BMJ Open

Feasibility Study on Implementing Consultation-based High-quality Palliative Care Services in Intensive Care Units

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-093558
Article Type:	Protocol
Date Submitted by the Author:	10-Sep-2024
Complete List of Authors:	Jeung, Ye Sul; Seoul National University Hospital, Center for Palliative Care and Clinical Ethics Kim, Yejin; Seoul National University Hospital, Center for Palliative Care and Clinical Ethics kim, seyeon; Seoul National University Hospital, Center for Palliative Care and Clinical Ethics Jung, Yoon Sun; Seoul National University Hospital, Department of Critical Care Medicine Kim, Tae Jung; Seoul National University Hospital, Department of Critical Care Medicine; Seoul National University Hospital, Department of Neurology Yoo, Shin Hye; Seoul National University Hospital, Center for Palliative Care and Clinical Ethics; Seoul National University College of Medicine, Department of Human Systems Medicine
Keywords:	Intensive Care Units, PALLIATIVE CARE, Decision Making

PROTOCOL

Feasibility Study on Implementing Consultation-based High-quality Palliative Care Services in Intensive Care Units

Ye Sul Jeung[1*], Yejin Kim[1*], Se Yeon Kim[1], Yoon Sun Jung[2], Tae Jung Kim[2,3] and Shin Hye Yoo[1,4]

Author affiliations:

[1]Center for Palliative Care and Clinical Ethics, Seoul National University Hospital, Seoul, Republic of Korea

[2]Department of Critical Care Medicine, Seoul National University Hospital, Seoul, Republic of Korea

[3]Department of Neurology, Seoul National University Hospital, Seoul, Republic of Korea

[4]Department of Human Systems Medicine, Seoul National University College of Medicine, Seoul, Republic of Korea

Address for correspondence:

Shin Hye Yoo, M.D., Ph.D.

Center for Palliative Care and Clinical Ethics, Seoul National University Hospital, 101 Daehak-ro, Jongno-gu, Seoul 03080, Republic of Korea

Phone: +82-2-2072-1589, Fax: +82-2-2072-0754

E-mail: ifi1024@snu.ac.kr

* The first two authors contributed equally to this work.

ABSTRACT

Introduction: Critically ill patients in intensive care units (ICUs) receive life-sustaining treatments aimed at restoring or maintaining organ function. ICU admission often involves substantial multidimensional suffering that can burden patients, their families, and surrogates. Multidisciplinary palliative care support can help alleviate their sufferings. In South Korea, however, palliative care has not yet been integrated into critical care settings, highlighting the need to explore the feasibility of its implementation within the ICU.

Methods and analysis: This study aims to test the feasibility of a consultation-based palliative care intervention in the ICU. The study will include 20 patients admitted to the ICU of a tertiary hospital due to sudden severe acute brain injury or progressive organ failure, along with their family caregivers. A palliative care team, comprising a social worker and a palliative care physician, will provide consultations to the ICU healthcare professionals based on the palliative care needs, following family counseling. Additional family meetings will be held if necessary. The primary outcomes will include participation rates, family counseling rates, and study completion rates. The intervention's effectiveness will be measured by changes in surrogate decision-making conflict, self-efficacy, depression and anxiety, post-decision regret, and the experience of patient- and family-centered care. The demand and acceptability of the intervention will be assessed through semi-structured interviews with family surrogates, followed by qualitative analysis.

Ethics and dissemination: This study will be conducted in accordance with the Declaration of Helsinki and applicable national laws and regulations. The clinical study protocol, along with any protocol amendments and the informed consent form, has been approved by the Institutional Review Board of the Hospital (2404-111-1532). We plan to submit the study results for presentation at conferences and for publication in international peer-reviewed journals. Data will also be made available upon request to participants, funding agencies, and interested researchers.

Trial registration number: NCT06490835

Strengths and limitations of this study

1. Given the lack of consistent statistical benefits from diverse palliative care interventions in ICUs implemented thus far, this study presents the prospective results on the effectiveness of consultation-based specialist palliative care in ICUs.

2. This study can help identify critically ill patients and their families who might benefit from high-quality consultation-based palliative care within ICUs.

3. This study proposes a collaboration model for a specialist palliative care team and an ICU team to provide high-quality palliative care, aiming to improve satisfaction with critical care.

4. By conducting efficacy testing, this study can suggest appropriate outcome measures for palliative care services in ICUs for patients and their families.

5. The absence of a control group may limit the interpretation of the results.

INTRODUCTION

Advancements in medical technology have improved the standard of care for critically ill patients and expanded treatment options. Nevertheless, mortality rates among patients in intensive care units (ICUs) remain high[1-3]. Critically ill patients in ICUs face significant challenges in making treatment decisions, including life-sustaining treatments, arising from factors such as the sudden onset of illness, uncertainty about prognosis, including potential recovery and disability, the involvement of various healthcare professionals due to complex medical issues, temporary or long-term limitations in decision-making capacity caused by the illness, and ethical conflicts[4-6].

Families of critically ill patients experience psychological distress due to the illness of their loved ones and encounter various challenges during surrogate decision-making, including insufficient information[7-11], uncertainty and confusion about values[12,13], communication issues[11,14-16] lack of support[17-19], and time constraints[9]. Consequently, they may experience psychological stress such as guilt or regret[9,20-22], as well as psychiatric symptoms, including depression, anxiety[23,24], and posttraumatic stress disorder[25-29]. To alleviate these challenges, providing information on the benefits and risks of the treatment options, clarifying personal values regarding the potential outcomes, and offering guidance and support from healthcare professionals is essential.

The need for palliative care in the ICU has already been supported[1,30,31]. The core areas of ICU palliative care include symptom management, effective communication, development of care plans that reflect the patient's values and preferences, support for surrogate decision-makers, coordination of care transitions, workforce support, and the provision of psychological and emotional support to both patients and families, including bereavement care[30,32-34]. ICU palliative care can offer enhanced symptom relief, higher satisfaction among patients, families, and healthcare providers, and improve overall quality of medical care[31]. Additionally, ICU palliative care has been shown to have economic benefits, such as reducing ICU length of stay

and lowering end-of-life (EOL) costs in hospitals[35,36].

A multidisciplinary team approach is essential to meet the complex palliative care needs of patients and their families. This approach can be implemented in two ways: by forming a multidisciplinary team within the ICU to provide palliative care directly, or by having a specialist palliative care team offer consultations to the primary ICU team[32,37]. The specialist palliative care addresses the needs of the referring primary ICU team while counseling the patient and family to identify their key values and preferences. They solidify patient-centered care goals and provide feedback to the primary ICU team to facilitate shared decision-making[38].

In South Korea, however, palliative care is not yet integrated into critical care settings, resulting in a lack of appropriate palliative care for ICU patients with poor prognoses. Moreover, national hospice palliative care services include only cancer patients in outpatient or general ward settings; it does not encompass the ICU setting. There remains a considerable gap in the provision of palliative care for non-cancerous diseases[39]. Therefore, this study investigates a consultation-based palliative care model as a feasible approach in the ICU environment in South Korea. This study aims to present the intervention protocol, detailing the process, components, and outcomes of the intervention.

METHODS AND ANALYSIS

Study design and setting

This clinical study utilizes a single-arm pre-post intervention design to explore the feasibility of applying consultation-based palliative care services to provide high-quality palliative care to families of critically ill patients in ICUs. Recruitment commenced in June 2024 and is anticipated to continue until June 2025. During this period, efforts are directed towards securing the maximum possible number of analyzable cases meeting the inclusion/exclusion criteria among critically ill patients admitted to the ICU. The expected recruitment target is

20 cases (comprising 20 patients and their 1:1 matched family caregiver, totaling 40 individuals). All subsequent data collection is projected to be completed by December 31, 2025. The study protocol has been registered at ClinicalTrials.gov (NCT06490835).

This study is conducted within the emergency ICU of a tertiary hospital in South Korea with approximately 1,800 beds, providing care for critically ill patients from across the country. The 20-bed emergency ICU operates as a closed unit, with separate teams of doctors and nurses providing 24-hour care throughout the year. This ICU team traditionally manages the palliative care needs of critically ill patients, including symptom management and discussions about treatment plans. The intervention in this study comprises a palliative care consultation team (PCCT), which includes a palliative care physician and a social worker, collaborating with an ICU attending physician (**Figure 1**).

Eligibility criteria

Detailed inclusion and exclusion criteria for patients and family caregivers are summarized in **Table 1**. Inclusion criteria for patient selection include individuals diagnosed with sudden, severe acute brain injury, who have been in a state of coma, semi-coma, or stupor for at least 24 hours and are incapable of communication. Additionally, patients with progressive chronic diseases with an acute physiology and chronic health evaluation (APACHE) II score of 14 or higher and a length of ICU stay of 7 days or longer are considered. For family caregivers, eligible individuals are family members of patients who satisfy the aforementioned criteria, are at least 19 years old, and have provided informed consent to participate in the study.

Patients younger than 19 years, refusing involvement of PCCT, referred to the PCCT before study enrollment, undergoing treatment for active cancer within 6 months of ICU admission, already having a treatment goal of comfort care at the time of enrollment, anticipated to die within 48 hours of enrollment, or incapable of participating in the study without an appropriate representative, will be excluded from the study.

Table 1. Eligibility criteria. Cases where either the patient or the family caregiver meets any of the following conditions.

	Inclusion criteria	Exclusion criteria
Patient	1. Diagnosis of sudden and severe acute brain injury due to at least one of etiology (vascular, traumatic, metabolic, toxic, infectious, or anoxic) AND 2. Glasgow Coma Scale score of 3-8 for at least 24 hours AND 3. Unable to express themselves verbally or non-verbally OR 1. Diagnosis of advanced stage organ failure (any of the following) - Chronic lung disease requiring long-term oxygen therapy or mechanical ventilation - Decompensated liver cirrhosis - Chronic heart failure with the New York Heart Association class III or IV - Progressive neurological disease with a modified Rankin Score of 3-5 (e.g., dementia, Parkinson's disease, and amyotrophic lateral sclerosis) - Three or more chronic comorbidities causing limitations in activities of daily living AND 2. APACHE II score ≥ 14 at the time of screening AND 3. ICU stay of 7 days or more	1. Under 19 years of age 2. Unable to speak, understand, or read Korean 3. Refusing palliative care consultation 4. Referred to palliative care prior to study enrollment 5. Within 48 hours of ICU admission 6. Presence of active cancer under treatment within 6 months prior to ICU admission 7. Care goals set to "comfort care" at the time of study enrollment 8. Death expected within 48 hours at the time of study enrollment 9. Lack of capacity to participate in the study without an appropriate surrogate

Family caregiver	1. Family caregiver of a patient who meets the inclusion criteria (Family: defined as the patient's spouse, lineal ascendants and descendants within two degrees of kinship and their spouses, siblings and their spouses, and relatives within eight degrees of kinship and their spouses) 2. Aged 19 or older 3. Willing and able to provide consent for participation in the study	1. Under 19 years of age 2. Unable to speak, understand, or read Korean 3. Determined by a physician to be in extremely poor health, making participation in the study infeasible 4. Refusing palliative care consultation

APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit.

Recruitment of Participants

Attending physicians of the primary ICU team, who serve as co-investigators in this study, initially assess whether patients admitted to the ICUs meet the eligibility criteria. He or she refers patients deemed eligible as participants to the PCCT using a separate referral form within the electronic medical record system (see **online supplemental file 1**). The referral form includes confirmation of the patient's verbal consent to participate in the study, along with detailed information regarding the patient's medical condition, treatment plans, discussions with the family, and reasons for the referral. Then, the social worker from the PCCT delivers a comprehensive explanation of the study's purpose and methods to potential participants. Written consent is obtained if they willingly express their intention to participate. After obtaining the consent, the palliative care physician from the PCCT reviews the patient's medical records and the referral form. If there is insufficient information, the palliative care physician discusses the case with the ICU physician either in person or over the phone.

Description of Intervention

Overview

The aim of the intervention is to offer psychosocial support to the patient's family, decision making support, and to enhance patient-centeredness. The intervention received by ICU patients and their families encompasses services provided by the PCCT and high-quality palliative care administered by the ICU attending physician, in addition to standard critical care. Key components of services from the PCCT include family counseling, family meeting support, and consultation on addressing identified palliative care needs through patient assessment and family counseling (**Table 2**). The overview of the intervention is shown in **Figure 2**.

Table 2. Major interventions of the PCCT

Intervention methods	Description
Family counseling	• Direct interviews with the patient's family, conducted by the social worker from the PCCT • Identification of the family's palliative care needs related to the patient's care and decision-making, serving as basic information for the consultation • Provision of psychological and emotional support to the family
Consultation	• Provision of consultation by the PCCT to the ICU attending physician, synthesizing the family's psychosocial and decision-making needs with the medical perspective of palliative care needs • Guidance for integrating holistic palliative care into the ICU treatment process. • Key content: management of the patient's pain and physical/mental symptoms, understanding of the disease and treatment options, decisional conflict, emotional and practical support for the patient and family, support in setting goal of care related to the patient's values and preferences, provision of information on support systems, bereavement and grief

	support.
Support for family meetings	• Family meetings held by the ICU attending physician as part of the standard provision of usual palliative care whenever the need arises • Discussion members convened depending on the issues at hand, such as the necessity for comprehensive medical judgment due to high uncertainty, insufficient information, value conflicts in decision-making, and communication problems between family members and healthcare professionals. • Support facilitation from the specialist or social worker from the PCCT, depending on the purpose and nature of the meeting convened

PCCT, palliative care consultation team; ICU, intensive care unit.

Family Counseling

Family counseling by the PCCT social worker is a supportive and therapeutic process that also gathers information to assess the palliative care needs of the patient and family. Using a patient- and family-centered approach, particularly for families in distress, the social worker encourages all family members to express their opinions and emotions, promotes communication, and helps to explore the patient's values and preferences. The social worker conducts a psychosocial assessment that includes the patient's personal history, psychological and emotional status, family evaluation, socioeconomic support needs, and available resources. Additionally, a decision-making assessment is performed, encompassing factors related to family decision-making, dealing with uncertainty in current medical decisions,

providing sufficient information, clarifying values, addressing communication issues, and facilitating shared decision-making. These assessments are conducted to provide foundational information for the PCCT in advising the attending physician and establishing intervention plans, including family meetings.

