients and volunteers from traveling to the sessions.

To ensure compliance with these three characteristics, as a research team, we developed four critical components for the intervention: (1) Design of the accompaniment sessions; (2) Generation and implementation of a training program for volunteers; (3) Creation of a manual for the volunteers; (4) Creation of a logbook for volunteers.

The accompaniment and spiritual care sessions consider a 1:1 ratio (patient: companion), and participants will always be "accompanied" by the same volunteer. Although ideally, the entire intervention should be carried out while the

patient is hospitalized in the ICU, taking into account the average stay of patients in the CASR ICU (25), the last session could be carried out after discharge from the unit in case it does not take place earlier. The sessions will last 45 to 60 minutes and will be coordinated by the research team, depending on the patients' and volunteers' availability and clinical condition. This coordination involves:

-Scheduling of the day and time of the session. Within the systematization of the intervention, it has been defined that the sessions will take place from Monday to Friday until 20:00 hours.

-Define whether they will be carried out via Zoom or video call. If Zoom is chosen, a researcher will generate and deliver the link to the participants and volunteers. A premium Zoom account is available for the project.

-During the sessions, there will be a member of the research team close to the participant in case a problem arises that requires their advice or intervention, such as technological problems that affect connectivity and the development of the session, the need to re-coordinate a session that cannot be carried out, the need to support a participant or volunteer who is emotionally overwhelmed during a session, etc.

Regarding exploring spirituality through the FICA, the sessions are based on the application of the FICA instrument by volunteers, which was developed by Dr. Christina Puchalski and allowed the exploration of spirituality in the context of the healthcare (26). It was originally written in English but has a Spanish translation validated by its creator (27). The FICA is a kind of "spiritual anamnesis" that helps identify a person's spiritual needs and resources. Balancing spiritual needs and resources can be complex while hospitalized in the ICU, so guided reflection on this may be helpful. By exploring spiritual needs through FICA, people can find/recognize elements of their lives that support them in difficult situations, such as having a serious illness. Thus, FICA proposes to explore four crucial dimensions of spirituality (the term FICA is an acronym for these four dimensions):

F: FAITH and beliefs.

I: Importance of faith and beliefs in my life.

C: Community, i.e., how important is my community, including my family, group of friends, co-workers, or other activities, in my living of faith and beliefs.

A: Focus of attention. This dimension may vary depending on who is asking. It refers to what the participant might ask the volunteer about SC during accompaniment.

Each session has specific objectives that should be considered by the volunteers for each session. In the first session, volunteers should get to know the patient in the context of the intervention and explore their spiritual needs through the FICA. Before applying the FICA, volunteers should introduce themselves and ask about the biographical context of the participant. To do this, they can use questions such as: can you tell me a little about yourself, your family, etc.? They can also ask general questions about the experience of being hospitalized in the ICU, such as how you have felt, whether you had any experience as a patient or family member in the ICU before, etc. To apply the FICA, volunteers should ask patients questions about the four dimensions of this instrument. Beforehand, they should explain that these questions will help them explore their spiritual needs and resources to offer them adequate accompaniment for what they are experiencing. This personalized but systematized accompaniment is one of the advantages of having sessions based on the FICA. In Table 1, there are examples of questions that volunteers can use to apply FICA. Ideally, exploring the four dimensions of FICA should be completed during the first session. This can be completed in the second session if this is not achieved.

The objective of the second and third sessions is to deepen those dimensions of the FICA where the volunteer detected that the participant has more spiritual needs. However, it could happen that patients would like to talk about a topic that had not been previously discussed, to which the volunteers should be open, bearing in mind that accompaniment implies "the encounter with someone who feels, who seeks, who needs to be heard and welcomed" (23). In this sense, active listening on the part of the volunteer is key in the three sessions of this intervention.

Before beginning the sessions, volunteers must sign a confidentiality agreement. In this agreement, they agree not to comment outside the context of the research project on anything the participants have told them during the accompaniment. Within the study, they will only be asked to briefly describe, in the volunteer diary (see Appendix 1), the application of the FICA, which will be explained to participants during the recruitment and informed consent process. However, if a volunteer detects that a patient is very emotionally compromised, which could translate into a significant mental health problem in the context of ICU hospitalization, he/she should alert the research team. As a team, we will contact

the patient and his or her treating physicians and activate a referral network for evaluation by mental health specialists.

The comparison or control group is the standard care group in this trial. Participants in the standard care group can request the hospital's current care if they deem it necessary. This consists of the possibility of being assisted by a Catholic priest or being contacted by pastors from Protestant churches.

Outcomes measures

Primary outcomes

The primary outcomes are related to the feasibility of implementing the intervention in the conditions described above and the participants' satisfaction with the systematic and periodic spiritual care and accompaniment program.

The enrollment rate will be measured, corresponding to the proportion of patients who consent and are enrolled in the study during the first six months. The attendance rate will be evaluated through the proportion of patients attending at least three intervention sessions two weeks after randomization. Likewise, the follow-up rate will be measured by the proportion of patients who complete the evaluation three months after discharge from the ICU.

The participants' satisfaction with the intervention group will be measured through a satisfaction questionnaire one to two weeks and three months after the last session of the intervention.

Before starting each session, while the participant is still in the hospital, will apply the CAM ICU (validated Chilean version) to ensure that there are no symptoms of delirium to conduct the intervention.

Secondary outcomes

Secondary outcomes will be the mean change of PTSD symptoms, anxiety, and depression from baseline to three and six months after recruitment (follow-up). PTSD will be assessed by the Impact of Event Scale (Chilean population version) (28). This scale has a score from 0 to 88, defining a post-traumatic stress disorder with a score higher than 43. The Hospital Anxiety and Depression (HADS)(29) instrument will be used, which has a depression subscale and an anxiety subscale. HADS is a self-assessment scale used to detect emotional distress (anxiety and depression) in the non-psychiatric population. It is a short instrument (14 items) that has shown its reliability and validity in Chile, for diagnosis and to assess the severity of the disorder. It comprises two subscales (HAD-A: anxiety and HAD-D: depression) of seven items, each with scores from 0 to 3. The authors recommend

the original cut-off points: eight for possible cases and >10 for probable cases in both subscales. Outcomes assessment will be conducted by research assistants blinded to randomization assignment at three- and six-months post ICU discharge. Other relevant outcomes will be the volunteers' satisfaction with the accompaniment and spiritual care intervention, measured by a satisfaction questionnaire one to two weeks after the end of the last accompaniment session. Once the intervention is over, the perceptions of the participants, volunteers, and research team about the intervention, its components, training and recommendations, and difficulties encountered will be evaluated in three focus groups. In the focus groups, the same questions will be asked to all participants, and the verbal responses to these questions will be recorded with voice recorders. The thematic analysis method will be used to analyze the data.

Participant timeline and recruitment

Patients will be examined in the morning to determine eligibility. Day 0 of the study corresponds to the day the informed consent is signed, where demographic and clinical data relevant to the study will be collected, psychological questionnaires will be administered, and the data collected will be documented on the case report form (CRF) by trained clinical research coordinators. Patients will be followed up during the ICU and hospital stay to record the mechanical ventilation days, ICU stay, and hospital stay. Patients will be evaluated three and six months after discharge from the ICU to record secondary outcomes. Assessment of psychological outcomes will be performed by evaluators blinded to group assignment. The evaluation schedule for the trial is shown in Fig. 1.

To improve participants' adherence to the intervention and follow-up, the investigators will visit participants before each accompaniment and spiritual care session, and they will contact each other telephonically to coordinate the long-term follow-up session. If participants do not wish to attend the intervention sessions, we will inquire about their non-attendance and try to encourage compliance and attendance.

Data collection and management

Data will be collected and stored using Research Electronic Data Capture (RED-Cap). At the time of enrollment, study staff will collect information about each participant, including demographics, dates of hospital and ICU admission, and severity of illness according to the Acute Physiology and Chronic Illness Classification System II (APACHE II), Chronic Health Assessment II and Sequential

Organ Failure Assessment (SOFA) Score, comorbidities according to the Charlson Comorbidity Index, admission diagnoses, and pre-existing neuropsychological impairment. The Impact of Event Scale and Hospital Anxiety and Depression questionnaires will also be applied.

During each patient's stay in the ICU, data will also be collected on Sequential Organ Failure Assessment Score (SOFA), hemodialysis and vasopressor use, duration of mechanical ventilation, length of ICU, and hospital stay. All patients will undergo a standardized follow-up at three- and six- months post ICU discharge, in which the Impact of Event Scale and Hospital Anxiety and Depression questionnaires will be administered telematically.

The research assistants will undergo training and certification procedures with a supervisor for quality assurance. The supervisor performs ongoing quality assurance checks at regular intervals. Subjects will be instructed to refrain from discussing their assigned intervention with the research assistants.

Statistical analysis

An independent statistical expert blinded to the group allocation will implement the statistical analysis.

Baseline characteristics will be reported using means ± standard deviation, medians (p25-75), and percentages. The use of parametric or nonparametric tests will depend on the data distribution. Continuous variables will be compared with the Student's t-test or the Mann-Whitney test, and categorical variables with the chi-squared test. A p-value < 0.05 will be considered for statistical significance. To assess the effect of the intervention on psychological outcomes, multilevel multivariate random intercept models will be used for the proposed outcomes in successive tests verified over time, which will be defined as linear if the outcome is quantitative and logistic if the outcome is dichotomous. In addition, the model will be adjusted for confounding factors (age, sex, socioeconomic status, comorbidities, severity score, drug consumption, days of mechanical ventilation, days of ICU stay, and days of hospital stay). An interaction between treatment and time will also be performed, assuming that outcomes may vary. The proposed models will be run using the "lme4" library of the free software R. Missing values due to participant withdrawals are expected. Methods such as multiple imputations will be utilized to improve precision and reduce bias in the estimates to deal with missing values. Sensitivity analysis will be performed, assuming different patterns of missingness in the data.

Since these pilot studies work with small samples, estimating the sample calculation is unnecessary. However, to obtain some preliminary results of the effect of the intervention, a sample of 15 people per group will be recruited and followed up until six months after discharge, allowing us to evaluate changes over time in PICS symptoms. It is proposed that the intervention begin during hospitalization so that it will have a preventive nature and help mitigate the impact of ICU hospitalization on the development of mental health symptoms in patients. Participants will be randomly assigned to groups and evaluated considering their intention to treat.

Ethics and dissemination

This study has been approved by the Ethics Committee of the Faculty of Medicine of the Pontificia Universidad Católica de Chile and by the Ethics Committee of the Servicio de Salud Metropolitano Sur Oriente, which evaluates CASR research projects. Before recruitment, the informed consent process will be carried out with the participants, including signing the consent form. This will be done by a research team member who will not be involved in the care of the participants.

On the part of the volunteers, before beginning the accompaniment and SC sessions, they must sign a confidentiality agreement regarding what was discussed with the participants during these sessions. They will also be asked for their consent and consequent signature of an informed consent document to analyze and disseminate the information generated regarding their satisfaction with the training and role as volunteers.

Data collection and storage will be carried out securely, safeguarding each participant's anonymity and always maintaining confidentiality. To achieve this, participants will be identified with a specific code. Only members of the research team will have access to the information generated in this study.

Discussion

This study seeks to generate information in two areas that, in recent years, have gained concern and interest among intensive care medicine professionals: the PICS and spiritual care. This shows how a paradigm shift has occurred in the ICU, from an exclusively biomedical perspective to a comprehensive view of patients, including their families.

Although the importance of spiritual care in the ICU has been recognized, few studies have evaluated its effect as part of a systematic, periodic intervention. This study will be a pilot, randomized, controlled, evaluator-blinded clinical trial

aimed at assessing the feasibility of applying a spiritual companionship intervention to patients cared for in the ICU and beginning to implement it during hospitalization. It will determine the feasibility of future large-scale clinical trials in critically ill patients.

This study has some strong points. First, it is the first randomized trial in Chile investigating SC. As a research team, it seems necessary to systematize and standardize this type of intervention so that its effects are secondary to the intervention itself and not to external factors. In addition, this would also make it easier for it to be a reproducible intervention. Another noteworthy feature of the proposed intervention, an innovation of this study, is that trained volunteers will deliver the SC. Some studies have found positive results in ICUs with SC provided by religious people (30)(31), but to our knowledge, the role of trained volunteers has yet to be evaluated. Another innovative aspect of this intervention is that it will be carried out telematically, using Zoom or video call; it will facilitate its feasibility by avoiding the need to travel to the sessions. Finally, we will collect subjective and objective data on long-term psychological outcomes in patients surviving critical illness.

The design of this study is not free of limitations. First, participants and treatment providers are not blinded, as a simulated spiritual companionship program cannot be implemented in this trial. Therefore, when interpreting the study results, the effects that other factors, such as participant expectations or the patient-volunteer relationship, may have had on the psychological outcomes must be considered. Secondly, this is not a multicenter study, so the results cannot be generalized. However, so far, no studies have been published on the prevention of PICS through accompaniment and SC performed by trained volunteers, it seems that a study conducted in a single center and with a pilot experimental design is adequate. Finally, the sample size of this trial is small (15 individuals per group) to examine the efficacy of SC for long-term psychological outcomes (PTSD, anxiety, and depression). However, the outcome of this study may have preliminary data for a large-scale randomized controlled trial to obtain solid evidence on the efficacy of a spiritual care and accompaniment program for long-term psychological disorders.

In conclusion, the present protocol corresponds to a study that seeks to generate knowledge in intensive care medicine, such as post-ICU syndrome and spiritual

care, using a simultaneously systematized and standardized innovative intervention.

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Authors' contributions:

L.A., C.R., P.O., P.R., and V.R. designed the study. CR and PR supervise the clinical study and recruitment and treatment of participants. L.A. and P.R. are responsible for the statistical analysis. C.R., P.O., V.R., and JB contributed to the analysis and data interpretation. L.A., P.R., and C.R. drafted the manuscript, while all other authors critically revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

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Competing interest

The authors declared that they had no competing interests. The funding agency had no role in developing the study design, collection, analysis, interpretation of data, manuscript development, or the decision to submit the manuscript.

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Patients and/or the public were not involved in this research's design, conduct, reporting, or dissemination plans.

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FIGURE LEGENDS

Figure 1. Timeline of recruitment, allocation, and assessments

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	T_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Program of Spiritual Accompaniment and Care			⟷	⟷		
ASSESSMENTS:						
Demographics information and co-morbidities	X					
Record Daily ICU interventions and events			X			
ICU and hospital LOS				X		
Psychological impairment (IES, HADS)	X				X	X

Fig 1. Timeline of recruitment, allocation, and assessment. -t1: Baseline; t1: Each day until ICU discharge; t2: Hospital discharge; t3: 3 months follow-up; t4: 6 months follow-up. Abbreviations: ICU Intensive Care Unit; LOS Length of stay; HADS Hospital Anxiety and Depression Scale; IES Impact of Event Scale.

TABLES

Table 1: Examples of possible questions for each FICA dimension

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Training program for volunteers

The training program for volunteers is described below.

A training program was developed for standardized volunteer training, ensuring the intervention is effectively systematic. In addition to being trained in FICA, the volunteers received training in (program contents) active listening, asking and affirming skills, psychological first aid, psychoeducation, spirituality, spiritual accompaniment, ICU care, and PICS.
Before beginning the training, a group of volunteers will be selected. For this purpose, a call will be made through social networks and e-mails explaining what the project consists of and what the role of the volunteers would be in the accompaniment and SC. It is expected to recruit at least ten volunteers, so each must accompany 1 to 2 participants, according to the study's design. This program, like the proposed intervention, was developed telematically and included:
1) Eleven narrated capsules with the contents of the program are available on the Google Classroom platform.
2) Nine Zoom sessions of 1.5 to 2 hours, in which the volunteers could resolve doubts and practice spiritual accompaniment through the role-playing strategy using scenarios developed by the research team. The volunteers will be divided into small groups (4 to 6 members).
3) Information about how the program will be delivered, zoom use, and contact information, among other practical tips.

Volunteer Manual

It consists of a guide that summarizes the contents of the training program. It also provides recommendations to facilitate the development of the accompaniment and SC sessions. These recommendations outline how to develop the sessions with resources such as Tables 1 and 2. The manual will be sent by e-mail (PDF format) to the volunteers at the end of the training. It will also be available on the Google Classroom and content capsules.

Volunteer's logbook

After each accompaniment and SC session, volunteers must complete the volunteer logbook (to be completed online via Google Docs) with the most relevant aspects of the sessions. For this, volunteers will have to answer some questions:
1) Generalities of the sessions: How they were developed (platform used), their duration, whether there were any connection and/or audio problems, etc.
2) Regarding the FICA: How was its application? Could it be completed in the first session, or was it completed in the second session? In addition, they will have to describe what the participant tells them about each dimension briefly, but taking special care that this description does not go into details that imply the loss of confidentiality. After the second and third sessions, they must explain which dimension of the FICA they took up again.

3) About the participant and their role as companions: How was the patient (calm, with some degree of emotional lability, very labile, etc.) during the session? How did they feel as volunteers (overwhelmed, calm, helpful, etc.)?

4) Regarding what was learned in the training: What elements of those learned in the training (active listening, psychological first aid, psychoeducation, spirituality, etc.) did they apply, and did they help them guide the sessions?
The logbook has multiple choice questions, questions that are answered using the Likert Scale (depending on how much the volunteer agrees or disagrees with the statement), and others whose response considers the possibility of free text.

Table 1: Examples of possible questions for each FICA dimension

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked

	something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Table 2 summarizes the recommendations that volunteers should remember for the accompaniment and spiritual care sessions. This was explained to them during the training and is available as reference material in the volunteer manual.

Table 2: Recommendations to be considered by the volunteers for the development of the spiritual care and accompaniment sessions

Accompanying component	Recommendations
First session	• Introduce yourself and make sure you are talking to the right person (good afternoon, I am AAA, you are Mrs. BBB?). • Explain to the participant the objective of the session (during recruitment, the research team will have explained to the patient about the accompaniment sessions and the objectives; however, it is important that each volunteer remind them especially about the first session). • Reinforce to the patient that the sessions imply a space of trust and confidentiality, so he/she will not discuss what he/she hears with other people.
Aspects to consider in all sessions	• Remember that the accompaniment has to be centered on the needs of the patient , being very important that as an accompanier to "be fully present'' during the sessions. • Spirituality, pain and, suffering are intimate, so show empathy and do not interrupt the patient when he/she is telling something. Likewise, share the silences that the patient makes.

	• During the sessions it is essential to show respect for the patient's values and beliefs, listening attentively as he/she shares them. If she/he asks you about your religion and beliefs, you can share them. It may also happen that you have beliefs in common, which we invite you to use as an element that enriches the sessions. • Do not judge the participant by what he or she tells you. This does not mean denying their convictions and values, but it does mean distinguishing between your own beliefs and what is important to her/him. • Use active listening, welcoming and validating what she/he tells you. • Avoid the temptation to offer solutions that you cannot guarantee in the face of the relative's suffering (avoid phrases such as "don't worry, everything will be fine"). It is important to remain calm in the face of uncertainty. Often, during the accompaniment, you will not have the answer that the patient, but remember that accompaniment is based on "being there for the other". • If the patient presents significant emotional lability, you can apply the stabilization exercises learned during the trainings, such as breathing exercises. If the patient shows significant distress, you can also ask for help from the support team available in the hospital. • Avoid wanting to lead the patient to your own religious or spiritual beliefs. Therefore, respect their emotional and spiritual limits. • Remember that these meetings are based on trust that the patient will have with you as a companion, so we reinforce the importance of confidentiality. • We suggest that you try to accept, if it occurs, an invitation from the patient to pray, pray, sing or participate in some religious or spiritual rite, in the context of the telematic accompaniment that you are providing.
Closing of the sessions	• At the end of a session (remember that these sessions should not last more than 1 hour, both for your time and the patient's time), you can briefly recap what you have discussed. • Remember to thank the patient for his or her time and define when your next meeting might be. The study team will coordinate the sessions, but it is important that you, as a volunteer, can confirm the most suitable days and times for you and the family member.

	• If you are closing the third session, remember to especially thank the patient for sharing his or her beliefs, values and convictions with you.
Technical aspects	Prior to the beginning of the sessions, check how your internet connection is, because a bad connection will make it difficult to carry out the session (Zoom or Video Call). It is also important that you check that the audio and camera of the device you will be using are adequate. In the volunteer's manual you will find more information in the "Technical Guide" section. • Both you and the patient need to be in a comfortable and quiet place for the sessions; noises or interruptions may hinder your development. Please check this before starting the session. • The research team will explain these aspects to the patients, and health personnel when coordinating the sessions. • If the patient health condition does not allow to attend the session, you will be notified promptly and the session will be rescheduled.

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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomized controlled pilot trial.

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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomized controlled pilot trial.

