PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

Title (Provisional)

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

Authors

Repetto, Paula; Ruiz , Carolina; Rojas , Verónica; Olivares , Patricia; Bakker, Jan; Alegria, Leyla

VERSION 1 - REVIEW

Reviewer	**1**
Name	**Cheng, Lei**
Affiliation	**Fudan University**
Date	**22-Mar-2024**
COI	**no**

This is a fairly well written protocol. My suggestion is:

1. Strengthen rational of spiritual care for this special population

2. Introducing and discussion similar study results

3. Detailed intervention dose for this study, e.g., frequency and duration and if any spiritual crisis protocol

4. Will the volunteers and participants be matched by confounders like faith?

Reviewer	**2**
Name	**Zumstein-Shaha, Maya**
Affiliation	**Bern University of Applied Sciences**
Date	**28-May-2024**
COI	**No competing interests are declared**

Thank you for your interesting manuscript. A few issues are found that are pointed out below.

- Abstract: It seems that the abstract is not quite complete. Please refer to the journal's guidelines for a complete abstract.

- Introduction:

In this study, the focus appears to be on patients who have been treated at ICU. Please start the introduction with epidemiology (facts and figures) on this patient group, i.e., patients who were in ICU treatment.

Not every patient going through ICU will develop a PICS. Please provide a more detailed account on patients who have a high risk of developing PICS.

Please explain in more detail the importance of spirituality in this context. It is not entirely adequate to link spirituality to mental health or psychological distress. Please indicate the potential problem for patients with PICS who do not receive spiritual care.

Methods:

- Exclusion criteria: How will mental and intellectual disability be assessed? What about patients who will have a cognitive impairment due to the underlying disease (i.e., stroke, etc.)?

- Inclusion criteria: Given the intervention, the inclusion criteria do not seem comprehensive (capability of using computers, zoom, etc.).

- Intervention: As it is stated that the multidisciplinary team is necessary for spiritual care, it is not understandable why volunteers were employed. Please provide an explanation. Was the intervention based on some model concerning the contents? Or how was it developed?

- Design: This is a feasibility study. Please include this in the title and the rest of the protocol. Please explain the selection of secondary outcomes. It is not quite conceivable how they relate to the contents of the intervention. Also, the structure of the methods might need to be adjusted. The following structure might be more suitable:

a) Design with mention of feasibility study and timeline

b) Intervention development

c) Outcomes: primary and secondary

d) Sampling and recruitment, allocation

e) Data collection including the detailed description of data collection methods (i.e., questionnaires, etc.)

f) Data analysis

g) Ethical considerations

- Discussion: This section is somewhat more like a defense of the study. Maybe it needs to be reconsidered. At the very least, more connection with existing literature must be demonstrated.

- Limitations: Why can there be no blinding?

- General comments:

Please review the reference system. Currently, each reference number features within two special brackets.

Sincerely,

Your reviewer

Reviewer	**3**
Name	**O'Callaghan, Clare**
Affiliation	**Department of Medicine, St. Vincent's Hospital, The University of Melbourne**
Date	**25-Aug-2024**
COI	**none**

This protocol is a sound description of a planned, valuable study examining the feasibility, acceptance, and efficacy of a spiritual care intervention for preventing psychological disorders in critically ill patients in Chile. I offer comments which I think would strengthen the quality of this report.

Abstract. Please put aims in the Introduction and further explain the methods and analytical procedures in the Methods and Analysis section.

Introduction

Page 6, line 5. Spiritual care does rely on a multidisciplinary team but please distinguish between specialist and generalist spiritual care

Page 6, line 18. Please provide a working definition on accompaniment when it is introduced.

Method

Page 8, Line 26. FICA needs to be spelt out and referenced

Page 9, line 33. Line 33. Are you using the Spanish version of FICA?

Page 12, lines 13 18. Please provide the focus group question framework and how the focus group participants will be organised into the three focus groups.

Line 22. Please explain and reference the approach to thematic analysis that will be used. Will it involve qualitative data management software?

Page 13. Please detail how the supervisor's "quality assurance checks" will be conducted.

Page 25 fwd. Table 2. Please cite references and/or other resources that informed these Recommendations, including the comment, "It may also happen that you have beliefs in

common, which we invite you to use as an element that enriches the sessions." I found this especially interesting. Is there a precedent in the literature for this?

Referencing. Further references are needed to support points on the following lines: Page 5, lines 26, 52, 53; Page 6, line 57 (SPIRIT guidelines; also their presence in the Appendices needs reporting); Page 7, line 33 (REDCAP); line 57 (Glasgow); line 26 (FICA); Page 11, line 39, CAM ICU. Also cite and reference the measures on bottom of Page 12 and top of Page 13, and the free software at the bottom of Page 13. Also please reference FICA in Table 1

Editing. The writing style would benefit from further review and revision to improve clarity. For example:

Page 6, line 10 – do you mean "critically ill patients"? Lines 24-30: spiritual care training for whom is associated with subsequent provision of spiritual care for whom? Please give an example of a "training intervention" which could standardize spiritual care and explain why that is important.

