RESEARCH PROTOCOL

Official Title: Effects of AINurse Orientation Program on Psychological Outcomes and Length of Hospital Stay: A Randomized Controlled Trial

Date of the document: September 1, 2025

Method

Aim

This study aimed to develop a structured AINurse and Human Nurse orientation training program for intensive care unit (ICU) patients and compare the effects of these training programs on ICU patients' delirium-free days, level of anxiety and depression, and length of stay in the ICU.

Study Type and Design

This study is designed as a single-center, randomized controlled experimental study. The study trial protocol will be registered on clinicaltrials.gov . The Consolidated Standards of Reporting Trials (CONSORT) diagram will be used for reporting the study.

Hypotheses of the Study

H1: Patients who receive the structured AINurse patient orientation training program will have longer delirium-free days than patients who receive Human Nurse orientation training.
H2: Patients who receive the structured AINurse patient orientation training program will have lower levels of anxiety and depression than patients who receive the Human Nurse orientation training.
H3: Patients who receive the structured AINurse patient orientation training program will have shorter lengths of stay in the intensive care unit than patients who receive the Human Nurse orientation training.

Setting, Participants, and Sample Size

The study is planned to be conducted between July 2025 and July 2026 in the adult intensive care unit of Koç University Hospital, a tertiary care hospital in Türkiye. The general intensive care unit (GICU) of Koç University Hospital has 16 beds and the cardiovascular surgery intensive care unit (CVSICU) has eight beds. The hospital where the study will be conducted has a total of 1950 patient admissions annually, 1500 in the NICU, and 450 adult patients in the CVSICU. While the experimental group will receive the AI Nurse Orientation Training Program, the control group will receive the Human Nurse Orientation Training Program. Since there is no similar study to this study, a pilot study will be conducted with 10 patients. After the pilot study, the sample size will be calculated using G-Power.

The inclusion criteria of the participants in the study included (1) intensive care unit confusion assessment scale (CAM-ICU scale) score of 0-2, (2) age 18 years or older, (3) hospitalized in the intensive care unit for at least 24 hours, (4) Glasgow coma scale score of 13-14-15 points, (5) RASS score between -1 and +1, (6) no hearing problems.

Participants with any of these characteristics will be excluded: (1) intensive care unit confusion assessment scale (CAM-ICU scale) score of 6-7, (2) any psychiatric illness or impaired brain function, (3) defined hearing loss, (4) advanced dementia, (5) younger than 18 years of age, (6) RASS score outside the range of -1 to +1, (7) sedative medication, (8) history of surgery or disease around the ear.

Recruitment, randomisation, and blinding

To assign eligible participants to study groups, a computer-assisted simple randomization method will be employed. The randomization process will be performed by a statistical expert other than the researcher and will be forwarded to the researcher. For this, the website *"https://www.random.org/integer-sets"* will be used. This approach aims to minimize selection bias and control for potential confounding variables by ensuring equal probability of assignment to either the intervention or control group.

Study Intervention

The study consists of four stages.

Phase 1: Development of the Structured Orientation Program: Structured orientation training programs will be developed by the researchers for both AI Nurse and Human Nurse interventions based on the literature (Kasapoğlu et al.,2022; Ma et al.,2025). While the AINurse training program will be implemented in the experimental group, the Human Nurse training program will be implemented in the control group. The content of the structured training program for both groups will be the same (Appendix-2). The training content will be sent to the opinion of 10 experts who are experts in intensive care and AI, and changes will be made in the training program.

In the AINurse training program, the training text will be written in a patient-friendly language to enhance comprehensibility. The Narrative Orientation Experience model will be used not only to deliver information but also to support the patient's psychosocial adaptation to the intensive care environment. Within this method, key information such as time, place, care

environment, relatives, and daily routine will be presented in the form of a scenario format in a "starting the day story" in which the patient is addressed by name to foster a sense of personal connection and orientation.

Phase 2: Development of AI-Nurse orientation program/software: The AI-Nurse orientation program to be implemented in the intervention group will be developed by a researcher with expertise in AI and engineering, who is also part of the study team. During the development phase, the content of the program will be structured by the researchers to be compatible with individual patient information. Voice-based orientation training will be delivered using the Google Cloud Text-to-Speech (TTS) API, which enables the conversion of written text into natural-sounding speech.