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ABSTRACT

Introduction: A significant number of critically ill patients who survive their illness will experience new sequelae or a worsening of their baseline health status following their discharge from the hospital. These consequences may be physical, cognitive, and/or psychological and have been labeled Post Intensive Care Syndrome (PICS). Prior research has demonstrated that spiritual care (SC) aligned with a specific creed during hospitalization in the Intensive Care Unit (ICU), as part of a comprehensive care plan, may be an effective strategy for preventing psychological sequelae in surviving critically ill patients. However, there is a gap in the clinical literature regarding the effectiveness of ecumenical spiritual care in preventing psychological sequelae associated with PICS. This pilot study aims to explore the feasibility of implementing an ecumenical spiritual care strategy in the ICU and to evaluate its preliminary effectiveness in preventing anxiety and depression symptoms and posttraumatic stress disorder in critically ill patients.

Methods and analysis: This is a single-site, feasibility, randomized controlled pilot trial of an ecumenical spiritual care intervention, which is being compared with the current standard of care. A total of 30 adults who are critically ill and have undergone invasive mechanical ventilation for a minimum of 72 hours without an alteration in consciousness will be randomly assigned to either the spiritual care (SC) group or the usual care group at a ratio of 1:1. The primary outcome will be the feasibility and acceptability of the SC strategy in critically ill patients. Secondary aims include evaluating the differences in anxiety and depression symptoms and posttraumatic stress disorder between the spiritual care group and the usual care control group at three months after ICU discharge. Subjects will be followed up until three months post-ICU discharge.

Ethics and dissemination: Ethical approval was obtained from the Ethics Committee for Medical Sciences of the Pontificia Universidad Católica de Chile (#220111005) and by the Ethics Committee of the Servicio de Salud Metropolitano Sur Oriente. The study has been funded by Pontificia Universidad Católica de Chile (project number #105699/DPCC2021). Study findings will be disseminated widely in peer-reviewed publications, academic conferences, local community-based presentations, partner organizations, and the Chilean Intensive Care Society.

Trial registration number NCT06048783.

Article Summary

Strengths and limitations of this study

- This pilot study aims to provide the feasibility, acceptance, and efficacy of a program of systematic and periodic spiritual care program in the prevention of post-ICU syndrome in surviving critically ill patients.
- The results of this feasibility study will provide data for an adequately powered effectiveness trial.
- Mixed-effects analyses will discriminate possible differences due to baseline characteristics and intervention variations.
- Due to the nature of the intervention, participants and practitioners will not be blinded.
- There needs to be more than the findings from this feasibility study to assess the efficacy of the treatment.

Introduction

The incidence of critical illness has increased due to the aging of the chronically ill population. Additionally, emerging viruses and bacteria, such as COVID-19, have resulted in an unprecedented increase in critically ill patients. At the same time, advances in intensive care medicine and critical care have decreased the mortality of critically ill patients [1]. Many patients who survive a critical illness suffer physical, psychological, and cognitive problems, which have been termed Post-ICU Syndrome (PICS) [2,3]. One study reported that, regardless of whether ICU admission was for a medical problem, urgent surgical intervention, or elective intervention, > 40% of ICU survivors experienced new or worsened deterioration of their physical, cognitive, and/or mental health status after hospital discharge [4]. The specific prevalence of different sequelae after critical illness varies depending on the population studied, how long post-ICU discharge assessments are performed, and the instruments used for evaluation [1]. The incidence of physical sequelae was evaluated in a systematic review that included 33 studies, with 1,080 of 2,686 patients (43%) meeting the criteria for acquired critical patient weakness (ICUAW) ([5]. However, the studies used different methods to assess ICUAW (e.g., physical examination, electrophysiologic testing, histologic assessment), leading to variation in the incidence of ICUAW between studies. Regarding cognitive sequelae, a recent systematic review of 46 studies indicates that the prevalence of cognitive impairment ranges from 35 (subjective assessment) to 81% (objective assessment) at 3 months post ICU discharge [6]. Psychological symptoms of PICS include symptoms of depression, anxiety, and posttraumatic stress disorder (PTSD)[7]. The reported prevalence of anxiety ranges from 12 to 43%, depressive symptoms from 10 to 30%, and PTSD from 5 to 64%. It is estimated that at least 50% of ICU survivors will present psychological symptoms of PICS at discharge, and other studies report that a quarter of survivors present with PTSD symptoms one year after discharge from the ICU [8–10]. Some studies have reported a residual effect several months after discharge from the ICU, affecting people's quality of life and functionality [3]. Risk factors for PICS are categorized into modifiable and non-modifiable. Non-modifiable risk factors include older age, female gender, severity of illness, delirium, and mechanical ventilation. For mental health disorders related to PICS, specific risk factors for three major mental health disorders are (1) depression, older age, and female sex; (2) anxiety, older age, and a "negative ICU

experience"; and (3) PTSD, higher severity of illness and a "negative ICU experience" [1]. These statistics suggest that it is a prevalent problem among patients who receive ICU care, and modifiable risk factors such as "ICU experience" could be the focus of interventions designed to improve aspects of PICS. For example, given that a "negative ICU experience" is associated with anxiety symptoms and PTSD, ICUs might consider implementing and evaluating interventions that improve this experience to address PICS [11–14].

In the last decade, interest in spirituality and spiritual care in ICUs has grown [15–17]. Spiritual care among participants in some studies is potentially a measure of healthcare quality [18]. Studies show that quality care in the ICU includes attention to the person [19]. Spiritual care in the ICU has usually been associated with end-of-life care. However, admission into an ICU is a stressful experience that produces psychological and emotional suffering; in this context, most patients and family members feel vulnerable and, therefore, require not only physical healing but also emotional and spiritual attention [20,21]. Studies have reported that patients who need care in the ICU are especially likely to affirm that spirituality is important to them [18,22,23]. However, this cannot be generalized to all critically ill patients.

According to Puchalski [24], spirituality is a dynamic and intrinsic aspect of humanity through which persons seek ultimate meaning, purpose, and transcendence and experience relationships to self, family, others, community, society, nature, and the significant or sacred. Spirituality is expressed through beliefs, values, traditions, and practices. While "connection," "meaning and purpose of the person's life," and "transcendence" are the three essential elements when defining spiritual care [16,25,26]. Spiritual care (SC) recognizes and pays attention to spirituality within health care. Spiritual care can be provided by spiritual caregivers or chaplains who are trained to deliver spiritual care in clinical settings. ICU staff (intensivists and ICU nurses) often leave the spiritual needs of patients and/or their families to the spiritual caregiver or the patient's parish clergy, as they consider them better qualified to address such issues due to scheduling or lack of experience [27]. Although spirituality is important to most patients with severe illness and their relatives and can influence medical decision-making, it is not common for ICUs to standardize SC methods to incorporate assessments of the spiritual needs of patients and/or their families in the ICU [19,23]. A growing number of studies show that the organization of spiritual care

in the ICU can be improved and become an integral part of daily ICU care based on holistic care [28–31].

In studies on patients with chronic diseases, SC has been associated with hope, meaning, and peace, causing essential relief among them. In critically ill patients, the spiritual dimension is related to quality of life from the perspective of patients and their families, especially in coping with severe and potentially life-threatening illnesses [19]. Studies in ICUs show that, from the perspective of healthcare professionals, providing spiritual care to ICU patients and their families has positive effects in four areas: 1) diagnosing and addressing the spiritual and emotional needs of patients and their families; 2) providing spiritual comfort to patients in distress; 3) increasing the spiritual well-being of patients and their families; and 4) increasing family satisfaction with ICU care in general and with decision-making in the ICU in particular [17,19,26,27]. A recent systematic review on the impact of spiritual care interventions in critically ill patients included 18 interventional studies (quasi-experimental or randomized clinical trials), all conducted in Asian countries, where the control group received the standard care of the center and the spiritual care intervention mainly was associated with a particular creed, provided by spiritual caregivers or nurses, and the outcomes of interest varied. This study showed that SC interventions could significantly reduce mean blood pressure and ICU length of stay and improve ICU patients' awareness, anxiety, spiritual well-being, and comfort. Furthermore, ICU professionals have recognized SC as positive, contributing to patients' and their families' psychological well-being and satisfaction [32]. Hospitalization is a significant stressor that can impact patients' physical and mental health, which is often experienced as overwhelming and threatening to their well-being. According to the transactional stress model, spirituality serves as a coping mechanism and can mitigate the effects of stressful events [33]. Specifically, it can ease the burden of hospitalization and alleviate psychological and emotional distress [34,35]. Spirituality can offer protection against anxiety and depression by providing a sense of meaning, purpose, and hope, especially during demanding times such as physical illness or hospitalization [36]. Consequently, patients who do not receive spiritual care may experience hospitalization as a significant stressor, with fewer tools to cope with this event, present more emotional and psychological distress, and therefore have a greater risk for adverse mental health outcomes.

However, spiritual care is frequently not part of the care patients receive in the ICU and many other hospital areas because clinicians do not have time, do not consider attention to spiritual needs as their responsibility, or are uncomfortable discussing spirituality with patients [37]. On the other hand, not all hospitals and ICUs have spiritual caregivers or chaplains.

Considering that, the proposed study aims to evaluate the feasibility of implementing a spiritual care intervention for patients who received care in the ICU and to assess the effects of the intervention on psychological disorders (anxiety, depression, and PTSD) in critically ill patients. The study will provide information regarding the feasibility of implementing an intervention of this type in this context. It will permit obtaining some preliminary results on the effect of the intervention. Showing spiritual care's impact on individuals' health outcomes through studies like this one may contribute to a paradigm shift from a biomedical perspective to a holistic view of ICU patients. Although the technological and advanced life support offered by the ICU is essential for critically ill patients, survival of a severe disease without a good quality of life makes it necessary to seek strategies to improve this problem, which undoubtedly requires a comprehensive approach to the person, through medical-physiological care and spiritual care. The study protocol is described below, with emphasis on the proposed intervention.

Methods

Study design and setting

This protocol is described as required by the 2013 SPIRIT guidelines [38] to ensure consistent reporting of clinical trials. The trial is a single-site pilot feasibility randomized controlled trial. A total of 30 patients will be enrolled, and 15 subjects will be randomized to each arm. The recruitment of patients will be between December 2024 and July 2025.

The study is aimed at the patients hospitalized in the ICU of the Complejo Asistencial Dr. Sótero del Río (CASR) in Santiago, Chile. The CASR is a highly complex public hospital with an assigned population of approximately 1.5 million inhabitants [39]. The ICU has 36 beds, and complicated procedures such as ECMO (extracorporeal membrane oxygenation), multimodal neuromonitoring, invasive hemodynamic monitoring, etc., can be performed. The ICU has a staff of professionals (physicians, nurses, kinesiologists, speech therapists, occupational therapists, clinical pharmacologists, etc.) trained in intensive care medicine.

Eligibility criteria

Critically ill patients are eligible for participation based on the following inclusion and exclusion criteria:

Inclusion Criteria

1. Adult patients (≥ 18 years)
2. Patients who have had at least 72 hours of Invasive Mechanical Ventilation (IMV)
3. Patient is currently in the ICU
4. Glasgow 15 [40] at the moment of the screening

Exclusion Criteria:

1. Presence of mental or intellectual disability before hospitalization or communication/language barriers
2. Patient with primary neurological or neurosurgical disease
3. Patient who required IMV in another episode of hospitalization in the two months before screening
4. Pre-existing comorbidity with a life expectancy not exceeding six months (e.g., metastatic cancer)
5. Readmission to the ICU (patients will be included if they are on their first ICU admission to the present hospitalization)
6. There is no fixed address for follow-up
7. Patients with moderate to severe visual or hearing impairment
8. Early limitation of therapeutic effort

Intervention

Enrolled participants included in the intervention will receive a systematic and periodic spiritual care program using the FICA Spiritual Assessment Tool (**F**aith and Belief, **I**mportance and Influence, **C**ommunity, and **A**ddress in Care) [41]. The intervention dosage entails three SC sessions to be conducted remotely via by volunteers who have undergone explicit training for the intervention. Each SC session will last between 45 and 60 minutes, occurring every other day over one week. The SC that will be provided does not adhere to any particular creed, thereby constituting an ecumenical intervention. The SC intervention proposed in this study has three distinctive characteristics: (1) it is systematic and periodic, which is achieved through a standardized schedule of 3 SC sessions based on the FICA Spiritual Assessment Tool (see below); (2) care is delivered by volunteers trained for the intervention (see Appendix 1), which is fundamental to ensure that

the intervention is systematic and standardized; (3) is delivered via telematics, thus preventing the need for volunteers to travel to the sessions.

To ensure compliance with these three characteristics, as a research team, we developed four critical components for the intervention: (1) Design of the SC sessions; (2) Generation and implementation of a training program for volunteers; (3) Creation of a manual for the volunteers; (4) Creation of a logbook for volunteers.

The SC sessions consider a 1:1 ratio (patient: companion), and participants will always be "accompanied" by the same volunteer. Although ideally, the entire intervention should be carried out while the patient is hospitalized in the ICU, considering the average stay of patients in the CASR ICU [42], the last session could be carried out after discharge from the unit in case it does not take place earlier. The sessions will last 45 to 60 minutes and will be coordinated by the research team, depending on the patients' and volunteers' availability and clinical condition. This coordination involves: (1) Scheduling of the day and time of the session. Within the systematization of the intervention, it has been defined that the sessions will take place from Monday to Friday until 20:00 hours. (2) Define whether they will be carried out via Zoom or video call. If Zoom is chosen, a researcher will generate and deliver the link to the participants and volunteers. A premium Zoom account is available for the project. (3) During the sessions, there will be a member of the research team close to the participant in case a problem arises that requires their advice or intervention, such as technological problems that affect connectivity and the development of the session, the need to re-coordinate a session that cannot be carried out, the need to support a participant or volunteer who is emotionally overwhelmed during a session, etc.

Regarding exploring spirituality through the FICA Spiritual Assessment Tool, the sessions are based on volunteers' application of the instrument developed by Dr. Christina Puchalski [41], which allowed the exploration of spirituality in the healthcare context. It was initially written in English but has a Spanish translation [43]. The FICA is a "spiritual anamnesis" that helps identify a person's spiritual needs and resources. By exploring spiritual needs through FICA, people can find/recognize elements of their lives that support them in difficult situations, such as having a serious illness. FICA proposes to explore four crucial dimensions of spirituality:

F: FAITH and beliefs.

I: Importance of faith and beliefs in my life.

C: Community, i.e., how important is my community, including my family, group of friends, co-workers, or other activities, in my living of faith and beliefs.

A: Focus of attention. This dimension may vary depending on who is asking. It refers to what the participant might ask the volunteer about SC during sessions.

Each session has specific objectives that the volunteers should consider for each session. In the first session, volunteers should get to know the patient in the context of the intervention and explore their spiritual needs through the FICA. Before applying for the FICA, volunteers should introduce themselves and ask about the biographical context of the participant. They can use questions such as: can you tell me a little about yourself, your family, etc.? They can also ask general questions about the experience of being hospitalized in the ICU, such as how you have felt, whether you had any experience as a patient or family member in the ICU before, etc. To apply the FICA, volunteers should ask patients questions about the four dimensions of this instrument. Beforehand, they should explain that these questions will help them explore their spiritual needs and resources to offer them adequate SC for what they are experiencing. This personalized but systematized SC is one of the advantages of having sessions based on the FICA. In Table 1, there are examples of questions that volunteers can use to apply FICA. Ideally, exploring the four dimensions of FICA should be completed during the first session. This can be completed in the second session if this is not achieved.

The objective of the second and third sessions is to deepen those dimensions of the FICA where the volunteer detected that the participant has more spiritual needs. However, it could happen that patients would like to talk about a topic that had not been previously discussed, to which the volunteers should be open, bearing in mind that SC implies "the encounter with someone who feels, who seeks, who needs to be heard and welcomed". In this sense, active listening on the part of the volunteer is critical in the three sessions of this intervention.

Before beginning the sessions, volunteers must sign a confidentiality agreement. In this agreement, they agree not to comment outside the context of the research project on anything the participants have told them during the intervention. Within the study, they will only be asked to briefly describe, in the volunteer diary (see Appendix 1), the application of the FICA, which will be explained to participants during the recruitment and informed consent process. However, suppose a volunteer detects that a patient is very emotionally compromised, which could

translate into a significant mental health problem in the context of ICU hospitalization. In that case, they should alert the research team. As a team, we will contact the patient and their treating physicians and activate a referral network for mental health specialists to evaluate them.

The comparison or control group is the standard care group in this trial. Participants in the standard care group can request the hospital's current care if necessary. It consists of the possibility of being assisted by a Catholic priest or being contacted by pastors from Protestant churches.

Outcomes

Primary outcomes

The primary outcomes are related to the feasibility of implementing the intervention in the conditions described above and the participants' satisfaction with the systematic and periodic spiritual care program.

The enrollment rate will be measured, corresponding to the proportion of patients who consent and are enrolled in the study during the first six months. The attendance rate will be evaluated through the proportion of patients attending at least three intervention sessions two weeks after randomization. Likewise, the follow-up rate will be measured by the proportion of patients who complete the evaluation three months after discharge from the ICU.

The participants' satisfaction with the intervention group will be measured through a satisfaction questionnaire one to two weeks and three months after the last session of the intervention.

Before starting each session, while the participant is still in the hospital, the CAM ICU (validated Chilean version) [44] will be applied to ensure that there are no symptoms of delirium so that the intervention can be conducted.

Secondary outcomes

Secondary outcomes will be the mean change of PTSD symptoms, anxiety, and depression from baseline to three and six months after recruitment (follow-up). PTSD will be assessed using the Impact of Event Scale (Chilean population version)[45] . This scale has a score from 0 to 88, defining a posttraumatic stress disorder with a score higher than 43. The Hospital Anxiety and Depression (HADS) instrument will be used, which has a depression subscale and an anxiety subscale. HADS is a self-assessment scale used to detect emotional distress (anxiety and depression) in the non-psychiatric population. It is a short instrument (14 items) that has shown its reliability and validity in Chile for diagnosis and assessment of

the severity of the disorder [46]. It comprises two subscales (HAD-A: anxiety and HAD-D: depression) of seven items, each with scores from 0 to 3. The authors recommend the original cut-off points: eight for possible cases and >10 for probable cases in both subscales. Outcomes assessment will be conducted by research assistants blinded to randomization assignment at three- and six-months post ICU discharge.

Other relevant outcomes will be the volunteers' satisfaction with the spiritual care intervention, measured by a satisfaction questionnaire one to two weeks after the end of the last SC session. Once the intervention is over, the perceptions of the participants, volunteers, and research team about the intervention, its components, training and recommendations, and difficulties encountered will be evaluated in three focus groups. We will invite subjects of interest to take part in focus groups (FG) to explore their perception of the facilitators and barriers of SC, according to their experience with the intervention. To facilitate the participation of patients, volunteers, and health personnel, the focus groups will be conducted via teleconferencing. We anticipate that the study will begin with approximately 24 participants from the three groups of interest: subjects who received the intervention, volunteers, and ICU health personnel during the study period. The initial sample size was determined based on the objectives of the study and the criteria for information saturation [47]. It is recommended that three focus groups be conducted, with eight to ten participants in each group. The FGs will be conducted by the research team and will be guided by a set of questions. Each session will last between 90 and 120 minutes and will be recorded and transcribed in full for subsequent analysis.

Participant timeline and recruitment

Patients will be examined in the morning to determine eligibility. Day 0 of the study corresponds to the day the informed consent is signed, where demographic and clinical data relevant to the study will be collected, psychological questionnaires will be administered, and the data collected will be documented on the case report form (CRF) by trained clinical research coordinators. Patients will be followed up during the ICU and hospital stay to record the mechanical ventilation days, ICU stay, and hospital stay. Patients will be evaluated three and six months after discharge from the ICU to record secondary outcomes. The assessment of psychological outcomes will be performed by evaluators who are

blinded to group assignments. The evaluation schedule for the trial is shown in Fig. 1.

To improve participants' adherence to the intervention and follow-up, the investigators will visit participants before each spiritual care session, and they will contact each other telephonically to coordinate the long-term follow-up session. If participants do not wish to attend the intervention sessions, we will inquire about their non-attendance and try to encourage compliance and attendance.

Sample size

Since these pilot studies work with small samples, estimating the sample calculation is unnecessary. However, to obtain some preliminary results of the effect of the intervention, a sample of 15 people per group will be recruited and followed up until six months after discharge, allowing us to evaluate changes over time in PICS symptoms. It is proposed that the intervention begin during hospitalization so that it will have a preventive nature and help mitigate the impact of ICU hospitalization on the development of mental health symptoms in patients. Participants will be randomly assigned to groups and evaluated considering their intention to treat.

Assignment of interventions

Once the Informed Consent is signed, the patients will be randomized to receive a systematic and periodic spiritual care program or standard care (control group). The randomization sequence will be generated by the Informatics Unit of the Faculty of Medicine of the Pontificia Universidad Católica de Chile through a computer program, and it will be carried out by random blocks of 5, with a 1:1 allocation. The allocation concealment will be achieved through a centralized randomization in REDCap [48,49] and implemented by our institution's informatics unit. The research staff will perform randomization. Due to the type of intervention under study, the patient and the research team cannot be blinded to group assignment. However, the statisticians, researchers responsible for data analysis, and those performing the long-term outcome evaluations will be blinded to group assignment.