Page 9, lines 44-47. "This makes it easier to carry out the intervention, as it prevents patients and volunteers from traveling to the sessions." Here do you mean "… prevents patients and volunteers needing to travel to sessions"?

Lines 40-44. "Balancing spiritual needs and resources can be complex while hospitalized in the ICU, so guided reflection on this may be helpful." Do you mean that it can be complex for staff to decide which patient receives which available spiritual resource in the ICU so that a guide for staff to make those decisions would be helpful?"

VERSION 1 - AUTHOR RESPONSE

Reviewer 1: Dr. Lei Cheng, Fudan University

This is a fairly well written protocol.

Response: Thank you for your thoughtful and positive comments.

1. Strengthen rational of spiritual care for this special population

Response: Thank you for this observation; we agree. We had changed the introduction and focused on spiritual care for critically ill patients.

Change in the manuscript: Please refer to the introduction in the "Main Document - marked copy" for further details.

2. Introducing and discussion similar study results

Response: Thank you for this observation. We have incorporated the findings of prior studies examining the eficacy of spiritual care interventions into the introduction and

discussion sections of the manuscript. Please refer to the changes made to the manuscript using the change control system.

3. Detailed intervention dose for this study, e.g., frequency and duration and if any spiritual crisis protocol

Response: Thank you for this suggestion; we agree. As detailed in the Methods section, the intervention dosage is as follows.

Regarding the question about a protocol for action in case of spiritual crisis, volunteers are trained in psychological first aid in case a subject sufers an emotional crisis during the intervention. The research support team includes a clinical psychologist who is available in case the participant requires it and can refer him/her if appropriate. In case of a spiritual crisis, the volunteer will refer the subject to the priest who is part of the research team.

Change in the manuscript: *"The dosage of the intervention entails three SC sessions to be conducted remotely via Zoom or video call 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 the course of one week. The SC that will be provided does not adhere to any particular creed, thereby constituting an ecumenical intervention."*

4. Will the volunteers and participants be matched by confounders like faith?

Response: Thank you for the question. Volunteers will be randomly assigned according to availability. Each participant will be assigned only one volunteer who will conduct the entire intervention. If either the participant or the volunteer feels uncomfortable in the patient-volunteer relationship, a change can be made without any detriment to either the participant or the volunteer. They will not be matched by faith because the intervention is ecumenical and is based on the application of the FICA questionnaire. Volunteers have been trained in providing CS without a particular creed.

Reviewer 2: Dr. Maya Zumstein-Shaha, Bern University of Applied Sciences

Thank you for your interesting manuscript. A few issues are found that are pointed out below.

Response: Dear Dr., Zumstein-Shaha, we encourage you to engage in a constructive dialogue by sharing your comments, questions, and suggestions. We invite you to review our comprehensive response to your comments, presented in a point-by-point format.

1. Abstract: It seems that the abstract is not quite complete. Please refer to the journal's guidelines for a complete abstract.

Response: Thank you for your comment. We have updated the abstract based on the review guidelines.

Change in the manuscript: Please refer to the changes made to the manuscript using the change control system.

2. Introduction: In this study, the focus appears to be on patients who have been treated at ICU. Please start the introduction with epidemiology (facts and figures) on this patient group, i.e., patients who were in ICU treatment. Not every patient going through ICU will develop a PICS. Please provide a more detailed account on patients who have a high risk of developing PICS. Please explain in more detail the importance of spirituality in this context. It is not entirely adequate to link spirituality to mental health or psychological distress. Please indicate the potential problem for patients with PICS who do not receive spiritual care.

Response: Thank you for this suggestion. We have reformulated our introduction with a focus on critically ill patients and PICS, and we have explained the importance of spirituality in this context.

Hospitalization in an ICU is a significant stressor for patients, often leading to psychological and emotional distress and increasing the risk of adverse mental health outcomes. However, studies on stress experiences suggest that spirituality can serve

as a coping strategy, helping to reduce the impact of ICU stays and providing patients with a sense of control and resilience when facing this experience. Consequently, spiritual coping can alleviate the efect of a stressful event, reducing distress and, in turn, lowering the risk of depression, anxiety, and other adverse mental health outcomes.

Change in the manuscript: Please refer to the introduction in the "Main Document - marked copy" for further details.

3. Methods:

- Exclusion criteria: How will mental and intellectual disability be assessed? What about patients who will have a cognitive impairment due to the underlying disease (i.e., stroke, etc.)?

Response: We are grateful for your comments. Prior mental disabilities will be assessed based on clinical history. Patients with a diagnosis of prior mental or intellectual disability will be ineligible to participate in the study, in accordance with the local regulatory framework.

Regarding patients who will have cognitive impairment due to the underlying disease, for example, patients with a stroke, exclusion criterion n°2 excludes them from the study.

- Inclusion criteria: Given the intervention, the inclusion criteria do not seem comprehensive (capability of using computers, zoom, etc.).

Response: Thank you for your observation. It should be noted that participants will be in the presence of a member of the research team who will facilitate the technological aspects of the intervention. Consequently, the ability to use technology is not an inclusion criterion.