The TTS engine allows for customization of voice parameters, including gender (female and male), speech tempo (slowed), and tone (calm). For Turkish language output, the use of 'tr-TR-Wavenet-A' or 'tr-TR-Standard-B' voice models is recommended. The training content can be personalized, with relevant information about the patient, weather, and family-related data will be automatically retrieved from the database. The AI Nurse system will be developed to work via mobile devices (e.g., an Android tablet). The patient will listen to the audio training through headphones and, if necessary, will be able to read the text on the screen.

The training program will include approximately 10 minutes of audio narration and will be administered twice daily over a period of three days. Existing orientation practices in the hospital will be observed and documented. During this observation, all elements of nurse-patient interaction, such as whether the nurse introduces herself/himself, whether she/he gives day information, and whether she/he provides information about the environment, will be detailed. The control group will receive a researcher-designed orientation training program of similar duration and frequency, comprising 10-minute sessions delivered over three consecutive days.

Phase 3: Piloting the AI-Nurse orientation training program: The developed AI-Nurse training program will be conducted as a pilot study with 10 patients hospitalized in the ICU. A sample calculation will be made as a result of the pilot study. Patients included in the pilot study will not be included in the sample.

Phase 4: Implementation of structured orientation training to intervention and experimental group: In the experimental group, the structured AI-Nurse orientation program will be listened to twice daily (10:00 and 14:00) through a headset connected to a structured

audio recording application. The content will include orientation to time and environment but will exclude any personally identifiable information such as the patient's name. Following each orientation session, the daily news will be played with the help of the television in the patient's room (at 10:30-14:30), aiming to enhance environmental awareness and perception of real-time audio streaming. The TTS engines to be used will be able to provide real-time audio streaming. This intervention will be implemented by the same researcher over a three-day period. Anxiety and depression levels, as well as the CAM-ICU score, will be assessed both before and after the intervention. After three days of structured AI-Nurse training, the patient's discharge time from the ICU will be followed and recorded. In the control group, the structured orientation training will be given face-to-face by the Human-Nurse researcher. The patient in this group will also be monitored for signs and symptoms of delirium for three days. Anxiety and depression levels will be measured prior to the intervention, while post-intervention evaluations will include the number of delirium-free days, anxiety and depression scores, and length of stay in the ICU.

Data Collection Instruments

Data will be collected using the sociodemographic characteristics form, a clinical patient information form, the Confusion Assessment Method-Intensive Care Unit (CAM-ICU), and the Hospital Anxiety and Depression Scale (HADS). In the initial stage, patients will be screened fort he presence of delirium using the CAM-ICU. Following this, their sedation and agitation levels will be assessed using the Richmond Agitation Sedation Scale (RASS), and eligibility for study inclusion will be determined based on these scores. The RASS is a validated tool used to assess the level of sedation and agitation in patients admitted to intensive care units, with scores ranging from +4 to -5. Positive scores indicate increasing levels of agitation (e.g., +4: combative, +3: very agitated, +1: restless), while negative scores reflect deeper levels of sedation (e.g., -1: drowsy, -2: lightly sedated, -5: unarousable). A score of 0 indicates an alert and calm state (Sessler et al., 2002).

Sociodemographic information form: The sociodemographic information form developed by the researchers consisted of eight questions about name, age, gender, occupation, marital status, education, smoking, and alcohol use. (Appendix-1)

Clinical patient information form: It was created by the researchers from a total of 11 questions, including the patient's diagnosis, acute physiological and chronic health evaluation II (APACHE II) score, mean arterial pressure (MAP), blood urea nitrogen (BUN), metabolic

acidosis, use of analgesic drugs, use of physical restraint, infection, respiratory failure and corticosteroid use, and the presence of catheters/tubes in the patient. (Appendix-1)

Confusion Assessment Method for the Intensive Care Unit (CAM-ICU): This form will be utilized to assess the presence of delirium in critically ill patients. Originally developed by Ely et al. (2001) to facilitate the identification of delirium by nurses and physicians in intensive care settings, the Turkish validity and reliability of the scale were established by Akıncı et al. (2005), with a reported Cronbach's alpha coefficient of 0.96, indicating excellent internal consistency. The CAM-ICU evaluates four key features in critically ill patients: (1) acute onset or fluctuating course of mental status, (2) inattention, (3) altered level of consciousness, and (4) disorganized thinking. A positive diagnosis of delirium is made when the first two criteria are present, along with either the third or fourth. The scale yields a total score ranging from 0 to 7, with interpretive cut-off points as follows: 0–2 indicating no delirium, 3–5 suggesting mild to moderate delirium, and 6–7 indicating severe delirium (Akıncı ve ark.,2005). (Appendix-1)