Data collection and management

Study data were collected and managed using REDCap electronic data capture tools hosted at Pontificia Universidad Católica de Chile [48,49] REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for

validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. At the time of enrollment, study staff will collect information about each participant, including demographics, dates of hospital and ICU admission, and severity of illness according to the Acute Physiology and Chronic Illness Classification System II (APACHE II) [50], Chronic Health Assessment II and Sequential Organ Failure Assessment (SOFA) Score [51], comorbidities according to the Charlson Comorbidity Index [52], admission diagnoses, and pre-existing neuropsychological impairment. The Impact of Event Scale and Hospital Anxiety and Depression questionnaires will also be applied.

During each patient's stay in the ICU, data will also be collected on Sequential Organ Failure Assessment Score (SOFA), hemodialysis and vasopressor use, duration of mechanical ventilation, length of ICU, and hospital stay. All patients will undergo a standardized follow-up at three- and six-month post-ICU discharge, in which the Impact of Event Scale and Hospital Anxiety and Depression questionnaires will be administered telematically.

The research assistants will undergo training and certification procedures with a supervisor for quality assurance. The supervisor performs ongoing quality assurance checks at regular intervals. Subjects will be instructed to refrain from discussing their assigned intervention with the research assistants.

Statistical analysis

An independent statistical expert blinded to the group allocation will implement the statistical analysis.

Baseline characteristics will be reported using means ± standard deviation, medians (p25-75), and percentages. The use of parametric or nonparametric tests will depend on the data distribution. Continuous variables will be compared with the Student's t-test or the Mann-Whitney test, and categorical variables will be compared with the chi-squared test. A p-value < 0.05 will be considered for statistical significance. To assess the effect of the intervention on psychological outcomes, multilevel multivariate random intercept models will be used for the proposed outcomes in successive tests verified over time, which will be defined as linear if the result is quantitative and logistic if the outcome is dichotomous. In addition, the model will be adjusted for confounding factors (age, sex, socioeconomic status, comorbidities, severity score, drug consumption, days of

mechanical ventilation, days of ICU stay, and days of hospital stay). An interaction between treatment and time will also be performed, assuming that outcomes may vary. The proposed models will be run using the "lme4" library of the free software R. Missing values due to participant withdrawals are expected. Methods such as multiple imputations will be utilized to improve precision and reduce bias in the estimates to deal with missing values. Sensitivity analysis will be performed, assuming different patterns of missingness in the data.

Regarding the qualitative analyses, the FGs will be analyzed using the strategy of thematic content analysis. This method allows for the identification and analysis of thematic patterns, with the creation of codes and categories. This enables the identification of contrasts and convergences. To this end, deductive coding will be employed to analyze the questionnaire's proposed thematic aspects, while inductive coding will be used for themes that emerge from the GF discussions. The level of analytical depth will be descriptive. The NVivo software will be used in accordance with the following criteria of rigor: triangulation, peer review, audit, reflection, and validation of participants.

Ethics and dissemination

This study has been approved by the Ethics Committee of the Faculty of Medicine of the Pontificia Universidad Católica de Chile and by the Ethics Committee of the Servicio de Salud Metropolitano Sur Oriente, which evaluates CASR research projects. Before recruitment, the participants will be informed of the study and sign the consent form. It will be done by a research team member who will not be involved in the participants' care.

Before beginning the SC sessions, the volunteers must sign a confidentiality agreement regarding what was discussed with the participants during these sessions. They will also be asked for consent and sign an informed consent document to analyze and disseminate the information generated regarding their satisfaction with the training and volunteer role.

Data collection and storage will be carried out securely, safeguarding each participant's anonymity and confidentiality. Participants will be identified with a specific code. Only members of the research team will have access to the information generated in this study.

Discussion

Spirituality is an intrinsic and fundamental aspect of human existence, which is why it has been incorporated into the definition of health. "Health is a state in

which a person is able to function well, physically, mentally, socially, and spiritually, to fully express his or her potential within the environment in which he or she lives" [53]. Spirituality is related to religion, as many people live it through their faiths; however, the two are not synonymous, and there are other ways of living spirituality, such as through a connection with nature or the cosmovision of native peoples [53]. The current evidence base indicates that SC interventions in the ICU can improve clinical outcomes in critically ill patients [32]. However, the studies conducted have based SC on religiosity and faith, which may limit the generalizability of the findings [54,55]. In this context, this study represents a novel contribution to the field, as it is the first randomized trial in Chile to investigate SC. As a research team, it seems necessary to establish a systematic and standardized approach to this type of intervention, ensuring that its effects are attributed to the intervention itself and not to external factors. Moreover, this would facilitate the reproducibility of the intervention in other ICUs. It is also noteworthy that the SC will be administered by trained volunteers, which may contribute to the sustainability of SC in the local context.

Prior to undertaking a larger randomized clinical trial comparing a Sc intervention with standard care in critically ill patients, with sufficient statistical power to assess outcomes of importance to patients, a pilot trial is required. The greatest perceived threat to the feasibility of this pilot trial is non-adherence to the protocol. Several measures have been taken to enhance protocol adherence, including the provision of intervention support staff, comprehensive training of volunteers, and the implementation of compliance checks to facilitate the study intervention. The results of this pilot trial will demonstrate the feasibility of delivering the study intervention as outlined. Attainment of the threshold consent rate will substantiate the trial's acceptability to both patients and clinicians. Ultimately, the recruitment parameters will assist in estimating the requisite number of sites, time period, and resources for conducting the main trial in an efficient manner.

The design of this study is not free of limitations. First, participants and treatment providers are not blinded, as a simulated spiritual companionship program cannot be implemented in this trial. Therefore, when interpreting the study results, the effects that other factors, such as participant expectations or the patient-volunteer relationship, may have had on the psychological outcomes must be considered. Secondly, this is not a multicenter study, so the results cannot be generalized. However, no studies have been published on preventing PICS through SC

performed by trained volunteers. A study conducted in a single center with a pilot experimental design seems adequate. Finally, the sample size of this trial is small (15 individuals per group) to examine the efficacy of SC for long-term psychological outcomes (PTSD, anxiety, and depression). This study is a pilot study to explore the effectiveness of SC in preventing psychological impairment and the feasibility of a large-scale clinical trial. The result of this study may have preliminary data for further full-scale randomized controlled trials to obtain strong evidence on the effectiveness of SC in preventing psychological impairment in critically ill patients.

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Authors' contributions:

L.A., C.R., P.O., P.R., and V.R. designed the study. CR and PR supervise the clinical research and recruitment and treatment of participants. L.A. and P.R. are responsible for the statistical analysis. C.R., P.O., V.R., and JB contributed to the analysis and data interpretation. L.A., P.R., and C.R. drafted the manuscript, while all other authors critically revised the manuscript for important intellectual content. LA is responsible for the overall content as guarantor. All authors read and approved the final manuscript.

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Competing interest

The authors declared that they had no competing interests. The funding agency had no role in developing the study design, collection, analysis, interpretation of data, manuscript development, or the decision to submit the manuscript.

Patient and public involvement

Patients and/or the public were not involved in this research's design, conduct, reporting, or dissemination plans.

FIGURE LEGENDS

Fig 1. Timeline of recruitment, allocation, and assessment. -t1: Baseline; t1: Each day until ICU discharge; t2: Hospital discharge; t3: 3 months follow-up; t4: 6 months follow-up. Abbreviations: ICU Intensive Care Unit; LOS Length of stay; HADS Hospital Anxiety and Depression Scale; IES Impact of Event Scale.

TABLES

Table 1: Examples of possible questions for each FICA dimension [56]

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Figure 1. Timeline of recruitment, allocation, and assessments

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	T_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Program of Spiritual Care			⟷	⟷		
ASSESSMENTS:						
Demographics information and comorbidities	X					
Record Daily ICU interventions and events			X			
ICU and hospital LOS				X		
Psychological impairment (IES, HADS)	X				X	X

Training program for volunteers

The training program for volunteers is described below.

A training program was developed for standardized volunteer training, ensuring the intervention is effectively systematic. In addition to being trained in FICA, the volunteers received training in (program contents) active listening, asking and affirming skills, psychological first aid, psychoeducation, spirituality, spiritual accompaniment, ICU care, and PICS.
Before beginning the training, a group of volunteers will be selected. For this purpose, a call will be made through social networks and e-mails explaining what the project consists of and what the role of the volunteers would be in the accompaniment and SC. It is expected to recruit at least ten volunteers, so each must accompany 1 to 2 participants, according to the study's design. This program, like the proposed intervention, was developed telematically and included:
1) Eleven narrated capsules with the contents of the program are available on the Google Classroom platform.
2) Nine Zoom sessions of 1.5 to 2 hours, in which the volunteers could resolve doubts and practice spiritual accompaniment through the role-playing strategy using scenarios developed by the research team. The volunteers will be divided into small groups (4 to 6 members).
3) Information about how the program will be delivered, zoom use, and contact information, among other practical tips.

Volunteer Manual

It consists of a guide that summarizes the contents of the training program. It also provides recommendations to facilitate the development of the accompaniment and SC sessions. These recommendations outline how to develop the sessions with resources such as Tables 1 and 2. The manual will be sent by e-mail (PDF format) to the volunteers at the end of the training. It will also be available on the Google Classroom and content capsules.

Volunteer's logbook

After each accompaniment and SC session, volunteers must complete the volunteer logbook (to be completed online via Google Docs) with the most relevant aspects of the sessions. For this, volunteers will have to answer some questions:
1) Generalities of the sessions: How they were developed (platform used), their duration, whether there were any connection and/or audio problems, etc.
2) Regarding the FICA: How was its application? Could it be completed in the first session, or was it completed in the second session? In addition, they will have to describe what the participant tells them about each dimension briefly, but taking special care that this description does not go into details that imply the loss of confidentiality. After the second and third sessions, they must explain which dimension of the FICA they took up again.

3) About the participant and their role as companions: How was the patient (calm, with some degree of emotional lability, very labile, etc.) during the session? How did they feel as volunteers (overwhelmed, calm, helpful, etc.)?

4) Regarding what was learned in the training: What elements of those learned in the training (active listening, psychological first aid, psychoeducation, spirituality, etc.) did they apply, and did they help them guide the sessions?
The logbook has multiple choice questions, questions that are answered using the Likert Scale (depending on how much the volunteer agrees or disagrees with the statement), and others whose response considers the possibility of free text.

Table 1: Examples of possible questions for each FICA dimension (1)

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked

	something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Table 2 summarizes the recommendations that volunteers should remember for the accompaniment and spiritual care sessions. This was explained to them during the training and is available as reference material in the volunteer manual.

Table 2: Recommendations to be considered by the volunteers for the development of the spiritual care and accompaniment sessions (1)

Accompanying component	Recommendations
First session	• Introduce yourself and make sure you are talking to the right person (good afternoon, I am AAA, you are Mrs. BBB?). • Explain to the participant the objective of the session (during recruitment, the research team will have explained to the patient about the accompaniment sessions and the objectives; however, it is important that each volunteer remind them especially about the first session). • Reinforce to the patient that the sessions imply a space of trust and confidentiality, so he/she will not discuss what he/she hears with other people.
Aspects to consider in all sessions	• Remember that the accompaniment has to be centered on the needs of the patient , being very important that as an accompanier to "be fully present'' during the sessions. • Spirituality, pain and, suffering are intimate, so show empathy and do not interrupt the patient when he/she is telling something. Likewise, share the silences that the patient makes.

	• During the sessions it is essential to show respect for the patient's values and beliefs, listening attentively as he/she shares them. If she/he asks you about your religion and beliefs, you can share them. It may also happen that you have beliefs in common, which we invite you to use as an element that enriches the sessions. • Do not judge the participant by what he or she tells you. This does not mean denying their convictions and values, but it does mean distinguishing between your own beliefs and what is important to her/him. • Use active listening, welcoming and validating what she/he tells you. • Avoid the temptation to offer solutions that you cannot guarantee in the face of the relative's suffering (avoid phrases such as "don't worry, everything will be fine"). It is important to remain calm in the face of uncertainty. Often, during the accompaniment, you will not have the answer that the patient, but remember that accompaniment is based on "being there for the other". • If the patient presents significant emotional lability, you can apply the stabilization exercises learned during the trainings, such as breathing exercises. If the patient shows significant distress, you can also ask for help from the support team available in the hospital. • Avoid wanting to lead the patient to your own religious or spiritual beliefs. Therefore, respect their emotional and spiritual limits. • Remember that these meetings are based on trust that the patient will have with you as a companion, so we reinforce the importance of confidentiality. • We suggest that you try to accept, if it occurs, an invitation from the patient to pray, pray, sing or participate in some religious or spiritual rite, in the context of the telematic accompaniment that you are providing.
Closing of the sessions	• At the end of a session (remember that these sessions should not last more than 1 hour, both for your time and the patient's time), you can briefly recap what you have discussed. • Remember to thank the patient for his or her time and define when your next meeting might be. The study team will coordinate the sessions, but it is important that you, as a volunteer, can confirm the most suitable days and times for you and the family member.

	• If you are closing the third session, remember to especially thank the patient for sharing his or her beliefs, values and convictions with you.
Technical aspects	Prior to the beginning of the sessions, check how your internet connection is, because a bad connection will make it difficult to carry out the session (Zoom or Video Call). It is also important that you check that the audio and camera of the device you will be using are adequate. In the volunteer's manual you will find more information in the "Technical Guide" section. • Both you and the patient need to be in a comfortable and quiet place for the sessions; noises or interruptions may hinder your development. Please check this before starting the session. • The research team will explain these aspects to the patients, and health personnel when coordinating the sessions. • If the patient health condition does not allow to attend the session, you will be notified promptly, and the session will be rescheduled.

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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomized controlled pilot trial.

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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomized controlled pilot trial.

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ABSTRACT

Introduction: A significant number of critically ill patients who survive their illness will experience new sequelae or a worsening of their baseline health status following their discharge from the hospital. These consequences may be physical, cognitive, and/or psychological and have been labeled Post Intensive Care Syndrome (PICS). Prior research has demonstrated that spiritual care (SC) aligned with a specific creed during hospitalization in the Intensive Care Unit (ICU), as part of a comprehensive care plan, may be an effective strategy for preventing psychological sequelae in surviving critically ill patients. However, there is a gap in the clinical literature regarding the effectiveness of generalist spiritual care in preventing psychological sequelae associated with PICS. This pilot study aims to explore the feasibility of implementing a generalist spiritual care strategy in the ICU and to evaluate its preliminary effectiveness in preventing anxiety and depression symptoms and posttraumatic stress disorder in critically ill patients.

Methods and analysis: This is a single-site, feasibility, randomized controlled pilot trial of a generalist spiritual care intervention, which is being compared with the current standard of care. A total of 30 adults who are critically ill and have undergone invasive mechanical ventilation for a minimum of 72 hours without an alteration in consciousness will be randomly assigned to either the spiritual care (SC) group or the usual care group at a ratio of 1:1. The primary outcome will be the feasibility and acceptability of the SC strategy in critically ill patients. Secondary aims include evaluating the differences in anxiety and depression symptoms and posttraumatic stress disorder between the spiritual care group and the usual care control group at three months after ICU discharge. Subjects will be followed up until three months post-ICU discharge.

Ethics and dissemination: Ethical approval was obtained from the Ethics Committee for Medical Sciences of the Pontificia Universidad Católica de Chile (#220111005) and by the Ethics Committee of the Servicio de Salud Metropolitano Sur Oriente. The study has been funded by Pontificia Universidad Católica de Chile (project number #105699/DPCC2021). Study findings will be disseminated widely in peer-reviewed publications, academic conferences, local community-based presentations, partner organizations, and the Chilean Intensive Care Society.

Trial registration number NCT06048783.

Article Summary

Strengths and limitations of this study

- To the best of our knowledge, this pilot study will be the first randomized controlled trial to explore the feasibility, acceptance, and efficacy of a spiritual care program in the prevention of post-ICU syndrome in surviving critically ill patients.
- This study will evaluate anxiety, depression, and post-traumatic stress disorder, which will support the clinical efficacy of spiritual care programs in surviving critically ill patients.
- Mixed-effects analyses will discriminate possible differences due to baseline characteristics and intervention variations.
- Due to the nature of the intervention, participants and practitioners will not be blinded.
- As a single-center study, the result must be confirmed in a large-scale multicenter study.

Introduction

The incidence of critical illness has increased due to the aging of the chronically ill population. Additionally, emerging viruses and bacteria, such as COVID-19, have resulted in an unprecedented increase in critically ill patients. At the same time, advances in intensive care medicine and critical care have decreased the mortality of critically ill patients [1]. Many patients who survive a critical illness suffer physical, psychological, and cognitive problems, which have been termed Post-ICU Syndrome (PICS)[2,3]. One study reported that, regardless of whether ICU admission was for a medical problem, urgent surgical intervention, or elective intervention, > 40% of ICU survivors experienced new or worsened deterioration of their physical, cognitive, and/or mental health status after hospital discharge [4]. The specific prevalence of different sequelae after critical illness varies depending on the population studied, how long post-ICU discharge assessments are performed, and the instruments used for evaluation [1]. The incidence of physical sequelae was evaluated in a systematic review that included 33 studies, with 1,080 of 2,686 patients (43%) meeting the criteria for acquired critical patient weakness (ICUAW) [5]. However, the studies used different methods to assess ICUAW (e.g., physical examination, electrophysiologic testing, histologic assessment), leading to variation in the incidence of ICUAW between studies. Regarding cognitive sequelae, a recent systematic review of 46 studies indicates that the prevalence of cognitive impairment ranges from 35 (subjective assessment) to 81% (objective assessment) at 3 months post ICU discharge [6]. Psychological symptoms of PICS include symptoms of depression, anxiety, and posttraumatic stress disorder (PTSD)[7]. The reported prevalence of anxiety ranges from 12 to 43%, depressive symptoms from 10 to 30%, and PTSD from 5 to 64%. It is estimated that at least 50% of ICU survivors will present psychological symptoms of PICS at discharge, and other studies report that a quarter of survivors present with PTSD symptoms one year after discharge from the ICU [8–10]. Some studies have reported a residual effect several months after discharge from the ICU, affecting people's quality of life and functionality [3]. Risk factors for PICS are categorized into modifiable and non-modifiable. Non-modifiable risk factors include older age, female gender, severity of illness, delirium, and mechanical ventilation. For mental health disorders related to PICS, specific risk factors for three major mental health disorders are (1) depression, older age, and female sex; (2) anxiety, older age, and a "negative ICU

experience"; and (3) PTSD, higher severity of illness and a "negative ICU experience" [1]. These statistics suggest that it is a prevalent problem among patients who receive ICU care, and modifiable risk factors such as "ICU experience" could be the focus of interventions designed to improve aspects of PICS. For example, given that a "negative ICU experience" is associated with anxiety symptoms and PTSD, ICUs might consider implementing and evaluating interventions that improve this experience to address PICS [11–14].

In the last decade, interest in spirituality and spiritual care in ICUs has grown [15–17]. Spiritual care among participants in some studies is potentially a measure of healthcare quality [18]. Studies show that quality care in the ICU includes attention to the person [19]. Spiritual care in the ICU has usually been associated with end-of-life care. However, admission into an ICU is a stressful experience that produces psychological and emotional suffering; in this context, most patients and family members feel vulnerable and, therefore, require not only physical healing but also emotional and spiritual attention [20,21]. Studies have reported that patients who need care in the ICU are especially likely to affirm that spirituality is important to them [18,22,23]. However, this cannot be generalized to all critically ill patients.

According to Puchalski [24], spirituality is a dynamic and intrinsic aspect of humanity through which persons seek ultimate meaning, purpose, and transcendence and experience relationships to self, family, others, community, society, nature, and the significant or sacred. Spirituality is expressed through beliefs, values, traditions, and practices. While "connection," "meaning and purpose of the person's life," and "transcendence" are the three essential elements when defining spiritual care [16,25,26]. Spiritual care (SC) recognizes and pays attention to spirituality within health care. Spiritual care can be provided by spiritual caregivers or chaplains who are trained to deliver spiritual care in clinical settings. It is recommended that spiritual care be provided by an interdisciplinary team, with each member assuming responsibility for spiritual care. As a trained spiritual care expert, the chaplain would lead this team. However, it is preferable that all healthcare professionals, including the chaplain, interact with each other to develop and implement the patient's spiritual care plan in a fully collaborative model [24]. However, ICU staff (intensivists and ICU nurses) often leave the spiritual needs of patients and/or their families to the spiritual caregiver or the patient’s parish clergy, as they consider them better qualified to address such

issues due to scheduling or lack of experience [27]. Although spirituality is important to most patients with severe illness and their relatives and can influence medical decision-making, it is not common for ICUs to standardize SC methods to incorporate assessments of the spiritual needs of patients and/or their families in the ICU [19,23]. A growing number of studies show that the organization of spiritual care in the ICU can be improved and become an integral part of daily ICU care based on holistic care [28–31].