The social worker contacts participants to schedule one-hour counseling appointments, aiming for all family members, including the primary caregiver, to gather in a private space. While face-to-face counseling is preferred, phone counseling is available if necessary. Sessions are recorded and transcribed for documentation.

Interim Consultation

The interim consultation provides the ICU team with comprehensive guidance on the management of symptoms, understanding of the disease and treatment options by the patient and family, decisional conflict, and communication to ensure the provision of high-quality palliative care. Additionally, when a family meeting is necessary, the reasons for recommending the meeting and the required preparations are provided in the form of a response to the referral. If a family meeting is deemed unnecessary, the interim consultation is bypassed, and the process proceeds directly to the final consultation.

Support for Family Meetings

Additional family meetings tailored to the family's needs are conducted as necessary. A family meeting, convened by an ICU attending physician as part of usual care, supports decision-making between healthcare professionals and the family to establish treatment and care plans. These meetings address the need for comprehensive multidisciplinary medical judgment, and to overcome high medical uncertainty, insufficient information, value conflicts in decision-making, and communication issues. During the intervention, the PCCT has supporting roles in resolving complex issues and mediating conflicts in the family meeting. While family

meetings follow basic procedures, they can be adjusted to fit specific purposes and situations (**Table 3**).

Table 3. Basic procedures and roles of family meetings

Standard protocols	**Specific instructions in case with high medical uncertainty**
• Share the purpose and focus of the family meeting • Confirm the family's understanding of the patient's condition and treatment options • Ensure the sufficiency of information needed for decision-making • Provide explanations and summaries of relevant healthcare professionals about patient's condition and treatment options. • Present discussion topics • Listen to the family's opinions on the discussion topics • Set goal of care appropriate for the patient • Establish detailed action plans • Provide emotional support to the family members	• Participation of the attending physician and all relevant medical teams with the aim of making comprehensive medical judgments and consolidating palliative care approaches. • Support for meeting facilitation by the palliative care physician from the PCCT • Assistance with family meeting preparation and provision of emotional support by the PCCT social worker
	Specific instructions in case with the aim of value clarification and facilitation of communication
	• Support for value seeking and pursuing processes to enhance patient-centeredness in surrogate decision-making, and support for resolving value conflicts and communication issues within the family and between the family and attending physician. • Family meeting facilitation support by the PCCT social worker

PCCT, palliative care consultation team.

Final consultation

Expanding upon the content of the interim consultation (symptom management, understanding of the disease and decision-making conflict factors, psychosocial support, and communication), the final consultation encompasses care goal setting in the patient's best interest and decision support aligned with these care goals. It also includes information on available support systems, support for EOL care and the bereavement process, and final recommendations in the form of an interdepartmental referral response.

High-quality palliative care by ICU attending physicians

The attending physicians appropriately integrate the recommendations of the PCCT into patient care and treatment, adjusting the goal of care and connecting necessary resources. The physicians also assess the need for further discussions, considering potential changes in the patient's condition or goal of care.

Outcomes

The primary outcome is the feasibility of applying consultation-based high-quality palliative care, determined by the proportion of eligible individuals who participate, undergo family counseling, and complete the study.

Secondary outcomes include changes in family caregiver's decisional conflict, self-efficacy, psychological distress, and decision regret as effects of intervention. Additional secondary outcomes are the level of patient- and family-centered care experienced by the caregiver[40,41], caregiver satisfaction with the services, length of hospital stay, survival discharge rate, and details of comfort care during ICU stay. Data collection completion rate and patient recruitment time are also included. To address the limitation of a small sample size in this study and to enhance the reliability of the research findings, a qualitative assessment of the feasibility and satisfaction with the intervention will also be conducted as a supplementary

measure. **Table 4** outlines the timing and methods for collecting all outcome measures and survey variables.

Table 4. Outcome measures

Outcomes	Instrument used	Data source	Timing of measurement
Primary Outcome			
Feasibility of applying consultation-based high-quality palliative care in ICUs	Participation rate, palliative care counseling rate, study completion rate	Families and patients	1 day (at discharge)
Secondary Outcomes			
Change in surrogates' decisional conflict before and after the intervention	Decisional Conflict Scale (DCS)	Family	Pre-post comparison (baseline vs. within one week after consultation)
Change in surrogates' decisional self-efficacy before and after the intervention	Decisional Self-Efficacy Scale	Family	Pre-post comparison (baseline vs. within one week after consultation)
Change in surrogates' psychological distress before and after the intervention	Hospital Anxiety and Depression Scale (HADS)	Family	Pre-post comparison (baseline vs. within one week after consultation)
Surrogates' decision regret after the intervention	Decision Regret Scale	Family	Follow-up (Within one week/one month after consultation; Up to three months after the final consultation for deceased patients)
Level of patient- and family-centered care experienced by surrogates after the intervention	Modified Patient Perception of Patient-Centeredness (PPPC) Scale	Family	Follow-up (Within one week/one month after consultation; Up to three months after the final consultation for deceased patients)
Surrogates' satisfaction with the intervention	Overall satisfaction with ICU palliative care,	Family	Within one week after the final consultation

services	family counseling, consultation, and family meeting, assessed on a 5-point scale (very dissatisfied, dissatisfied, neutral, satisfied, very satisfied)		
Length of hospital stay		Chart abstraction	1 day (at discharge)
Survival to discharge rate		Chart abstraction	1 day (at discharge)
Days of symptom relief treatments received in the ICU		Chart abstraction	1 day (at discharge)
Proportion of patients receiving symptom relief treatments during the ICU stay		Chart abstraction	1 day (at discharge)
Use of life-sustaining procedures within 48 hours before death		Chart abstraction	1 day (at discharge)
Use of symptom relief treatments within 48 hours before death		Chart abstraction	1 day (at discharge)
Data collection completion rate	Proportion of data collected at each time point exceeding 90%	Chart abstraction, Families and patients	Within three months after the final consultation
Time taken to recruit patients		Chart abstraction, Families and patients	Within the first year of study initiation
Other Outcomes			
Qualitative evaluation of intervention feasibility and	Evaluation of feasibility and satisfaction through semi-structured, one-on-	Family	Within three months after the final consultation

satisfaction	one interviews with surrogates		
Additional analysis of surrogates' psychological distress changes before and after the intervention	Hospital Anxiety and Depression Scale (HADS)	Family	One month after the final consultation (within three months for deceased patients)

ICU, intensive care unit.

Statistical analysis

The outcome measures encompass both categorical variables and continuous variables. For continuous outcomes measuring changes before and after the intervention, a paired t-test or Wilcoxon signed-rank test will be utilized. Categorical variables will be assessed using frequencies (%). All statistical analyses will be two-sided, with a value of $P<0.05$ considered statistically significant.

Ethics and dissemination

The study protocol has received approval from the Institutional Review Board of Seoul National University Hospital (No. 2404-111-1532). The results of this study will be shared with critical care societies, interested researchers, and funding agencies. We intend to disseminate the findings extensively through multiple channels, including presentations at academic conferences, submissions to peer-reviewed journals, and posts on relevant social media platforms. Additionally, the study results will be submitted to ClinicalTrials.gov for broader accessibility.

DISCUSSION

To the best of our knowledge, our study is the first to investigate the feasibility of implementing consultation-based, high-quality palliative care services in an ICU setting where specialist

palliative care is not routinely available. Previous studies have indicated that palliative care consultations in the ICU tend to be provided too close to the time of death, limiting their potential benefits[42]. This highlights the need for research exploring the feasibility and effects of interventions that provide early palliative care to patients who might benefit the most from it[43]. In this context, our intervention is significant, as it identifies patients who could benefit from palliative care early on, integrating specialist palliative care into critical care to deliver high-quality palliative care from the outset.

In our study, the selected palliative care intervention focuses on delivering palliative care tailored to the overall situation of the patient and family through early consultation. This approach ensures continuous and effective interaction and communication between the primary ICU team and the patient's family throughout the ICU care process. Various models of ICU palliative care delivery exist, such as consultative and integrative[44]. In an environment lacking established ICU palliative care, we opted for an intervention model where the PCCT's role is not to consistently manage symptoms directly, but rather to enhance the capacity for primary palliative care through consultation[45,46]. This approach aims to maximize the effectiveness of palliative care delivery while efficiently utilizing limited resources[47], positioning the PCCT as facilitators and mediators. Unlike previous studies[40,43,46,48,49], which predominantly employed independent roles of PCCT or interventions in terms of quality improvement within the primary ICU team, our approach presents a distinct model.

In previous studies on ICU palliative care interventions[43,46-48], the primary outcomes were typically subjective measures, such as family satisfaction and depression, or clinical outcomes for patients. Our study shares the limitation of difficulty in assessing patient outcomes due to the medical conditions of ICU patients, but it stands out by including person-centered care outcomes, like the Patient Perception of Patient-Centeredness Questionnaire[41], proxy-reported by caregivers as a secondary outcome. As a feasibility study with an exploratory focus, we aimed to incorporate a range of outcomes from patient and family perspectives, as well as

healthcare system and process aspects, while qualitatively evaluating those less suited to quantitative assessment.

Despite these strengths, our study has several limitations. First, we used a single-arm design for the pilot trial at a single center. Since PCCTs for ICUs are not widely implemented across healthcare institutions, and our intervention included both the PCCT and primary palliative care by ICU attending physicians, we considered a randomized design unsuitable for this pilot study. Second, defining a specific target outcome to determine feasibility is challenging. ICU palliative care delivery varies based on healthcare systems and resources, making it difficult to set a standard in this first-of-its-kind study in Korea. As a result, interpreting feasibility solely through quantitative outcomes has limitations, so we also employed qualitative methods for a comprehensive evaluation. Third, our study only included ICU physicians as direct participants, even though ICU nurses play a critical role in palliative care[50]. This may limit the interpretation of our intervention's effectiveness. However, given our focus on decision-making support, we prioritized enhancing ICU physicians' competency.

In conclusion, this study would have the potential to investigate the provision of high-quality palliative care via a consultative palliative care model integrated into ICU care as a feasible and acceptable approach. The results of this study can give insights for modeling the effective palliative care delivery in an ICU environment.

Funding: This research was supported by a grant from the Patient-Centered Clinical Research Coordinating Center (PACEN) funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HC23C0160).

Competing interests: None declared.

References

1. Mercadante S, Gregoretti C, Cortegiani A. Palliative care in intensive care units: why, where, what,

who, when, how. *BMC Anesthesiol* 2018;18(1):106. doi: 10.1186/s12871-018-0574-9 [published Online First: 2018/08/17]:30111299

2. Angus DC, Barnato AE, Linde-Zwirble WT, et al. Use of intensive care at the end of life in the United States: an epidemiologic study. *Crit Care Med* 2004;32(3):638-43. doi: 10.1097/01.ccm.0000114816.62331.08 [published Online First: 2004/04/20]:15090940

3. Angus DC, Truog RD. Toward Better ICU Use at the End of Life. *JAMA* 2016;315(3):255-6. doi: 10.1001/jama.2015.18681 [published Online First: 2016/01/20]:26784767

4. Bibas L, Peretz-Larochelle M, Adhikari NK, et al. Association of Surrogate Decision-making Interventions for Critically Ill Adults With Patient, Family, and Resource Use Outcomes: A Systematic Review and Meta-analysis. *JAMA Netw Open* 2019;2(7):e197229. doi: 10.1001/jamanetworkopen.2019.7229 [published Online First: 2019/07/20]:31322688

5. Herridge MS, Tansey CM, Matte A, et al. Functional disability 5 years after acute respiratory distress syndrome. *N Engl J Med* 2011;364(14):1293-304. doi: 10.1056/NEJMoa1011802 [published Online First: 2011/04/08]:21470008

6. Detsky ME, Harhay MO, Bayard DF, et al. Six-Month Morbidity and Mortality among Intensive Care Unit Patients Receiving Life-Sustaining Therapy. A Prospective Cohort Study. *Ann Am Thorac Soc* 2017;14(10):1562-70. doi: 10.1513/AnnalsATS.201611-875OC [published Online First: 2017/06/18]:28622004

7. Clark JA, Wray NP, Ashton CM. Living with treatment decisions: regrets and quality of life among men treated for metastatic prostate cancer. *J Clin Oncol* 2001;19(1):72-80. doi: 10.1200/JCO.2001.19.1.72 [published Online First: 2001/01/03]:11134197

8. Feiler D, Muller-Trede J. The One That Got Away: Overestimation of Forgone Alternatives as a Hidden Source of Regret. *Psychol Sci* 2022;33(2):314-24. doi: 10.1177/09567976211032657 [published Online First: 2022/01/22]:35060808

9. Hilger C, Schostak M, Otto I, et al. Time pressure predicts decisional regret in men with localized prostate cancer: data from a longitudinal multicenter study. *World J Urol* 2021;39(10):3755-61. doi: 10.1007/s00345-021-03727-0 [published Online First: 2021/05/23]:34021406

10. October TW, Jones AH, Greenlick Michals H, et al. Parental Conflict, Regret, and Short-term Impact on Quality of Life in Tracheostomy Decision-Making. *Pediatr Crit Care Med*

2020;21(2):136-42. doi: 10.1097/PCC.0000000000002109 [published Online First: 2019/10/01]:31568244

11. Iverson E, Celious A, Kennedy CR, et al. Factors affecting stress experienced by surrogate decision makers for critically ill patients: implications for nursing practice. *Intensive Crit Care Nurs* 2014;30(2):77-85. doi: 10.1016/j.iccn.2013.08.008 [published Online First: 2013/11/12]:24211047

12. Jezewski MA. Do-not-resuscitate status: conflict and culture brokering in critical care units. *Heart Lung* 1994;23(6):458-65. https://www.ncbi.nlm.nih.gov/pubmed/78520607852060 [published Online First: 1994/11/01]:7852060

13. Schenker Y, Crowley-Matoka M, Dohan D, et al. I don't want to be the one saying 'we should just let him die': intrapersonal tensions experienced by surrogate decision makers in the ICU. *J Gen Intern Med* 2012;27(12):1657-65. doi: 10.1007/s11606-012-2129-y [published Online First: 2012/09/27]:23011253