- Intervention: As it is stated that the multidisciplinary team is necessary for spiritual care, it is not understandable why volunteers were employed. Please provide an explanation. Was the intervention based on some model concerning the contents? Or how was it developed?

Response: Thank you for taking the time to provide us with your feedback. Spiritual caregivers (also known as chaplains) and members of the healthcare team are the two main categories of SC. In our local context, there is currently no training available for specialized spiritual caregivers. Consequently, when a patient requests spiritual care, it is usually provided by priests, nuns, or other individuals belonging to the patient's religious community, in the case of non-Catholic patients. On the other hand,

healthcare professionals lack the requisite undergraduate or graduate training in spiritual care, which makes it challenging for them to deliver spiritual care. Additionally, the reality of our ICUs is that they are highly complex, and the care load is high. For instance, an ICU nurse is responsible for three or four critically ill patients per shift, which further complicates the delivery of spiritual care by the multidisciplinary team. In this context, we have opted to employ volunteers.

Regarding the intervention model, the proposed intervention is based on Puchalski's SC suggestions for the application of the FICA. Three sessions were selected to provide participants with suficient time to elaborate on their spirituality and the various components of the FICA. It is important to note that the study subjects will be patients recovering from a critical illness and undergoing rehabilitation. Given these circumstances, longer sessions may prove exhausting for them. Furthermore, three sessions of 45 to 60 minutes each will not disrupt the logistics of patient care.

- Design: This is a feasibility study. Please include this in the title and the rest of the protocol. Please explain the selection of secondary outcomes. It is not quite conceivable how they relate to the contents of the intervention. Also, the structure of the methods might need to be adjusted. The following structure might be more suitable:

a) Design with mention of feasibility study and timeline

b) Intervention development

c) Outcomes: primary and secondary

d) Sampling and recruitment, allocation

e) Data collection including the detailed description of data collection methods (i.e., questionnaires, etc.)

f) Data analysis

g) Ethical considerations

Response: Thank you for your suggestions. We have taken them into account and made the necessary modifications to the title of the paper and the protocol, which now reflect a pilot feasibility study.

Regarding the selection of secondary outcomes, the hospitalization in the ICU is a significant stressor that can impact patients' physical and mental health. According to the transactional stress model, spirituality serves as a coping mechanism and can mitigate the efects of stressful events. It can ease the burden of hospitalization and alleviate psychological and emotional distress. Spirituality can ofer protection against

anxiety and depression by providing a sense of meaning, purpose, and hope, especially during demanding times such as physical illness or hospitalization. In light of the aforementioned factors, our selected secondary outcomes of interest pertain to the psychological sequelae associated with PICS, namely post-traumatic stress, anxiety, and depression.

Finally, we have updated the structure of the Methods section in accordance with the SPIRIT 2013 Guidelines.

Change in the manuscript: Please refer to the introduction in the "Main Document - marked copy" for further details.

- Discussion: This section is somewhat more like a defense of the study. Maybe it needs to be reconsidered. At the very least, more connection with existing literature must be demonstrated.

Response: Thank you for your feedback. We concur with your assessment. We have revised the paper discussion in accordance with your suggestions. We have incorporated a discussion of our proposal with the available evidence and stated the strengths and limitations of our study.

Change in the manuscript: Please refer to the introduction in the "Main Document - marked copy" for further details.

- Limitations: Why can there be no blinding?

Response: Thank you for your inquiry. It is not possible to blind the study to the patient or study staf, as the control group will receive the standard of care that corresponds to the subject being visited by the priest, which is available at the hospital if required. The subject will be informed that this option is available to them. For this reason, the patient who is randomized to the intervention group will be aware of their allocation, as will the research support team. However, we will ensure that the individual responsible for assigning the event and the person undertaking the analyses are blinded.

- General comments: Please review the reference system. Currently, each reference number features within two special brackets. Sincerely, Your reviewer

Response: Thank you for bringing this to our attention. We have conducted a thorough review of our references to ensure accuracy.

Reviewer 3: Dr. Clare O'Callaghan, Department of Medicine, St. Vincent's Hospital, The University of Melbourne

This protocol is a sound description of a planned, valuable study examining the feasibility, acceptance, and eficacy of a spiritual care intervention for preventing psychological disorders in critically ill patients in Chile. I ofer comments which I think would strengthen the quality of this report.

Response: Dear Dr. O'Callaghan, we would like to thank you for your comments and suggestions, which have proved invaluable in improving our work. We will now address the comments that you have provided.

1. Abstract. Please put aims in the Introduction and further explain the methods and analytical procedures in the Methods and Analysis section.

Response: Thank you for your comment. We have updated the abstract based on the review guidelines.

Change in the manuscript: Please refer to the changes made to the manuscript using the change control system.

2. Introduction

-Page 6, line 5. Spiritual care does rely on a multidisciplinary team but please distinguish between specialist and generalist spiritual care

Response: Thank you for your suggestion. We concur with your proposal. We have included a new paragraph in the introduction that outlines the distinction between specialized and general spiritual care.