In studies on patients with chronic diseases, SC has been associated with hope, meaning, and peace, causing essential relief among them. In critically ill patients, the spiritual dimension is related to quality of life from the perspective of patients and their families, especially in coping with severe and potentially life-threatening illnesses [19]. Studies in ICUs show that, from the perspective of healthcare professionals, providing spiritual care to ICU patients and their families has positive effects in four areas: 1) diagnosing and addressing the spiritual and emotional needs of patients and their families; 2) providing spiritual comfort to patients in distress; 3) increasing the spiritual well-being of patients and their families; and 4) increasing family satisfaction with ICU care in general and with decision-making in the ICU in particular [17,19,26,27]. A recent systematic review on the impact of spiritual care interventions in critically ill patients included 18 interventional studies (quasi-experimental or randomized clinical trials), all conducted in Asian countries, where the control group received the standard care of the center and the spiritual care intervention mainly was associated with a particular creed, provided by spiritual caregivers or nurses, and the outcomes of interest varied. This study showed that SC interventions could significantly reduce mean blood pressure and ICU length of stay and improve ICU patients' awareness, anxiety, spiritual well-being, and comfort.

Furthermore, ICU professionals have recognized SC as positive, contributing to patients' and their families' psychological well-being and satisfaction [32]. Hospitalization is a significant stressor that can impact patients' physical and mental health, which is often experienced as overwhelming and threatening to their well-being. According to the transactional stress model, spirituality serves as a coping mechanism and can mitigate the effects of stressful events [33]. Specifically, it can ease the burden of hospitalization and alleviate psychological and emotional distress [34,35]. Spirituality can offer protection against anxiety and depression by providing a sense of meaning, purpose, and hope, especially

during demanding times such as physical illness or hospitalization [36]. Consequently, patients who do not receive spiritual care may experience hospitalization as a significant stressor, with fewer tools to cope with this event, present more emotional and psychological distress, and therefore have a greater risk for adverse mental health outcomes.

However, spiritual care is frequently not part of the care patients receive in the ICU and many other hospital areas because clinicians do not have time, do not consider attention to spiritual needs as their responsibility, or are uncomfortable discussing spirituality with patients [37]. On the other hand, not all hospitals and ICUs have spiritual caregivers or chaplains.

Considering that, the proposed study aims to evaluate the feasibility of implementing a spiritual care intervention for patients who received care in the ICU and to assess the effects of the intervention on psychological disorders (anxiety, depression, and PTSD) in critically ill patients. The study will provide information regarding the feasibility of implementing an intervention of this type in this context. It will permit obtaining some preliminary results on the effect of the intervention. Showing spiritual care's impact on individuals' health outcomes through studies like this one may contribute to a paradigm shift from a biomedical perspective to a holistic view of ICU patients. Although the technological and advanced life support offered by the ICU is essential for critically ill patients, survival of a severe disease without a good quality of life makes it necessary to seek strategies to improve this problem, which undoubtedly requires a comprehensive approach to the person, through medical-physiological care and spiritual care. The study protocol is described below, with emphasis on the proposed intervention.

Methods

Study design and setting

This protocol is described as required by the 2013 SPIRIT guidelines [38] to ensure consistent reporting of clinical trials. The trial is a single-site pilot feasibility randomized controlled trial. A total of 30 patients will be enrolled, and 15 subjects will be randomized to each arm. The recruitment of patients will be between December 2024 and July 2025.

The study is aimed at the patients hospitalized in the ICU of the Complejo Asistencial Dr. Sótero del Río (CASR) in Santiago, Chile. The CASR is a highly complex public hospital with an assigned population of approximately 1.5 million

inhabitants [39]. The ICU has 36 beds, and complicated procedures such as ECMO (extracorporeal membrane oxygenation), multimodal neuromonitoring, invasive hemodynamic monitoring, etc., can be performed. The ICU has a staff of professionals (physicians, nurses, kinesiologists, speech therapists, occupational therapists, clinical pharmacologists, etc.) trained in intensive care medicine.

Eligibility criteria

Critically ill patients are eligible for participation based on the following inclusion and exclusion criteria:

Inclusion Criteria

1. Adult patients (≥ 18 years)
2. Patients who have had at least 72 hours of Invasive Mechanical Ventilation (IMV)
3. Patient is currently in the ICU
4. Glasgow 15 [40] at the moment of the screening

Exclusion Criteria:

1. Presence of mental or intellectual disability before hospitalization or communication/language barriers
2. Patient with primary neurological or neurosurgical disease
3. Patient who required IMV in another episode of hospitalization in the two months before screening
4. Pre-existing comorbidity with a life expectancy not exceeding six months (e.g., metastatic cancer)
5. Readmission to the ICU (patients will be included if they are on their first ICU admission to the present hospitalization)
6. There is no fixed address for follow-up
7. Patients with moderate to severe visual or hearing impairment
8. Early limitation of therapeutic effort

Intervention

Enrolled participants included in the intervention will receive a systematic and periodic generalist spiritual care (GSC) program using the FICA Spiritual Assessment Tool (**F**aith and Belief, **I**mportance and Influence, **C**ommunity, and **A**ddress in Care) [41]. The intervention dosage entails three GSC sessions to be conducted remotely by volunteers who have undergone explicit training for the intervention. Each SC session will last between 45 and 60 minutes, occurring every other day over one week. The GSC that will be provided does not adhere to any

particular creed; that is, it provides spiritual care and attention in its broadest sense, respecting the dignity, humanity, individuality, and diversity of people whose cultures, faiths, and beliefs coexist in society. The GSC intervention proposed in this study has three distinctive characteristics: (1) it is systematic and periodic, which is achieved through a standardized schedule of 3 GSC sessions based on the FICA Spiritual Assessment Tool (see below); (2) care is delivered by volunteers trained for the intervention (see Appendix 1), which is fundamental to ensure that the intervention is systematic and standardized; (3) is delivered via telematics, thus preventing the need for volunteers to travel to the sessions.

To ensure compliance with these three characteristics, as a research team, we developed four critical components for the intervention: (1) Design of the GSC sessions; (2) Generation and implementation of a training program for volunteers; (3) Creation of a manual for the volunteers; (4) Creation of a logbook for volunteers.

The GSC sessions consider a 1:1 ratio (patient: companion), and participants will always be "accompanied" by the same volunteer. Although ideally, the entire intervention should be carried out while the patient is hospitalized in the ICU, considering the average stay of patients in the CASR ICU [42], the last session could be carried out after discharge from the unit in case it does not take place earlier. The sessions will last 45 to 60 minutes and will be coordinated by the research team, depending on the patients' and volunteers' availability and clinical condition. This coordination involves: (1) Scheduling of the day and time of the session. Within the systematization of the intervention, it has been defined that the sessions will take place from Monday to Friday until 20:00 hours. (2) Define whether they will be carried out via Zoom or video call. If Zoom is chosen, a researcher will generate and deliver the link to the participants and volunteers. A premium Zoom account is available for the project. (3) During the sessions, there will be a member of the research team close to the participant in case a problem arises that requires their advice or intervention, such as technological problems that affect connectivity and the development of the session, the need to re-coordinate a session that cannot be carried out, the need to support a participant or volunteer who is emotionally overwhelmed during a session, etc.

Regarding exploring spirituality through the FICA Spiritual Assessment Tool, the sessions are based on volunteers' application of the instrument developed by Dr. Christina Puchalski [41], which allowed the exploration of spirituality in the

healthcare context. It was initially written in English but has a Spanish translation [43]. The FICA is a "spiritual anamnesis" that helps identify a person's spiritual needs and resources. By exploring spiritual needs through FICA, people can find/recognize elements of their lives that support them in difficult situations, such as having a serious illness. FICA proposes to explore four crucial dimensions of spirituality:

F: FAITH and beliefs.

I: Importance of faith and beliefs in my life.

C: Community, i.e., how important is my community, including my family, group of friends, co-workers, or other activities, in my living of faith and beliefs.

A: Focus of attention. This dimension may vary depending on who is asking. It refers to what the participant might ask the volunteer about SC during sessions.

Each session has specific objectives that the volunteers should consider for each session. In the first session, volunteers should get to know the patient in the context of the intervention and explore their spiritual needs through the FICA. Before applying for the FICA, volunteers should introduce themselves and ask about the biographical context of the participant. They can use questions such as: can you tell me a little about yourself, your family, etc.? They can also ask general questions about the experience of being hospitalized in the ICU, such as how you have felt, whether you had any experience as a patient or family member in the ICU before, etc. To apply the FICA, volunteers should ask patients questions about the four dimensions of this instrument. Beforehand, they should explain that these questions will help them explore their spiritual needs and resources to offer them adequate GSC for what they are experiencing. This personalized but systematized GSC is one of the advantages of having sessions based on the FICA. In Table 1, there are examples of questions that volunteers can use to apply FICA. Ideally, exploring the four dimensions of FICA should be completed during the first session. This can be completed in the second session if this is not achieved.

The objective of the second and third sessions is to deepen those dimensions of the FICA where the volunteer detected that the participant has more spiritual needs. However, it could happen that patients would like to talk about a topic that had not been previously discussed, to which the volunteers should be open, bearing in mind that GSC implies "the encounter with someone who feels, who seeks, who needs to be heard and welcomed [41]." In this sense, active listening on the part of the volunteer is critical in the three sessions of this intervention.

Before beginning the sessions, volunteers must sign a confidentiality agreement. In this agreement, they agree not to comment outside the context of the research project on anything the participants have told them during the intervention. Within the study, they will only be asked to briefly describe, in the volunteer diary (see Appendix 1), the application of the FICA, which will be explained to participants during the recruitment and informed consent process. However, suppose a volunteer detects that a patient is very emotionally compromised, which could translate into a significant mental health problem in the context of ICU hospitalization. In that case, they should alert the research team. As a team, we will contact the patient and their treating physicians and activate a referral network for mental health specialists to evaluate them.

Before starting each session, while the participant is still in the hospital, the Confusion Assessment Method for the Intensive Care Unit (CAM- ICU) (validated Chilean version) [44] will be applied to ensure that there are no symptoms of delirium so that the intervention can be conducted. CAM-ICU is a tool that has been specifically designed to assess confusional syndrome in the context of ICU patients, including those who are on mechanical ventilation [45].

The comparison or control group is the standard care group in this trial. Participants in the standard care group can request the hospital's current care if necessary. It consists of the possibility of being assisted by a Catholic priest or being contacted by pastors from Protestant churches.

Outcomes measures

Primary outcomes

In light of the study's nature as a feasibility and pilot investigation, the primary outcomes are focused on the viability of implementing the intervention within the aforementioned conditions and the participants' satisfaction with the systematic and periodic generalist spiritual care program.

The enrollment rate will be measured, corresponding to the proportion of patients who consent and are enrolled in the study during the first six months. The attendance rate will be evaluated through the proportion of patients receiving at least three intervention sessions two weeks after randomization. Likewise, the follow-up rate will be measured by the proportion of patients who complete the evaluation three months after discharge from the ICU.

The participants' satisfaction with the intervention group will be measured through a satisfaction questionnaire (see appendix 2) one to two weeks and three months after the last session of the intervention.

Secondary outcomes

Secondary outcomes will be the mean change of PTSD symptoms, anxiety, and depression from baseline to three and six months after recruitment (follow-up). PTSD will be assessed using the Impact of Event Scale (Chilean population version)[46]. This scale has a score from 0 to 88, with a cut-off score higher than 43. The Hospital Anxiety and Depression (HADS) instrument will be used, to assess depression and anxiety. HADS is a self-assessment scale used to evaluate anxiety and depression in the non-psychiatric population. It is a short instrument (14 items) that has shown its reliability and validity in Chile for diagnosis and assessment of the severity of the disorder [47]. It comprises two subscales (HAD-A: anxiety and HAD-D: depression) of seven items, each with scores from 0 to 3. The authors recommend the following cut-off points: eight for possible cases and >10 for probable cases in both subscales. Outcomes assessment will be conducted by research assistants blinded to randomization assignment at three- and six-months post ICU discharge.

Other relevant outcomes will be the volunteers' satisfaction with the generalist spiritual care intervention, measured by a satisfaction questionnaire one to two weeks after the end of the last GSC session. Once the intervention is over, the perceptions of the participants, volunteers, and research team about the intervention, its components, training and recommendations, and difficulties encountered will be evaluated in three focus groups (FG), one for patients, another for volunteers, and the third one with health personnel. We will invite participants to focus groups (FG) to explore their perception of the facilitators and barriers of GSC according to their experience with the intervention (See Appendix 3). The FG will be conducted via teleconferencing [48] to facilitate the participation of patients, volunteers, and health personnel. The research team will perform the FGs and be guided by a script. Each session will last between 90 and 120 minutes and will be recorded and transcribed in full for subsequent analysis. To analyze this material, we will use thematic analysis.

Participant timeline and recruitment

Patients will be examined in the morning to determine eligibility. Day 0 of the study corresponds to the day the informed consent is signed, where demographic

and clinical data relevant to the study will be collected, psychological questionnaires will be administered, and the data collected will be documented on the case report form (CRF) by trained clinical research coordinators. Patients will be followed up during the ICU and hospital stay to record the mechanical ventilation days, ICU stay, and hospital stay. Patients will be evaluated three and six months after discharge from the ICU to record secondary outcomes. The assessment of psychological outcomes will be performed by evaluators who are blinded to group assignments. The evaluation schedule for the trial is shown in Fig. 1.

To improve participants' adherence to the intervention and follow-up, the investigators will visit participants before each generalist spiritual care session, and they will contact each other telephonically to coordinate the long-term follow-up session. If participants do not wish to attend the intervention sessions, we will inquire about their non-attendance and try to encourage compliance and attendance.

Sample size

Since these pilot studies work with small samples, estimating the sample calculation is unnecessary. However, to obtain some preliminary results of the effect of the intervention, a sample of 15 people per group will be recruited and followed up until six months after discharge, allowing us to evaluate changes over time in PICS symptoms. It is proposed that the intervention begin during hospitalization so that it will have a preventive nature and help mitigate the impact of ICU hospitalization on the development of mental health symptoms in patients. Participants will be randomly assigned to groups and evaluated considering their intention to treat.

Regarding the FGs, we anticipate that the study will begin with approximately 24 participants from the three groups of interest: subjects who received the intervention, volunteers, and ICU health personnel during the study period. The initial sample size was determined based on the objectives of the study and the criteria for information saturation [48]. It is recommended that three focus groups be conducted, with eight to ten participants in each group.

Assignment of interventions

Once the Informed Consent is signed, the patients will be randomized to receive a systematic and periodic generalist spiritual care program or standard care (control group). The randomization sequence will be generated by the Informatics

Unit of the Faculty of Medicine of the Pontificia Universidad Católica de Chile through a computer program, and it will be carried out by random blocks of 5, with a 1:1 allocation. The allocation concealment will be achieved through a centralized randomization in REDCap [49,50] and implemented by our institution's informatics unit. The research staff will perform randomization. Due to the type of intervention under study, the patient and the research team cannot be blinded to group assignment. However, the statisticians, researchers responsible for data analysis, and those performing the long-term outcome evaluations will be blinded to group assignment.

Data collection and management

Study data will be collected and managed using REDCap electronic data capture tools hosted at Pontificia Universidad Católica de Chile [49,50] REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. At the time of enrollment, study staff will collect information about each participant, including demographics, dates of hospital and ICU admission, and severity of illness according to the Acute Physiology and Chronic Illness Classification System II (APACHE II) [51], Chronic Health Assessment II and Sequential Organ Failure Assessment (SOFA) Score [52], comorbidities according to the Charlson Comorbidity Index [53], admission diagnoses, and pre-existing neuropsychological impairment. The Impact of Event Scale and Hospital Anxiety and Depression questionnaires will also be applied.

During each patient's stay in the ICU, data will also be collected on Sequential Organ Failure Assessment Score (SOFA), hemodialysis and vasopressor use, duration of mechanical ventilation, length of ICU, and hospital stay. All patients will undergo a standardized follow-up at three- and six-month post-ICU discharge, in which the Impact of Event Scale and Hospital Anxiety and Depression questionnaires will be administered telematically.

The research assistants will undergo training and certification procedures with a supervisor for quality assurance. The supervisor performs ongoing quality assurance checks at regular intervals. Subjects will be instructed to refrain from discussing their assigned intervention with the research assistants.

Statistical analysis

An independent statistical expert blinded to the group allocation will implement the statistical analysis.

Baseline characteristics will be reported using means ± standard deviation, medians (p25-75), and percentages. The use of parametric or nonparametric tests will depend on the data distribution. Continuous variables will be compared with the Student's t-test or the Mann-Whitney test, and categorical variables will be compared with the chi-squared test. A p-value < 0.05 will be considered for statistical significance. To assess the effect of the intervention on psychological outcomes, multilevel multivariate random intercept models will be used for the proposed outcomes in successive tests verified over time, which will be defined as linear if the result is quantitative and logistic if the outcome is dichotomous. In addition, the model will be adjusted for confounding factors (age, sex, socioeconomic status, comorbidities, severity score, drug consumption, days of mechanical ventilation, days of ICU stay, and days of hospital stay). An interaction between treatment and time will also be performed, assuming that outcomes may vary. The proposed models will be run using the "lme4" library of the free software R. Missing values due to participant withdrawals are expected. Methods such as multiple imputations will be utilized to improve precision and reduce bias in the estimates to deal with missing values. Sensitivity analysis will be performed, assuming different patterns of missingness in the data.

Regarding the qualitative analyses, the FGs will be analyzed using the thematic content analysis strategy [54]. This method allows for the identification and analysis of thematic patterns with the creation of codes and categories. This enables the identification of contrasts and convergences. To achieve this, deductive coding will be used to analyze the pre-defined thematic aspects from the questionnaire (e.g., Faith and Belief, Importance and Influence, Community, and Address in care), while inductive coding will be used to identify emerging themes from the FG discussions. The level of analytical depth will be descriptive. The NVivo® software (Version 11- QSR International Pty Ltd, Doncaster, Victoria, Australia) [55] will be used in accordance with the following criteria of rigor: triangulation, peer review, audit, reflection, and validation of participants.

Ethics and dissemination

This study has been approved by the Ethics Committee of the Faculty of Medicine of the Pontificia Universidad Católica de Chile and by the Ethics Committee of the

Servicio de Salud Metropolitano Sur Oriente, which evaluates CASR research projects. Before recruitment, the participants will be informed of the study and sign the consent form. It will be done by a research team member who will not be involved in the participants' care.

Before beginning the GSC sessions, the volunteers must sign a confidentiality agreement regarding what was discussed with the participants during these sessions. They will also be asked for consent and sign an informed consent document to analyze and disseminate the information generated regarding their satisfaction with the training and volunteer role.

Data collection and storage will be carried out securely, safeguarding each participant's anonymity and confidentiality. Participants will be identified with a specific code. Only members of the research team will have access to the information generated in this study.

Discussion

Spirituality is an intrinsic and fundamental aspect of human existence, which is why it has been incorporated into the definition of health. "Health is a state in which a person is able to function well, physically, mentally, socially, and spiritually, to fully express his or her potential within the environment in which he or she lives" [56]. Spirituality is related to religion, as many people live it through their faiths; however, the two are not synonymous, and there are other ways of living spirituality, such as through a connection with nature or the cosmovision of native peoples [56]. The current evidence base indicates that SC interventions in the ICU can improve clinical outcomes in critically ill patients [32]. However, the studies conducted have based SC on religiosity and faith, which may limit the generalizability of the findings [57,58]. In this context, this study represents a novel contribution to the field, as it is the first randomized trial in Chile to investigate GSC. As a research team, it seems necessary to establish a systematic and standardized approach to this type of intervention, ensuring that its effects are attributed to the intervention itself and not to external factors. Moreover, this would facilitate the reproducibility of the intervention in other ICUs. It is also noteworthy that the GSC will be administered by trained volunteers, which may contribute to the sustainability of GSC in the local context.

Prior to undertaking a larger randomized clinical trial comparing a GSC intervention with standard care in critically ill patients, with sufficient statistical power to assess outcomes of importance to patients, a pilot trial is required. The

greatest perceived threat to the feasibility of this pilot trial is non-adherence to the protocol. Several measures have been taken to enhance protocol adherence, including the provision of intervention support staff, comprehensive training of volunteers, and the implementation of compliance checks to facilitate the study intervention. The results of this pilot trial will demonstrate the feasibility of delivering the study intervention as outlined. Attainment of the threshold consent rate will substantiate the trial's acceptability to both patients and clinicians. Ultimately, the recruitment parameters will assist in estimating the requisite number of sites, time period, and resources for conducting the main trial in an efficient manner.

The design of this study is not free of limitations. First, participants and treatment providers are not blinded, as a simulated spiritual companionship program cannot be implemented in this trial. Therefore, when interpreting the study results, the effects that other factors, such as participant expectations or the patient-volunteer relationship, may have had on the psychological outcomes must be considered. Secondly, this is not a multicenter study, so the results cannot be generalized. However, no studies have been published on preventing PICS through GSC performed by trained volunteers. A study conducted in a single center with a pilot experimental design seems adequate. Finally, the sample size of this trial is small (15 individuals per group) to examine the efficacy of GSC for long-term psychological outcomes (PTSD, anxiety, and depression). This study is a pilot study to explore the effectiveness of GSC in preventing psychological impairment and the feasibility of a large-scale clinical trial. The result of this study may have preliminary data for further full-scale randomized controlled trials to obtain strong evidence on the effectiveness of GSC in preventing psychological impairment in critically ill patients.