14. Curtis JR, Engelberg RA, Nielsen EL, et al. Patient-physician communication about end-of-life care for patients with severe COPD. *Eur Respir J* 2004;24(2):200-5. doi: 10.1183/09031936.04.00010104 [published Online First: 2004/08/31]:15332385

15. Davidson JE, Powers K, Hedayat KM, et al. Clinical practice guidelines for support of the family in the patient-centered intensive care unit: American College of Critical Care Medicine Task Force 2004-2005. *Crit Care Med* 2007;35(2):605-22. doi: 10.1097/01.CCM.0000254067.14607.EB [published Online First: 2007/01/06]:17205007

16. Majesko A, Hong SY, Weissfeld L, et al. Identifying family members who may struggle in the role of surrogate decision maker. *Crit Care Med* 2012;40(8):2281-6. doi: 10.1097/CCM.0b013e3182533317 [published Online First: 2012/07/20]:22809903

17. Bowman K. Trepidation: a family member's response to shift change in the intensive care unit. *Dimens Crit Care Nurs* 2010;29(6):288-92. doi: 10.1097/DCC.0b013e3181f0c1b5 [published Online First: 2010/10/14]:20940584

18. Mitchell ML, Courtney M, Coyer F. Understanding uncertainty and minimizing families' anxiety at the time of transfer from intensive care. *Nurs Health Sci* 2003;5(3):207-17. doi:

10.1046/j.1442-2018.2003.00155.x [published Online First: 2003/07/25]:12877722

19. Nelson JE, Puntillo KA, Pronovost PJ, et al. In their own words: patients and families define high-quality palliative care in the intensive care unit. *Crit Care Med* 2010;38(3):808-18. doi: 10.1097/ccm.0b013e3181c5887c [published Online First: 2010/03/04]:20198726

20. Cohan JN, Orleans B, Brecha FS, et al. Factors Associated With Decision Regret Among Patients With Diverticulitis in the Elective Setting. *J Surg Res* 2021;261:159-66. doi: 10.1016/j.jss.2020.12.019 [published Online First: 2021/01/12]:33429225

21. Szproch AK, Maguire R. A systematic review of the factors associated with regret post-cancer treatment. *J Psychosoc Oncol* 2022;40(1):1-25. doi: 10.1080/07347332.2020.1844846 [published Online First: 2020/11/17]:33191874

22. Wilson A, Winner M, Yahanda A, et al. Factors associated with decisional regret among patients undergoing major thoracic and abdominal operations. *Surgery* 2017;161(4):1058-66. doi: 10.1016/j.surg.2016.10.028 [published Online First: 2016/12/21]:27993362

23. Lautrette A, Darmon M, Megarbane B, et al. A communication strategy and brochure for relatives of patients dying in the ICU. *N Engl J Med* 2007;356(5):469-78. doi: 10.1056/NEJMoa063446 [published Online First: 2007/02/03]:17267907

24. Siegel MD, Hayes E, Vanderwerker LC, et al. Psychiatric illness in the next of kin of patients who die in the intensive care unit. *Crit Care Med* 2008;36(6):1722-8. doi: 10.1097/CCM.0b013e318174da72 [published Online First: 2008/06/04]:18520637

25. Anderson WG, Arnold RM, Angus DC, et al. Posttraumatic stress and complicated grief in family members of patients in the intensive care unit. *J Gen Intern Med* 2008;23(11):1871-6. doi: 10.1007/s11606-008-0770-2 [published Online First: 2008/09/10]:18780129

26. Paparrigopoulos T, Melissaki A, Efthymiou A, et al. Short-term psychological impact on family members of intensive care unit patients. *J Psychosom Res* 2006;61(5):719-22. doi: 10.1016/j.jpsychores.2006.05.013 [published Online First: 2006/11/07]:17084152

27. Pochard F, Darmon M, Fassier T, et al. Symptoms of anxiety and depression in family members of intensive care unit patients before discharge or death. A prospective multicenter study. *J Crit Care* 2005;20(1):90-6. doi: 10.1016/j.jcrc.2004.11.004 [published Online First: 2005/07/15]:16015522

28. Wendler D, Rid A. Systematic review: the effect on surrogates of making treatment decisions for others. *Ann Intern Med* 2011;154(5):336-46. doi: 10.7326/0003-4819-154-5-201103010-00008 [published Online First: 2011/03/02]:21357911

29. Azoulay E, Pochard F, Kentish-Barnes N, et al. Risk of post-traumatic stress symptoms in family members of intensive care unit patients. *Am J Respir Crit Care Med* 2005;171(9):987-94. doi: 10.1164/rccm.200409-1295OC [published Online First: 2005/01/25]:15665319

30. Hua M, Wunsch H. Integrating palliative care in the ICU. *Curr Opin Crit Care* 2014;20(6):673-80. doi: 10.1097/MCC.0000000000000149 [published Online First: 2014/09/19]:25233330

31. Michels G, Schallenburger M, Neukirchen M, et al. Recommendations on palliative care aspects in intensive care medicine. *Crit Care* 2023;27(1):355. doi: 10.1186/s13054-023-04622-3 [published Online First: 2023/09/19]:37723595

32. Doherty C, Feder S, Gillespie-Heyman S, et al. Easing Suffering for ICU Patients and Their Families: Evidence and Opportunities for Primary and Specialty Palliative Care in the ICU. *J Intensive Care Med* 2024;39(8):715-32. doi: 10.1177/08850666231204305 [published Online First: 2023/10/12]:37822226

33. O'Mahony S, McHenry J, Blank AE, et al. Preliminary report of the integration of a palliative care team into an intensive care unit. *Palliat Med* 2010;24(2):154-65. doi: 10.1177/0269216309346540 [published Online First: 2009/10/15]:19825893

34. Kim JM, Godfrey S, O'Neill D, et al. Integrating palliative care into the modern cardiac intensive care unit: a review. *Eur Heart J Acute Cardiovasc Care* 2022;11(5):442-49. doi: 10.1093/ehjacc/zuac034 [published Online First: 2022/04/02]:35363258

35. Chung TH, Nguyen LK, Lal LS, et al. Palliative Care Consultation in the Intensive Care Unit Reduces Hospital Costs: A Cost-Analysis. *J Palliat Care* 2022:8258597221095986. doi: 10.1177/08258597221095986 [published Online First: 2022/04/27]:35469500

36. Kyeremanteng K, Gagnon LP, Thavorn K, et al. The Impact of Palliative Care Consultation in the ICU on Length of Stay: A Systematic Review and Cost Evaluation. *J Intensive Care Med* 2018;33(6):346-53. doi: 10.1177/0885066616664329 [published Online First: 2016/09/02]:27582396

37. Aslakson RA, Curtis JR, Nelson JE. The changing role of palliative care in the ICU. *Crit Care Med*

2014;42(11):2418-28. doi: 10.1097/CCM.0000000000000573 [published Online First: 2014/08/29]:25167087

38. Nelson JE, Bassett R, Boss RD, et al. Models for structuring a clinical initiative to enhance palliative care in the intensive care unit: a report from the IPAL-ICU Project (Improving Palliative Care in the ICU). *Crit Care Med* 2010;38(9):1765-72. doi: 10.1097/CCM.0b013e3181e8ad23 [published Online First: 2010/06/22]:20562699

39. Kim K, Park B, Gu B, et al. The National Hospice and Palliative Care registry in Korea. *Epidemiol Health* 2022;44:e2022079. doi: 10.4178/epih.e2022079 [published Online First: 2022/10/01]:36177979

40. White DB, Angus DC, Shields AM, et al. A Randomized Trial of a Family-Support Intervention in Intensive Care Units. *N Engl J Med* 2018;378(25):2365-75. doi: 10.1056/NEJMoa1802637 [published Online First: 2018/05/24]:29791247

41. Andersen SK, Vincent G, Butler RA, et al. ProPACC: Protocol for a Trial of Integrated Specialty Palliative Care for Critically Ill Older Adults. *J Pain Symptom Manage* 2022;63(6):e601-e10. doi: 10.1016/j.jpainsymman.2022.02.344 [published Online First: 2022/05/21]:35595373

42. Seaman JB, Barnato AE, Sereika SM, et al. Patterns of palliative care service consultation in a sample of critically ill ICU patients at high risk of dying. *Heart Lung* 2017;46(1):18-23. doi: 10.1016/j.hrtlng.2016.08.008 [published Online First: 2016/10/09]:27717509

43. Helgeson SA, Burnside RC, Robinson MT, et al. Early Versus Usual Palliative Care Consultation in the Intensive Care Unit. *Am J Hosp Palliat Care* 2023;40(5):544-51. doi: 10.1177/10499091221115732 [published Online First: 2022/07/15]:35833450

44. Curtis JR, Higginson IJ, White DB. Integrating palliative care into the ICU: a lasting and developing legacy. *Intensive Care Med* 2022;48(7):939-42. doi: 10.1007/s00134-022-06729-7 [published Online First: 2022/05/17]:35577992

45. Halangk W, Dietz H. Capacities of oxidative metabolism in digitonin-treated bovine epididymal spermatozoa. *Biomed Biochim Acta* 1986;45(10):1249-57. https://www.ncbi.nlm.nih.gov/pubmed/35667163566716 [published Online First: 1986/01/01]:3566716

46. Ma J, Chi S, Buettner B, et al. Early Palliative Care Consultation in the Medical ICU: A Cluster Randomized Crossover Trial. *Crit Care Med* 2019;47(12):1707-15. doi: 10.1097/CCM.0000000000004016 [published Online First: 2019/10/15]:31609772

47. Kamdar HA, Gianchandani S, Strohm T, et al. Collaborative Integration of Palliative Care in Critically Ill Stroke Patients in the Neurocritical Care Unit: A Single Center Pilot Study. *J Stroke Cerebrovasc Dis* 2022;31(8):106586. doi: 10.1016/j.jstrokecerebrovasdis.2022.106586 [published Online First: 2022/06/07]:35667164

48. Chang DW, Neville TH, Parrish J, et al. Evaluation of Time-Limited Trials Among Critically Ill Patients With Advanced Medical Illnesses and Reduction of Nonbeneficial ICU Treatments. *JAMA Intern Med* 2021;181(6):786-94. doi: 10.1001/jamainternmed.2021.1000 [published Online First: 2021/04/13]:33843946

49. Carson SS, Cox CE, Wallenstein S, et al. Effect of Palliative Care-Led Meetings for Families of Patients With Chronic Critical Illness: A Randomized Clinical Trial. *JAMA* 2016;316(1):51-62. doi: 10.1001/jama.2016.8474 [published Online First: 2016/07/06]:27380343

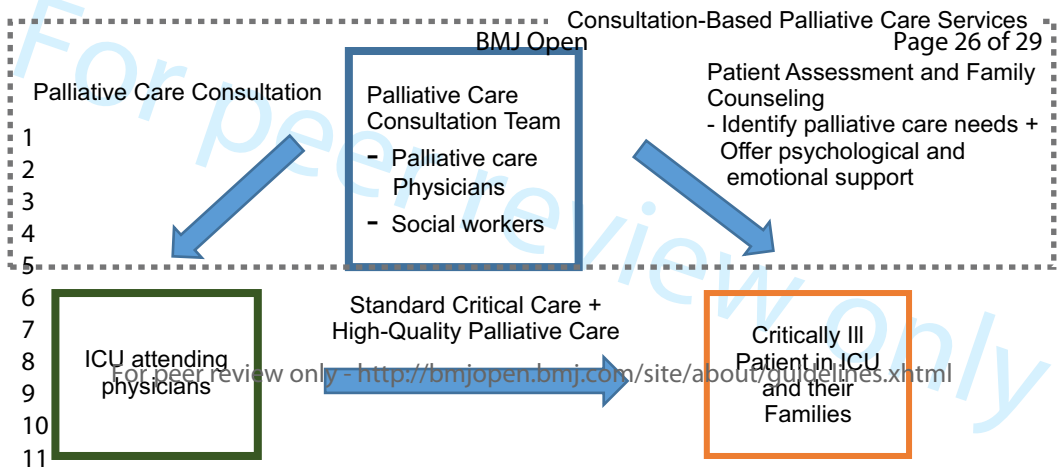
50. Nelson JE, Cortez TB, Curtis JR, et al. Integrating Palliative Care in the ICU: The Nurse in a Leading Role. *J Hosp Palliat Nurs* 2011;13(2):89-94. doi: 10.1097/NJH.0b013e318203d9ff [published Online First: 2011/08/30]:21874122

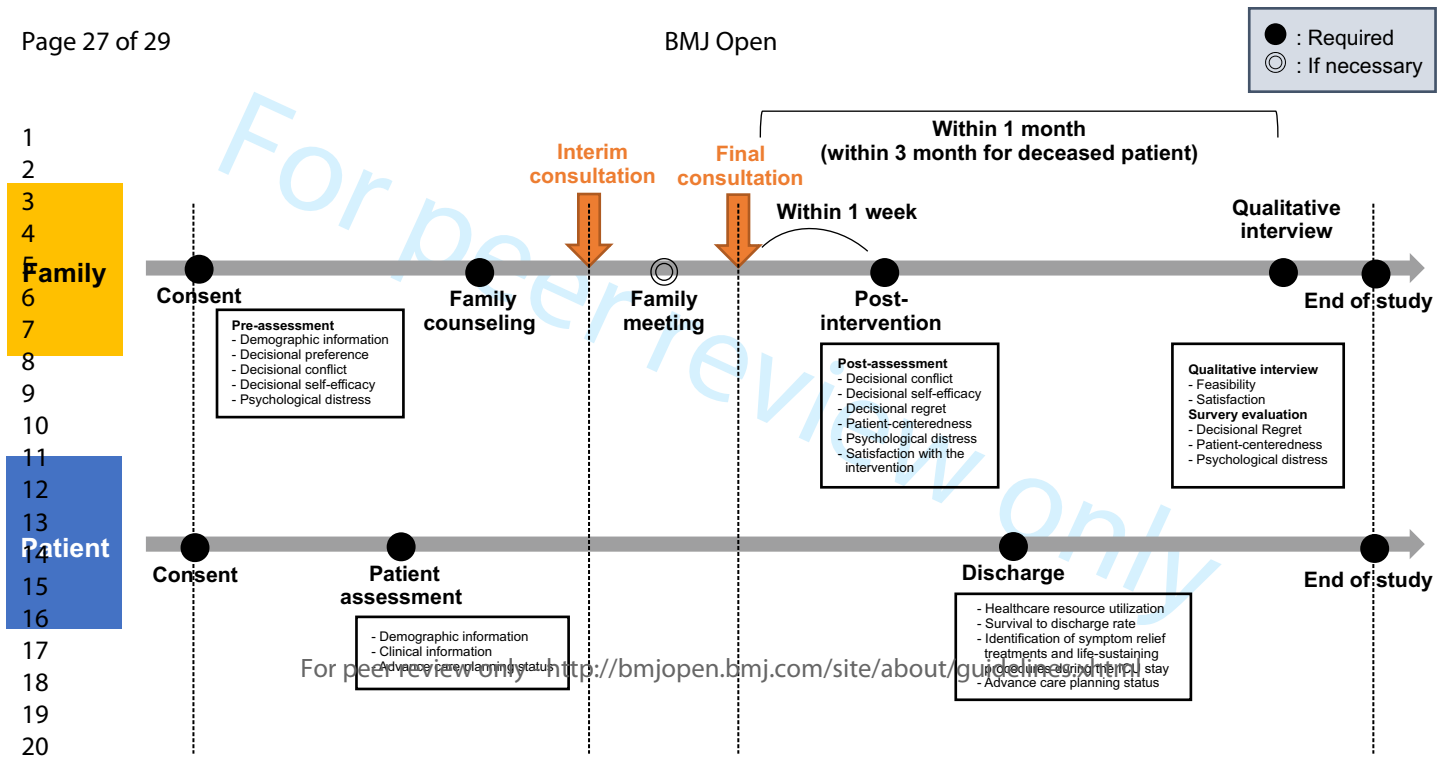
Figure Legends

Figure 1. Scheme of consultation-based palliative care services to provide high-quality palliative care to families of critically ill patients in the intensive care units (ICUs).