Change in the manuscript: *"According to Puchalski, 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 basic elements when defining spiritual care. 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 sta; (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"*

Page 6, line 18. Please provide a working definition on accompaniment when it is introduced.

Response: Thank you for your suggestion. In the text, we refer to spiritual accompaniment as the provision of spiritual care. Therefore, we have removed the word "accompaniment" from the text and only refer to "spiritual care."

Change in the manuscript: Please refer to the changes made to the manuscript using the change control system.

3. Method

-Page 8, Line 26. FICA needs to be spelt out and referenced

Response: Thank you for your comment. Please be advised that we have referenced the FICA Spiritual Assessment Tool.

-Page 9, line 33. Line 33. Are you using the Spanish version of FICA?

Response: Thank you for your comment. Precisely. We are utilizing a Spanish translation that has been validated by the creator.

-Page 12, lines 13 18. Please provide the focus group question framework and how the focus group participants will be organized into the three focus groups.

Response: Thank you for your feedback. The framework of questions that will be used for the semi-structured interview for the focus group is provided in the methods section of the protocol. 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. 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.

-Line 22. Please explain and reference the approach to thematic analysis that will be used. Will it involve qualitative data management software?

Response: Thank you for your feedback. Please refer to the "Analysis" section of the Methods for details regarding the qualitative analysis.

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.

-Page 13. Please detail how the supervisor's "quality assurance checks" will be conducted.

Response: We appreciate your question and wish to assure you that the quality of the intervention will be monitored by the intervention support staf. Their role is to ensure that the intervention runs smoothly. Furthermore, after each SC session, volunteers will complete a logbook (see supplementary material), which will then be reviewed by the research team. This review will ensure that the spiritual session was conducted according to the protocol.

-Page 25 fwd. Table 2. Please cite references and/or other resources that informed these Recommendations, including the comment, "It may also happen that you have beliefs in common, which we invite you to use as an element that enriches the sessions." I found this especially interesting. Is there a precedent in the literature for this?

Response: Thank you for your observations. We have referenced the evidence supporting the recommendations made. Regarding the comment *"It may also happen that you have beliefs in common, which we invite you to use as an element that enriches the sessions*", it is a recommendation made by the author of FICA; however, we have not found specific evidence related to this recommendation. We believe that this pilot feasibility study, specifically concerning the qualitative methodology, could provide us with relevant information in this regard. Therefore, as you may have seen previously, we have added a question related to this suggestion to the semi-structured interview for the focus groups.

4. Referencing. Further references are needed to support points on the following lines: Page 5, lines 26, 52, 53; Page 6, line 57 (SPIRIT guidelines; also, their presence in the Appendices needs reporting); Page 7, line 33 (REDCAP); line 57 (Glasgow); line 26 (FICA); Page 11, line 39, CAM ICU. Also cite and reference the measures on bottom of Page 12 and top of Page 13, and the free software at the bottom of Page 13. Also please reference FICA in Table 1

Response: We are grateful for your insightful observations. The following points are supported by additional references, which are listed below: Please refer to page 6, line 57; page 7, lines 33, 57, and 26; page 11, line 39. Additionally, we have referenced the measurements on pages 12 and 13, as well as the free software on page 13. Finally, we

have referenced the FICA in Table 1.

5. Editing. The writing style would benefit from further review and revision to improve clarity. For example:

- Page 6, line 10 – do you mean “critically ill patients”? Lines 24-30: spiritual care training for whom is associated with subsequent provision of spiritual care for whom? Please give an example of a “training intervention” which could standardize spiritual care and explain why that is important.

-Page 9, lines 44-47. “This makes it easier to carry out the intervention, as it prevents patients and volunteers from traveling to the sessions.” Here do you mean “… prevents patients and volunteers needing to travel to sessions”?

-Lines 40-44. “Balancing spiritual needs and resources can be complex while hospitalized in the ICU, so guided reflection on this may be helpful.” Do you mean that it can be complex for staf to decide which patient receives which available spiritual resource in the ICU so that a guide for staf to make those decisions would be helpful?”

Response: Thank you for your observations and suggestions. We have conducted a comprehensive review of the text, particularly focusing on the areas you highlighted, and have revised the wording to ensure clarity.

VERSION 2 - REVIEW

Reviewer	**2**
Name	**Zumstein-Shaha, Maya**
Affiliation	**Bern University of Applied Sciences**
Date	**04-Dec-2024**
COI	

Thank you for the revised version of the manuscript. An interesting study is being presented. However, there are some issues that may need to be addressed:

- In the methods' section: For eligibility, no criteria that was detailed before (i.e., PICS syndrome or ICUAW was used. Could this be explained? It seems relevant that such participants are included in the study so as to have the real target audience.

- In the methods' section: Please provide specific introduction of all measures used to determine outcomes. At present, they are mentioned here and there without proper detailing.

- In the methods' section: Please explain the background of the interventionists. Are these chaplains or other clergy representatives? Is a short introductory course sufficient for these persons to being able to respond to patients' concerns and needs?

- In the methods' section: Please explain the ecumenical aspect of the intervention. This remains unclear.