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Authors' contributions:

L.A., C.R., P.O., P.R., and V.R. designed the study. CR and PR supervise the clinical research and recruitment and treatment of participants. L.A. and P.R. are responsible for the statistical analysis. C.R., P.O., V.R., and JB contributed to the analysis and data interpretation. L.A., P.R., and C.R. drafted the manuscript, while all other authors critically revised the manuscript for important intellectual content. LA is responsible for the overall content as guarantor. All authors read and approved the final manuscript.

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Competing interest

The authors declared that they had no competing interests. The funding agency had no role in developing the study design, collection, analysis, interpretation of data, manuscript development, or the decision to submit the manuscript.

Patient and public involvement

Patients and/or the public were not involved in this research's design, conduct, reporting, or dissemination plans.

FIGURE LEGENDS

Fig 1. Timeline of recruitment, allocation, and assessment. -t1: Baseline; t1: Each day until ICU discharge; t2: Hospital discharge; t3: 3 months follow-up; t4: 6 months follow-up. Abbreviations: ICU Intensive Care Unit; LOS Length of stay; HADS Hospital Anxiety and Depression Scale; IES Impact of Event Scale.

TABLES

Table 1: Examples of possible questions for each FICA dimension(58)

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Figure 1. Timeline of recruitment, allocation, and assessments

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	T_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Program of Spiritual Care			⟷	⟷		
ASSESSMENTS:						
Demographics information and comorbidities	X					
Record Daily ICU interventions and events			X			
ICU and hospital LOS				X		
Psychological impairment (IES, HADS)	X				X	X

Training program for volunteers

The training program for volunteers is described below.

A training program was developed for standardized volunteer training, ensuring the intervention is effectively systematic. In addition to being trained in FICA, the volunteers received training in (program contents) active listening, asking and affirming skills, psychological first aid, psychoeducation, spirituality, spiritual accompaniment, ICU care, and PICS.
Before beginning the training, a group of volunteers will be selected. For this purpose, a call will be made through social networks and e-mails explaining what the project consists of and what the role of the volunteers would be in the accompaniment and SC. It is expected to recruit at least ten volunteers, so each must accompany 1 to 2 participants, according to the study's design. This program, like the proposed intervention, was developed telematically and included:
1) Eleven narrated capsules with the contents of the program are available on the Google Classroom platform.
2) Nine Zoom sessions of 1.5 to 2 hours, in which the volunteers could resolve doubts and practice spiritual accompaniment through the role-playing strategy using scenarios developed by the research team. The volunteers will be divided into small groups (4 to 6 members).
3) Information about how the program will be delivered, zoom use, and contact information, among other practical tips.

Volunteer Manual

It consists of a guide that summarizes the contents of the training program. It also provides recommendations to facilitate the development of the accompaniment and SC sessions. These recommendations outline how to develop the sessions with resources such as Tables 1 and 2. The manual will be sent by e-mail (PDF format) to the volunteers at the end of the training. It will also be available on the Google Classroom and content capsules.

Volunteer's logbook

After each accompaniment and SC session, volunteers must complete the volunteer logbook (to be completed online via Google Docs) with the most relevant aspects of the sessions. For this, volunteers will have to answer some questions:
1) Generalities of the sessions: How they were developed (platform used), their duration, whether there were any connection and/or audio problems, etc.
2) Regarding the FICA: How was its application? Could it be completed in the first session, or was it completed in the second session? In addition, they will have to describe what the participant tells them about each dimension briefly, but taking special care that this description does not go into details that imply the loss of confidentiality. After the second and third sessions, they must explain which dimension of the FICA they took up again.

3) About the participant and their role as companions: How was the patient (calm, with some degree of emotional lability, very labile, etc.) during the session? How did they feel as volunteers (overwhelmed, calm, helpful, etc.)?

4) Regarding what was learned in the training: What elements of those learned in the training (active listening, psychological first aid, psychoeducation, spirituality, etc.) did they apply, and did they help them guide the sessions?
The logbook has multiple choice questions, questions that are answered using the Likert Scale (depending on how much the volunteer agrees or disagrees with the statement), and others whose response considers the possibility of free text.

Table 1: Examples of possible questions for each FICA dimension (1)

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked

	something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Table 2 summarizes the recommendations that volunteers should remember for the accompaniment and spiritual care sessions. This was explained to them during the training and is available as reference material in the volunteer manual.

Table 2: Recommendations to be considered by the volunteers for the development of the spiritual care and accompaniment sessions (1)

Accompanying component	Recommendations
First session	• Introduce yourself and make sure you are talking to the right person (good afternoon, I am AAA, you are Mrs. BBB?). • Explain to the participant the objective of the session (during recruitment, the research team will have explained to the patient about the accompaniment sessions and the objectives; however, it is important that each volunteer remind them especially about the first session). • Reinforce to the patient that the sessions imply a space of trust and confidentiality, so he/she will not discuss what he/she hears with other people.
Aspects to consider in all sessions	• Remember that the accompaniment has to be centered on the needs of the patient , being very important that as an accompanier to "be fully present'' during the sessions. • Spirituality, pain and, suffering are intimate, so show empathy and do not interrupt the patient when he/she is telling something. Likewise, share the silences that the patient makes.

	• During the sessions it is essential to show respect for the patient's values and beliefs, listening attentively as he/she shares them. If she/he asks you about your religion and beliefs, you can share them. It may also happen that you have beliefs in common, which we invite you to use as an element that enriches the sessions. • Do not judge the participant by what he or she tells you. This does not mean denying their convictions and values, but it does mean distinguishing between your own beliefs and what is important to her/him. • Use active listening, welcoming and validating what she/he tells you. • Avoid the temptation to offer solutions that you cannot guarantee in the face of the relative's suffering (avoid phrases such as "don't worry, everything will be fine"). It is important to remain calm in the face of uncertainty. Often, during the accompaniment, you will not have the answer that the patient, but remember that accompaniment is based on "being there for the other". • If the patient presents significant emotional lability, you can apply the stabilization exercises learned during the trainings, such as breathing exercises. If the patient shows significant distress, you can also ask for help from the support team available in the hospital. • Avoid wanting to lead the patient to your own religious or spiritual beliefs. Therefore, respect their emotional and spiritual limits. • Remember that these meetings are based on trust that the patient will have with you as a companion, so we reinforce the importance of confidentiality. • We suggest that you try to accept, if it occurs, an invitation from the patient to pray, pray, sing or participate in some religious or spiritual rite, in the context of the telematic accompaniment that you are providing.
Closing of the sessions	• At the end of a session (remember that these sessions should not last more than 1 hour, both for your time and the patient's time), you can briefly recap what you have discussed. • Remember to thank the patient for his or her time and define when your next meeting might be. The study team will coordinate the sessions, but it is important that you, as a volunteer, can confirm the most suitable days and times for you and the family member.

	• If you are closing the third session, remember to especially thank the patient for sharing his or her beliefs, values and convictions with you.
Technical aspects	Prior to the beginning of the sessions, check how your internet connection is, because a bad connection will make it difficult to carry out the session (Zoom or Video Call). It is also important that you check that the audio and camera of the device you will be using are adequate. In the volunteer's manual you will find more information in the "Technical Guide" section. • Both you and the patient need to be in a comfortable and quiet place for the sessions; noises or interruptions may hinder your development. Please check this before starting the session. • The research team will explain these aspects to the patients, and health personnel when coordinating the sessions. • If the patient health condition does not allow to attend the session, you will be notified promptly, and the session will be rescheduled.

Satisfaction Survey on Spiritual Care Intervention

Instructions:

1. Please select one option for each statement.
2. If you wish to leave a comment, you can use the last column.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Comment
The spiritual care program met your expectations.						
The spiritual care volunteer was empathetic and respectful.						
The one-on-one relationship (patient:volunteer) felt appropriate.						
The topics discussed during the sessions (e.g., meaning of suffering, uncertainty, death, life after life, ideas about healing, forgiveness, guilt, etc.) addressed your current concerns while hospitalized.						
You feel that during the spiritual care sessions you had adequate time to express yourself and ask questions.						
The duration of the spiritual care sessions (approximately 1 hour) was appropriate.						
The frequency of the spiritual care sessions (every other day) was appropriate.						
You believe that similar spiritual care programs should be implemented in other hospital services.						
You would recommend this spiritual care program to other ICU patients.						

Interview guides will guide focus groups.

Each focus group will discuss the following themes, and the emphasis will be adapted between patients, volunteers, and team members based on their role in the study.

1. Please describe your experience with the intervention.
2. What do you think are the most valuable parts of the intervention for helping patients? Explain why you think so.
3. Which components or strategies of the intervention do you believe may require revision?
4. What are your thoughts on the delivery format, time of day, number of sessions, and length of the intervention?
5. What are your thoughts on the training and tools required to carry out the intervention?
6. What difficulties did you encounter during the intervention?
7. What recommendations could you offer to improve intervention and training?
8. What would they change?
9. What would they keep?

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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomized controlled pilot trial.

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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomized controlled pilot trial.

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ABSTRACT

Introduction: A significant number of critically ill patients who survive their illness will experience new sequelae or a worsening of their baseline health status following their discharge from the hospital. These consequences may be physical, cognitive, and/or psychological and have been labeled Post Intensive Care Syndrome (PICS). Prior research has demonstrated that spiritual care (SC) aligned with a specific creed during hospitalization in the Intensive Care Unit (ICU), as part of a comprehensive care plan, may be an effective strategy for preventing psychological sequelae in surviving critically ill patients. However, there is a gap in the clinical literature regarding the effectiveness of generalist spiritual care in preventing psychological sequelae associated with PICS. This pilot study aims to explore the feasibility of implementing a generalist spiritual care strategy in the ICU and to evaluate its preliminary effectiveness in preventing anxiety and depression symptoms and posttraumatic stress disorder in critically ill patients.

Methods and analysis: This is a single-site, feasibility, randomized controlled pilot trial of a generalist spiritual care intervention, which is being compared with the current standard of care. A total of 30 adults who are critically ill and have undergone invasive mechanical ventilation for a minimum of 72 hours without an alteration in consciousness will be randomly assigned to either the spiritual care (SC) group or the usual care group at a ratio of 1:1. The primary outcome will be the feasibility and acceptability of the SC strategy in critically ill patients. Secondary aims include evaluating the differences in anxiety and depression symptoms and posttraumatic stress disorder between the spiritual care group and the usual care control group at three months after ICU discharge. Subjects will be followed up until three months post-ICU discharge.

Ethics and dissemination: Ethical approval was obtained from the Ethics Committee for Medical Sciences of the Pontificia Universidad Católica de Chile (#220111005) and by the Ethics Committee of the Servicio de Salud Metropolitano Sur Oriente. The study has been funded by Pontificia Universidad Católica de Chile (project number #105699/DPCC2021). Study findings will be disseminated widely in peer-reviewed publications, academic conferences, local community-based presentations, partner organizations, and the Chilean Intensive Care Society.

Trial registration number NCT06048783.

Article Summary

Strengths and limitations of this study

- This study will evaluate anxiety, depression, and post-traumatic stress disorder, which will support the clinical efficacy of spiritual care programs in surviving critically ill patients.
- Mixed-effects analyses will discriminate possible differences due to baseline characteristics and intervention variations.
- Due to the nature of the intervention, participants and practitioners will not be blinded.
- As a single-center study, the result must be confirmed in a large-scale multicenter study.

Introduction

The incidence of critical illness has increased due to the aging of the chronically ill population. Additionally, emerging viruses and bacteria, such as COVID-19, have resulted in an unprecedented increase in critically ill patients. At the same time, advances in intensive care medicine and critical care have decreased the mortality of critically ill patients [1]. Many patients who survive a critical illness suffer physical, psychological, and cognitive problems, which have been termed Post-ICU Syndrome (PICS)[2,3]. One study reported that, regardless of whether ICU admission was for a medical problem, urgent surgical intervention, or elective intervention, > 40% of ICU survivors experienced new or worsened deterioration of their physical, cognitive, and/or mental health status after hospital discharge [4]. The specific prevalence of different sequelae after critical illness varies depending on the population studied, how long post-ICU discharge assessments are performed, and the instruments used for evaluation [1]. The incidence of physical sequelae was evaluated in a systematic review that included 33 studies, with 1,080 of 2,686 patients (43%) meeting the criteria for acquired critical patient weakness (ICUAW) [5]. However, the studies used different methods to assess ICUAW (e.g., physical examination, electrophysiologic testing, histologic assessment), leading to variation in the incidence of ICUAW between studies. Regarding cognitive sequelae, a recent systematic review of 46 studies indicates that the prevalence of cognitive impairment ranges from 35 (subjective assessment) to 81% (objective assessment) at 3 months post ICU discharge [6]. Psychological symptoms of PICS include symptoms of depression, anxiety, and posttraumatic stress disorder (PTSD)[7]. The reported prevalence of anxiety ranges from 12 to 43%, depressive symptoms from 10 to 30%, and PTSD from 5 to 64%. It is estimated that at least 50% of ICU survivors will present psychological symptoms of PICS at discharge, and other studies report that a quarter of survivors present with PTSD symptoms one year after discharge from the ICU [8–10]. Some studies have reported a residual effect several months after discharge from the ICU, affecting people's quality of life and functionality [3]. Risk factors for PICS are categorized into modifiable and non-modifiable. Non-modifiable risk factors include older age, female gender, severity of illness, delirium, and mechanical ventilation. For mental health disorders related to PICS, specific risk factors for three major mental health disorders are (1) depression, older age, and female sex; (2) anxiety, older age, and a "negative ICU

experience"; and (3) PTSD, higher severity of illness and a "negative ICU experience" [1]. These statistics suggest that it is a prevalent problem among patients who receive ICU care, and modifiable risk factors such as "ICU experience" could be the focus of interventions designed to improve aspects of PICS. For example, given that a "negative ICU experience" is associated with anxiety symptoms and PTSD, ICUs might consider implementing and evaluating interventions that improve this experience to address PICS [11–14].

In the last decade, interest in spirituality and spiritual care in ICUs has grown [15–17]. Spiritual care among participants in some studies is potentially a measure of healthcare quality [18]. Studies show that quality care in the ICU includes attention to the person [19]. Spiritual care in the ICU has usually been associated with end-of-life care. However, admission into an ICU is a stressful experience that produces psychological and emotional suffering; in this context, most patients and family members feel vulnerable and, therefore, require not only physical healing but also emotional and spiritual attention [20,21]. Studies have reported that patients who need care in the ICU are especially likely to affirm that spirituality is important to them [18,22,23]. However, this cannot be generalized to all critically ill patients.

According to Puchalski [24], spirituality is a dynamic and intrinsic aspect of humanity through which persons seek ultimate meaning, purpose, and transcendence and experience relationships to self, family, others, community, society, nature, and the significant or sacred. Spirituality is expressed through beliefs, values, traditions, and practices. While "connection," "meaning and purpose of the person's life," and "transcendence" are the three essential elements when defining spiritual care [16,25,26]. Spiritual care (SC) recognizes and pays attention to spirituality within health care. Spiritual care can be provided by spiritual caregivers or chaplains who are trained to deliver spiritual care in clinical settings. It is recommended that spiritual care be provided by an interdisciplinary team, with each member assuming responsibility for spiritual care. As a trained spiritual care expert, the chaplain would lead this team. However, it is preferable that all healthcare professionals, including the chaplain, interact with each other to develop and implement the patient's spiritual care plan in a fully collaborative model [24]. However, ICU staff (intensivists and ICU nurses) often leave the spiritual needs of patients and/or their families to the spiritual caregiver or the patient’s parish clergy, as they consider them better qualified to address such

issues due to scheduling or lack of experience [27]. Although spirituality is important to most patients with severe illness and their relatives and can influence medical decision-making, it is not common for ICUs to standardize SC methods to incorporate assessments of the spiritual needs of patients and/or their families in the ICU [19,23]. A growing number of studies show that the organization of spiritual care in the ICU can be improved and become an integral part of daily ICU care based on holistic care [28–31].

In studies on patients with chronic diseases, SC has been associated with hope, meaning, and peace, causing essential relief among them. In critically ill patients, the spiritual dimension is related to quality of life from the perspective of patients and their families, especially in coping with severe and potentially life-threatening illnesses [19]. Studies in ICUs show that, from the perspective of healthcare professionals, providing spiritual care to ICU patients and their families has positive effects in four areas: 1) diagnosing and addressing the spiritual and emotional needs of patients and their families; 2) providing spiritual comfort to patients in distress; 3) increasing the spiritual well-being of patients and their families; and 4) increasing family satisfaction with ICU care in general and with decision-making in the ICU in particular [17,19,26,27]. A recent systematic review on the impact of spiritual care interventions in critically ill patients included 18 interventional studies (quasi-experimental or randomized clinical trials), all conducted in Asian countries, where the control group received the standard care of the center and the spiritual care intervention mainly was associated with a particular creed, provided by spiritual caregivers or nurses, and the outcomes of interest varied. This study showed that SC interventions could significantly reduce mean blood pressure and ICU length of stay and improve ICU patients' awareness, anxiety, spiritual well-being, and comfort.

Furthermore, ICU professionals have recognized SC as positive, contributing to patients' and their families' psychological well-being and satisfaction [32]. Hospitalization is a significant stressor that can impact patients' physical and mental health, which is often experienced as overwhelming and threatening to their well-being. According to the transactional stress model, spirituality serves as a coping mechanism and can mitigate the effects of stressful events [33]. Specifically, it can ease the burden of hospitalization and alleviate psychological and emotional distress [34,35]. Spirituality can offer protection against anxiety and depression by providing a sense of meaning, purpose, and hope, especially

during demanding times such as physical illness or hospitalization [36]. Consequently, patients who do not receive spiritual care may experience hospitalization as a significant stressor, with fewer tools to cope with this event, present more emotional and psychological distress, and therefore have a greater risk for adverse mental health outcomes.

However, spiritual care is frequently not part of the care patients receive in the ICU and many other hospital areas because clinicians do not have time, do not consider attention to spiritual needs as their responsibility, or are uncomfortable discussing spirituality with patients [37]. On the other hand, not all hospitals and ICUs have spiritual caregivers or chaplains.

Considering that, the proposed study aims to evaluate the feasibility of implementing a spiritual care intervention for patients who received care in the ICU and to assess the effects of the intervention on psychological disorders (anxiety, depression, and PTSD) in critically ill patients. The study will provide information regarding the feasibility of implementing an intervention of this type in this context. It will permit obtaining some preliminary results on the effect of the intervention. Showing spiritual care's impact on individuals' health outcomes through studies like this one may contribute to a paradigm shift from a biomedical perspective to a holistic view of ICU patients. Although the technological and advanced life support offered by the ICU is essential for critically ill patients, survival of a severe disease without a good quality of life makes it necessary to seek strategies to improve this problem, which undoubtedly requires a comprehensive approach to the person, through medical-physiological care and spiritual care. The study protocol is described below, with emphasis on the proposed intervention.

Methods

Study design and setting

This protocol is described as required by the 2013 SPIRIT guidelines [38] to ensure consistent reporting of clinical trials. The trial is a single-site pilot feasibility randomized controlled trial. A total of 30 patients will be enrolled, and 15 subjects will be randomized to each arm. The recruitment of patients will be between December 2024 and July 2025.

The study is aimed at the patients hospitalized in the ICU of the Complejo Asistencial Dr. Sótero del Río (CASR) in Santiago, Chile. The CASR is a highly complex public hospital with an assigned population of approximately 1.5 million

inhabitants [39]. The ICU has 36 beds, and complicated procedures such as ECMO (extracorporeal membrane oxygenation), multimodal neuromonitoring, invasive hemodynamic monitoring, etc., can be performed. The ICU has a staff of professionals (physicians, nurses, kinesiologists, speech therapists, occupational therapists, clinical pharmacologists, etc.) trained in intensive care medicine.

Eligibility criteria

Critically ill patients are eligible for participation based on the following inclusion and exclusion criteria:

Inclusion Criteria

1. Adult patients (18 years)
2. Patients who have had at least 72 hours of Invasive Mechanical Ventilation (IMV)
3. Patient is currently in the ICU
4. Glasgow 15 [40] at the moment of the screening

Exclusion Criteria:

1. Presence of mental or intellectual disability before hospitalization or communication/language barriers
2. Patient with primary neurological or neurosurgical disease
3. Patient who required IMV in another episode of hospitalization in the two months before screening
4. Pre-existing comorbidity with a life expectancy not exceeding six months (e.g., metastatic cancer)
5. Readmission to the ICU (patients will be included if they are on their first ICU admission to the present hospitalization)
6. There is no fixed address for follow-up
7. Patients with moderate to severe visual or hearing impairment
8. Early limitation of therapeutic effort

Intervention

Enrolled participants included in the intervention will receive a systematic and periodic generalist spiritual care (GSC) program using the FICA Spiritual Assessment Tool (**F**aith and Belief, **I**mportance and Influence, **C**ommunity, and **A**ddress in Care) [41].

The GSC intervention proposed in this study has three distinctive characteristics: (1) it is systematic and periodic, which is achieved through a standardized

schedule of 3 GSC sessions based on the FICA Spiritual Assessment Tool (see below); (2) care is delivered by volunteers trained for the intervention (see Appendix 1), which is fundamental to ensure that the intervention is systematic and standardized; (3) is delivered via telematics, thus preventing the need for volunteers to travel to the sessions.