Figure 2. Overall flow of the intervention.

ICU, intensive care unit.





Referral note for Palliative care consultation

Date of referral	YYYY-MM-DD	
Purpose of consultation (multiple choices allowed)	□ management of patient's pain, physical, and psychological symptoms □ enhancement of understanding about the disease and mediation decisional conflict □ psychosocial and emotional support for patients and families □ supporting setting care goals related to patient values and preferences □ providing information on available resources □ bereavement support □ consultation for medical assessment (etc. terminal and end-of-life phases) □ etc( )	
	Primary reason for consultation	
Preference for the specialized services of the Center for Palliative Care and Clinical Ethics (multiple choices allowed)	□ Registration for SNUH Consultative Hospice (※Eligibility and conditions can be confirmed by the center) □ Provision of hospice information (including guidance on facilities) □ Use of end-of-life care rooms □ clinical ethics consultation (including consideration by ethics committee) □ None of the above	
Patient's medical issues/ concerns		
Patient's medical condition	□ Terminal stage: No possibility of fundamental recovery despite active treatment, with progressively worsening symptoms □ End-of-life stage: No possibility of recovery, with rapidly worsening symptoms despite treatment, and death is imminent □ Neither in the terminal nor end-of-life stage, but requires palliative care	
Expected prognosis	□ A few days □ a few weeks □ a few months □ a few years □ uncertain	
Potential for functional recovery	**Recovery to normal life (ADL, social engagement, etc)**	□ High likelihood □ low likelihood □ nolikelihood □ uncertain
	Recovery to pre-ICU admission status	□ High likelihood □ low likelihood □ nolikelihood □ uncertain
	Significant consciousness recovery	□ High likelihood □ low likelihood □ nolikelihood □ uncertain

Treatment plan	*The best treatment plan as determined by the attending physician*	
	Consistency of medical team opinions on treatment plan	□ consensus □ disagreement within the department □ disagreement within other departments
Decisional issues	*Issues to be addressed in decision-making based on the anticipated progression of the disease*	
Physician-family discussion process	*Briefly describe the progress of discussions with family members*	
Family evaluation	**Level of caregiving burden**	□ none □ slight □ moderate to significant □ severe □ uncertain
	Level of psychological stress	□ none □ slight □ moderate to significant □ severe □ uncertain

BMJ Open

Feasibility Study Protocol: Implementing Consultation-based High-quality Palliative Care Services in Intensive Care Units

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-093558.R1
Article Type:	Protocol
Date Submitted by the Author:	01-May-2025
Complete List of Authors:	Jeung, Ye Sul; Seoul National University Hospital, Center for Palliative Care and Clinical Ethics Kim, Yejin; Seoul National University Hospital, Center for Palliative Care and Clinical Ethics kim, seyeon; Seoul National University Hospital, Center for Palliative Care and Clinical Ethics Jung, Yoon Sun; Seoul National University Hospital, Department of Critical Care Medicine Kim, Tae Jung; Seoul National University Hospital, Department of Critical Care Medicine; Seoul National University Hospital, Department of Neurology Yoo, Shin Hye; Seoul National University Hospital, Center for Palliative Care and Clinical Ethics; Seoul National University College of Medicine, Department of Human Systems Medicine
Primary Subject Heading:	Palliative care
Secondary Subject Heading:	Intensive care
Keywords:	Intensive Care Units, PALLIATIVE CARE, Decision Making

PROTOCOL

Feasibility Study Protocol: Implementing Consultation-based High-quality Palliative Care Services in Intensive Care Units

Ye Sul Jeung[1*], Yejin Kim[1*], Se Yeon Kim[1], Yoon Sun Jung[2], Tae Jung Kim[2,3] and Shin Hye Yoo[1,4]

Author affiliations:

[1]Center for Palliative Care and Clinical Ethics, Seoul National University Hospital, Seoul, Republic of Korea

[2]Department of Critical Care Medicine, Seoul National University Hospital, Seoul, Republic of Korea

[3]Department of Neurology, Seoul National University Hospital, Seoul, Republic of Korea

[4]Department of Human Systems Medicine, Seoul National University College of Medicine, Seoul, Republic of Korea

Address for correspondence:

Shin Hye Yoo, M.D., Ph.D.

Center for Palliative Care and Clinical Ethics, Seoul National University Hospital, 101 Daehak-ro, Jongno-gu, Seoul 03080, Republic of Korea

Phone: +82-2-2072-1589, Fax: +82-2-2072-0754

E-mail: ifi1024@snu.ac.kr

* The first two authors contributed equally to this work.

ABSTRACT

Introduction: Critically ill patients in intensive care units (ICUs) receive life-sustaining treatments aimed at restoring or maintaining organ function. ICU admission often involves substantial multidimensional suffering that can burden patients, their families, and surrogates. Multidisciplinary palliative care support can help alleviate their sufferings. In South Korea, however, palliative care has not yet been integrated into critical care settings, highlighting the need to explore the feasibility of its implementation within the ICU.

Methods and analysis: This study aims to test the feasibility of a consultation-based palliative care intervention in the ICU. The study will include 20 patients admitted to the ICU of a tertiary hospital due to sudden severe acute brain injury or progressive organ failure, along with their family caregivers. A palliative care team, comprising a social worker and a palliative care physician, will provide consultations to the ICU healthcare professionals based on the palliative care needs, following family counseling. Additional family meetings will be held if necessary. The primary outcomes will include participation rates, family counseling rates, and study completion rates. The intervention's potential impact will be assessed by changes in surrogate decision-making conflict, self-efficacy, depression and anxiety, post-decision regret, and the experience of patient- and family-centered care. The demand and acceptability of the intervention will be assessed through semi-structured interviews with family surrogates, followed by qualitative analysis.

Ethics and dissemination: This study will be conducted in accordance with the Declaration of Helsinki and applicable national laws and regulations. The clinical study protocol, along with any protocol amendments and the informed consent form, has been approved by the Institutional Review Board of the Hospital (2404-111-1532). We plan to submit the study results for presentation at conferences and for publication in international peer-reviewed journals. Data will also be made available upon request to participants, funding agencies, and interested researchers.

Trial registration number: NCT06490835

Strengths and limitations of this study

1. Prospective single-arm pre-post design to explore feasibility in an ICU setting.
2. Inclusion criteria targeting patients with severe acute brain injury or advanced organ failure.
3. Integration of both ICU healthcare professionals and family caregivers in data collection processes.
4. Use of mixed-methods combining quantitative outcomes and qualitative interviews.
5. Lack of a control group limits causal inference..

INTRODUCTION

Advancements in medical technology have improved the standard of care for critically ill patients and expanded treatment options. Nevertheless, mortality rates among patients in intensive care units (ICUs) remain high[1-3]. Critically ill patients in ICUs face significant challenges in making treatment decisions, including life-sustaining treatments, arising from factors such as the sudden onset of illness, uncertainty about prognosis, including potential recovery and disability, the involvement of various healthcare professionals due to complex medical issues, temporary or long-term limitations in decision-making capacity caused by the illness, and ethical conflicts[4-6].

Families of critically ill patients experience psychological distress due to the illness of their loved ones and encounter various challenges during surrogate decision-making, including insufficient information[7-11], uncertainty and confusion about values[12,13], communication issues[11,14-16] lack of support[17-19], and time constraints[9]. Consequently, they may experience psychological stress such as guilt or regret[9,20-22], as well as psychiatric symptoms, including depression, anxiety[23,24], and posttraumatic stress disorder[25-29]. To alleviate these challenges, providing information on the benefits and risks of the treatment options, clarifying personal values regarding the potential outcomes, and offering guidance and support from healthcare professionals is essential.

The need for palliative care in the ICU has already been supported[1,30,31]. The core areas of ICU palliative care include symptom management, effective communication, development of care plans that reflect the patient's values and preferences, support for surrogate decision-makers, coordination of care transitions, workforce support, and the provision of psychological and emotional support to both patients and families, including bereavement care[30,32-34]. ICU palliative care can offer enhanced symptom relief, higher satisfaction among patients, families, and healthcare providers, and improve overall quality of medical care[31]. Additionally, ICU palliative care has been shown to have economic benefits, such as reducing ICU length of stay

and lowering end-of-life (EOL) costs in hospitals[35,36].

A multidisciplinary team approach is essential to meet the complex palliative care needs of patients and their families. This approach can be implemented in two ways: by forming a multidisciplinary team within the ICU to provide palliative care directly, or by having a specialist palliative care team offer consultations to the primary ICU team[32,37]. The specialist palliative care addresses the needs of the referring primary ICU team while counseling the patient and family to identify their key values and preferences. They solidify patient-centered care goals and provide feedback to the primary ICU team to facilitate shared decision-making[38].

In South Korea, however, palliative care is not yet integrated into critical care settings, resulting in a lack of appropriate palliative care for ICU patients with poor prognoses. Moreover, national hospice palliative care services include only cancer patients in outpatient or general ward settings; it does not encompass the ICU setting. There remains a considerable gap in the provision of palliative care for non-cancerous diseases[39]. Therefore, this study investigates a consultation-based palliative care model as a feasible approach in the ICU environment in South Korea. This study aims to present the intervention protocol, detailing the process, components, and outcomes of the intervention.

METHODS AND ANALYSIS

Study design and setting

This clinical study utilizes a single-arm pre-post intervention design to explore the feasibility of applying consultation-based palliative care services to provide high-quality palliative care to families of critically ill patients in ICUs. Recruitment commenced in June 2024 and is anticipated to continue until June 2025. During this period, efforts are directed towards securing the maximum possible number of analyzable cases meeting the inclusion/exclusion criteria among critically ill patients admitted to the ICU. The expected recruitment target is

20 cases (comprising 20 patients and their 1:1 matched family caregiver, totaling 40 individuals). The sample size was determined based on the average annual number of palliative care consultations requested from the ICU at this tertiary hospital. An average of 60 palliative care consultations were requested each year from the emergency ICU, with approximately 30 involving patients with non-cancer illnesses, who represent the target population of this study. Based on this, fewer than 30 patients per year were estimated to meet the eligibility criteria. Therefore, a target sample size of 20 patients was deemed feasible for this exploratory study assessing feasibility and acceptability of the intervention. All subsequent data collection is projected to be completed by December 31, 2025. The study protocol has been registered at ClinicalTrials.gov (NCT06490835).

This study is conducted within the emergency ICU of a tertiary hospital in South Korea with approximately 1,800 beds, providing care for critically ill patients from across the country. The 20-bed emergency ICU operates as a closed unit, with separate teams of doctors and nurses providing 24-hour care throughout the year. This ICU team traditionally manages the palliative care needs of critically ill patients, including symptom management and discussions about treatment plans. The intervention in this study comprises a palliative care consultation team (PCCT), which includes a palliative care physician and a social worker, collaborating with an ICU attending physician (**Figure 1**).

Eligibility criteria

Detailed inclusion and exclusion criteria for patients and family caregivers are summarized in **Table 1**. Patients are selected based on diagnoses of severe acute brain injury or advanced organ failure, meeting specific criteria for Glasgow Coma Scale, an acute physiology and chronic health evaluation (APACHE) II score, and ICU stay duration. Family caregivers must meet age and consent requirements. Exclusion criteria include individuals under 19 years of age, recent active cancer treatment, refusal of palliative care consultation, or other conditions

detailed in Table 1. Patients expected to die within 48 hours were excluded, as the structured palliative care consultation process requires sufficient time for meaningful implementation, including family counselling and decision-making support. In South Korea, where there is no formal proxy system, healthcare decision-making is limited to spouses and direct blood relatives; therefore, palliative care discussions were confined to these individuals.

Table 1. Eligibility criteria. Cases where either the patient or the family caregiver meets any of the following conditions.