The Hospital Anxiety and Depression Scale (HADS): This scale was developed by Zigmond and Snaith (1983) to assess the severity and risk of anxiety and depression in hospitalized patients. The Turkish validity and reliability study of the scale was conducted by Aydemir et al. (1997), reporting a Cronbach's alpha coefficient of 0.85, inter-item correlation coefficients ranging between 0.81 and 0.85, and a split-half reliability coefficient of 0.85, indicating strong internal consistency. The scale comprises 14 items in a 4-point Likert format. Odd-numbered items assess anxiety symptoms, while even-numbered items assess depressive symptoms. Items 1, 3, 5, 6, 8, 10, 11, and 13 are reverse scored (3, 2, 1, 0), while items 2, 4, 7, 9, 12, and 14 are scored progressively (0, 1, 2, 3). Subscale scores are obtained by summing the relevant items: questions 1, 3, 5, 7, 9, 11, and 13 for the anxiety subscale (HAD-A), and questions 2, 4, 6, 8, 10, 12, and 14 for the depression subscale (HAD-D). In the Turkish adaptation, the cut-off scores were identified as 10/11 for the anxiety subscale and 7/8 for the depression subscale. Scores exceeding these thresholds indicate a risk of clinically significant anxiety or depression (Yiğitoğlu et al., 2021). (Appendix-1)

Data Collection and Follow-up

Data collection will take place between July 2025 and July 2026. After obtaining written informed consent, randomization will be performed among patients hospitalized in the intensive care unit and the cardiovascular surgery intensive care unit who meet the inclusion criteria and voluntarily agree to participate in the study. In the first stage, patients' CAM-ICU form and RASS scores will be calculated. For patients who meet the inclusion criteria, the

sociodemographic characteristics form and clinical patient information form will be completed by the researchers. Patients in the intervention group included in the study will be given structured AI-Nurse orientation training starting at 10:00 am (approximately 10 minutes), and then the patient will listen to the daily morning news on television. At the end of the day, at 16:00, CAM-ICU and HADS will be evaluated. This process will continue with the same patient for three days. If the delirium score is between 3 and 7 points for three days and the RASS value is +4 belligerent, +3 very agitated, -2 slightly sedated, -3 moderately sedated, -4 deep sedation, -5 unstimulated, this training and follow-up process will be stopped, and the intervention will be ended. Patients assigned to the control group will fill in the same forms, and after the structured orientation training is given by the researcher (Human Nurse), the television will be turned on in the same way, and the daily news will be listened to. At the end of the day, CAM-ICU and HADS will be evaluated at 16:00. This practice will continue with the same patients for three days. After three days of follow-up, the length of stay of the patients in the intensive care unit will be monitored until discharge.

Data Analysis

Data will be analyzed using IBM SPSS Statistics, Version 28.0 (Armonk, NY: IBM Corp., 2021). Sociodemographic characteristics will be reported using descriptive statistics such as frequency, percentage, mean, and standard deviation. Descriptive statistics will be used to analyze the data. Whether the data are normally distributed will be evaluated with the Shapiro-Wilk test. The t-test will be used for normally distributed data. If the data are not normally distributed, the Mann-Whitney U test will be used.

Ethical Consideration

Ethical approval will be obtained from the Koç University Biomedical Research Ethics Committee (2025.258.IRB2.124; Date: July 31, 2025). In addition, institutional permission will be obtained from Koç University Hospital for this study. Participation of the participants in the study will be voluntary. Patients and their relatives will be informed about the study, and written informed consent will be obtained from patients who agree to participate. Participants will be able to leave the study at any time without any justification. No incentive will be given for participation. Only the research team will have access to the collected data. The data will be used for research purposes only, and appropriate security measures will be taken to ensure that it is not shared with third parties. In the AINurse training program, only the patient's first name will be identified, and surname and other identifying information will not be used.