The intervention dosage entails three GSC sessions to be. Each SC session will last between 45 and 60 minutes, occurring every other day over one week. The GSC that will be provided does not adhere to any particular creed; it provides spiritual care and attention in its broadest sense, respecting the dignity, humanity, individuality, and diversity of people whose cultures, faiths, and beliefs coexist in society. To ensure compliance with three characteristics of the GSC, as a research team, we developed four critical components for the intervention: (1) Design of the GSC sessions; (2) Generation and implementation of a training program for volunteers; (3) Creation of a manual for the volunteers; (4) Creation of a logbook for volunteers. The GSC sessions consider a 1:1 ratio (patient: companion), and participants will always be "accompanied" by the same volunteer. Although ideally, the entire intervention should be carried out while the patient is hospitalized in the ICU, considering the average stay of patients in the CASR ICU [42], the last session could be carried out after discharge from the unit in case it does not place earlier. The research team will coordinate the sessions, depending on the patients' and volunteers' availability and clinical condition. This coordination involves: (1) Scheduling of the day and time of the session. Within the systematization of the intervention, it has been defined that the sessions will take place from Monday to Friday until 20:00 hours. (2) Define whether they will be carried out via Zoom or video call. If Zoom is chosen, a researcher will generate and deliver the link to the participants and volunteers. A premium Zoom account is available for the project. (3) During the sessions, there will be a member of the research team close to the participant in case a problem arises that requires their advice or intervention, such as technological problems that affect connectivity and the development of the session, the need to re-coordinate a session that cannot be carried out, the need to support a participant or volunteer who is emotionally overwhelmed during a session, etc.

Regarding exploring spirituality through the FICA Spiritual Assessment Tool, the sessions are based on volunteers' application of the instrument developed by Dr. Christina Puchalski [41], which allowed the exploration of spirituality in the

healthcare context. It was initially written in English but has a Spanish translation [43]. The FICA is a "spiritual anamnesis" that helps identify a person's spiritual needs and resources. By exploring spiritual needs through FICA, people can find/recognize elements of their lives that support them in difficult situations, such as having a serious illness. FICA proposes to explore four crucial dimensions of spirituality:

F: FAITH and beliefs.

I: Importance of faith and beliefs in my life.

C: Community, i.e., how important is my community, including my family, group of friends, co-workers, or other activities, in my living of faith and beliefs.

A: Focus of attention. This dimension may vary depending on who is asking. It refers to what the participant might ask the volunteer about SC during sessions.

Each session has specific objectives that the volunteers should consider for each session. In the first session, volunteers should get to know the patient in the context of the intervention and explore their spiritual needs through the FICA. Before applying for the FICA, volunteers should introduce themselves and ask about the biographical context of the participant. They can use questions such as: can you tell me a little about yourself, your family, etc.? They can also ask general questions about the experience of being hospitalized in the ICU, such as how you have felt, whether you had any experience as a patient or family member in the ICU before, etc. To apply the FICA, volunteers should ask patients questions about the four dimensions of this instrument. Beforehand, they should explain that these questions will help them explore their spiritual needs and resources to offer them adequate GSC for what they are experiencing. This personalized but systematized GSC is one of the advantages of having sessions based on the FICA. In Table 1, there are examples of questions that volunteers can use to apply FICA. Ideally, exploring the four dimensions of FICA should be completed during the first session. This can be completed in the second session if this is not achieved.

The objective of the second and third sessions is to deepen those dimensions of the FICA where the volunteer detected that the participant has more spiritual needs. However, it could happen that patients would like to talk about a topic that had not been previously discussed, to which the volunteers should be open, bearing in mind that GSC implies "the encounter with someone who feels, who seeks, who needs to be heard and welcomed [41]." In this sense, active listening on the part of the volunteer is critical in the three sessions of this intervention.

The volunteers are adults who have generously and selflessly committed to providing spiritual care to critically ill patients and their families. They are volunteers, professionals, students in their final years of health careers, or members of pastoral, and they do not receive financial compensation for their services.

Before beginning the sessions, volunteers must sign a confidentiality agreement. In this agreement, they agree not to comment outside the context of the research project on anything the participants have told them during the intervention. Within the study, they will only be asked to briefly describe, in the volunteer diary (see Appendix 1), the application of the FICA, which will be explained to participants during the recruitment and informed consent process. However, suppose a volunteer detects that a patient is very emotionally compromised, which could translate into a significant mental health problem in the context of ICU hospitalization. In that case, they should alert the research team. As a team, we will contact the patient and their treating physicians and activate a referral network for mental health specialists to evaluate them.

Before starting each session, while the participant is still in the hospital, the Confusion Assessment Method for the Intensive Care Unit (CAM- ICU) (validated Chilean version) [44] will be applied to ensure that there are no symptoms of delirium so that the intervention can be conducted. CAM-ICU is a tool that has been specifically designed to assess confusional syndrome in the context of ICU patients, including those who are on mechanical ventilation [45].

The comparison or control group is the standard care group in this trial. Participants in the standard care group can request the hospital's current care if necessary. It consists of the possibility of being assisted by a Catholic priest or being contacted by pastors from Protestant churches.

Outcomes measures

Primary outcomes

In light of the study's nature as a feasibility and pilot investigation, the primary outcomes are focused on the viability of implementing the intervention within the aforementioned conditions and the participant's satisfaction with the systematic and periodic generalist spiritual care program.

The enrollment rate will be measured, corresponding to the proportion of patients who consent and are enrolled in the study during the first six months. The attendance rate will be evaluated through the proportion of patients receiving at

least three intervention sessions two weeks after randomization. Likewise, the follow-up rate will be measured by the proportion of patients who complete the evaluation three months after discharge from the ICU.

The participants' satisfaction with the intervention group will be measured through a satisfaction questionnaire (see Appendix 2) one to two weeks and three months after the last session of the intervention.

Secondary outcomes

Secondary outcomes will be the mean change of PTSD symptoms, anxiety, and depression from baseline to three and six months after recruitment (follow-up). PTSD will be assessed using the Impact of Event Scale (Chilean population version)[46]. This scale has a score from 0 to 88, with a cut-off score higher than 43. The Hospital Anxiety and Depression (HADS) instrument will be used to assess depression and anxiety. HADS is a self-assessment scale used to evaluate anxiety and depression in the non-psychiatric population. It is a short instrument (14 items) that has shown its reliability and validity in Chile for diagnosis and assessment of the severity of the disorder [47]. It comprises two subscales (HAD-A: anxiety and HAD-D: depression) of seven items, each with scores from 0 to 3. The authors recommend the following cut-off points: eight for possible cases and >10 for probable cases in both subscales. Outcomes assessment will be conducted by research assistants blinded to randomization assignment at three- and six-months post ICU discharge.

Other relevant outcomes will be the volunteers' satisfaction with the generalist spiritual care intervention, measured by a satisfaction questionnaire one to two weeks after the end of the last GSC session. Once the intervention is over, the perceptions of the participants, volunteers, and research team about the intervention, its components, training and recommendations, and difficulties encountered will be evaluated in three focus groups (FG), one for patients, another for volunteers, and the third one with health personnel [48]. We will invite participants to focus groups (FG) to explore their perception of the facilitators and barriers of GSC according to their experience with the intervention (See Appendix 3). The FG will be conducted via teleconferencing to facilitate the participation of patients, volunteers, and health personnel. The research team will perform the FGs and be guided by a script. Each session will last between 90 and 120 minutes and will be recorded and transcribed in full for subsequent analysis.

Participant timeline and recruitment

Patients will be examined in the morning to determine eligibility. Day 0 of the study corresponds to the day the informed consent is signed, where demographic and clinical data relevant to the study will be collected, psychological questionnaires will be administered, and the data collected will be documented on the case report form (CRF) by trained clinical research coordinators. Patients will be followed up during the ICU and hospital stay to record the mechanical ventilation days, ICU stay, and hospital stay. Patients will be evaluated three and six months after discharge from the ICU to record secondary outcomes. The assessment of psychological outcomes will be performed by evaluators who are blinded to group assignments. The evaluation schedule for the trial is shown in Fig. 1.

To improve participants' adherence to the intervention and follow-up, the investigators will visit participants before each generalist spiritual care session, and they will contact each other telephonically to coordinate the long-term follow-up session. If participants do not wish to attend the intervention sessions, we will inquire about their non-attendance and try to encourage compliance and attendance.

Sample size

There are no similar studies, so we plan this study as a pilot study. The objective of this pilot study is to examine the feasibility and acceptability of the protocol. Given the above, the orientation of the pilot and feasibility RCTs is to base the potential sample size on the ability to detect a significant feasibility problem that could interfere with a subsequent full-size RCT. These calculations indicate that a sample size of 30 participants (15 participants per group) will be sufficient to identify problems with a 10% chance of occurring, with a 95% CI [49].

The qualitative component of the study aims to assess whether the intervention can work from the perspectives of patients who received it, volunteers who delivered it, and the research team located in the ICU, which will provide logistical support when implementing it. The number of participants per focus group considers that the topics addressed are not complex, more concrete, and focus mainly on their perceptions of the intervention from the perspective of these three groups, which requires conducting fewer focus groups to reach saturation [50,51]. The number of participants in each focus group follows recommendations from previous studies, which suggest that the number of participants per group should range between 6 to 10 [52].

Regarding the FGs, we anticipate that the study will begin with approximately 24 participants from the three groups of interest: subjects who received the intervention, volunteers, and ICU health personnel during the study period. The initial sample size was determined based on the objectives of the study and the criteria for information saturation [48]. It is recommended that three focus groups be conducted, with eight to ten participants in each group.

Assignment of interventions

Once the Informed Consent is signed, the patients will be randomized to receive a systematic and periodic generalist spiritual care program or standard care (control group). The randomization sequence will be generated by the Informatics Unit of the Faculty of Medicine of the Pontificia Universidad Católica de Chile through a computer program, and it will be carried out by random blocks of 5, with a 1:1 allocation. The allocation concealment will be achieved through a centralized randomization in REDCap [53,54] and implemented by our institution's informatics unit. The research staff will perform randomization.

Data collection and management

Study data will be collected and managed using REDCap electronic data capture tools hosted at Pontificia Universidad Católica de Chile [53,54]. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. At the time of enrollment, study staff will collect information about each participant, including demographics, dates of hospital and ICU admission, and severity of illness according to the Acute Physiology and Chronic Illness Classification System II (APACHE II) [55], Chronic Health Assessment II and Sequential Organ Failure Assessment (SOFA) Score [56], comorbidities according to the Charlson Comorbidity Index [57], admission diagnoses, and pre-existing neuropsychological impairment. The Impact of Event Scale and Hospital Anxiety and Depression questionnaires will also be applied.

During each patient's stay in the ICU, data will also be collected on Sequential Organ Failure Assessment Score (SOFA), hemodialysis and vasopressor use, duration of mechanical ventilation, length of ICU, and hospital stay. All patients will undergo a standardized follow-up at three- and six-month post-ICU discharge,

in which the Impact of Event Scale and Hospital Anxiety and Depression questionnaires will be administered telematically.

The research assistants will undergo training and certification procedures with a supervisor for quality assurance. The supervisor performs ongoing quality assurance checks at regular intervals. Subjects will be instructed to refrain from discussing their assigned intervention with the research assistants.

Statistical analysis

An independent statistical expert in the group allocation will implement the statistical analysis.

Baseline characteristics will be reported using means ± standard deviation, medians (p25-75), and percentages. The use of parametric or nonparametric tests will depend on the data distribution. Continuous variables will be compared with the Student's t-test or the Mann-Whitney test, and categorical variables will be compared with the chi-squared test. A p-value < 0.05 will be considered for statistical significance. To assess the effect of the intervention on psychological outcomes, multilevel multivariate random intercept models will be used for the proposed outcomes in successive tests verified over time, which will be defined as linear if the result is quantitative and logistic if the outcome is dichotomous. In addition, the model will be adjusted for confounding factors (age, sex, socioeconomic status, comorbidities, severity score, drug consumption, days of mechanical ventilation, days of ICU stay, and days of hospital stay). An interaction between treatment and time will also be performed, assuming that outcomes may vary. The proposed models will be run using the "lme4" library of the free software R. Missing values due to participant withdrawals are expected. Methods such as multiple imputations will be utilized to improve precision and reduce bias in the estimates to deal with missing values. Sensitivity analysis will be performed, assuming different patterns of missingness in the data.

Regarding the qualitative analyses, the FGs will be analyzed using the thematic analysis [58]. This method allows for the identification and analysis of thematic patterns using predetermined codes for the data. This enables the identification of contrasts and convergences between focus groups. To achieve this, deductive coding will be used to analyze the pre-defined themes from the focus group script (e.g., Faith and Belief, Importance and Influence, Community, and Address in Care), while maintaining the main focus of the study. The level of analytical depth

will be descriptive. The NVivo→ software (Version 11- QSR International Pty Ltd, Doncaster, Victoria, Australia) [59] will be used in accordance with the following criteria of rigor: triangulation, peer review, audit, reflection, and validation of participants.

Ethics and dissemination

This study has been approved by the Ethics Committee of the Faculty of Medicine of the Pontificia Universidad Católica de Chile and by the Ethics Committee of the Servicio de Salud Metropolitano Sur Oriente, which evaluates CASR research projects. Before recruitment, the participants will be informed of the study and sign the consent form. It will be done by a research team member who will not be involved in the participants' care.

Before beginning the GSC sessions, the volunteers must sign a confidentiality agreement regarding what was discussed with the participants during these sessions. They will also be asked for consent and sign an informed consent document to analyze and disseminate the information generated regarding their satisfaction with the training and volunteer role.

Data collection and storage will be carried out securely, safeguarding each participant's anonymity and confidentiality. Participants will be identified with a specific code. Only members of the research team will have access to the information generated in this study.

Discussion

Spirituality is an intrinsic and fundamental aspect of human existence, which is why it has been incorporated into the definition of health. "Health is a state in which a person is able to function well, physically, mentally, socially, and spiritually, to fully express his or her potential within the environment in which he or she lives" [60]. Spirituality is related to religion, as many people live it through their faiths; however, the two are not synonymous, and there are other ways of living spirituality, such as through a connection with nature or the cosmovision of native peoples [60]. The current evidence base indicates that SC interventions in the ICU can improve clinical outcomes in critically ill patients [32]. However, the studies conducted have based SC on religiosity and faith, which may limit the generalizability of the findings [61,62]. In this context, this study represents a novel contribution to the field, as it is the first randomized trial in Chile to investigate GSC. As a research team, it seems necessary to establish a systematic

and standardized approach to this type of intervention, ensuring that its effects are attributed to the intervention itself and not to external factors. Moreover, this would facilitate the reproducibility of the intervention in other ICUs. It is also noteworthy that the GSC will be administered by trained volunteers, which may contribute to the sustainability of GSC in the local context.

Prior to undertaking a larger randomized clinical trial comparing a GSC intervention with standard care in critically ill patients, with sufficient statistical power to assess outcomes of importance to patients, a pilot trial is required. The greatest perceived threat to the feasibility of this pilot trial is non-adherence to the protocol. Several measures have been taken to enhance protocol adherence, including the provision of intervention support staff, comprehensive training of volunteers, and the implementation of compliance checks to facilitate the study intervention. The results of this pilot trial will demonstrate the feasibility of delivering the study intervention as outlined. Attainment of the threshold consent rate will substantiate the trial's acceptability to both patients and clinicians. Ultimately, the recruitment parameters will assist in estimating the requisite number of sites, time period, and resources for conducting the main trial in an efficient manner.

The design of this study is not free of limitations. First, participants and treatment providers are not blinded, as a simulated spiritual companionship program cannot be implemented in this trial. Therefore, when interpreting the study results, the effects that other factors, such as participant expectations or the patient-volunteer relationship, may have had on the psychological outcomes must be considered. Secondly, this is not a multicenter study, so the results cannot be generalized. However, no studies have been published on preventing PICS through GSC performed by trained volunteers. A study conducted in a single center with a pilot experimental design seems adequate. Finally, the sample size of this trial is small (15 individuals per group) to examine the efficacy of GSC for long-term psychological outcomes (PTSD, anxiety, and depression). This study is a pilot study to explore the effectiveness of GSC in preventing psychological impairment and the feasibility of a large-scale clinical trial. The result of this study may have preliminary data for further full-scale randomized controlled trials to obtain strong evidence on the effectiveness of GSC in preventing psychological impairment in critically ill patients.

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Authors' contributions:

L.A., C.R., P.O., P.R., and V.R. designed the study. CR and PR supervise the clinical research and recruitment and treatment of participants. L.A. and P.R. are responsible for the statistical analysis. C.R., P.O., V.R., and JB contributed to the analysis and data interpretation. L.A., P.R., and C.R. drafted the manuscript, while all other authors critically revised the manuscript for important intellectual content. LA is responsible for the overall content as guarantor. All authors read and approved the final manuscript.

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Competing interest

The authors declared that they had no competing interests. The funding agency had no role in developing the study design, collection, analysis, interpretation of data, manuscript development, or the decision to submit the manuscript.

Patient and public involvement

Patients and/or the public were not involved in this research's design, conduct, reporting, or dissemination plans.

FIGURE LEGENDS

Fig 1. Timeline of recruitment, allocation, and assessment. -t1: Baseline; t1: Each day until ICU discharge; t2: Hospital discharge; t3: 3 months follow-up; t4: 6 months follow-up. Abbreviations: ICU Intensive Care Unit; LOS Length of stay; HADS Hospital Anxiety and Depression Scale; IES Impact of Event Scale.

TABLES

Table 1: Examples of possible questions for each FICA dimension(63)

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Figure 1. Timeline of recruitment, allocation, and assessments

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	T_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Program of Spiritual Care			⟷	⟷		
ASSESSMENTS:						
Demographics information and comorbidities	X					
Record Daily ICU interventions and events			X			
ICU and hospital LOS				X		
Psychological impairment (IES, HADS)	X				X	X

Training program for volunteers

The training program for volunteers is described below.

A training program was developed for standardized volunteer training, ensuring the intervention is effectively systematic. In addition to being trained in FICA, the volunteers received training in (program contents) active listening, asking and affirming skills, psychological first aid, psychoeducation, spirituality, spiritual accompaniment, ICU care, and PICS.
Before beginning the training, a group of volunteers will be selected. For this purpose, a call will be made through social networks and e-mails explaining what the project consists of and what the role of the volunteers would be in the accompaniment and SC. It is expected to recruit at least ten volunteers, so each must accompany 1 to 2 participants, according to the study's design. This program, like the proposed intervention, was developed telematically and included:
1) Eleven narrated capsules with the contents of the program are available on the Google Classroom platform.
2) Nine Zoom sessions of 1.5 to 2 hours, in which the volunteers could resolve doubts and practice spiritual accompaniment through the role-playing strategy using scenarios developed by the research team. The volunteers will be divided into small groups (4 to 6 members).
3) Information about how the program will be delivered, zoom use, and contact information, among other practical tips.

Volunteer Manual

It consists of a guide that summarizes the contents of the training program. It also provides recommendations to facilitate the development of the accompaniment and SC sessions. These recommendations outline how to develop the sessions with resources such as Tables 1 and 2. The manual will be sent by e-mail (PDF format) to the volunteers at the end of the training. It will also be available on the Google Classroom and content capsules.

Volunteer's logbook

After each accompaniment and SC session, volunteers must complete the volunteer logbook (to be completed online via Google Docs) with the most relevant aspects of the sessions. For this, volunteers will have to answer some questions:
1) Generalities of the sessions: How they were developed (platform used), their duration, whether there were any connection and/or audio problems, etc.
2) Regarding the FICA: How was its application? Could it be completed in the first session, or was it completed in the second session? In addition, they will have to describe what the participant tells them about each dimension briefly, but taking special care that this description does not go into details that imply the loss of confidentiality. After the second and third sessions, they must explain which dimension of the FICA they took up again.

3) About the participant and their role as companions: How was the patient (calm, with some degree of emotional lability, very labile, etc.) during the session? How did they feel as volunteers (overwhelmed, calm, helpful, etc.)?

4) Regarding what was learned in the training: What elements of those learned in the training (active listening, psychological first aid, psychoeducation, spirituality, etc.) did they apply, and did they help them guide the sessions?
The logbook has multiple choice questions, questions that are answered using the Likert Scale (depending on how much the volunteer agrees or disagrees with the statement), and others whose response considers the possibility of free text.

Table 1: Examples of possible questions for each FICA dimension (1)

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked

	something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Table 2 summarizes the recommendations that volunteers should remember for the accompaniment and spiritual care sessions. This was explained to them during the training and is available as reference material in the volunteer manual.

Table 2: Recommendations to be considered by the volunteers for the development of the spiritual care and accompaniment sessions (1)

Accompanying component	Recommendations
First session	• Introduce yourself and make sure you are talking to the right person (good afternoon, I am AAA, you are Mrs. BBB?). • Explain to the participant the objective of the session (during recruitment, the research team will have explained to the patient about the accompaniment sessions and the objectives; however, it is important that each volunteer remind them especially about the first session). • Reinforce to the patient that the sessions imply a space of trust and confidentiality, so he/she will not discuss what he/she hears with other people.
Aspects to consider in all sessions	• Remember that the accompaniment has to be centered on the needs of the patient , being very important that as an accompanier to "be fully present'' during the sessions. • Spirituality, pain and, suffering are intimate, so show empathy and do not interrupt the patient when he/she is telling something. Likewise, share the silences that the patient makes.

