Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Impact of Problem-Solving-Based Palliative Care Training via Tele-Nursing on Knowledge, Attitudes, and Moral Distress of Nurses Working in Intensive Care Units: A Randomized Controlled Trial

Protocol summary

Study aim
Impact of Problem-Solving-Based Tele-Nursing Training on Moral Distress, Knowledge, and Attitudes Toward Palliative Care Among ICU Nurses.

Design
"Parallel-group, double-blind, randomized controlled trial"

Settings and conduct
Study population: Nurses working in the intensive care units of hospitals in Shiraz, Iran. Study setting: Public hospitals affiliated with Shiraz University of Medical Sciences, Shiraz, Iran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Nurses working in the intensive care units of the specified hospitals in Shiraz Holding at least a Bachelor's degree in nursing Having a minimum of one year of ICU work experience Completion of a written informed consent form to participate in the study Exclusion criteria: Absence for any reason during the study period (e.g., transfer to another hospital, leave, retirement, etc.) Nurses who, within the past year, have experienced events such as emotional crises, trauma, or psychological issues outside of routine work conditions that could potentially affect their psychological state, and consequently their moral distress, thereby influencing study outcomes Incompletion of more than 10% of questionnaire items Presence of psychiatric disorders as self-reported by the participant Use of medications related to psychiatric disorders as self-reported by the participant

Intervention groups
The intervention group will receive four weeks of blended problem-solving-based palliative care training via a messaging platform and Sky Room. The program follows seven steps of problem-based learning, supported by weekly online and occasional face-to-face sessions. After completion, all educational materials will also be provided to the control group.

Main outcome variables
Knowledge, Attitudes Palliative care, and Moral Distress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230926059518N1**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

Registration date
2025-10-07, 1404/07/15

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2026-03-21, 1405/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Impact of Problem-Solving-Based Palliative Care Training via Tele-Nursing on Knowledge, Attitudes, and Moral Distress of Nurses Working in Intensive Care Units: A Randomized Controlled Trial

Public title
Tele-Nursing Palliative Care Training and Nurses' Outcomes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Nurses working in the intensive care units of the specified hospitals in Shiraz Holding at least a Bachelor's degree in nursing Having a minimum of one year of work experience in intensive care units Completion of a written informed consent form to participate in the study
Exclusion criteria:
Absence for any reason during the study period (e.g., transfer to another hospital, leave of absence, retirement, etc.) Nurses who, during the past year, have experienced events such as emotional crises, trauma, or psychological issues outside of routine work conditions that could potentially influence their mental state and, consequently, their moral distress and the study outcomes Incompletion of more than 10% of the questionnaire items Presence of psychiatric disorders as self-reported by the participant Use of medications related to psychiatric disorders as self-reported by the participant
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a randomized controlled trial with a two-stage cluster design. Stage 1: Selection of hospitals (clusters) Out of the four hospitals meeting the inclusion criteria, two hospitals will be randomly selected through simple lottery sampling. One hospital will be assigned to the intervention group and the other to the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding will be implemented for both the questionnaire assessor and the statistical analyst (double-blind design). Specifically, when the assessor distributes the questionnaires to the nurses for completion, they will not be aware of which hospital is assigned to the intervention group and which to the control group. Accordingly, the hospitals will be labeled with unidentified codes (e.g., A and B), and the data will be collected in coded form. Only one individual, who is not a member of the research team, will have access to the code assignments.
Placebo
Not used
Assignment
Parallel
Other design features
MethodsStudy DesignThis study is an interventional trial conducted as a parallel-group, single-blind, randomized controlled clinical trial with a two-stage cluster design.Participants and SettingThe study population consisted of nurses working in intensive care units (ICUs) of hospitals in Shiraz, Iran. The study was conducted in public hospitals affiliated with Shiraz University of Medical Sciences.Inclusion criteria:Nurses working in the ICUs of the selected hospitals in ShirazHolding at least a Bachelor's degree in nursingHaving a minimum of one year of ICU work experienceCompletion of a written informed consent formExclusion criteria:Absence for any reason during the study period (e.g., transfer to another hospital, leave, retirement, etc.)Nurses who, within the past year, had experienced extraordinary events such as emotional crises, trauma, or psychological issues outside of routine work conditions that could potentially influence their mental state and subsequent moral distress, thereby affecting study outcomesIncompletion of more than 10% of questionnaire itemsPresence of psychiatric disorders, based on self-reportUse of medications related to psychiatric disorders, based on self-reportSample SizeBased on a previous study by Qiu et al. (2024) with parameters of $\alpha = 0.05$, $\beta = 0.05$, power = 95%, and group means/SDs of 36.97 ± 5.06 and 42.82 ± 8.00, the required total sample size was estimated at 72 (36 per group). Considering a 20% dropout rate, the final sample size was determined as 100 participants.Cluster effect was also adjusted using the following parameters:ICC = 0.02M = 50 (number of individuals per cluster)Ultimately, 50 participants were included in each group.Randomization and ClusteringStage 1: Out of four eligible hospitals, two were randomly selected using a simple lottery method. One hospital was assigned to the intervention group and the other to the control group.Stage 2: In each selected hospital, 50 ICU nurses were randomly recruited, resulting in a total of 100 participants.To prevent contamination bias, each hospital was assigned exclusively to either intervention or control.BlindingDouble blinding was implemented for both the questionnaire assessor and the statistical analyst. The assessor, when distributing questionnaires, was unaware of which hospital was allocated to intervention or control. Hospitals were coded anonymously (e.g., A and B), and data were collected in coded form. Only one individual outside the research