Sincerely,

Your reviewer.

Reviewer **3**

Name **O'Callaghan, Clare**

Affiliation **Department of Medicine, St. Vincent's Hospital, The University of Melbourne**

Date **27-Nov-2024**

COI

Thank you for revising the manuscript. I still have a some comments, which I think need to be addressed.

1. Please review the section on specialist and generalist spiritual care. The idea of specialist and generalist spiritual care providers refers to a model whereby the chaplain (or pastoral carers) is considered a spiritual care specialist, with authority on all aspects of spiritual care, whereas other members of the team, such as doctors, nurses, and volunteers, can offer generalist spiritual care. Providers of generalist spiritual care can assist patients' and families' overall sense of well-being and feeling that what is sacred or important to them is respected. Chaplains may educate other team members about how they can offer generalist spiritual care. I suggest that your study would be examining a generalist spiritual care intervention, as volunteers are being trained in the spiritual care intervention.

The following references may help.

a) Handzo G, Koenig H. Spiritual care: whose job is it anyway? South Med J. 2004;97(12):1242–5.

b) Jones KF, Washington J, Kearney M, Best MC. What is the role of spiritual care specialists in teaching generalist spiritual care? The perspectives of pastoral care staff in a large Catholic health and aged care organisation. J Health Care Chaplain. 2022;29:368–80.

c) O'Callaghan, C., Brooker, J., De Silva, W., Glenister, D., Melia, A., Symons, X., Kissane, D., & Michael, N. (2019). Patients' and caregivers' contested perspectives on spiritual care for those affected by advanced illnesses: a qualitative descriptive study. Journal of Pain and Symptom Management, 58, 977-988. doi:10.1016/j.jpainsymman.2019.08.004

2. Please reference the following quote on page 11 line 45: "the encounter with someone who feels, who seeks, who needs to be heard and welcomed".

3. What does CAM refer to on page 12 line 40?

4. I think you need to provide the visitor's satisfaction questionnaire and focus group question guide (page 13) in appendices.

5. Please clarify the apparent inconsistency between these two statements: "The

initial sample size was determined based on the objectives of the study and the

criteria for information saturation [47]" (page 13), and "Since these pilot studies work with small samples, estimating the sample calculation is unnecessary" (page 14). I presume one statement focuses on patients, volunteers and the research team members, and the other only focusses on patient participants but greater clarity in the writing would be helpful.

6. On page 14 you state that "Study data were collected". You need to make this future tense (because you are writing a research protocol)

7. Please provide references for thematic content analysis and NVivo software (page 16).

8. What do you mean by the "questionnaire's proposed thematic aspects" (page 16) on which you will use deductive coding? What are the codes that you will use to inform this deductive search? Will they be the four FICA dimensions?

VERSION 2 - AUTHOR RESPONSE

Reviewer: 3

Dr. Clare O'Callaghan, Department of Medicine, St. Vincent's Hospital, The University of Melbourne

Comments to the Author: Thank you for revising the manuscript. I still have some comments, which I think need to be addressed.

1. Please review the section on specialist and generalist spiritual care. The idea of specialist and generalist spiritual care providers refers to a model whereby the chaplain (or pastoral carers) is considered a spiritual care specialist, with authority on all aspects of spiritual care, whereas other members of the team, such as doctors, nurses, and volunteers, can o`er generalist spiritual care. Providers of generalist spiritual care can assist patients' and families' overall sense of well-being and feeling that what is sacred or important to them is respected. Chaplains may educate other team members about how they can o`er generalist spiritual care. I suggest that your study would be examining a generalist spiritual care intervention, as volunteers are being trained in the spiritual care intervention. The following references may help.

a) Handzo G, Koenig H. Spiritual care: whose job is it anyway? South Med J. 2004;97(12):1242–5.

b) Jones KF, Washington J, Kearney M, Best MC. What is the role of spiritual care specialists in teaching generalist spiritual care? The perspectives of pastoral care sta` in a large Catholic health and aged care organisation. J Health Care Chaplain. 2022;29:368–80.

c) O'Callaghan, C., Brooker, J., De Silva, W., Glenister, D., Melia, A., Symons, X., Kissane, D., & Michael, N. (2019). Patients' and caregivers' contested perspectives on spiritual care for those a`ected by advanced illnesses: a qualitative descriptive study. Journal of Pain and Symptom Management, 58, 977-988. doi:10.1016/j.jpainsymman.2019.08.004

Response: We are most grateful for your comments and suggestions. We concur with this assessment. To ensure consistency in terminology throughout the manuscript, we have employed the term "generalist" when referring to spiritual care. However, the proposed intervention represents an "intermediate" spiritual care between specialized and generalist spiritual care. Our understanding of generalist spiritual care is that it is relatively basic and does not delve deeply into the spiritual dimension. Our proposal is distinctive and innovative because it is an intervention focused on the individual's understanding of spirituality. We contend that this approach could no longer be considered generalist spiritual care.

Furthermore, the manuscript's introductory section provides a more detailed explanation of the concept of specialized spiritual care.