	• During the sessions it is essential to show respect for the patient's values and beliefs, listening attentively as he/she shares them. If she/he asks you about your religion and beliefs, you can share them. It may also happen that you have beliefs in common, which we invite you to use as an element that enriches the sessions. • Do not judge the participant by what he or she tells you. This does not mean denying their convictions and values, but it does mean distinguishing between your own beliefs and what is important to her/him. • Use active listening, welcoming and validating what she/he tells you. • Avoid the temptation to offer solutions that you cannot guarantee in the face of the relative's suffering (avoid phrases such as "don't worry, everything will be fine"). It is important to remain calm in the face of uncertainty. Often, during the accompaniment, you will not have the answer that the patient, but remember that accompaniment is based on "being there for the other". • If the patient presents significant emotional lability, you can apply the stabilization exercises learned during the trainings, such as breathing exercises. If the patient shows significant distress, you can also ask for help from the support team available in the hospital. • Avoid wanting to lead the patient to your own religious or spiritual beliefs. Therefore, respect their emotional and spiritual limits. • Remember that these meetings are based on trust that the patient will have with you as a companion, so we reinforce the importance of confidentiality. • We suggest that you try to accept, if it occurs, an invitation from the patient to pray, pray, sing or participate in some religious or spiritual rite, in the context of the telematic accompaniment that you are providing.
Closing of the sessions	• At the end of a session (remember that these sessions should not last more than 1 hour, both for your time and the patient's time), you can briefly recap what you have discussed. • Remember to thank the patient for his or her time and define when your next meeting might be. The study team will coordinate the sessions, but it is important that you, as a volunteer, can confirm the most suitable days and times for you and the family member.

	• If you are closing the third session, remember to especially thank the patient for sharing his or her beliefs, values and convictions with you.
Technical aspects	Prior to the beginning of the sessions, check how your internet connection is, because a bad connection will make it difficult to carry out the session (Zoom or Video Call). It is also important that you check that the audio and camera of the device you will be using are adequate. In the volunteer's manual you will find more information in the "Technical Guide" section. • Both you and the patient need to be in a comfortable and quiet place for the sessions; noises or interruptions may hinder your development. Please check this before starting the session. • The research team will explain these aspects to the patients, and health personnel when coordinating the sessions. • If the patient health condition does not allow to attend the session, you will be notified promptly, and the session will be rescheduled.

Satisfaction Survey on Spiritual Care Intervention

Instructions:

1. Please select one option for each statement.
2. If you wish to leave a comment, you can use the last column.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Comment
The spiritual care program met your expectations.						
The spiritual care volunteer was empathetic and respectful.						
The one-on-one relationship (patient:volunteer) felt appropriate.						
The topics discussed during the sessions (e.g., meaning of suffering, uncertainty, death, life after life, ideas about healing, forgiveness, guilt, etc.) addressed your current concerns while hospitalized.						
You feel that during the spiritual care sessions you had adequate time to express yourself and ask questions.						
The duration of the spiritual care sessions (approximately 1 hour) was appropriate.						
The frequency of the spiritual care sessions (every other day) was appropriate.						
You believe that similar spiritual care programs should be implemented in other hospital services.						
You would recommend this spiritual care program to other ICU patients.						

Interview guides will guide focus groups.

Each focus group will discuss the following themes, and the emphasis will be adapted between patients, volunteers, and team members based on their role in the study.

1. Please describe your experience with the intervention.
2. What do you think are the most valuable parts of the intervention for helping patients? Explain why you think so.
3. Which components or strategies of the intervention do you believe may require revision?
4. What are your thoughts on the delivery format, time of day, number of sessions, and length of the intervention?
5. What are your thoughts on the training and tools required to carry out the intervention?
6. What difficulties did you encounter during the intervention?
7. What recommendations could you offer to improve intervention and training?
8. What would they change?
9. What would they keep?

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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomized controlled pilot trial.

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Spiritual Care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomized controlled pilot trial.

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ABSTRACT

Introduction: A significant number of critically ill patients who survive their illness will experience new sequelae or a worsening of their baseline health status following their discharge from the hospital. These consequences may be physical, cognitive, and/or psychological and have been labeled Post Intensive Care Syndrome (PICS). Prior research has demonstrated that spiritual care (SC) aligned with a specific creed during hospitalization in the Intensive Care Unit (ICU), as part of a comprehensive care plan, may be an effective strategy for preventing psychological sequelae in surviving critically ill patients. However, there is a gap in the clinical literature regarding the effectiveness of generalist spiritual care in preventing psychological sequelae associated with PICS. This pilot study aims to explore the feasibility of implementing a generalist spiritual care strategy in the ICU and to evaluate its preliminary effectiveness in preventing anxiety and depression symptoms and posttraumatic stress disorder in critically ill patients.

Methods and analysis: This is a single-site, feasibility, randomized controlled pilot trial of a generalist spiritual care intervention, which is being compared with the current standard of care. A total of 30 adults who are critically ill and have undergone invasive mechanical ventilation for a minimum of 72 hours without an alteration in consciousness will be randomly assigned to either the spiritual care (SC) group or the usual care group at a ratio of 1:1. The primary outcome will be the feasibility and acceptability of the SC strategy in critically ill patients. Secondary aims include evaluating the differences in anxiety and depression symptoms and posttraumatic stress disorder between the spiritual care group and the usual care control group at three months after ICU discharge. Subjects will be followed up until three months post-ICU discharge.

Ethics and dissemination: The Ethics Committee for Medical Sciences of the Pontificia Universidad Católica de Chile (#220111005) and the Ethics Committee of the Servicio de Salud Metropolitano Sur Oriente approved the study. Pontificia Universidad Católica de Chile funded the study (project number #105699/DPCC2021) The findings will be widely disseminated through peer-reviewed publications, academic conferences, local community-based presentations, partner organizations, and the Chilean Intensive Care Society.

Trial registration number NCT06048783.

Article Summary

Strengths and limitations of this study

- This study will evaluate anxiety, depression, and post-traumatic stress disorder, which will support the clinical efficacy of spiritual care programs among surviving critically ill patients.
- Mixed-effects analyses will discriminate possible differences due to baseline characteristics and intervention variations.
- Due to the nature of the intervention, participants and practitioners will not be blinded.
- As a single-center study, the result must be confirmed in a large-scale multicenter study.

Introduction

The incidence of critical illness has increased due to the aging of the chronically ill population. Additionally, emerging viruses and bacteria, such as COVID-19, have resulted in an unprecedented increase in critically ill patients. At the same time, advances in intensive care medicine and critical care have decreased the mortality of critically ill patients [1]. Many patients who survive a critical illness suffer physical, psychological, and cognitive problems, which have been termed Post-ICU Syndrome (PICS) [2,3]. A previous study reported that, regardless of whether ICU admission was for a medical problem, urgent or elective surgical intervention, > 40% of ICU survivors experienced new or worsened deterioration of their physical, cognitive, and/or mental health status after hospital discharge [1]. The specific prevalence of different sequelae after critical illness varies depending on the population studied, the time after post-ICU discharge assessments is performed, and the instruments used for evaluation [1]. The incidence of physical sequelae was evaluated in a systematic review that included 33 studies, with 1,080 of 2,686 patients (43%) meeting the criteria for acquired critical patient weakness (ICUAW) [5]. However, the studies used different methods to assess ICUAW (e.g., physical examination, electrophysiologic testing, histologic assessment), leading to variation in the incidence of ICUAW between studies. Regarding cognitive sequelae, a recent systematic review of 46 studies indicates that the prevalence of cognitive impairment ranges from 35 (subjective assessment) to 81% (objective assessment) at 3 months post ICU discharge [6]. Psychological symptoms of PICS include symptoms of depression, anxiety, and posttraumatic stress disorder (PTSD) [7]. The reported prevalence of anxiety ranges from 12 to 43%, depressive symptoms from 10 to 30%, and PTSD from 5 to 64%. It is estimated that at least 50% of ICU survivors will present psychological symptoms of PICS at discharge, and other studies report that a quarter of survivors present with PTSD symptoms one year after discharge from the ICU [8–10]. Some studies have reported a residual effect several months after discharge from the ICU, affecting people's quality of life and functionality [3]. Risk factors for PICS are categorized into modifiable and non-modifiable. Non-modifiable risk factors include older age, female gender, severity of illness, delirium, and mechanical ventilation. For mental health disorders related to PICS, specific risk factors for the three major mental health disorders are (1) depression, older age, and female sex; (2) anxiety, older age, and a "negative ICU

experience"; and (3) PTSD, higher severity of illness and a "negative ICU experience" [1]. These statistics suggest that it is a prevalent problem among patients who receive ICU care, and modifiable risk factors such as "ICU experience" could be the focus of interventions designed to improve aspects of PICS. For example, given that a "negative ICU experience" is associated with anxiety symptoms and PTSD, ICUs might consider implementing and evaluating interventions that improve this experience to address PICS [11–14].

In the last decade, interest in spirituality and spiritual care in ICUs has grown [15–17]. In some studies, spiritual care among patients is a measure of healthcare quality [18]. Studies show that quality care in the ICU involves attention to the person [19]. Spiritual care in the ICU has usually been associated with end-of-life care. However, admission into an ICU is a stressful experience that produces psychological and emotional suffering; in this context, most patients and family members feel vulnerable and, therefore, require not only physical healing but also emotional and spiritual attention [20,21]. Studies have reported that patients who need care in the ICU are especially likely to affirm that spirituality is important to them [18,22,23].

According to Puchalski [24], spirituality is a dynamic and intrinsic aspect of humanity through which persons seek ultimate meaning, purpose, and transcendence and experience relationships to self, family, others, community, society, nature, and the significant or sacred. Spirituality is expressed through beliefs, values, traditions, and practices. While "connection," "meaning and purpose of the person's life," and "transcendence" are the three essential elements when defining spiritual care [16,25,26]. Spiritual care (SC) recognizes and pays attention to spirituality within health care. SC can be provided by spiritual caregivers or chaplains trained to deliver this spiritual care in clinical settings. It is advised that an interdisciplinary team provide SC, each member assuming responsibility for its provision. As a trained SC expert, the chaplain would lead this team. However, it is preferable for all healthcare professionals, including the chaplain, to collaborate and communicate effectively in developing and implementing the patient's SC plan within a fully collaborative model [24]. However, ICU staff (intensivists and ICU nurses) often delegate the spiritual needs of patients and/or their families to the spiritual caregivers or the patient's parish clergy, believing they are better qualified to address such issues due to scheduling or lack of experience [27]. Although spirituality is important to most patients with

severe illness and their relatives and can influence medical decision-making, it is not common for ICUs to standardize SC methods to assess the spiritual needs of patients and/or their families in the ICU [19,23]. A growing number of studies show that the organization of spiritual care in the ICU can be enhanced and integrated into daily ICU care following a holistic care [28–31].

In studies on patients with chronic diseases, SC has been associated with hope, meaning, and peace, causing relief among them. In critically ill patients, the spiritual dimension is closely linked to the quality of life of patients and their families, helping them cope with severe and potentially life-threatening illnesses [19]. Studies in ICUs show that healthcare professionals perceive that providing SC to ICU patients and their families has positive effects in four areas: 1) diagnosing and addressing the spiritual and emotional needs of patients and their families; 2) providing spiritual comfort to patients in distress; 3) increasing the spiritual well-being of patients and their families; and 4) increasing family satisfaction with ICU care in general and with decision-making in the ICU [17,19,26,27]. A recent systematic review on the impact of SC interventions in critically ill patients included 18 interventional studies (quasi-experimental or randomized clinical trials), all conducted in Asian countries. The control group received the standard care of the center, and the SC intervention mainly was associated with a particular creed, provided by spiritual caregivers or nurses, and assessed different outcomes. This study showed that SC interventions could significantly reduce mean blood pressure and ICU length of stay and improve ICU patients' awareness, anxiety, spiritual well-being, and comfort.

Furthermore, ICU professionals have recognized SC as positive, contributing to patients' and their families' psychological well-being and satisfaction [32]. Hospitalization is a significant stressor that can impact patients' physical and mental health, which is often experienced as overwhelming and threatening to their well-being. According to the transactional stress model, spirituality serves as a coping mechanism to mitigate the effects of stressful events [33]. Specifically, it can ease the burden of hospitalization and alleviate psychological and emotional distress [34,35]. Spirituality can offer protection against anxiety and depression by providing a sense of meaning, purpose, and hope, especially during demanding times such as physical illness or hospitalization [36]. Consequently, patients who do not receive SC may experience hospitalization as a significant stressor, with

fewer tools to cope with this event, present more emotional and psychological distress, and therefore have a greater risk for adverse mental health outcomes. However, SC is included as part of the care patients receive in the ICU and many other hospital areas because clinicians do not have time, do not consider attention to spiritual needs their responsibility, or are uncomfortable discussing spirituality with patients [37]. On the other hand, not all hospitals and ICUs have spiritual caregivers or chaplains among their staff.

Considering that, the proposed study aims to evaluate the feasibility of implementing a SC intervention for patients who received care in the ICU and to assess the effects of the intervention on psychological disorders (anxiety, depression, and PTSD) in critically ill patients. The study will provide information regarding the feasibility of implementing an intervention of this type in this context. It will obtain some preliminary results on the effect of the intervention. Showing SC's impact on individuals' health outcomes through studies like this one may contribute to a paradigm shift from a biomedical perspective to a holistic view of ICU patients. Although the technological and advanced life support offered by the ICU is essential for critically ill patients, survival of a severe disease without a good quality of life makes it necessary to seek strategies to improve this problem, which undoubtedly requires a comprehensive approach to the person, through medical-physiological care and spiritual care. The study protocol is described below, with emphasis on the proposed intervention.

Methods

Study design and setting

This protocol follows the 2013 SPIRIT guidelines [38] to ensure consistent reporting of clinical trials. The trial is a single-site pilot feasibility randomized controlled trial. Thirty patients will be enrolled, and 15 subjects will be randomized to each arm. Patients will be recruited between December 2024 and July 2025.

The study focuses on patients hospitalized in the ICU of the Complejo Asistencial Dr. Sótero del Río (CASR) in Santiago, Chile. The CASR is a highly complex public hospital with an assigned population of approximately 1.5 million [39]. The ICU has 36 beds, and complicated procedures such as ECMO (extracorporeal membrane oxygenation), multimodal neuromonitoring, invasive hemodynamic monitoring, etc., can be performed. The ICU has a staff of professionals (physicians, nurses, kinesiologists, speech therapists, occupational therapists,

clinical pharmacologists, etc.) trained in intensive care medicine. In the CASR, the ICU and the intermediate care unit have the same administrative and clinical dependency; they are called Critical Patient Units (CPU).

Eligibility criteria

The target population of the present study comprises critically ill patients who have been on invasive mechanical ventilation for a minimum of 72 hours, have been extubated, and are in the recovery phase of an acute illness.

Critically ill patients are eligible for participation based on the following inclusion and exclusion criteria:

Inclusion Criteria

1. Adult patients (≥ 18 years)
2. Patients who have had at least 72 hours of Invasive Mechanical Ventilation (IMV)
3. Patient is currently in the ICU
4. Glasgow 15 [40] at the moment of the screening

Exclusion Criteria:

1. Presence of mental or intellectual disability before hospitalization or communication/language barriers
2. Patient with primary neurological or neurosurgical disease
3. Patient who required IMV in another episode of hospitalization in the two months before screening
4. Pre-existing comorbidity with a life expectancy not exceeding six months (e.g., metastatic cancer)
5. Readmission to the ICU (patients will be included if they are on their first ICU admission to the present hospitalization)
6. There is no fixed address for follow-up
7. Patients with moderate to severe visual or hearing impairment
8. Early limitation of therapeutic effort

Intervention

Enrolled participants included in the intervention will receive a systematic and periodic generalist spiritual care (GSC) program using the FICA Spiritual Assessment Tool (**F**aith and Belief, **I**mportance and Influence, **C**ommunity, and **A**ddress in Care) [41].

The GSC intervention proposed in this study has three distinctive characteristics: (1) it is systematic and periodic, which is achieved through a standardized schedule of 3 GSC sessions based on the FICA Spiritual Assessment Tool (see below); (2) care is delivered by volunteers trained for the intervention (see Appendix 1), which is fundamental to ensure that the intervention is systematic and standardized; (3) is delivered via telematics, thus preventing the need for volunteers to travel to the sessions.

The intervention dosage entails three GSC sessions. Each SC session will last between 45 and 60 minutes, occurring every other day over one week. The GSC that will be provided does not adhere to any creed; it offers SC and attention in its broadest sense, respecting the dignity, humanity, individuality, and diversity of people whose cultures, faiths, and beliefs coexist in society. To ensure compliance with three characteristics of the GSC, as a research team, we developed four critical components for the intervention: (1) design of the GSC sessions; (2) generation and implementation of a training program for volunteers; (3) development of a manual for the volunteers; (4) implementing a logbook for volunteers. The GSC sessions consider a 1:1 ratio (patient: companion), and participants will always be "accompanied" by the same volunteer. Although ideally, the entire intervention should be carried out while the patient is hospitalized in the ICU, considering the average stay of patients in the CASR ICU [42], the last session could be carried out after discharge from the unit, in case they were transferred to another service. Consequently, the volunteers can provide spiritual care sessions outside the ICU. The research team will coordinate the sessions, depending on the patients' and volunteers' availability and clinical condition. This coordination involves: (1) Scheduling of the day and time of the session. To systematize the delivery of the intervention, all sessions will take place from Monday to Friday until 20:00 hours. (2) Determine whether it will be done via Zoom or video call. If Zoom is chosen, a researcher will generate and provide the link to the patients and volunteers. A premium Zoom account is available for the project. (3) During the sessions, there will be a member of the research team close to the participant in case a problem arises that requires their advice or intervention, such as technological problems that affect connectivity and the development of the session, the need to re-coordinate a session that cannot be carried out, the need to support a participant or volunteer who is emotionally overwhelmed during a session, etc.

Spirituality will be explored following the FICA Spiritual Assessment Tool; the sessions are based on volunteers' application of the instrument developed by Dr. Christina Puchalski [41], which allowed the exploration of spirituality in the healthcare context. It was initially written in English but has a Spanish translation [43]. The FICA is a "spiritual anamnesis tool" that helps identify a person's spiritual needs and resources. By exploring spiritual needs through FICA, people can find/recognize elements of their lives that support them in difficult situations, such as having a serious illness. FICA proposes to explore four crucial dimensions of spirituality:

F: FAITH and beliefs.

I: Importance of faith and beliefs in my life.

C: Community, i.e., how important is my community, including my family, group of friends, co-workers, or other activities, in living of faith and beliefs.

A: Focus of attention. This dimension may vary depending on who is asking. Participants may ask the volunteer about SC during sessions.

Each session has specific goals that the volunteers should consider. In the first session, volunteers should get to know the patient in the context of the intervention and explore their spiritual needs through the FICA. Before applying the FICA, volunteers should introduce themselves and ask about the biographical context of the participant. They can use questions such as: can you tell me a little about yourself, your family, etc.? They can also ask general questions about the experience of being hospitalized in the ICU, such as: how have you felt? whether you had any experience as a patient or family member in the ICU before? etc. To apply the FICA, volunteers should ask patients questions about the four dimensions of this instrument. Beforehand, they should explain that these questions will help them explore their spiritual needs and resources to offer them adequate GSC for what they are experiencing. This personalized but systematized GSC is one of the advantages of having sessions based on the FICA. In Table 1, there are examples of questions that volunteers can use to apply FICA. Ideally, exploring the four dimensions of FICA should be completed during the first session. This can be completed in the second session if it is not achieved.

The goal of the second and third sessions is to deepen the dimensions of FICA, where the volunteer detects that the participant has spiritual needs. However, it could happen that patients would like to talk about a topic that had not been previously discussed, to which the volunteers should be open, bearing in mind that

GSC implies "the encounter with someone who feels, who seeks, who needs to be heard and welcomed [41]." In this sense, active listening on the part of the volunteer is critical in the three sessions of this intervention.

Volunteers correspond with adults who have committed generously and selflessly to provide spiritual care to critically ill patients and their families. These volunteers do not receive financial compensation for their services. They are health professionals (physicians, nurses, psychologists), medical and psychology students, and pastoral staff.

Before beginning with the intervention, volunteers must sign a confidentiality agreement. In this agreement, they commit not to comment outside the context of the research project on anything the participants have told them during the intervention. Within the study, they will only be asked to briefly describe how the FICA was applied in the volunteer diary (see Appendix 1), which will be explained to participants during the recruitment and informed consent process. However, if a volunteer detects that a patient is very emotionally compromised, which could translate into significant mental health distress in the context of ICU hospitalization. In that case, they should alert the research team. As a team, we will contact the patient and their treating physicians and activate a referral network for mental health specialists to evaluate them.

Before starting each session, while the participant is still in the hospital, the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) (validated Chilean version) [44] will be applied to ensure that there are no symptoms of delirium to allow the intervention to be conducted. CAM-ICU is a tool specifically designed to assess confusional syndrome in the context of ICU patients, including those who are on mechanical ventilation [45].