team had access to the code assignments.Data Collection InstrumentsAfter obtaining ethical approval from Shiraz University of Medical Sciences, registration in the Iranian Registry of Clinical Trials (IRCT), and the required permissions, the researcher introduced the study to hospital authorities. Written informed consent was obtained from all participants prior to data collection.Demographic and occupational questionnaire: Included questions on age, gender, marital status, number of monthly shifts, working hours, work experience, shift type, and employment status.Moral Distress Scale–Revised (MDS-R) by Hamric et al.: This 21-item instrument assesses frequency (0–4) and intensity (0–4) of moral distress. Scores range from low (0–31), moderate (32–64), to high (65–96). The Persian version was validated by Soleimani et al., with CVI ranging from 0.8 to 1 and Cronbach's alpha ≥ 0.7. The validated version used here consisted of 18 items.Knowledge and Attitudes toward Palliative Care Questionnaire: Developed by Rafiei et al. (2024). It contains 15 items assessing knowledge (scored 0–15, with correct = 1, incorrect = 0), and 25 items assessing attitudes toward palliative care on a 5-point Likert scale (25–125, higher scores = more positive attitudes). Validity and reliability were confirmed (CVI = 0.87, CVR = 0.83, Cronbach's alpha = 0.79).All questionnaires were self-administered at three time points: baseline, immediately post-intervention, and one month post-intervention. Average completion time was ~15 minutes.InterventionAfter random allocation, participants in both groups were enrolled into separate WhatsApp groups. The platform was used as a tele-nursing tool for educational content delivery.Educational content: Developed specifically using a problem-solving learning approach and based on real clinical scenarios in palliative care and moral distress. Content was delivered in three formats with identical material:Video clips (10–15 min each)Audio podcasts (10–15 min each)Written documentsTopics included: theoretical foundations of palliative care, ethical challenges in clinical practice, strategies for managing moral distress, and practical/field experiences.Problem-solving learning steps:Clarification of ambiguous conceptsProblem definitionBrainstormingProblem analysisDivision of responsibilitiesIndividual study and findingsPresentation of solutions and rationaleContent was provided individually via WhatsApp. Weekly online meetings were held in Sky Room to review scenarios, address questions, and promote discussion. Additional face-to-face sessions were arranged as needed. The intervention lasted four weeks. At study completion, all educational content was also made available to the control group.Statistical AnalysisNormality of quantitative variables will be assessed using the Kolmogorov–Smirnov test. Parametric or non-parametric tests will be applied accordingly. Continuous variables will be described using mean ± SD, and categorical variables using frequency and percentage.Between-group comparisons: Independent t-test (for normally distributed continuous data) and Chi-square test (for categorical variables).Within-group comparisons over three time points: Repeated measures ANOVA.Clustered data analysis: Generalized Estimating Equations (GEE) or Mixed-Effects Models will be used to account for clustering.Significance level: $P < 0.05$.All analyses will be performed using SPSS version 24. An intention-to-treat approach will be applied, with reasons for dropout carefully documented. Follow-up strategies, including reminder messages and phone calls, will be used to minimize attrition

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Schools of Nursing and Midwifery, Management and Medical Information s

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Province
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Approval date
2025-06-07, 1404/03/17

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1404.036

Health conditions studied

1

Description of health condition studied
Knowledge, Attitudes, and Moral Distress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Knowledge, Attitudes, and Moral Distress

Timepoint
"At baseline, immediately after the intervention, and one month post-intervention"

Method of measurement
Nurses' Knowledge and Attitudes toward Palliative Care Questionnaire (Rafiei et al.)Moral Distress Scale–Revised (MDS-R) by Hamric et al.

Secondary outcomes

empty

Intervention groups

1

Description

In this group, the training will be delivered through a combination of online and face-to-face methods. The educational content is specifically designed to focus on problem-based learning in palliative care and the management of ethical distress.Intervention Method:Type of Intervention: Virtual problem-based education using real clinical scenarios.Educational Tools: WhatsApp messenger will serve as the primary communication tool for delivering educational materials and creating learning groups.Platforms Used:WhatsApp messenger for content delivery and interaction.Sky Room platform for online sessions.Face-to-face sessions for discussion and clarification.Educational Content:The content will be delivered in three formats: video clips (10-15 minutes), audio podcasts (10-15 minutes), and text files.The main topics of the educational content will include:Theoretical foundations of palliative care.Ethical challenges and issues in clinical settings.Strategies for managing ethical distress.Practical examples and field experiences.Session Duration:Training Duration: Four weeks.Number of Online Sessions: Weekly online sessions on the Sky Room platform.Face-to-Face Sessions: Face-to-face sessions will be held as needed for clarification and discussion.Session Length: One online session per week, with face-to-face sessions lasting between 1 to 2 hours for addressing ambiguities and group discussions.Intervention Process:Phase 1 (Online Education): Educational materials will be sent through WhatsApp, followed by online sessions for discussion and clarification.Phase 2 (Group Discussion): Through either face-to-face or online sessions, more complex concepts will be clarified and discussed.

Category

Other

2

Description

In the control group, no educational intervention is provided. The members of this group will only receive the educational content after the intervention period is completed.Intervention for the Control Group:No Educational Intervention: Members of the control group will not receive any specific training.Receiving Educational Content: After the intervention period, the educational content will be made available to the control group so that they can study the materials if needed.Follow-up and Evaluation:Follow-up through Messenger: Researchers will contact participants through phone calls or messenger to follow up on the receipt of educational materials and ensure proper understanding.Online Sessions: A weekly online session will be held, and face-to-face sessions will be arranged if necessary to clarify any ambiguities.End of Intervention:Ceasing Educational Content Delivery: The delivery of educational materials will end after four weeks.Providing Materials to the Control Group: At the end of the intervention period, the educational content will also be provided to the control group so they can benefit from it.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital - Faghihi Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It will be made available privately to the requesting individual upon request from the corresponding author; however, it will not be made publicly available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available