	Inclusion criteria	Exclusion criteria
Patient	1. Diagnosis of sudden and severe acute brain injury due to at least one of etiology (vascular, traumatic, metabolic, toxic, infectious, or anoxic) AND 2. Glasgow Coma Scale score of 3-8 for at least 24 hours AND 3. Unable to express themselves verbally or non-verbally OR 1. Diagnosis of advanced stage organ failure (any of the following) - Chronic lung disease requiring long-term oxygen therapy or mechanical ventilation - Decompensated liver cirrhosis - Chronic heart failure with the New York Heart Association class III or IV - Progressive neurological disease with a modified Rankin Score of 3-5 (e.g., dementia, Parkinson's disease, and amyotrophic lateral sclerosis) - Three or more chronic comorbidities causing limitations in activities of daily living AND 2. APACHE II score ≥ 14 at the time of screening AND 3. ICU stay of 7 days or more	1. Under 19 years of age 2. Unable to speak, understand, or read Korean 3. Refusing palliative care consultation 4. Referred to palliative care prior to study enrollment 5. Within 48 hours of ICU admission 6. Presence of active cancer under treatment within 6 months prior to ICU admission 7. Care goals set to "comfort care" at the time of study enrollment 8. Death expected within 48 hours at the time of study enrollment 9. Lack of capacity to participate in the study without an appropriate surrogate

Family caregiver	1. Family caregiver of a patient who meets the inclusion criteria (Family: defined as the patient's spouse, lineal ascendants and descendants within two degrees of kinship and their spouses, siblings and their spouses, and relatives within eight degrees of kinship and their spouses) 2. Aged 19 or older 3. Willing and able to provide consent for participation in the study	1. Under 19 years of age 2. Unable to speak, understand, or read Korean 3. Determined by a physician to be in extremely poor health, making participation in the study infeasible 4. Refusing palliative care consultation

APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit.

Recruitment of Participants

Attending physicians of the primary ICU team, who serve as co-investigators in this study, initially assess whether patients admitted to the ICUs meet the eligibility criteria. He or she refers patients deemed eligible as participants to the PCCT using a separate referral form within the electronic medical record system (see **online supplemental file 1**). The referral form includes confirmation of the patient's verbal consent to participate in the study, along with detailed information regarding the patient's medical condition, treatment plans, discussions with the family, and reasons for the referral. Then, the social worker from the PCCT delivers a comprehensive explanation of the study's purpose and methods to potential participants. Written consent is obtained if they willingly express their intention to participate (see **online supplemental file 2**). After obtaining the consent, the palliative care physician from the PCCT reviews the patient's medical records and the referral form. If there is insufficient information, the palliative care physician discusses the case with the ICU physician either in person or over the phone.

Description of Intervention

Overview

The aim of the intervention is to offer psychosocial support to the patient's family, decision

making support, and to enhance patient-centeredness. The intervention received by ICU patients and their families encompasses services provided by the PCCT and high-quality palliative care administered by the ICU attending physician, in addition to standard critical care. Key components of services from the PCCT include family counseling, family meeting support, and consultation on addressing identified palliative care needs through patient assessment and family counseling (**Table 2**). If a participant requests to discontinue the intervention at any point, the intervention will be paused, and the participant will be allowed to withdraw from the study. The overview of the intervention is shown in **Figure 2**.

Table 2. Major interventions of the PCCT

Intervention methods	Description
Family counseling	• Direct interviews with the patient's family, conducted by the social worker from the PCCT • Identification of the family's palliative care needs related to the patient's care and decision-making, serving as basic information for the consultation • Provision of psychological and emotional support to the family
Consultation	• Provision of consultation by the PCCT to the ICU attending physician, synthesizing the family's psychosocial and decision-making needs with the medical perspective of palliative care needs • Guidance for integrating holistic palliative care into the ICU treatment process. • Key content: management of the patient's pain and physical/mental symptoms, understanding of the disease and treatment options, decisional conflict, emotional and practical support for the patient and family, support in setting goal of care related to the patient's values and preferences, provision of information on support systems, bereavement and grief

	support.
Support for family meetings	• Family meetings held by the ICU attending physician as part of the standard provision of usual palliative care whenever the need arises • Discussion members convened depending on the issues at hand, such as the necessity for comprehensive medical judgment due to high uncertainty, insufficient information, value conflicts in decision-making, and communication problems between family members and healthcare professionals. • Support facilitation from the specialist or social worker from the PCCT, depending on the purpose and nature of the meeting convened

PCCT, palliative care consultation team; ICU, intensive care unit.

Family Counseling

Family counseling by the PCCT social worker is a supportive and therapeutic process that also gathers information to assess the palliative care needs of the patient and family. Using a patient- and family-centered approach, particularly for families in distress, the social worker encourages all family members to express their opinions and emotions, promotes communication, and helps to explore the patient's values and preferences. The social worker conducts a psychosocial assessment that includes the patient's personal history, psychological and emotional status, family evaluation, socioeconomic support needs, and available resources. Additionally, a decision-making assessment is performed, encompassing factors related to family decision-making, dealing with uncertainty in current medical decisions, providing sufficient information, clarifying values, addressing communication issues, and facilitating shared decision-making. These assessments are conducted to provide foundational information for the PCCT in advising the attending physician and establishing intervention plans, including family meetings.

The social worker contacts participants to schedule one-hour counseling appointments, aiming for all family members, including the primary caregiver, to gather in a private space. While face-to-face counseling is preferred, phone counseling is available if necessary. Sessions are recorded and transcribed for documentation.

Interim Consultation

The interim consultation provides the ICU team with comprehensive guidance on the management of symptoms, understanding of the disease and treatment options by the patient and family, decisional conflict, and communication to ensure the provision of high-quality palliative care. Additionally, when a family meeting is necessary, the reasons for recommending the meeting and the required preparations are provided in the form of a response to the referral. If a family meeting is deemed unnecessary, the interim consultation is bypassed, and the process proceeds directly to the final consultation.

Support for Family Meetings

Additional family meetings tailored to the family's needs are conducted as necessary. A family meeting, convened by an ICU attending physician as part of usual care, supports decision-making between healthcare professionals and the family to establish treatment and care plans. These meetings address the need for comprehensive multidisciplinary medical judgment, and to overcome high medical uncertainty, insufficient information, value conflicts in decision-making, and communication issues. During the intervention, the PCCT has supporting roles in resolving complex issues and mediating conflicts in the family meeting. While family meetings follow basic procedures, they can be adjusted to fit specific purposes and situations (**Table 3**).

Table 3. Basic procedures and roles of family meetings

Standard protocols	Specific instructions in case with high medical uncertainty
• Share the purpose and focus of the family meeting • Confirm the family's understanding of the patient's condition and treatment options • Ensure the sufficiency of information needed for decision-making • Provide explanations and summaries of relevant healthcare professionals about patient's condition and treatment options. • Present discussion topics • Listen to the family's opinions on the discussion topics • Set goal of care appropriate for the patient • Establish detailed action plans • Provide emotional support to the family members	• Participation of the attending physician and all relevant medical teams with the aim of making comprehensive medical judgments and consolidating palliative care approaches. • Support for meeting facilitation by the palliative care physician from the PCCT • Assistance with family meeting preparation and provision of emotional support by the PCCT social worker
	Specific instructions in case with the aim of value clarification and facilitation of communication
	• Support for value seeking and pursuing processes to enhance patient-centeredness in surrogate decision-making, and support for resolving value conflicts and communication issues within the family and between the family and attending physician. • Family meeting facilitation support by the PCCT social worker

PCCT, palliative care consultation team.

Final consultation

Expanding upon the content of the interim consultation (symptom management, understanding of the disease and decision-making conflict factors, psychosocial support, and communication), the final consultation encompasses care goal setting in the patient's best

interest and decision support aligned with these care goals. It also includes information on available support systems, support for EOL care and the bereavement process, and final recommendations in the form of an interdepartmental referral response.

High-quality palliative care by ICU attending physicians

The attending physicians appropriately integrate the recommendations of the PCCT into patient care and treatment, adjusting the goal of care and connecting necessary resources. The physicians also assess the need for further discussions, considering potential changes in the patient's condition or goal of care.

Outcomes

The primary outcome is the feasibility of applying consultation-based high-quality palliative care, determined by the proportion of eligible individuals who participate, undergo family counseling, and complete the study. All secondary outcomes are exploratory in nature, intended to generate hypotheses and inform future research, given the limited sample size. Secondary outcomes include changes in family caregiver's decisional conflict, self-efficacy, psychological distress, and decision regret as effects of intervention. Additional secondary outcomes are the level of patient- and family-centered care experienced by the caregiver[40,41], caregiver satisfaction with the services, length of hospital stay, survival discharge rate, and details of comfort care during ICU stay. Data collection completion rate and patient recruitment time are also included. To address the limitation of a small sample size in this study and to enhance the reliability of the research findings, a qualitative assessment of the feasibility and satisfaction with the intervention will also be conducted as a supplementary measure. Additionally, relevant data up to the point of withdrawal will be included in the analysis to ensure comprehensive reporting. **Table 4** outlines the timing and methods for collecting all outcome measures and survey variables.

271

272 **Table 4.** Outcome measures

Outcomes	Instrument used	Data source	Timing of measurement
Primary Outcome			
Feasibility of applying consultation-based high-quality palliative care in ICUs	Participation rate, palliative care counseling rate, study completion rate	Families and patients	1 day (at discharge)
Secondary Outcomes			
Change in surrogates' decisional conflict	Decisional Conflict Scale (DCS)	Family	Pre-post comparison (baseline vs. within one week after consultation)
Change in surrogates' decisional self-efficacy	Decisional Self-Efficacy Scale	Family	Pre-post comparison (baseline vs. within one week after consultation)
Change in surrogates' psychological distress	Hospital Anxiety and Depression Scale (HADS)	Family	Pre-post comparison (baseline vs. within one week after consultation)
Surrogates' decision regret after the intervention	Decision Regret Scale	Family	Follow-up (Within one week/one month after consultation; Up to three months after the final consultation for deceased patients)
Level of patient- and family-centered care experienced by surrogates after the intervention	Modified Patient Perception of Patient-Centeredness (PPPC) Scale	Family	Follow-up (Within one week/one month after consultation; Up to three months after the final consultation for deceased patients)
Surrogates' satisfaction with the intervention services	Overall satisfaction (5-point scale: very dissatisfied, dissatisfied, neutral, satisfied, very satisfied)	Family	Within one week after the final consultation
Length of hospital stay		Chart review	1 day (at discharge)
Survival to discharge		Chart review	1 day (at discharge)

rate			
Days of symptom relief treatments received in the ICU		Chart review	1 day (at discharge)
Proportion of patients receiving symptom relief treatments during the ICU stay		Chart review	1 day (at discharge)
Use of life-sustaining procedures within 48 hours before death		Chart review	1 day (at discharge)
Use of symptom relief treatments within 48 hours before death		Chart review	1 day (at discharge)
Data collection completion rate	Proportion of data collected at each time point exceeding 90%	Chart review, Families and patients	Within three months after the final consultation
Time taken to recruit patients		Chart review, Families and patients	Within the first year of study initiation
Other Outcomes			
Qualitative evaluation of intervention feasibility and satisfaction	Semi-structured, one-on-one interviews with surrogates	Family	Within three months after the final consultation
Additional analysis of surrogates' psychological distress changes	Hospital Anxiety and Depression Scale (HADS)	Family	One month after the final consultation (within three months for deceased patients)

ICU, intensive care unit.

Statistical analysis

The outcome measures encompass both categorical variables and continuous variables. For continuous outcomes measuring changes before and after the intervention, a paired t-test or Wilcoxon signed-rank test will be utilized. Categorical variables will be assessed using

frequencies (%). All statistical analyses will be two-sided, with a value of $P<0.05$ considered statistically significant.

Ethics and dissemination

The study protocol has received approval from the Institutional Review Board of Seoul National University Hospital (No. 2404-111-1532). The results of this study will be shared with critical care societies, interested researchers, and funding agencies. We intend to disseminate the findings extensively through multiple channels, including presentations at academic conferences, submissions to peer-reviewed journals, and posts on relevant social media platforms. Additionally, the study results will be submitted to ClinicalTrials.gov for broader accessibility.

DISCUSSION

To the best of our knowledge, our study is the first to investigate the feasibility of implementing consultation-based, high-quality palliative care services in an ICU setting where specialist palliative care is not routinely available. Previous studies have indicated that palliative care consultations in the ICU tend to be provided too close to the time of death, limiting their potential benefits[42]. This highlights the need for research exploring the feasibility and effects of interventions that provide early palliative care to patients who might benefit the most from it[43]. In this context, our intervention is significant, as it identifies patients who could benefit from palliative care early on, integrating specialist palliative care into critical care to deliver high-quality palliative care from the outset.

In our study, the selected palliative care intervention focuses on delivering palliative care tailored to the overall situation of the patient and family through early consultation. This approach ensures continuous and effective interaction and communication between the primary ICU team and the patient's family throughout the ICU care process. Various models

of ICU palliative care delivery exist, such as consultative and integrative[44]. In an environment lacking established ICU palliative care, we opted for an intervention model where the PCCT's role is not to consistently manage symptoms directly, but rather to enhance the capacity for primary palliative care through consultation[45,46]. This approach aims to enhance the delivery of palliative care while efficiently utilizing limited resources[47], positioning the PCCT as facilitators and mediators. Unlike previous studies[40,43,46,48,49], which predominantly employed independent roles of PCCT or interventions in terms of quality improvement within the primary ICU team, our approach presents a context-specific, pragmatic adaptive, consultative model. Here, PCCT acts as a facilitator, selectively supporting cases with complex needs to enhance primary palliative care capacity. This targeted strategy optimizes resource use while improving the overall quality of palliative care delivery in the ICU.

In previous studies on ICU palliative care interventions[43,46-48], the primary outcomes were typically subjective measures, such as family satisfaction and depression, or clinical outcomes for patients. Our study shares the limitation of difficulty in assessing patient outcomes due to the medical conditions of ICU patients, but it stands out by including person-centered care outcomes, like the Patient Perception of Patient-Centeredness Questionnaire[41], proxy-reported by caregivers as a secondary outcome. As a feasibility study with an exploratory focus, we aimed to incorporate a range of outcomes from patient and family perspectives, as well as healthcare system and process aspects, while qualitatively evaluating those less suited to quantitative assessment.