The comparison or control group is the standard care group in this trial. Participants in the standard care group can request the hospital's current SC if necessary. It consists of the possibility of being assisted by a Catholic priest or by pastors from Protestant churches.

Outcomes measures

Primary outcomes

Given the study's nature as a feasibility and pilot investigation, the primary outcomes are the viability of implementing the intervention within the conditions mentioned earlier and the participant's satisfaction with the GSC care program.

The enrollment rate will be measured, corresponding to the proportion of patients who consent and are enrolled in the study during the first six months. The attendance rate will be evaluated through the proportion of patients receiving at least three intervention sessions two weeks after randomization. Likewise, the follow-up rate will be measured by the proportion of patients who complete the evaluation three months after discharge from the ICU.

The participants' satisfaction with the intervention group will be measured through a satisfaction questionnaire (see Appendix 2) one to two weeks and three months after the last session of the intervention.

Secondary outcomes

Secondary outcomes will be the mean change of PTSD symptoms, anxiety, and depression from baseline to three and six months after recruitment (follow-up). PTSD will be assessed using the Impact of Event Scale (Chilean population version) [46]. This scale has a score from 0 to 88, with a cut-off score higher than 43. The Hospital Anxiety and Depression (HADS) instrument will be used to assess depression and anxiety. HADS is a self-assessment scale used to evaluate anxiety and depression in the non-psychiatric population. It is a short instrument (14 items) that has shown its reliability and validity in Chile for diagnosis and assessment of the severity of the disorder [47]. It comprises two subscales (HAD-A: anxiety and HAD-D: depression) of seven items, each with scores from 0 to 3. The authors recommend the following cut-off points: eight for possible cases and >10 for probable cases in both subscales.

Other relevant outcomes will be the volunteers' satisfaction with the GSC intervention, measured by a satisfaction questionnaire one to two weeks after the end of the last GSC session. Once the intervention is over, the perceptions of the participants, volunteers, and research team about the intervention, its components, training and recommendations, and difficulties encountered will be evaluated in three focus groups (FG), one for patients, another for volunteers, and the third one with health personnel [48]. We will invite participants to focus groups (FG) to explore their perception of the facilitators and barriers of GSC according to their experience with the intervention (See Appendix 3). The FGs will be conducted via teleconferencing to facilitate the participation of patients, volunteers, and health personnel. The research team will perform the FGs and be

guided by a script. Each session will last between 90 and 120 minutes and will be recorded and transcribed in full for subsequent analysis.

Participant timeline and recruitment

Patients will be examined in the morning to determine eligibility. Day 0 of the study corresponds to the day the informed consent is signed, where demographic and clinical data relevant to the study will be collected, psychological questionnaires will be administered, and the data collected will be documented on the case report form (CRF) by trained clinical research coordinators. Patients will be followed up during the ICU and hospital stay to record the mechanical ventilation days, ICU stay, and hospital stay. Patients will be evaluated three and six months after discharge from the ICU to assess secondary outcomes. Evaluation of psychological outcomes will be performed by trained interviewers. The evaluation schedule for the trial is shown in Fig. 1.

To improve participants' adherence to the intervention and follow-up, the research team will visit them before each GSC session and contact each other telephonically to coordinate the long-term follow-up session. If participants do not wish to attend the intervention sessions, we will inquire about their reasons for non-attendance and try to encourage compliance and attendance.

Sample size

There are no similar studies, so we plan this study as a pilot study. The objective of this pilot study is to examine the feasibility and acceptability of the protocol. Given the above, the orientation of the pilot and feasibility RCTs is to estimate the potential sample size on the ability to detect a significant feasibility problem that could interfere with a subsequent full-size RCT. These calculations indicate that a sample size of 30 participants (15 participants per group) will be sufficient to identify problems with a 10% chance of occurring, with a 95% CI [49].

The qualitative component of the study aims to assess whether the intervention can work from the perspectives of patients who received it, volunteers who delivered it, and the research team located in the ICU, which will provide logistical support when implementing it. The number of participants per focus group considers that the topics addressed are not complex, more concrete, and focus mainly on their perceptions of the intervention from the perspective of these three groups, consequently, requires conducting fewer focus groups to reach saturation

[50,51]. The number of participants in each focus group follows recommendations from previous studies, which suggest that the number of participants per group should range between 6 to 10 [52].

Assignment of interventions

Once the Informed Consent is signed, the patients will be randomized to receive a systematic and periodic GSC program or standard care (control group). The randomization sequence will be generated by the Informatics Unit of the Faculty of Medicine of the Pontificia Universidad Católica de Chile through a computer program, and it will be carried out by random blocks of 5, with a 1:1 allocation. The allocation concealment will be achieved through a centralized randomization in REDCap [53,54] and implemented by our institution's informatics unit. The research staff will perform randomization.

Due to the type of intervention under study, the patient and the research team cannot be blinded to group assignment. However, those performing the long-term outcome evaluations will be blinded to group assignment.

Data collection and management

Study data will be collected and managed using REDCap electronic data capture tools hosted at Pontificia Universidad Católica de Chile [53,54]. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to standard statistical packages; and 4) procedures for data integration and interoperability with external sources. At the time of enrollment, study staff will collect information about each participant, including demographics, dates of hospital and ICU admission, and severity of illness according to the Acute Physiology and Chronic Illness Classification System II (APACHE II) [55], Chronic Health Assessment II and Sequential Organ Failure Assessment (SOFA) Score [56], comorbidities according to the Charlson Comorbidity Index [57], admission diagnoses, and pre-existing neuropsychological impairment. The Impact of Event Scale and Hospital Anxiety and Depression questionnaires will also be applied.

During each patient's stay in the ICU, data will also be collected on the Sequential Organ Failure Assessment Score (SOFA), hemodialysis and vasopressor use,

duration of mechanical ventilation, length of ICU and hospital stay. All patients will undergo a standardized follow-up at three- and six-months post-ICU discharge, in which the Impact of Event Scale and Hospital Anxiety and Depression questionnaires will be administered by a teleconference.

The research assistants will undergo training and certification procedures with a supervisor for quality assurance. The supervisor will perform ongoing quality assurance checks at regular intervals. Subjects will be instructed to refrain from discussing their assigned intervention with the research assistants.

Statistical analysis

An independent statistical expert in the group allocation will implement the statistical analysis.

Baseline characteristics will be reported using means ± standard deviation, medians (p25-75), and percentages. The use of parametric or nonparametric tests will depend on the data distribution. Continuous variables will be compared with the Student's t-test or the Mann-Whitney test, and categorical variables will be compared with the chi-squared test. A p-value < 0.05 will be considered for statistical significance. To assess the effect of the intervention on psychological outcomes, multilevel multivariate random intercept models will be used for the proposed outcomes in successive tests verified over time, which will be defined as linear if the result is quantitative and logistic if the outcome is dichotomous. In addition, the model will be adjusted for confounding factors (age, sex, socioeconomic status, comorbidities, severity score, drug consumption, days of mechanical ventilation, days of ICU stay, and days of hospital stay). An interaction between treatment and time will also be performed, assuming that outcomes may vary. The proposed models will be run using the "lme4" library of the free software R. Missing values due to participant withdrawals are expected. Methods such as multiple imputations will be utilized to improve precision and reduce bias in the estimates to deal with missing values. Sensitivity analysis will be performed, assuming different patterns of missingness in the data.

Regarding the qualitative analyses, the FGs will be analyzed using the thematic analysis [58]. This method allows for the identification and analysis of thematic patterns using predetermined codes for the data. This enables the identification of contrasts and convergences between focus groups. Deductive coding will be used to analyze the pre-defined themes from the focus group script (e.g., Faith and

Belief, Importance and Influence, Community, and Address in Care) while maintaining the main focus of the study. The level of analytical depth will be descriptive. The NVivo→ software (Version 11- QSR International Pty Ltd, Doncaster, Victoria, Australia) [59] will be used under the following criteria of rigor: triangulation, peer review, audit, reflection, and validation of participants.

Ethics and dissemination

This study has been approved by the Faculty of Medicine Ethics Committee of the Pontificia Universidad Católica de Chile and by the Servicio de Salud Metropolitano Sur Oriente, which evaluates CASR research projects. Before recruitment, the participants will be informed of the study and sign the consent form. It will be done by a research team member who will not be involved in the participants' care.

Before beginning the GSC sessions, the volunteers must sign a confidentiality agreement regarding what was discussed with the participants during these sessions. They will also be asked for consent and sign an informed consent document to analyze and disseminate the information generated regarding their satisfaction with the training and volunteer role.

Data collection and storage will be carried out securely, safeguarding each participant's anonymity and confidentiality. Participants will be identified with a specific code. Only members of the research team will have access to the information generated in this study.

Discussion

Spirituality is an intrinsic and fundamental aspect of human existence, which is why it has been incorporated into the definition of health. "Health is a state in which a person can function well, physically, mentally, socially, and spiritually, to fully express his or her potential within the environment in which he or she lives" [60]. Spirituality is related to religion, as many people live it through their faiths; however, the two are not synonymous, and there are other ways of living spirituality, such as through a connection with nature or cosmovision of native peoples [60]. The current evidence base indicates that SC interventions in the ICU can improve clinical outcomes in critically ill patients [32]. However, the studies conducted have been based on SC on religiosity and faith, which may limit the generalizability of the findings [61,62]. In this context, this study represents a

novel contribution to the field, as it is the first randomized trial in Chile to investigate GSC. As a research team, it seems necessary to establish a systematic and standardized approach to this type of intervention, ensuring that its effects are attributed to the intervention itself and not to external factors. Moreover, this would facilitate the reproducibility of the intervention in other ICUs. It is also noteworthy that the GSC will be administered by trained volunteers, which may contribute to the sustainability of the intervention in the local context.

A pilot trial is required before undertaking a larger randomized clinical trial comparing a GSC intervention with standard care in critically ill patients, with sufficient statistical power to assess outcomes of importance to patients, a pilot trial is required. The greatest perceived threat to the feasibility of this pilot trial is non-adherence to the protocol. Several measures have been taken to enhance protocol adherence, including providing intervention support staff, comprehensive training of volunteers, and implementing compliance checks to facilitate the study intervention. The results of this pilot trial will demonstrate the feasibility of delivering the study intervention as outlined. Attainment of the threshold consent rate will substantiate the trial's acceptability to both patients and clinicians. Ultimately, the recruitment parameters will assist in estimating the requisite number of sites, time, and resources for conducting the main trial efficiently.

The design of this study is not free of limitations. First, participants and treatment providers are not blinded, as a simulated spiritual companionship program cannot be implemented in this trial. Therefore, when interpreting the study results, the effects that other factors, such as participant expectations or the patient-volunteer relationship, may have had on the psychological outcomes must be considered. Secondly, this is not a multicenter study, so the results cannot be generalized. However, no studies have been published on preventing PICS through GSC performed by trained volunteers. A study conducted in a single center with a pilot experimental design seems adequate. Finally, the sample size of this trial is small (15 individuals per group) to examine the efficacy of GSC for long-term psychological outcomes (PTSD, anxiety, and depression). This study is a pilot study to explore the effectiveness of GSC in preventing psychological impairment and the feasibility of a large-scale clinical trial. The results of this study may provide preliminary data for further full-scale randomized controlled trials to obtain strong evidence on the effectiveness of GSC in preventing psychological impairment in critically ill patients.

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Authors' contributions:

L.A., C.R., P.O., P.R., and V.R. designed the study. CR and PR supervise the clinical research and recruitment and treatment of participants. L.A. and P.R. are responsible for the statistical analysis. C.R., P.O., V.R., and JB contributed to the analysis and data interpretation. L.A., P.R., and C.R. drafted the manuscript, while all other authors critically revised the manuscript for important intellectual content. LA is responsible for the overall content as guarantor. All authors read and approved the final manuscript.

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Competing interest

The authors declared that they had no competing interests. The funding agency had no role in developing the study design, collection, analysis, interpretation of data, manuscript development, or the decision to submit the manuscript.

Patient and public involvement

Patients and/or the public were not involved in this research's design, conduct, reporting, or dissemination plans.

FIGURE LEGENDS

Fig 1. Timeline of recruitment, allocation, and assessment. -t1: Baseline; t1: Each day until ICU discharge; t2: Hospital discharge; t3: 3 months follow-up; t4: 6 months follow-up. Abbreviations: ICU Intensive Care Unit; LOS Length of stay; HADS Hospital Anxiety and Depression Scale; IES Impact of Event Scale.

TABLES

Table 1: Examples of possible questions for each FICA dimension (63)

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you are/have been in ICU? (for this, it is essential to have previously asked something about the family or who the participant lives with) • Do you currently have the support of friends (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Figure 1. Timeline of recruitment, allocation, and assessments

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	T_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Program of Spiritual Care			⟷	⟷		
ASSESSMENTS:						
Demographics information and comorbidities	X					
Record Daily ICU interventions and events			X			
ICU and hospital LOS				X		
Psychological impairment (IES, HADS)	X				X	X

Training program for volunteers

The training program for volunteers is described below.

A training program was developed for standardized volunteer training, ensuring the intervention is effectively systematic. In addition to being trained in FICA, the volunteers received training in (program contents) active listening, asking and affirming skills, psychological first aid, psychoeducation, spirituality, spiritual accompaniment, ICU care, and PICS.
Before beginning the training, a group of volunteers will be selected. For this purpose, a call will be made through social networks and e-mails explaining what the project consists of and what the role of the volunteers would be in the accompaniment and SC. It is expected to recruit at least ten volunteers, so each must accompany 1 to 2 participants, according to the study's design. This program, like the proposed intervention, was developed telematically and included:
1) Eleven narrated capsules with the contents of the program are available on the Google Classroom platform.
2) Nine Zoom sessions of 1.5 to 2 hours, in which the volunteers could resolve doubts and practice spiritual accompaniment through the role-playing strategy using scenarios developed by the research team. The volunteers will be divided into small groups (4 to 6 members).
3) Information about how the program will be delivered, zoom use, and contact information, among other practical tips.

Volunteer Manual

It consists of a guide that summarizes the contents of the training program. It also provides recommendations to facilitate the development of the accompaniment and SC sessions. These recommendations outline how to develop the sessions with resources such as Tables 1 and 2. The manual will be sent by e-mail (PDF format) to the volunteers at the end of the training. It will also be available on the Google Classroom and content capsules.

Volunteer's logbook

After each accompaniment and SC session, volunteers must complete the volunteer logbook (to be completed online via Google Docs) with the most relevant aspects of the sessions. For this, volunteers will have to answer some questions:
1) Generalities of the sessions: How they were developed (platform used), their duration, whether there were any connection and/or audio problems, etc.
2) Regarding the FICA: How was its application? Could it be completed in the first session, or was it completed in the second session? In addition, they will have to describe what the participant tells them about each dimension briefly, but taking special care that this description does not go into details that imply the loss of confidentiality. After the second and third sessions, they must explain which dimension of the FICA they took up again.

3) About the participant and their role as companions: How was the patient (calm, with some degree of emotional lability, very labile, etc.) during the session? How did they feel as volunteers (overwhelmed, calm, helpful, etc.)?

4) Regarding what was learned in the training: What elements of those learned in the training (active listening, psychological first aid, psychoeducation, spirituality, etc.) did they apply, and did they help them guide the sessions?
The logbook has multiple choice questions, questions that are answered using the Likert Scale (depending on how much the volunteer agrees or disagrees with the statement), and others whose response considers the possibility of free text.

Table 1: Examples of possible questions for each FICA dimension (1)

FICA's dimension	Possible questions
Faith	• Do you consider yourself a spiritual or religious person? • Is spirituality, religion, or other beliefs in the supernatural or sacred important to you? • Do you have spiritual beliefs that help you overcome stress or cope with difficult times? • Does your religion or beliefs influence how you are coping with your hospitalization in the ICU?
Importance	• How important is spirituality or religion in your daily life? • Has your spirituality, religion, or beliefs influenced your self-care? • Has your spirituality, religion, or beliefs influenced the decisions you make regarding your health?
Community	• Are you part of a spiritual or religious community? • Does this community support you in difficult times, and in what way? • In this dimension, you can also ask about family or friends as a "nuclear community" and support to face problems and difficult situations: Do you have the support of your relatives now that you have a loved one in ICU? (for this, it is essential to have previously asked

	something about the family or about who the participant lives with) • Do you have the support of friends at this time (sometimes "the community" is made up of neighbors, members of a senior citizens' club, sports club, etc.)?
Approach to care	• How would you like me to support you during these coaching sessions?

Table 2 summarizes the recommendations that volunteers should remember for the accompaniment and spiritual care sessions. This was explained to them during the training and is available as reference material in the volunteer manual.

Table 2: Recommendations to be considered by the volunteers for the development of the spiritual care and accompaniment sessions (1)

Accompanying component	Recommendations
First session	• Introduce yourself and make sure you are talking to the right person (good afternoon, I am AAA, you are Mrs. BBB?). • Explain to the participant the objective of the session (during recruitment, the research team will have explained to the patient about the accompaniment sessions and the objectives; however, it is important that each volunteer remind them especially about the first session). • Reinforce to the patient that the sessions imply a space of trust and confidentiality, so he/she will not discuss what he/she hears with other people.
Aspects to consider in all sessions	• Remember that the accompaniment has to be centered on the needs of the patient , being very important that as an accompanier to "be fully present'' during the sessions. • Spirituality, pain and, suffering are intimate, so show empathy and do not interrupt the patient when he/she is telling something. Likewise, share the silences that the patient makes.

	• During the sessions it is essential to show respect for the patient's values and beliefs, listening attentively as he/she shares them. If she/he asks you about your religion and beliefs, you can share them. It may also happen that you have beliefs in common, which we invite you to use as an element that enriches the sessions. • Do not judge the participant by what he or she tells you. This does not mean denying their convictions and values, but it does mean distinguishing between your own beliefs and what is important to her/him. • Use active listening, welcoming and validating what she/he tells you. • Avoid the temptation to offer solutions that you cannot guarantee in the face of the relative's suffering (avoid phrases such as "don't worry, everything will be fine"). It is important to remain calm in the face of uncertainty. Often, during the accompaniment, you will not have the answer that the patient, but remember that accompaniment is based on "being there for the other". • If the patient presents significant emotional lability, you can apply the stabilization exercises learned during the trainings, such as breathing exercises. If the patient shows significant distress, you can also ask for help from the support team available in the hospital. • Avoid wanting to lead the patient to your own religious or spiritual beliefs. Therefore, respect their emotional and spiritual limits. • Remember that these meetings are based on trust that the patient will have with you as a companion, so we reinforce the importance of confidentiality. • We suggest that you try to accept, if it occurs, an invitation from the patient to pray, pray, sing or participate in some religious or spiritual rite, in the context of the telematic accompaniment that you are providing.
Closing of the sessions	• At the end of a session (remember that these sessions should not last more than 1 hour, both for your time and the patient's time), you can briefly recap what you have discussed. • Remember to thank the patient for his or her time and define when your next meeting might be. The study team will coordinate the sessions, but it is important that you, as a volunteer, can confirm the most suitable days and times for you and the family member.

	• If you are closing the third session, remember to especially thank the patient for sharing his or her beliefs, values and convictions with you.
Technical aspects	Prior to the beginning of the sessions, check how your internet connection is, because a bad connection will make it difficult to carry out the session (Zoom or Video Call). It is also important that you check that the audio and camera of the device you will be using are adequate. In the volunteer's manual you will find more information in the "Technical Guide" section. • Both you and the patient need to be in a comfortable and quiet place for the sessions; noises or interruptions may hinder your development. Please check this before starting the session. • The research team will explain these aspects to the patients, and health personnel when coordinating the sessions. • If the patient health condition does not allow to attend the session, you will be notified promptly, and the session will be rescheduled.

Satisfaction Survey on Spiritual Care Intervention

Instructions:

1. Please select one option for each statement.
2. If you wish to leave a comment, you can use the last column.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Comment
The spiritual care program met your expectations.						
The spiritual care volunteer was empathetic and respectful.						
The one-on-one relationship (patient:volunteer) felt appropriate.						
The topics discussed during the sessions (e.g., meaning of suffering, uncertainty, death, life after life, ideas about healing, forgiveness, guilt, etc.) addressed your current concerns while hospitalized.						
You feel that during the spiritual care sessions you had adequate time to express yourself and ask questions.						
The duration of the spiritual care sessions (approximately 1 hour) was appropriate.						
The frequency of the spiritual care sessions (every other day) was appropriate.						
You believe that similar spiritual care programs should be implemented in other hospital services.						
You would recommend this spiritual care program to other ICU patients.						

Interview guides will guide focus groups.

Each focus group will discuss the following themes, and the emphasis will be adapted between patients, volunteers, and team members based on their role in the study.

1. Please describe your experience with the intervention.
2. What do you think are the most valuable parts of the intervention for helping patients? Explain why you think so.
3. Which components or strategies of the intervention do you believe may require revision?
4. What are your thoughts on the delivery format, time of day, number of sessions, and length of the intervention?
5. What are your thoughts on the training and tools required to carry out the intervention?
6. What difficulties did you encounter during the intervention?
7. What recommendations could you offer to improve intervention and training?
8. What would they change?
9. What would they keep?