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Spiritual care for prevention of psychological disorders in critically ill patients: study protocol of a feasibility randomised 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 labelled postintensive care syndrome (PICS). Prior research has demonstrated that spiritual care aligned with a specific creed during hospitalisation 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 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 post-traumatic stress disorder in critically ill patients.

Methods and analysis This is a single-site, feasibility randomised controlled pilot trial of a generalist spiritual care intervention 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 alterations in consciousness will be randomly assigned to either the spiritual care group or the usual care group at a ratio of 1:1. The primary outcome will be 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 at 3 months after ICU discharge. Subjects will be followed up until 3 months post-ICU discharge.

Ethics and dissemination The Ethics Committee for Medical Sciences of Pontificia Universidad Católica de Chile (#220111005) and the Ethics Committee of 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 organisations and the Chilean Intensive Care Society.

Trial registration number NCT06048783.

STRENGTHS AND LIMITATIONS OF THIS STUDY

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

INTRODUCTION

The incidence of critical illness has increased due to ageing of the chronically ill population. Additionally, emerging viruses and bacteria, such as COVID-19, have resulted in an unprecedented increase in the number of 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 postintensive care syndrome (PICS).[2 3] A previous study reported that, regardless of whether intensive care unit (ICU) admission is for a medical problem or for an urgent or elective surgical intervention, >40% of ICU survivors will experience new or worsening 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 assessment is performed and the instruments used for evaluation.[1] The incidence of physical sequelae has been evaluated in a systematic review that included 33 studies, with 1080

of 2686 patients (43%) meeting the criteria for acquired critical patient weakness (ICUAW).[4] However, the studies used different methods to assess ICUAW (eg, physical examination, electrophysiological testing, histological assessment), leading to a 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.[5] Psychological symptoms of PICS include symptoms of depression, anxiety and post-traumatic stress disorder (PTSD).[6] 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, while other studies have reported that a quarter of survivors present with PTSD symptoms 1 year after discharge from the ICU.[7–9] Some studies have reported a residual effect several months after discharge from the ICU, affecting people's quality of life and functionality.[3] The risk factors for PICS are categorised 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 include the following: (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] 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 in order to address PICS.[10–13]

In the last decade, interest in spirituality and spiritual care (SC) in ICUs has grown.[14–16] In some studies, SC among patients is a measure of healthcare quality.[17] Studies have also shown that quality care in the ICU involves attention to the person.[18] SC in the ICU has usually been associated with end-of-life care. However, admission to the ICU is a stressful experience that causes 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.[19 20] Studies have reported that patients who need care in the ICU are especially likely to affirm that spirituality is important to them.[17 21 22]

According to Puchalski,[23] spirituality is a dynamic and intrinsic aspect of humanity through which persons seek ultimate meaning, purpose and transcendence and experience relationships with self, family, others, community, society, nature and the significant or sacred. Spirituality is expressed through beliefs, values, traditions and practices. Meanwhile, 'connection', 'meaning and purpose of the person's life' and 'transcendence' are the three essential elements when defining SC.[15 24 25] SC recognises and pays attention to spirituality within healthcare. SC can be provided by spiritual caregivers or chaplains trained to deliver SC in clinical settings. It is advised that an interdisciplinary team provide SC, with 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.[23] Nevertheless, ICU staff (intensivists and ICU nurses) often delegate the spiritual needs of patients and/or their families to a spiritual caregiver or the patient's parish clergy, believing they are better qualified to address such issues due to scheduling or lack of experience.[26] 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 standardise SC methods to assess the spiritual needs of patients and/or their families in the ICU.[18 22] A growing number of studies show that the organisation of SC in the ICU can be enhanced and integrated into daily ICU care following a holistic care.[27–30]

In studies on patients with chronic diseases, SC has been associated with hope, meaning and peace, bringing relief to these patients. 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.[18] 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) improving 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.[16 18 25 26] A recent systematic review on the impact of SC interventions in critically ill patients included 18 interventional studies (quasi-experimental or randomised clinical trials), all conducted in Asian countries. The control group received the usual care from the center, while the SC intervention was mainly associated with a particular creed, provided by spiritual caregivers or nurses, and different outcomes were assessed. The 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 recognised SC as positive, contributing to patients' and their families' psychological well-being and satisfaction.[31] Hospitalisation is a significant stressor that can impact patients' physical and mental health and 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.[32] Specifically, it can ease the burden of hospitalisation and alleviate psychological and emotional distress.[33 34] Spirituality can offer protection against anxiety and depression by providing a sense of meaning, purpose and hope, especially during demanding times such as a physical illness or hospitalisation.[35] Consequently, patients who do not receive SC may experience hospitalisation as a significant stressor. They may have fewer tools to cope with this event, wich can lead to more emotional and psychological. This increases the risk of adverse mental health outcomes.