Despite these strengths, our study has several limitations. First, we used a single-arm design for the pilot trial at a single center. Since PCCTs for ICUs are not widely implemented across healthcare institutions, and our intervention included both the PCCT and primary palliative care by ICU attending physicians, we considered a randomized design unsuitable for this pilot study. Second, the small sample size and single-arm pre-post design limit statistical power and introduce potential confounding. Patient-specific factors—such as underlying conditions,

prior ICU management, and ICU length of stay—may influence outcomes. While relevant clinical variables will be recorded to aid interpretation, all secondary outcomes should be considered exploratory and hypothesis-generating. Furthermore, defining a standard target for feasibility is challenging due to variations in ICU palliative care delivery across healthcare systems. To address these issues, qualitative methods were incorporated to provide contextual insights and support comprehensive evaluation. Third, patients expected to die within 48 hours were excluded. As the structured palliative care consultation requires a minimum window for effective implementation, immediate end-of-life care in such cases is more appropriately provided by ICU clinicians. Future studies could explore rapid-response palliative care models or enhanced ICU-based primary palliative care to support families facing imminent death. Finally, our study only included ICU physicians as direct participants, even though ICU nurses play a critical role in palliative care[50]. This may limit the interpretation of our intervention's potential impact. However, given our focus on decision-making support, we prioritized enhancing ICU physicians' competency.

In conclusion, this study would have the potential to investigate the provision of high-quality palliative care via a consultative palliative care model integrated into ICU care as a feasible and acceptable approach. The results of this study can give insights for modeling the effective palliative care delivery in an ICU environment.

Contributors: YSJ and YK: conception and design of study, drafting and critically revising the manuscript. SYK: conception and design of study. YSJ and TJK: development of the protocol and manuscript review. SHY: conception and design of study, drafting and critically revising the manuscript, development of the protocol and manuscript review. SHY is responsible for the overall content as the guarantor. All authors approved of the final version of the manuscript. The funder had no involvement in any aspect of the study or publication process.

Funding: This research was supported by a grant from the Patient-Centered Clinical Research Coordinating Center (PACEN), funded by the Ministry of Health & Welfare of the Republic of Korea (grant number: RS-2023-KH137917).

Competing interests: None declared.

Patient and public involvement: None

Patient consent for publication: Not applicable.

Provenance and peer review: Not commissioned; externally peer reviewed.

References

1. Mercadante S, Gregoretti C, Cortegiani A. Palliative care in intensive care units: why, where, what, who, when, how. *BMC Anesthesiol* 2018;18(1):106. doi: 10.1186/s12871-018-0574-9 [published Online First: 2018/08/17]:30111299

2. Angus DC, Barnato AE, Linde-Zwirble WT, et al. Use of intensive care at the end of life in the United States: an epidemiologic study. *Crit Care Med* 2004;32(3):638-43. doi: 10.1097/01.ccm.0000114816.62331.08 [published Online First: 2004/04/20]:15090940

3. Angus DC, Truog RD. Toward Better ICU Use at the End of Life. *JAMA* 2016;315(3):255-6. doi: 10.1001/jama.2015.18681 [published Online First: 2016/01/20]:26784767

4. Bibas L, Peretz-Larochelle M, Adhikari NK, et al. Association of Surrogate Decision-making Interventions for Critically Ill Adults With Patient, Family, and Resource Use Outcomes: A Systematic Review and Meta-analysis. *JAMA Netw Open* 2019;2(7):e197229. doi: 10.1001/jamanetworkopen.2019.7229 [published Online First: 2019/07/20]:31322688

5. Herridge MS, Tansey CM, Matte A, et al. Functional disability 5 years after acute respiratory distress syndrome. *N Engl J Med* 2011;364(14):1293-304. doi: 10.1056/NEJMoa1011802 [published Online First: 2011/04/08]:21470008

6. Detsky ME, Harhay MO, Bayard DF, et al. Six-Month Morbidity and Mortality among Intensive Care Unit Patients Receiving Life-Sustaining Therapy. A Prospective Cohort Study. *Ann Am Thorac Soc* 2017;14(10):1562-70. doi: 10.1513/AnnalsATS.201611-875OC [published Online First: 2017/06/18]:28622004

7. Clark JA, Wray NP, Ashton CM. Living with treatment decisions: regrets and quality of life among men treated for metastatic prostate cancer. *J Clin Oncol* 2001;19(1):72-80. doi: 10.1200/JCO.2001.19.1.72 [published Online First: 2001/01/03]:11134197

8. Feiler D, Muller-Trede J. The One That Got Away: Overestimation of Forgone Alternatives as a Hidden Source of Regret. *Psychol Sci* 2022;33(2):314-24. doi: 10.1177/09567976211032657 [published Online First: 2022/01/22]:35060808

9. Hilger C, Schostak M, Otto I, et al. Time pressure predicts decisional regret in men with localized prostate cancer: data from a longitudinal multicenter study. *World J Urol* 2021;39(10):3755-61. doi: 10.1007/s00345-021-03727-0 [published Online First: 2021/05/23]:34021406

10. October TW, Jones AH, Greenlick Michals H, et al. Parental Conflict, Regret, and Short-term Impact on Quality of Life in Tracheostomy Decision-Making. *Pediatr Crit Care Med* 2020;21(2):136-42. doi: 10.1097/PCC.0000000000002109 [published Online First: 2019/10/01]:31568244

11. Iverson E, Celious A, Kennedy CR, et al. Factors affecting stress experienced by surrogate decision makers for critically ill patients: implications for nursing practice. *Intensive Crit Care Nurs* 2014;30(2):77-85. doi: 10.1016/j.iccn.2013.08.008 [published Online First: 2013/11/12]:24211047

12. Jezewski MA. Do-not-resuscitate status: conflict and culture brokering in critical care units. *Heart Lung* 1994;23(6):458-65. https://www.ncbi.nlm.nih.gov/pubmed/78520607852060 [published Online First: 1994/11/01]:7852060

13. Schenker Y, Crowley-Matoka M, Dohan D, et al. I don't want to be the one saying 'we should just let him die': intrapersonal tensions experienced by surrogate decision makers in the ICU. *J Gen Intern Med* 2012;27(12):1657-65. doi: 10.1007/s11606-012-2129-y [published Online First: 2012/09/27]:23011253

14. Curtis JR, Engelberg RA, Nielsen EL, et al. Patient-physician communication about end-of-life care for patients with severe COPD. *Eur Respir J* 2004;24(2):200-5. doi: 10.1183/09031936.04.00010104 [published Online First: 2004/08/31]:15332385

15. Davidson JE, Powers K, Hedayat KM, et al. Clinical practice guidelines for support of the family in the patient-centered intensive care unit: American College of Critical Care Medicine Task Force 2004-2005. *Crit Care Med* 2007;35(2):605-22. doi: 10.1097/01.CCM.0000254067.14607.EB [published Online First: 2007/01/06]:17205007

16. Majesko A, Hong SY, Weissfeld L, et al. Identifying family members who may struggle in the role of surrogate decision maker. *Crit Care Med* 2012;40(8):2281-6. doi: 10.1097/CCM.0b013e3182533317 [published Online First: 2012/07/20]:22809903

17. Bowman K. Trepidation: a family member's response to shift change in the intensive care unit. *Dimens Crit Care Nurs* 2010;29(6):288-92. doi: 10.1097/DCC.0b013e3181f0c1b5 [published Online First: 2010/10/14]:20940584

18. Mitchell ML, Courtney M, Coyer F. Understanding uncertainty and minimizing families' anxiety at the time of transfer from intensive care. *Nurs Health Sci* 2003;5(3):207-17. doi: 10.1046/j.1442-2018.2003.00155.x [published Online First: 2003/07/25]:12877722

19. Nelson JE, Puntillo KA, Pronovost PJ, et al. In their own words: patients and families define high-quality palliative care in the intensive care unit. *Crit Care Med* 2010;38(3):808-18. doi: 10.1097/ccm.0b013e3181c5887c [published Online First: 2010/03/04]:20198726

20. Cohan JN, Orleans B, Brecha FS, et al. Factors Associated With Decision Regret Among Patients With Diverticulitis in the Elective Setting. *J Surg Res* 2021;261:159-66. doi: 10.1016/j.jss.2020.12.019 [published Online First: 2021/01/12]:33429225

21. Szproch AK, Maguire R. A systematic review of the factors associated with regret post-cancer treatment. *J Psychosoc Oncol* 2022;40(1):1-25. doi: 10.1080/07347332.2020.1844846 [published Online First: 2020/11/17]:33191874

22. Wilson A, Winner M, Yahanda A, et al. Factors associated with decisional regret among patients undergoing major thoracic and abdominal operations. *Surgery* 2017;161(4):1058-66. doi: 10.1016/j.surg.2016.10.028 [published Online First: 2016/12/21]:27993362

23. Lautrette A, Darmon M, Megarbane B, et al. A communication strategy and brochure for relatives of patients dying in the ICU. *N Engl J Med* 2007;356(5):469-78. doi: 10.1056/NEJMoa063446 [published Online First: 2007/02/03]:17267907

24. Siegel MD, Hayes E, Vanderwerker LC, et al. Psychiatric illness in the next of kin of patients who die in the intensive care unit. *Crit Care Med* 2008;36(6):1722-8. doi: 10.1097/CCM.0b013e318174da72 [published Online First: 2008/06/04]:18520637

25. Anderson WG, Arnold RM, Angus DC, et al. Posttraumatic stress and complicated grief in family members of patients in the intensive care unit. *J Gen Intern Med* 2008;23(11):1871-6. doi: 10.1007/s11606-008-0770-2 [published Online First: 2008/09/10]:18780129

26. Paparrigopoulos T, Melissaki A, Efthymiou A, et al. Short-term psychological impact on family members of intensive care unit patients. *J Psychosom Res* 2006;61(5):719-22. doi: 10.1016/j.jpsychores.2006.05.013 [published Online First: 2006/11/07]:17084152

27. Pochard F, Darmon M, Fassier T, et al. Symptoms of anxiety and depression in family members of intensive care unit patients before discharge or death. A prospective multicenter study. *J Crit*

Care 2005;20(1):90-6. doi: 10.1016/j.jcrc.2004.11.004 [published Online First: 2005/07/15]:16015522

28. Wendler D, Rid A. Systematic review: the effect on surrogates of making treatment decisions for others. *Ann Intern Med* 2011;154(5):336-46. doi: 10.7326/0003-4819-154-5-201103010-00008 [published Online First: 2011/03/02]:21357911

29. Azoulay E, Pochard F, Kentish-Barnes N, et al. Risk of post-traumatic stress symptoms in family members of intensive care unit patients. *Am J Respir Crit Care Med* 2005;171(9):987-94. doi: 10.1164/rccm.200409-1295OC [published Online First: 2005/01/25]:15665319

30. Hua M, Wunsch H. Integrating palliative care in the ICU. *Curr Opin Crit Care* 2014;20(6):673-80. doi: 10.1097/MCC.0000000000000149 [published Online First: 2014/09/19]:25233330

31. Michels G, Schallenburger M, Neukirchen M, et al. Recommendations on palliative care aspects in intensive care medicine. *Crit Care* 2023;27(1):355. doi: 10.1186/s13054-023-04622-3 [published Online First: 2023/09/19]:37723595

32. Doherty C, Feder S, Gillespie-Heyman S, et al. Easing Suffering for ICU Patients and Their Families: Evidence and Opportunities for Primary and Specialty Palliative Care in the ICU. *J Intensive Care Med* 2024;39(8):715-32. doi: 10.1177/08850666231204305 [published Online First: 2023/10/12]:37822226

33. O'Mahony S, McHenry J, Blank AE, et al. Preliminary report of the integration of a palliative care team into an intensive care unit. *Palliat Med* 2010;24(2):154-65. doi: 10.1177/0269216309346540 [published Online First: 2009/10/15]:19825893

34. Kim JM, Godfrey S, O'Neill D, et al. Integrating palliative care into the modern cardiac intensive care unit: a review. *Eur Heart J Acute Cardiovasc Care* 2022;11(5):442-49. doi: 10.1093/ehjacc/zuac034 [published Online First: 2022/04/02]:35363258

35. Chung TH, Nguyen LK, Lal LS, et al. Palliative Care Consultation in the Intensive Care Unit Reduces Hospital Costs: A Cost-Analysis. *J Palliat Care* 2022:8258597221095986. doi: 10.1177/08258597221095986 [published Online First: 2022/04/27]:35469500

36. Kyeremanteng K, Gagnon LP, Thavorn K, et al. The Impact of Palliative Care Consultation in the ICU on Length of Stay: A Systematic Review and Cost Evaluation. *J Intensive Care Med* 2018;33(6):346-53. doi: 10.1177/0885066616664329 [published Online First:

2016/09/02]:27582396

37. Aslakson RA, Curtis JR, Nelson JE. The changing role of palliative care in the ICU. *Crit Care Med* 2014;42(11):2418-28. doi: 10.1097/CCM.0000000000000573 [published Online First: 2014/08/29]:25167087

38. Nelson JE, Bassett R, Boss RD, et al. Models for structuring a clinical initiative to enhance palliative care in the intensive care unit: a report from the IPAL-ICU Project (Improving Palliative Care in the ICU). *Crit Care Med* 2010;38(9):1765-72. doi: 10.1097/CCM.0b013e3181e8ad23 [published Online First: 2010/06/22]:20562699

39. Kim K, Park B, Gu B, et al. The National Hospice and Palliative Care registry in Korea. *Epidemiol Health* 2022;44:e2022079. doi: 10.4178/epih.e2022079 [published Online First: 2022/10/01]:36177979

40. White DB, Angus DC, Shields AM, et al. A Randomized Trial of a Family-Support Intervention in Intensive Care Units. *N Engl J Med* 2018;378(25):2365-75. doi: 10.1056/NEJMoa1802637 [published Online First: 2018/05/24]:29791247

41. Andersen SK, Vincent G, Butler RA, et al. ProPACC: Protocol for a Trial of Integrated Specialty Palliative Care for Critically Ill Older Adults. *J Pain Symptom Manage* 2022;63(6):e601-e10. doi: 10.1016/j.jpainsymman.2022.02.344 [published Online First: 2022/05/21]:35595373

42. Seaman JB, Barnato AE, Sereika SM, et al. Patterns of palliative care service consultation in a sample of critically ill ICU patients at high risk of dying. *Heart Lung* 2017;46(1):18-23. doi: 10.1016/j.hrtlng.2016.08.008 [published Online First: 2016/10/09]:27717509

43. Helgeson SA, Burnside RC, Robinson MT, et al. Early Versus Usual Palliative Care Consultation in the Intensive Care Unit. *Am J Hosp Palliat Care* 2023;40(5):544-51. doi: 10.1177/10499091221115732 [published Online First: 2022/07/15]:35833450