Change in the manuscript: *"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]."*

2. Please reference the following quote on page 11 line 45: "the encounter with someone who feels, who seeks, who needs to be heard and welcomed".

Response: We are grateful for your feedback and have incorporated the citation.

Change in the manuscript: *"the encounter with someone who feels, who seeks, who needs to be heard and welcomed [41]."*

3. What does CAM refer to on page 12 line 40?

Response: We are grateful for your inquiry. The CAM-ICU acronym is the Confusion Assessment Method for the Intensive Care Unit. The 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. This item has been incorporated into the manuscript.

Change in the manuscript: *"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]."*

4. I think you need to provide the visitor's satisfaction questionnaire and focus group question guide (page 13) in appendices.

Response: We are grateful for your proposal. The questionnaire used to assess satisfaction with the intervention (appendix 2) and the guiding questions for the focus groups are included in the appendices (appendix 3).

5. Please clarify the apparent inconsistency between these two statements: "The initial sample size was determined based on the objectives of the study and the criteria for information saturation [47]" (page 13), and "Since these pilot studies work with small samples, estimating the sample calculation is unnecessary" (page 14). I presume one statement focuses on patients, volunteers and the research team members, and the other only focusses on patient participants but greater clarity in the writing would be helpful.

Response: Thank you for your observation. The phrase "The initial sample size was determined based on the objectives of the study and the criteria for information saturation [47]" pertains to the sample size for the focus groups, in which we will examine the barriers and facilitators of the intervention. While the phrase " Since these pilot studies work with small samples, estimating the sample calculation is unnecessary " refers to the number of patients we will recruit to assess the e`ectiveness of the intervention.

We have modified the manuscript to avoid confusion among readers. Everything related to sample size (FGs and pilot study in patients) is specified in the "Sample size" section of the manuscript.

Change in the manuscript: "*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 [47]. It is recommended that three focus groups be conducted, with eight to ten participants in each group."*

5. On page 14 you state that "Study data were collected". You need to make this future tense (because you are writing a research protocol)

Response: We apologize and thank you for your comment. The error has been corrected in the manuscript.

Change in the manuscript: "*Study data will be collected and managed using REDCap electronic data capture tools hosted at Pontificia Universidad Católica de Chile [48,49].*"

6. Please provide references for thematic content analysis and NVivo software (page 16).

Response: We are grateful for your feedback and have incorporated the citation.

Change in the manuscript: *"The NVivo® software (Version 11- QSR International Pty Ltd, Doncaster, Victoria, Australia)"*

8. What do you mean by the "questionnaire's proposed thematic aspects" (page 16) on which you will use deductive coding? What are the codes that you will use to inform this deductive search? Will they be the four FICA dimensions?

Response: Thank you for your question. We mean that thematic content analysis will analyze the focus group discussions. This method will help us to find and understand patterns or important themes in what the participants say by organizing the information into codes and categories. In terms of deductive coding, predefined themes (e.g., those suggested in the questionnaire: Faith and Belief, Importance and Influence, Community, and Address in Care) will be used as a basis for analysis. In order to provide greater clarity in the manuscript, the phrase in question has been modified.

Change in the manuscript: "*To achieve this, deductive coding will be used to analyze the predefined 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.*"

Reviewer: 2. Dr. Maya Zumstein-Shaha, Bern University of Applied Sciences

Comments to the Author: Thank you for the revised version of the manuscript. An interesting study is being presented. However, there are some issues that may need to be addressed:

1. In the methods' section: For eligibility, no criteria that was detailed before (i.e., PICS syndrome or ICUAW was used. Could this be explained? It seems relevant that such participants are included in the study so as to have the real target audience.

Response: Thank you for your question. The inclusion and exclusion criteria for the study are designed to facilitate the recruitment of patients at risk of developing PICS. The objective of our intervention is to prevent PICS, particularly the psychological aspects of PICS (anxiety, depression, and post-traumatic stress disorder). Consequently, we hypothesize that patients who require IMV for a minimum of 72 hours will be subjected to a series of The aforementioned risk factors for PICS, including delirium, the use of sedatives, invasive mechanical ventilation, greater severity, and organ dysfunction, and a longer duration of ICU stay, among others, could potentially benefit from a spiritual care intervention, thereby preventing the psychological component of PICS.

2. In the methods' section: Please provide specific introduction of all measures used to determine outcomes. At present, they are mentioned here and there without proper detailing.

Response: We appreciate your suggestion and have rewritten the "Outcomes Measures" section to enhance the clarity of the manuscript.

Change in the manuscript:

"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-o> 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-o> 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 di>iculties 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. 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."

3. In the methods' section: Please explain the background of the interventionists. Are these chaplains or other clergy representatives? Is a short introductory course su`icient for these persons to being able to respond to patients' concerns and needs?