However, SC is not 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.[36] On the other hand, not all hospitals and ICUs have spiritual caregivers or chaplains among their staff.

Considering this, the proposed study aims to evaluate the feasibility of implementing an SC intervention in 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 the impact of SC on individuals' health outcomes through studies like this may contribute to a paradigm shift from a biomedical perspective to a holistic view of ICU patients. Although the technological and advanced life support in the ICU are essential for treating critically ill patients, the possibility of survival from a severe disease without a good quality of life necessitates the development of strategies to address this issue. A comprehensive approach to the patient,encompassing medical-physiological care and SC, is essential to address this challenge. The study protocol is described in the following section, with a focus on the proposed intervention.

METHODS

Study design and setting

This protocol follows the 2013 guidelines of the Standard Protocol Items: Recommendations for Interventional Trials[37] to ensure consistent reporting of clinical trials. The trial is a single-site pilot feasibility randomised controlled trial. Thirty patients will be enrolled, and 15 subjects will be randomised to each arm. Patients will be recruited between December 2024 and July 2025.

The study focuses on patients hospitalised in the ICU of 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.[38] The ICU has 36 beds and has the capability of performing complicated procedures, such as extracorporeal membrane oxygenation, multimodal neuromonitoring, invasive haemodynamic monitoring, etc. The ICU has a staff of professionals (physicians, nurses, kinesiologists, speech therapists, occupational therapists, clinical pharmacologists, etc) trained in intensive care medicine. At the CASR, the ICU and the intermediate care unit have the same administrative and clinical dependency; they are called critical patient units.

Eligibility criteria

The target population of the present study comprises critically ill patients who have been on invasive mechanical ventilation (IMV) 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

- Adult patients (≥18 years).
- Patients who have had at least 72 hours of IMV.
- Patients currently in the ICU.
- Glasgow Score of 15[39] at the time of screening.

Exclusion criteria

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

Intervention

Enrolled participants included in the intervention will receive a systematic and periodic generalist spiritual care (GSC) programme using the FICA Spiritual Assessment Tool (*F*aith and Belief, *I*mportance and Influence, *C*ommunity and *A*ddress in Care).[40] The GSC intervention proposed in this study has three distinctive characteristics: (1) it is systematic and periodic, achieved through a standardised schedule of three GSC sessions based on the FICA Spiritual Assessment Tool (see below); (2) care is delivered by volunteers trained for the intervention (see online supplemental appendix 1), which is fundamental in ensuring that the intervention is systematic and standardised; and (3) generalist spiritual care is delivered via telematics, 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 min, occurring every other day over 1 week. The GSC that will be provided does not adhere to any creed, but 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. In order to guarantee adherence to the three characteristics of GSC, we developed four critical components for the intervention: (1) design of the GSC sessions; (2) generation and implementation of a training programme for volunteers; (3) development of a manual for volunteers; and (4) implementing a logbook for volunteers. The GSC sessions consider a 1:1 ratio (patient to companion ratio), and participants will always be 'accompanied' by the same volunteer. Although ideally the entire intervention should be carried out while the patient is hospitalised in the ICU, considering the average stay of patients in the CASR ICU,[41] 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 SC sessions outside the ICU. The research team will coordinate the sessions, depending on the patients' and the volunteers' availability and clinical condition. This coordination involves the following:

- Scheduling of the day and time of the session. To systematise the delivery of the intervention, all sessions will take place from Monday to Friday until 20:00 hours.
- 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.
- 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 recoordinate 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,[40] which allows the exploration of spirituality in the healthcare context. The tool was initially written in English but has a Spanish translation.[42] The FICA is a 'spiritual anamnesis tool' that helps identify a person's spiritual needs and resources. By exploring spiritual needs through the FICA, people can find/recognise elements of their lives that support them in difficult situations, such as having a serious illness. The FICA proposes exploration of four crucial dimensions of spirituality:

- F: faith and beliefs.
- I: importance of faith and beliefs in a person's life.
- C: community, that is, the importance of the community to the person, including family, friends, coworkers, or other activities, in living their faith and beliefs.
- A: focus of attention, which may vary depending on who is asking. Participants may ask the volunteers about SC during sessions.