44. Curtis JR, Higginson IJ, White DB. Integrating palliative care into the ICU: a lasting and developing legacy. *Intensive Care Med* 2022;48(7):939-42. doi: 10.1007/s00134-022-06729-7 [published Online First: 2022/05/17]:35577992

45. Halangk W, Dietz H. Capacities of oxidative metabolism in digitonin-treated bovine epididymal spermatozoa. *Biomed Biochim Acta* 1986;45(10):1249-57. https://www.ncbi.nlm.nih.gov/pubmed/35667163566716 [published Online First:

1986/01/01]:3566716

46. Ma J, Chi S, Buettner B, et al. Early Palliative Care Consultation in the Medical ICU: A Cluster Randomized Crossover Trial. *Crit Care Med* 2019;47(12):1707-15. doi: 10.1097/CCM.0000000000004016 [published Online First: 2019/10/15]:31609772

47. Kamdar HA, Gianchandani S, Strohm T, et al. Collaborative Integration of Palliative Care in Critically Ill Stroke Patients in the Neurocritical Care Unit: A Single Center Pilot Study. *J Stroke Cerebrovasc Dis* 2022;31(8):106586. doi: 10.1016/j.jstrokecerebrovasdis.2022.106586 [published Online First: 2022/06/07]:35667164

48. Chang DW, Neville TH, Parrish J, et al. Evaluation of Time-Limited Trials Among Critically Ill Patients With Advanced Medical Illnesses and Reduction of Nonbeneficial ICU Treatments. *JAMA Intern Med* 2021;181(6):786-94. doi: 10.1001/jamainternmed.2021.1000 [published Online First: 2021/04/13]:33843946

49. Carson SS, Cox CE, Wallenstein S, et al. Effect of Palliative Care-Led Meetings for Families of Patients With Chronic Critical Illness: A Randomized Clinical Trial. *JAMA* 2016;316(1):51-62. doi: 10.1001/jama.2016.8474 [published Online First: 2016/07/06]:27380343

50. Nelson JE, Cortez TB, Curtis JR, et al. Integrating Palliative Care in the ICU: The Nurse in a Leading Role. *J Hosp Palliat Nurs* 2011;13(2):89-94. doi: 10.1097/NJH.0b013e318203d9ff [published Online First: 2011/08/30]:21874122

Figure Legends

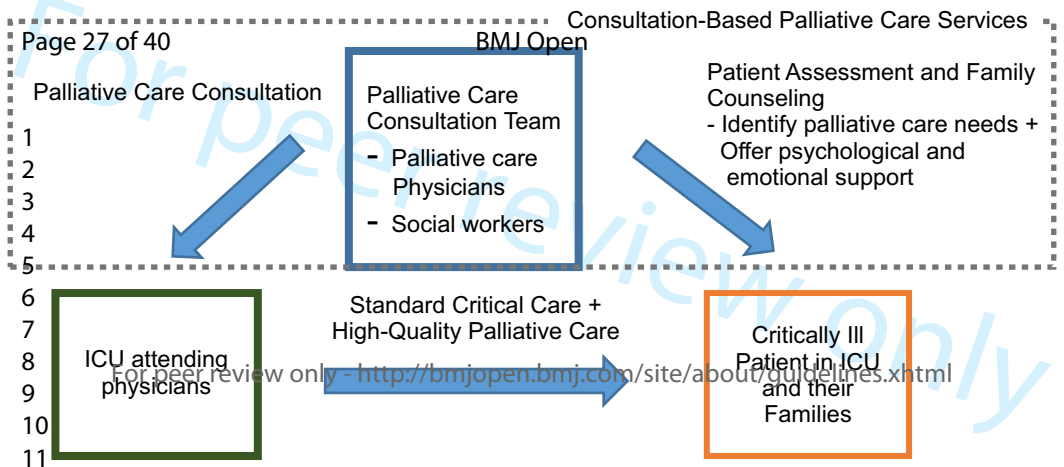
Figure 1. Scheme of consultation-based palliative care services to provide high-quality palliative care to families of critically ill patients in the ICU.

The arrows indicate the flow of consultation processes between the palliative care team, ICU physicians, patients, and families.

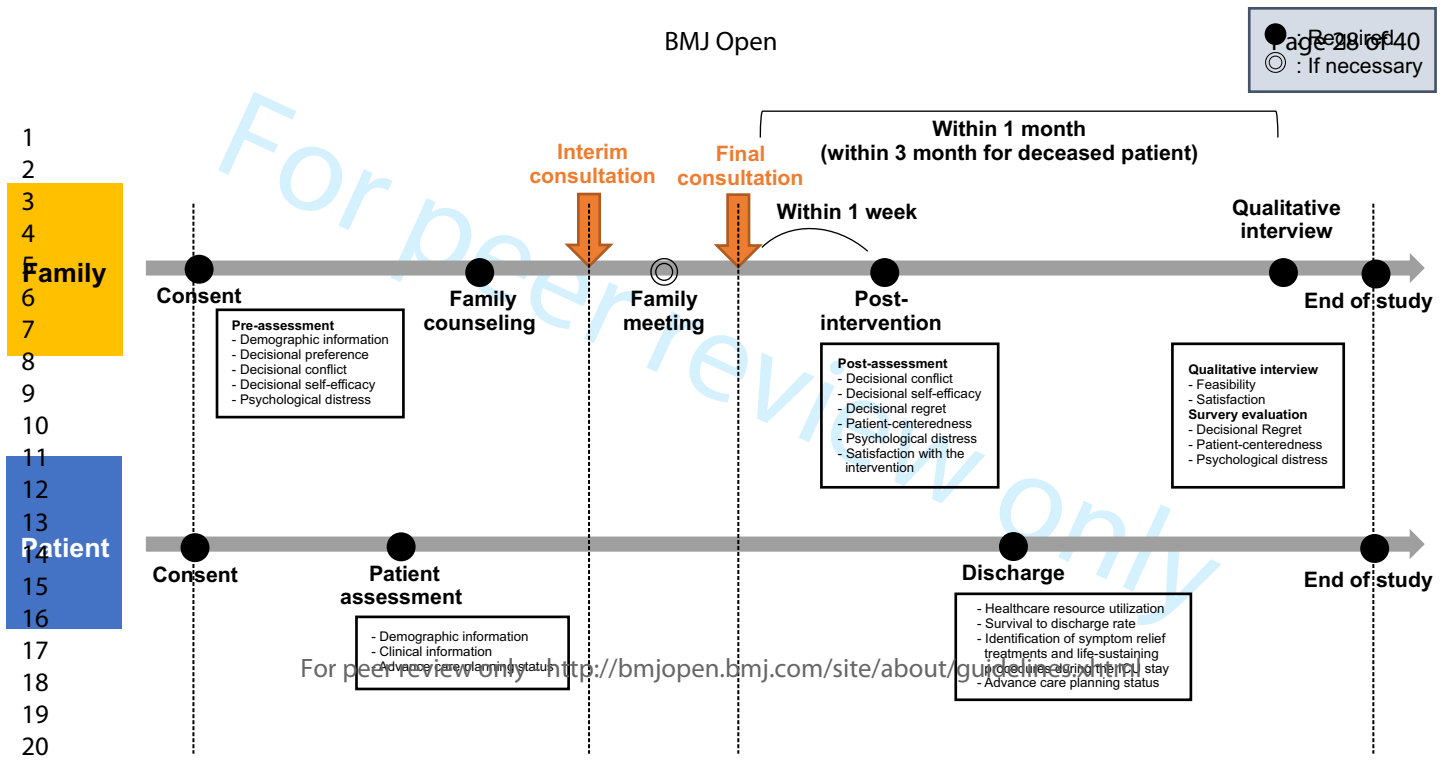
ICU, intensive care unit.

Figure 2. Overall flow of the intervention.

ICU, intensive care unit.



● : Required
◎ : If necessary



Referral note for Palliative care consultation

Date of referral	YYYY-MM-DD	
Purpose of consultation (multiple choices allowed)	□ management of patient's pain, physical, and psychological symptoms □ enhancement of understanding about the disease and mediation decisional conflict □ psychosocial and emotional support for patients and families □ supporting setting care goals related to patient values and preferences □ providing information on available resources □ bereavement support □ consultation for medical assessment (etc. terminal and end-of-life phases) □ etc( )	
	Primary reason for consultation	
Preference for the specialized services of the Center for Palliative Care and Clinical Ethics (multiple choices allowed)	□ Registration for SNUH Consultative Hospice (※Eligibility and conditions can be confirmed by the center) □ Provision of hospice information (including guidance on facilities) □ Use of end-of-life care rooms □ clinical ethics consultation (including consideration by ethics committee) □ None of the above	
Patient's medical issues/ concerns		
Patient's medical condition	□ Terminal stage: No possibility of fundamental recovery despite active treatment, with progressively worsening symptoms □ End-of-life stage: No possibility of recovery, with rapidly worsening symptoms despite treatment, and death is imminent □ Neither in the terminal nor end-of-life stage, but requires palliative care	
Expected prognosis	□ A few days □ a few weeks □ a few months □ a few years □ uncertain	
Potential for functional recovery	**Recovery to normal life (ADL, social engagement, etc)**	□ High likelihood □ low likelihood □ nolikelihood □ uncertain
	Recovery to pre-ICU admission status	□ High likelihood □ low likelihood □ nolikelihood □ uncertain
	Significant consciousness recovery	□ High likelihood □ low likelihood □ nolikelihood □ uncertain

Treatment plan	*The best treatment plan as determined by the attending physician*	
	Consistency of medical team opinions on treatment plan	□ consensus □ disagreement within the department □ disagreement within other departments
Decisional issues	*Issues to be addressed in decision-making based on the anticipated progression of the disease*	
Physician-family discussion process	*Briefly describe the progress of discussions with family members*	
Family evaluation	**Level of caregiving burden**	□ none □ slight □ moderate to significant □ severe □ uncertain
	Level of psychological stress	□ none □ slight □ moderate to significant □ severe □ uncertain

Participant Information Sheet and Consent Form

You are being invited to take part in this clinical study. This study has been reviewed and approved by the Institutional Review Board of Seoul National University Hospital, which is responsible for protecting the rights and welfare of research participants. We would now like to provide you with information about the purpose of this study, as well as your rights and responsibilities as a participant.

Before agreeing to take part in the study, you should carefully read and fully understand the contents of this document. This information sheet includes detailed explanations of the study's purpose, procedures, potential benefits and risks, and other important considerations. It also describes your right to make your own decision and to withdraw from the study at any time.

Please read this document carefully. If you have any questions or concerns, you are encouraged to ask the study doctor or research staff at any time. You should sign the consent form only after you fully understand all of the information described below and have received satisfactory answers to all your questions. Your participation in this study is entirely voluntary, and you may decline or withdraw at any time without any penalty or loss of benefits to which you are otherwise entitled.

1. Background and Purpose of the Study

Palliative care is an approach aimed at improving the quality of life of patients and their families who are facing problems associated with life-threatening illnesses. Recent studies have shown that providing palliative care early in the course of chronic serious illnesses, such as cancer, alongside disease-directed treatment can enhance quality of life and support appropriate use of healthcare services. Patients with acute critical illness admitted to the intensive care unit (ICU) experience rapidly changing medical conditions and face significant uncertainty in terms of prognosis, including potential recovery or disability. In many cases, patients are unable to make decisions for themselves, leaving their families to make urgent and complex medical decisions on their behalf, often under significant emotional distress. These circumstances make it difficult to reflect the patient's own wishes in decision-making, and can impose a psychological burden on families, sometimes leading to conflict among family members or between families and healthcare providers.

While the importance of providing palliative care to critically ill patients and their families in the ICU is increasingly recognized, little is known about the feasibility and impact of implementing consultation-based palliative care services in this setting to improve the quality of palliative care delivery. This study is a pilot investigation designed to explore the feasibility of delivering high-quality, consultation-based palliative care to patients with acute critical illness in the ICU and their families.

2. Number of Participants and Duration of Participation

This study will involve patients with acute critical illness and their family members who meet the inclusion and exclusion criteria. A total of approximately 20 critically ill patients and 20 family caregivers will be enrolled at Seoul National University Hospital.

The study will be conducted from the date of IRB approval until December 31, 2025. If you agree to participate, your participation will last from the time of enrollment until the end of follow-up. You may withdraw from the study at any time without any penalty or loss of benefits.

3. Voluntary Participation and Right to Withdraw

Participation in this study is entirely voluntary. If you decide to take part, you are free to withdraw at any time. Choosing not to participate, or deciding to withdraw from the study later, will not affect your usual medical care in any way.

Even if you initially agree to participate, you may revoke your consent at any point without facing any disadvantage or discrimination. Please note that by signing this consent form or agreeing to participate, you are not waiving any of your legal rights.

If you decide to withdraw from the study, you may inform the study doctor or research staff either

verbally or in writing. Once you withdraw, no further data will be collected, and you will no longer be contacted for research purposes. However, any data already collected prior to your withdrawal may still be used for the study.

4. Study Procedures and Assessments

This study is a single-arm interventional study, and all participants will receive the intervention. Before any study-related procedures begin, you will be asked to listen to an explanation of the study's purpose and procedures, read this consent form, and sign it if you agree to participate.

The study consists of two main components: the intervention and evaluation. The intervention includes four components: (1) family counseling, (2) consultation with the ICU team, (3) support for family meetings, and (4) provision of palliative care by the primary physician. Evaluations will be conducted at baseline and during two follow-up periods.

Intervention

1) Family Counseling

An appointment will be scheduled for a counseling session with a social worker from the palliative care consultation team. This will take place in a private space within the hospital. The aim of this session is to help support future medical decision-making in the best interests of the patient in the ICU. The social worker will explore the family's understanding of the patient's condition, the patient's values and preferences, the care or treatments the family wishes to prioritize, and any challenges the family may be facing.

The session will last approximately one hour, and the conversation will be audio-recorded and later transcribed for analysis.

2) Provision of Consultation

Based on an assessment of the family's psychosocial needs, decision-making challenges, and the patient's medical condition, the palliative care consultation team will provide recommendations to the ICU medical team. This process supports the integration of holistic palliative care into the ICU treatment plan.