Response: The interventionists in the present study are volunteers and adults who have accepted the invitation to be trained and subsequently provide spiritual care in the ICU setting. It should be noted that these individuals are not chaplains or clergy. We believe that the optimal methodology for implementing our intervention is through the use of volunteers who are members of the community for two reasons:

(1) Our study is being developed in Chile in Latin America (LATAM). In Latin America, there is no formal formation for pastoral care. Priests, pastors, and others who dedicate themselves to the care of the sick are not trained; they do it with the general formation they receive in their communities. No formal programs in Chile have been demonstrated to meet established quality standards.

(2) A brief training would be inadequate if our intervention is proposed as specialized spiritual care. Therefore, we propose an intermediate spiritual care intervention between specialized and general spiritual care. However, we have designated it as general spiritual care to avoid confusion in the manuscript. Moreover, our team is

trained and will be available during the intervention to attend to any issues that extend beyond the scope of this space. This may include referrals to clergy or psychologists, monitoring of volunteer logbooks, training in recognizing critical situations, and constant access to the research team. The provision of spiritual support should not be regarded as inherently beneficial merely because it may potentially cause harm. However, our study enables us to present a safe alternative that may prove advantageous.

4. In the methods' section: Please explain the ecumenical aspect of the intervention. This remains unclear.

Response: Your proposal has been received and acknowledged. The Latin American and Caribbean (LAC) region is a notable example of Christianity's historical predominance, where spiritual practices are often intertwined with religious traditions. However, as in many parts of the world, there has been a gradual shift towards a more distinct separation between institutional religion and spirituality. There has been a notable shift in perception where individuals increasingly distinguish between spirituality and religious a`iliation, often with a sense of disillusionment or rejection of Christian practices. Our study aims to address spiritual needs in a way that is accessible to all. We believe that the concept of "ecumenical" could lead to confusion among readers, which is why we decided to eliminate it from the manuscript and refer to “generalist spiritual care” in the context of healthcare spirituality.

Change in the manuscript: *“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.”*

VERSION 3 - REVIEW

Reviewer	**2**
Name	**Zumstein-Shaha, Maya**
Affiliation	**Bern University of Applied Sciences**
Date	**14-Jan-2025**
COI	

Thank you for this inter sting study protocol. Indeed, spiritual care could be an interesting option to care for persons in ICU. However, a few questions have surfaced:

- It seems important to clearly denote the sample population. In this study, persons who have been admitted to ICU, who had to undergo ventilation and are no recovering (?) constitute the target population. This raises worries that patients may be transferred to

other units during the length of the intervention (given it is more than one sequence). In addition,

- The intervention itself remains unclear: Who exactly is going to provide the intervention and what does it entail? Who does what exactly?

- Methods: For this study, the design is given as a randomized controlled trial. However, the intervention consists of several sequences. How does that fit? What do you do to account for attrition?

- Sample size: As this should be a randomized controlled trial, it seems relevant to calculate the sample size. Please explain why not.

- Statistics: Whether or not the statistical advisor is blinded, does not make any difference. Please review again the rationale for blinding or not blinding in RCTs.

Your reviewer.

Reviewer **3**

Name **O'Callaghan, Clare**

Affiliation **Department of Medicine, St. Vincent's Hospital, The University of Melbourne**

Date **13-Jan-2025**

COI

Thankyou for your attention to the requests for revision. I am satisfied with your revision except for two aspects as folows:

1. Your use of the term “thematic content analysis” and its referencing. The Braun and Clarke reference referred to (page 56) uses the term “thematic analysis” only. While “thematic analysis” may be used to explain the predominantly inductive analysis component of the planned research, it cannot be used to explain the planned “deductive content analysis”. I suggest that you review the following reference, which should help to explain the difference between the two approaches, and their need for different terms: Kyngäs H, Kaakinen P. Deductive content analysis. In: The application of content analysis in nursing science research. In: Kyngäs H, Mikkonen K, Kääriäinen M. (eds.). Oulu, Finland: Springer, 2020; pp. 23-30.

2. Pre-specifying a sample size anticipated to provide “information saturation” (page 54) This is contentious in qualitative research.

See: Vasileiou, K., J. Barnett, S. Thorpe, and T. Young. 2018. Characterising and justifying sample size sufficiency in interview-based studies: Systematic analysis of qualitative health research over a 15-year period. BMC Medical Research Methodology 18 (1):148. doi:10.1186/s12874-018-0594-7

I suggest that the editor can decide on whether you need to address this aspect.

VERSION 3 - AUTHOR RESPONSE

Reviewer: 3. Dr. Clare O'Callaghan, Department of Medicine, St. Vincent's Hospital, The University of Melbourne

Thank you for your attention to the requests for revision. I am satisfied with your revision except for two aspects as follows:

1. Your use of the term "thematic content analysis" and its referencing. The Braun and Clarke reference referred to (page 56) uses the term "thematic analysis" only. While "thematic analysis" may be used to explain the predominantly inductive analysis component of the planned research, it cannot be used to explain the planned "deductive content analysis". I suggest that you review the following reference, which should help to explain the difference between the two approaches, and their need for different terms: Kyngäs H, Kaakinen P. Deductive content analysis. In: The application of content analysis in nursing science research. In: Kyngäs H, Mikkonen K, Kääriäinen M. (eds.). Oulu, Finland: Springer, 2020; pp. 23-30.