Each session has specific goals that the volunteers should consider. In the first session, volunteers should get to know the patients 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 participants. 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 hospitalised in the ICU, such as: how have you felt? have you had any experience as a patient 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 in order to offer them adequate GSC for what they are experiencing. This personalised but systematised GSC is one of the advantages of having sessions based on the FICA. Table 1 shows examples of questions that volunteers can use to apply the FICA. Ideally, exploring the four dimensions of the FICA should be completed during the first session; however, if it is not achieved, this can be completed in the second session.

The goal of the second and third sessions is to obtain a deeper understanding of the dimensions of the 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'.[40] In this sense, active listening on the part of the volunteer is critical during the three sessions of the intervention.

Volunteers correspond to adults who have committed generously and selflessly to provide SC 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 starting 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 that 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 online supplemental appendix 1), which will be explained to the participants during the recruitment and informed consent process. However, if the volunteer detects that a patient is emotionally compromised, they should alert the research team. As a team, we will contact these patients and their treating physicians and activate a referral network for mental health specialist 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

Table 1 Examples of possible questions for each FICA dimension[62]

FICA 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 hospitalisation 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 made 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 neighbours, members of a senior citizens' club, sports club, etc)?
Approach to care	► How would you like me to support you during these coaching sessions?

FICA, faith and belief, importance and influence, community and address in care; ICU, intensive care unit.

version)[43] will be administered to evaluate symptoms of delirium that could interfere with the intervention. CAM-ICU is a tool specifically designed to assess confusional syndrome in the context of ICU patients, including those who are on mechanical ventilation.[44]

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, which consists of the possibility of being assisted by a Catholic priest or by pastors from Protestant churches.

Outcome 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 participants' satisfaction with the GSC care programme.

The enrolment rate will be measured, corresponding to the proportion of patients who consent and are enrolled in the study during the first 6 months. The attendance rate will be evaluated through the proportion of patients receiving at least three intervention sessions 2 weeks after randomisation. Likewise, the follow-up rate will be measured by the proportion of patients who complete the evaluation 3 months after discharge from the ICU.

Participants' satisfaction with the intervention will be measured through a satisfaction questionnaire (see online supplemental appendix 2) administered 1–2 weeks and 3 months after the last session of the intervention.

Secondary outcomes

The secondary outcomes will be the mean change in PTSD symptoms, anxiety and depression from baseline to 3 and 6 months after recruitment (follow-up). PTSD will be assessed using the Impact of Event Scale (Chilean population version).[45] This scale has a score ranging from 0 to 88, with a cut-off score higher than 43. The Hospital Anxiety and Depression Scale (HADS) 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 reliability and validity in Chile in the diagnosis and assessment of the severity of the disorder.[46] It comprises two subscales (HAD-A: anxiety and HAD-D: depression) with seven items, each with scores ranging from 0 to 3. The authors recommend the following cut-off points for both subscales: 8 for possible cases and >10 for probable cases.

Other relevant outcomes will be volunteers' satisfaction with the GSC intervention, measured by a satisfaction questionnaire administered 1–2 weeks after the end of the last GSC session. Once the intervention is over, the perceptions of the participants, volunteers and research team regarding the intervention, its components, training and recommendations, and the difficulties encountered will be evaluated in three focus groups (FGs): one for the patients, another for the volunteers and the third with the health personnel.[47] We will invite participants to FGs to explore their perceptions regarding the facilitators and barriers to GSC according to their experience with the intervention (see online supplemental appendix 3). The FG will be conducted through teleconferencing to facilitate participation of patients, volunteers and health personnel. The research team will perform the FG and will be guided by a script. Each session will last between 90 and 120 min 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

	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

Figure 1 Timeline of recruitment, allocation and assessment: –t1, baseline; t1, each day until ICU discharge; t2, hospital discharge; t3, 3-month follow-up; t4, 6-month follow-up. HADS, Hospital Anxiety and Depression Scale; ICU, intensive care unit; IES, Impact of Event Scale; LOS, length of stay.

collected, psychological questionnaires will be administered and the data collected will be documented on the case report form by trained clinical research coordinators. Patients will be followed up during their ICU and hospital stay, and mechanical ventilation days, ICU stay and hospital stay will be recorded. Patients will be evaluated 3 and 6 months after discharge from the ICU to assess the secondary outcomes. Evaluation of psychological outcomes will be performed by trained interviewers. The evaluation schedule for the trial is shown in figure 1.

To improve participants' adherence to the intervention and follow-up, the research team will visit them before each GSC 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 enquire about their reasons for non-attendance and attempt to encourage compliance and attendance.