Consultation content may include pain and symptom management, understanding of the illness and decision-making conflicts, emotional and practical support for the patient and family, assistance with setting care goals based on patient values and preferences, provision of support resources, and bereavement care.

When a family meeting is recommended, an intermediate consultation may be provided to explain the rationale and help plan for the meeting, including discussion topics.

3) Support for Family Meetings

Family meetings will be arranged as part of the ICU physician's palliative care strategy when needed. These meetings are held when medical uncertainty exists, when key information is lacking, when values conflict in decision-making, or when communication challenges arise between the family and healthcare providers.

Depending on the purpose and nature of the meeting, a physician or social worker from the palliative care consultation team may facilitate the meeting. Each session is expected to last approximately one hour and will be audio-recorded.

4) Provision of Palliative Care by the Primary Physician

The primary physician will adjust the treatment plan based on the recommendations from the palliative care consultation team and the goals of care discussed. The physician will also address the patient's and family's psychological and spiritual needs and provide appropriate support.

Documentation of these care goals will be shared among the medical team to ensure continuity, even if the care setting changes. Since care goals may evolve based on the patient's condition or the family's psychological state, regular reassessment and further discussions may be needed.

Assessments

Among the participants in this study, family caregivers will be asked to complete one questionnaire

before the intervention and two follow-up assessments: one within one week after the final consultation and another one month after the final consultation. Additionally, a one-on-one interview will be conducted at the one-month follow-up point.

There will be no questionnaires or interviews conducted directly with patients. Patient information will be collected through a review of medical records.

1) Baseline Assessment

If you decide to participate in this study, you will be asked to sign the consent form, after which the research staff will provide the baseline questionnaire.

This questionnaire is to be completed by the family caregiver and includes the following topics: demographic information of the patient and family caregiver, decision-making preferences, decisional conflict, decision-making self-efficacy, and emotional status of the family caregiver.

It is a self-administered questionnaire. You are encouraged to read each item carefully and respond to all questions. The questionnaire consists of 1 to 8 pages and is expected to take approximately 20 minutes to complete.

2) Follow-Up Assessments

There will be two follow-up assessments, both conducted by the family caregiver:

- Within 1 week after the final consultation (Questionnaire)

This questionnaire includes items related to decisional conflict, decision-making self-efficacy, decision regret, patient- and family-centered care, emotional status of the family caregiver, and satisfaction with the intervention services.

As with the baseline assessment, this is a self-administered questionnaire. It consists of 1 to 9 pages and is expected to take approximately 25 minutes to complete.

- One month after the final consultation (Questionnaire and Interview)

This assessment includes a self-administered questionnaire that focuses on decision regret, patient- and family-centered care, and the family caregiver's emotional well-being. The questionnaire consists of 1 to 5 pages and is expected to take about 15 minutes to complete.

Additionally, a semi-structured one-on-one interview will be conducted at this time to explore the family caregiver's perception of the applicability of palliative care consultation services.

If the patient has passed away by this point, the questionnaire and interview will be conducted within three months of the final consultation, taking into account the caregiver's emotional and psychological state. The interview will be audio-recorded and later transcribed for analysis.

5. Responsibilities of Study Participants

Participants in this study are expected to respond to all questions sincerely and accurately, without providing any false information.

6. Anticipated Side Effects, Risks, and Discomforts

Patients and family caregivers receiving the intervention in this study will continue to receive the standard care typically provided in the intensive care unit (including medical treatment and nursing care). In addition, they will receive counseling, education, and palliative care consultation services as part of routine clinical care. Therefore, no specific risks or adverse effects related to participation in the study are anticipated.

7. Financial Burden and Compensation for Patients and Families

There is no participation fee required to take part in this study. Any medical expenses related to clinical procedures during the study will be the responsibility of the participant and will be charged according to standard clinical practice and national health insurance regulations.

Since there will be no additional hospital visits beyond the usual care procedures during the intervention period, no transportation costs will be reimbursed for this period.

However, the family caregiver will receive a small token of appreciation (valued at 10,000 KRW) for completing each questionnaire. A total of 30,000 KRW will be provided if all three questionnaires are

completed.

Additionally, if the family caregiver participates in the one-on-one interview conducted during the final follow-up, transportation costs will be reimbursed (actual costs up to a maximum of 50,000 KRW, regardless of place of residence) due to the extra hospital visit.

These compensations will be provided based on each completed assessment, regardless of whether the participant completes the entire study.

8. Anticipated Benefits

There are no direct benefits to you from participating in this study. However, the information obtained through this study may serve as foundational evidence to support the integration of consultation-based palliative care services into routine care for critically ill patients in the intensive care unit (ICU), a population for whom such services are not yet well-established in Korea. The findings may help determine the feasibility and effectiveness of delivering high-quality palliative care to patients and their family caregivers as part of standard ICU care.

9. Ongoing Provision of New Information

If any new information becomes available during the study that may affect your willingness to continue participation, you or your legal representative will be promptly informed.

10. Withdrawal from the Clinical Trial

Your participation in this study is entirely voluntary. You may choose to withdraw from the study at any time by contacting the investigator, without any penalty or loss of benefits to which you are otherwise entitled. If you decide to discontinue your participation, please inform your physician or the study personnel to ensure that the withdrawal process is carried out safely. If you choose to withdraw from the study, you may also decide whether or not your data can continue to be used for research purposes after your withdrawal. Your decision in this regard will be respected and may contribute to the overall objectives of the study. If you decide to stop the intervention but continue with the research participation, the physician or study staff will explain which procedures will continue and what types of data will still be collected. You may be withdrawn from the study at any time for reasons including, but not limited to, the following:

Criteria for Withdrawal or Discontinuation of the Clinical Trial

(1) Criteria for Early Termination: The clinical trial will be terminated in the following cases:

① The participant (patient or family caregiver) withdraws their consent to participate in the study.

② The participant (patient or family caregiver) no longer wishes to receive further interventions.

③ The patient is discharged before the final consultation (includes both discharge due to death and survival).

④ The family caregiver passes away before the final consultation.

⑤ The investigator determines that discontinuing participation is in the best interest of the participant.

⑥ The participant fails to cooperate with the principal investigator or does not follow the investigator's instructions.

⑦ The regulatory authorities or the ethics committee/clinical research review board discontinues the study.

(2) Early Termination Procedures and Follow-up for Withdrawn Participants

Once participation is discontinued, no further interventions will be carried out, and the investigator will record the endpoint in the Case Report Form (CRF). If the participant withdraws consent, the investigator will determine whether previously collected data can still be used for research purposes. If consent is not given, any collected data will not be used, and the study records, including the withdrawal, will be stored for at least 3 years from the completion of the study and then destroyed.

For participants who discontinue the trial, with the exception of those who withdraw consent, mandatory medical record reviews will be conducted for the remaining follow-up period, but no further survey evaluations will be conducted. For those who withdraw their consent (criterion ①), the investigator will check whether previously collected data can still be used. If consent is not granted, the

collected data will be discarded. In cases where the participant decides not to proceed with further interventions (criterion ②), any post-consultation surveys (post-1) or interviews (post-2) will only be administered to those who consent to participate. Additional medical record investigations will also proceed only for those who agree to continue.

11. Compensation and Treatment Measures for Harm

Patients and family caregivers participating in this study will receive interventions consisting of education and counseling. Therefore, it is anticipated that there will be no physical, mental, or specific injuries caused by participation in this study. However, if any unforeseen psychological or mental harm arises as a result of the additional procedures and interventions related to this clinical trial, apart from the standard medical care, the research team will take appropriate actions to ensure that the participant receives the necessary treatment. Since clinical information will be collected only through medical records without direct intervention with the patient, no harm is anticipated from the research.

12. Collection and Use of Personal and Sensitive Information and Consent for Disclosure to Third Parties

All information provided for this study will be strictly confidential and protected. If you agree to participate in this study, the collected data will be anonymized and may be submitted to relevant institutions. Monitors, auditors, committee members, and government authorities may access the records to verify the procedures and data integrity of the study without violating confidentiality.

The research physician and study staff will collect and use your personal information, including demographic details (e.g., gender, age), personally identifiable information (e.g., name, registration number, contact details, address), and sensitive information (e.g., socioeconomic data—income, marital status, disease status, treatment history). The records, results, and consent forms will be retained for three years, and you have the right to request the disposal of your records. The confidentiality of personally identifiable information will be strictly maintained, and health information will be provided anonymously, ensuring that the identity and location of participants cannot be discerned. Even if the study results are published, the participants' personal information will remain confidential.

During the family counseling, family meetings, and 1:1 interviews conducted as part of the study, the subjective experiences of patients and families are valuable data. Therefore, these sessions will be recorded and transcribed. Any personally identifiable information (e.g., name, birth date, address, contact details) will be anonymized to prevent identification. These materials will only be used for research purposes and will be securely stored on password-protected personal computers accessible only to the researcher. The data will be destroyed in compliance with retention policies.

The personal and sensitive information collected for this study may be used for secondary purposes outside of this study, depending on your consent. In such cases, your personal (sensitive) information will be anonymized before being used for secondary purposes. You will be asked to indicate whether you agree to the secondary use of your information. You have the right to refuse consent for the secondary use of your personal data without any disadvantage, and you may withdraw your consent at any time, even after agreeing to participate in the primary study.

13. Confidentiality of Personal Information and Records

The records collected during your participation in this study will be kept confidential. Even when the results of the study are reported, published, or presented, your personal information will remain confidential. Individuals monitoring or auditing this study, the Institutional Review Board (IRB), and relevant government authorities are allowed to access the records and personally identifiable information of participants in accordance with the relevant laws and regulations, in order to verify the study procedures and the reliability of the data. By signing this consent form, you or your legal representative consent to the direct review of these materials.

14. Additional Information

This study has been reviewed and approved by the Seoul National University Hospital Institutional Review Board (IRB). This committee is an organization established to protect the safety of clinical research participants. If any new, significant information that could potentially affect your participation

in the study is obtained, you or your representative will be informed as soon as possible. You will have the option to decide whether to continue or discontinue your participation based on this information.

If you would like to obtain additional information about the study or if any issues arise during the study, please contact the provided number.

If you have read all the information above, please ask the research staff (researcher) any questions and decide whether to participate.

If you decide to participate in the study, please sign the following form (consent form) to confirm that you have understood all the information about this study. Afterward, a copy of this form will be provided to you. Please keep the “Participant Information and Consent Form (Copy)” for your records.

Consent Form: For Patients

1. I have received an oral explanation of the study and have read the above study information. I have had sufficient discussions with the research staff about this study.
2. I have been informed of the risks and benefits of the study, and I have received satisfactory answers to my questions.
3. I voluntarily consent to participate in this study.
4. I understand that I can refuse to participate in the study or withdraw from the study at any time without affecting my future treatment, and I acknowledge that such a decision will not cause me any harm.
5. I understand that if I need to receive other treatment, fail to follow the study protocol, experience harm related to the study, or for any other reason, my participation in the study may be discontinued without my consent.
6. By signing this consent form, I agree that my personal information may be collected and processed by the researcher for medical research purposes, in accordance with current laws and regulations.
7. My signature indicates that I have received a copy of this explanation and consent form, and I understand that I can keep the copy. I have recorded my name, signature, and the date by hand.

I agree to participate in this study of my own free will.	□ **Yes** □ **No**

8. (Optional) I consent to the use of my personal (sensitive) information for secondary purposes beyond the scope of this study, and I understand the procedures for collecting and utilizing personal (sensitive) information.

(Optional) I voluntarily consent to the collection and use of my personal (sensitive) information for secondary purposes related to this study.	□ **Yes** □ **No**

Research Participant's Name	Signature	Date (YYYY/MM/DD)
Legal Representative's Name	Signature	Date (YYYY/MM/DD)
(Relationship to the Participant)		

<For Investigator Use Only>

✓ **I confirm that I have provided the person named above with sufficient and thorough**

explanation about this study, and to the best of my knowledge, the individual clearly understands the nature, risks, and benefits of participating in this study.

✓ I confirm that I have given the individual the opportunity to ask questions about this study and have answered all questions accurately and to the best of my ability.

✓ I confirm that the individual was not coerced into signing the consent form and has agreed to participate freely and voluntarily.

✓ I confirm that I have provided the individual with a copy of the study explanation and consent form.

Investigator/Researcher's Name	Signature	Date (YYYY/MM/DD)

Consent Form: For Family caregiver

1. I have received a verbal explanation about the study, read the above information sheet, and had sufficient discussion with the responsible researcher regarding the study.
2. I have been informed about the risks and benefits of participating in this study and have received satisfactory answers to my questions.
3. I voluntarily agree to participate in this study.
4. I understand that I may refuse to participate or withdraw from the study at any time without affecting my future treatment, and that such a decision will not result in any disadvantage to me.
5. I understand that my participation in the study may be discontinued without my consent if I need to receive other treatments, if I do not follow the study protocol, if I experience harm related to the study, or for other reasons.
6. By signing this consent form, I agree that my personal information may be collected and processed by the researcher for medical research purposes within the scope permitted by applicable laws and regulations.
7. My signature indicates that I have received a copy of the information sheet and consent form and understand that I may keep this copy. I have personally written my full name, signature, and date.

I voluntarily agree to participate in this study.	□ **Yes** □ **No**

8. (Optional) I understand that, if I agree, my personal (sensitive) information may be used for secondary purposes beyond this study, and I understand the procedures for the collection and use of such information.

(Optional) I voluntarily agree to the collection and use of my personal (sensitive) information for secondary purposes beyond this study.	□ **Yes** □ **No**

Legally Authorized Representative's Name	Signature	Date (YYYY/MM/DD)

<For Investigator Use Only>

✓ I confirm that I have provided the person named above with sufficient and thorough explanation about this study, and to the best of my knowledge, the individual clearly understands the nature, risks, and benefits of participating in this study.

✓ I confirm that I have given the individual the opportunity to ask questions about this study and have answered all questions accurately and to the best of my ability.

✓ I confirm that the individual was not coerced into signing the consent form and has agreed to participate freely and voluntarily.

✓ I confirm that I have provided the individual with a copy of the study explanation and consent form.

Investigator/Researcher's Name	Signature	Date (YYYY/MM/DD)