Response: We appreciate your comments and suggestions. We have modified the text in the manuscript to clarify the type of qualitative analysis we will perform and to avoid any confusion.

Change in the manuscript:

"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."

2. Pre-specifying a sample size anticipated to provide "information saturation" (page 54) This is contentious in qualitative research. See: Vasileiou, K., J. Barnett, S. Thorpe, and T. Young. 2018. Characterising and justifying sample size sufficiency in interview-based studies: Systematic analysis of qualitative health research over a 15-year period. BMC Medical Research Methodology 18 (1):148. doi:10.1186/s12874-018-0594-7
I suggest that the editor can decide on whether you need to address this aspect.

Response:

Change in the manuscript:

"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 (). 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."

Reviewer: 2. Dr. Maya Zumstein-Shaha, Bern University of Applied Sciences

Thank you for this interesting study protocol. Indeed, spiritual care could be an interesting option to care for persons in ICU. However, a few questions have surfaced:

1. It seems important to clearly denote the sample population. In this study, persons who have been admitted to ICU, who had to undergo ventilation and are no recovering (?) constitute the target population. This raise worries that patients may be transferred to other units during the length of the intervention (given it is more than one sequence).

Response: Thank you for your comment. You are correct; the target population of our study is critically ill patients who have been on invasive mechanical ventilation for at least 72 hours but have already been extubated and are in the recovery phase of an acute illness. At CASR (the hospital where we will conduct our study), patients with these characteristics typically stay in the ICU for 3 to 7 days after weaning from mechanical ventilation, and they are then transferred to an intermediate care unit where they are likely to stay until discharge from the hospital [42]. In the CASR, the ICU and the intermediate care unit have the same administrative and clinical dependency; in our country, they are called Critical Patient Units (CPU), so it is not a problem for our study that the participant is transferred from the ICU to the intermediate care unit during the intervention since the research team that will facilitate the intervention can move between the ICU and the intermediate care unit.

2. In addition, the intervention itself remains unclear: Who exactly is going to provide the intervention and what does it entail? Who does what exactly?

Response: Thank you for the comment; we agree. The volunteers are adults who volunteered to provide spiritual care to critically ill patients and their families. They did this without expecting to receive money. The volunteers are adults, professionals, students in their final years of health careers, or members of pastoral. The intervention is equivalent to three GEC sessions, during which a volunteer-patient pair will utilize the FICA instrument explicitly developed to explore spirituality. The research team is responsible for coordinating and providing technical support for each session and offering assistance to the patient-volunteer pair as needed. The training that the volunteers received is outlined in Appendix 1.

We have restructured the intervention section to enhance clarity and avoid any potential confusion for the reader.

Change in the manuscript:

"Intervention

Enrolled participants included in the intervention will receive a systematic and periodic generalist spiritual care (GSC) program using the FICA Spiritual Assessment Tool (Faith and Belief, Importance and Influence, Community, and Address in Care) [41] conducted remotely by volunteers who have undergone explicit training for the intervention.

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 occur 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."

3. Methods: For this study, the design is given as a randomized controlled trial. However, the intervention consists of several sequences. How does that fit? What do you do to account for attrition?

Response: Thank you for your comment and question. This is a pilot randomized clinical trial. We have proposed three GEC sessions on spirituality to be explored at leisure and at the time that patients wish. The feasibility and practicality of the number and duration of sessions is something we will evaluate in this study and amend, if necessary, in a larger RCT. Likewise, attrition is one of the anticipated problems we seek to study. For this, we have made a sample size calculation where 30 participants (15 per group) are required to have a 95% confidence that one or more cases of this type will occur. If the probability is higher, the confidence level will exceed 95% when 30 participants are screened. Therefore, screening 30 participants will ensure high confidence (i.e., at least 95%) for the minimum problem probability (attrition).

4. Sample size: As this should be a randomized controlled trial, it seems relevant to calculate the sample size. Please explain why not.

Response: Thank you for your comment and question. A pilot study is a preliminary investigation that helps assess the practicality and feasibility of the methods used in a subsequent, more extensive, and more comprehensive investigation. There are different approaches to the sample size required for a pilot study; for example, some authors suggest recruiting ten subjects per condition per group, which is the approach we decided for our pilot study. However, we agree with your assessment and suggestion to perform a sample size calculation. For this reason, we based our pilot study on the sample size calculation method proposed by Viechtbauer et al. Viechtbauer suggests the identification of unanticipated problems that could affect a subsequent more extensive study. Therefore, to investigate these unanticipated problems, which could manifest themselves in at least 1 in 10 patients (10%) at a 95%

confidence level, a total of 29 participants would be required, 15 participants per group.

Change in the manuscript:

"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 (46)."

5. Statistics: Whether or not the statistical advisor is blinded, does not make any difference. Please review again the rationale for blinding or not blinding in RCTs.

Response: We appreciate your feedback and concur with your perspective. To address your concerns, we have amended the text in accordance with the CONSORT guidelines for randomized clinical trials concerning the blind.

Change in the manuscript: *"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."*