Sample size

There have been no similar studies and therefore we planned a pilot study. The objective of this pilot study is to examine the feasibility and acceptability of the protocol. The orientation of the pilot and feasibility randomised controlled trials is to estimate the potential sample size on the ability to detect a significant feasibility problem that could interfere with a subsequent full-size randomised controlled trial. 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.[48]

The qualitative component of the study aims to assess whether the intervention can work from the perspectives of the patients who received it, the volunteers who delivered it and the research team in the ICU. The number of participants per FG considers that the topics addressed are not complex, are more concrete and focus mainly on the perceptions of these three groups regaeding the

intervention, consequently, requires conducting fewer FGs to reach saturation.[49 50] The number of participants in each FG follows the recommendations from previous studies suggesting that the number of participants per group should range between 6 and 10.[51]

Assignment of interventions

Once the informed consent is signed, the patients will be randomised to receive a systematic and periodic GSC programme or standard care (control group). Randomisation 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 will be carried out by random blocks of 5, with a 1:1 allocation. Allocation concealment will be achieved through a centralised randomisation in REDCap (Research Electronic Data Capture)[52 53] and implemented by our institution's informatics unit. The research staff will perform randomisation.

Due to the type of intervention under study, the patients 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

Data for the study will be collected and managed using the REDCap electronic data capture tool hosted at Pontificia Universidad Católica de Chile.[52 53] REDCap 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 enrolment, the study staff will collect information from 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,[54] Chronic Health Assessment II and Sequential Organ Failure Assessment (SOFA),[55] comorbidities according to the Charlson Comorbidity Index,[56] admission diagnoses, and pre-existing neuropsychological impairment. The Impact of Event Scale and HADS will also be used.

During each patient's stay in the ICU, data will also be collected on SOFA, haemodialysis and vasopressor use, duration of mechanical ventilation, and length of ICU and hospital stay. All patients will undergo a standardised follow-up at 3 and 6 months post-ICU discharge, in which the Impact of Event Scale and HADS will be administered by 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 group allocation will implement the statistical analysis. Baseline characteristics will be reported using mean±SD, median (p25–75) and percentages. The use of parametric or non-parametric tests will depend on data distribution. Continuous variables will be compared using the Student's t-test or the Mann-Whitney test, and categorical variables will be compared using the χ^2 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 models will be adjusted for confounding factors (age, sex, socioeconomic status, comorbidities, severity score, drug consumption, days on mechanical ventilation, days of ICU stay and days of hospital stay). An interaction analysis 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 used 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 analysed using thematic analysis.[57] This method allows for identification and analysis of thematic patterns using predetermined codes for the data. This enables the identification of contrasts and convergences between FGs. Deductive coding will be used to analyse the predefined themes from the FG script (eg, 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 (V.11; QSR International, Doncaster, Victoria, Australia)[58] will be used under the following criteria for rigour: 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 will sign the consent form. This will be done by a research team member who will not be involved in the participants' care.

Before starting the GSC sessions, the volunteers must sign a confidentiality agreement regarding what was discussed with the participants during these sessions. Also, they will be asked to sign an informed consent document providing permission to analyse 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 and thus 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'.[59] 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 connection with nature or cosmovision of native peoples.[59] The current evidence base indicates that SC interventions in the ICU can improve clinical outcomes in critically ill patients.[31] However, the studies conducted have been based on SC on religiosity and faith, which may limit the generalisability of the findings.[60 61] In this context, this study represents a novel contribution to the field, as it is the first randomised trial in Chile to investigate GSC. As a research team, it seems necessary to establish a systematic and standardised 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 randomised clinical trial comparing a GSC intervention with standard care in critically ill patients, with sufficient statistical power to assess the outcomes of importance to patients. The greatest perceived threat to the feasibility of this pilot trial is non-adherence to the protocol. Several measures have been taken to enhance adherence to the protocol, 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 programme cannot be implemented in this trial. Therefore, when interpreting the results of the study, the effects that other factors, such as participant expectations or the patient–volunteer relationship, may have had on the psychological outcomes must be considered. Second, this is not a multicentre study and therefore the results cannot be generalised. However, no studies have been published on preventing PICS through GSC performed by trained volunteers. A study conducted in a single centre 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 in long-term psychological outcomes (PTSD, anxiety and depression). This is a pilot study designed 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 randomised controlled trials to obtain strong evidence on the effectiveness of GSC in preventing psychological impairment in critically ill patients.

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