Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Family Participation in Patient Care on Delirium Prevention and Sleep Quality of Patients Hospitalized in Intensive Care Units of Shahid Beheshti Educational and Therapeutic Center

Protocol summary

Study aim
The aim of this study is to investigate the effect of family participation on delirium prevention and sleep quality in ICU patients.

Design
Parallel single-blind randomized controlled trial with 60 patients in two groups: intervention (n=30) and control (n=30). Randomization is done using blocks of four, and the outcome assessor is blinded. Delirium is assessed with CAM-ICU and sleep quality with RCSQ at baseline and Days 1–3.

Settings and conduct
This is a parallel, single-blind randomized controlled trial. Sixty patients admitted to the ICU of Shahid Beheshti Educational and Therapeutic Center in Hamadan are randomly assigned to either the intervention group (family participation) or the control group (routine care). Delirium is assessed with CAM-ICU and sleep quality with RCSQ at baseline and on Days 1–3.

Participants/Inclusion and exclusion criteria
Participant conditions include patients aged ≥18 years, admitted to ICU, expected stay ≥72 hours, no delirium (CAM-ICU negative), RASS ≥ -3, having a first-degree family member, and written informed consent; and family members aged ≥18 years, first-degree relative, able to attend three shifts regularly, no contagious disease, and informed consent. Individuals with age <18 years, stay <72 hours, delirium at admission, RASS < -3, no eligible family member, or no informed consent are excluded.

Intervention groups
Intervention (n=30): routine care + family participation (first-degree relative, 3 days, 3 shifts, 60 min each; communication, therapeutic touch, simple care assistance, night presence). Control (n=30): routine care only. Delirium (CAM-ICU) and sleep (RCSQ) assessed identically in both groups.

Main outcome variables
Primary outcome variables: delirium incidence (CAM-ICU) and sleep quality (RCSQ).

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20261003071276N1**
Registration date: **2026-11-04, 1405/08/13**
Registration timing: **prospective**

Last update: **2026-11-04, 1405/08/13**
Update count: **0**

Registration date
2026-11-04, 1405/08/13

Registrant information

Name
Negin Saadat
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3838 0535
Email address
neginsaadat2001@gmail.com

Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2026-11-11, 1405/08/20
Expected recruitment end date
2027-02-20, 1405/12/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Family Participation in Patient Care on Delirium Prevention and Sleep Quality of Patients Hospitalized in Intensive Care Units of Shahid Beheshti Educational and Therapeutic Center

Public title
Can family participation help prevent delirium and improve sleep in ICU patients?
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Key inclusion criteria before randomization for patients include admission to the Intensive Care Unit (ICU) of Shahid Beheshti Educational and Therapeutic Center in Hamadan, age ≥ 18 years, expected ICU stay of at least 72 hours, no delirium at baseline according to CAM-ICU, adequate level of consciousness for delirium assessment (RASS ≥ -3), having at least one first-degree family member (spouse, child, parent, sibling) willing and able to participate in the care program, and written informed consent from the patient or legal guardian and the family member. For the family member, criteria include age ≥ 18 years, being a first-degree relative, ability to attend regularly in three shifts (morning, evening, night) according to the study schedule, ability to communicate effectively with the patient, no acute or contagious infectious disease preventing ICU presence, and willingness to participate and sign the informed consent form. Randomization to the intervention and control groups is performed only after all these criteria are met and informed consent is obtained.
Exclusion criteria:
Key exclusion criteria before randomization for patients include age < 18 years, expected ICU stay < 72 hours, presence of delirium at baseline according to CAM-ICU, level of consciousness lower than RASS -3, absence of at least one first-degree family member (spouse, child, parent, sibling) willing and able to participate in the care program, and lack of written informed consent from the patient or legal guardian and the family member. For family members, exclusion criteria include age < 18 years, not being a first-degree relative, inability to attend regularly in three shifts (morning, evening, night) according to the study schedule, inability to communicate effectively with the patient, acute or contagious infectious disease preventing ICU presence, and unwillingness to participate or failure to sign the informed consent form.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients to the intervention and control groups is performed using block randomization with a block size of 4. The random sequence is generated using a random number table. For allocation concealment, opaque, sealed, and numbered envelopes are used. The envelopes are opened sequentially as patients are enrolled, and based on the content inside the envelope, the patient is assigned to either the intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is single-blind, and only the outcome assessor is blinded to group allocation. The assessor of delirium (CAM-ICU) and sleep quality (RCSQ) is unaware of whether the patient is in the intervention or control group. To maintain blinding, the assessor does not attend family training sessions or intervention sessions and performs assessments using patient identification codes rather than names or group labels. The assessor is also not informed about the exact study hypotheses and only completes the assessment tools according to the protocol. The principal investigator who delivers the intervention does not participate in outcome assessment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Boulevard, Pazhohesh Square, Hamadan, Iran
City
Hamadan
Province
Hamadan
Postal code
6517838736
Approval date
2026-09-28, 1405/07/06
Ethics committee reference number

IR.UMSHA.REC.1405.508

Health conditions studied

1

Description of health condition studied
Delirium
ICD-10 code
F05.9
ICD-10 code description
Delirium, unspecified

Primary outcomes

1

Description
Delirium incidence: Delirium incidence in patients admitted to intensive care units, assessed daily using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU). A positive CAM-ICU result will be considered as the presence of delirium, while a negative result will indicate the absence of delirium.
Timepoint
Daily assessment using CAM-ICU, at baseline (before intervention) and then daily on Days 1, 2, and 3 of the intervention. If hospitalization continues, assessment continues until ICU discharge.
Method of measurement
Incidence of delirium is assessed daily at a fixed time by a trained researcher using the Persian version of the CAM-ICU (Confusion Assessment Method for the Intensive Care Unit). Before assessment, the patient's level of consciousness is evaluated using the RASS (Richmond Agitation-Sedation Scale); if RASS ≥ -3, the CAM-ICU is performed. The result is recorded as presence/absence of delirium. Assessment is performed at baseline (before intervention) and then daily on Days 1–3 of the intervention; if hospitalization continues, it is continued until ICU discharge.

2

Description
Sleep quality: Sleep quality in patients admitted to intensive care units, assessed daily using the Richards-Campbell Sleep Questionnaire (RCSQ). A higher score indicates better sleep quality.
Timepoint
Assessed every morning using RCSQ, at baseline (before intervention) and then every morning on Days 1, 2, and 3 of the intervention. If hospitalization continues, assessment continues until ICU discharge.
Method of measurement
Measured every morning using the Persian version of the RCSQ (Richards-Campbell Sleep Questionnaire). The RCSQ contains 5 items, each scored on a 0–100 mm visual analogue scale (VAS). The mean of the 5 item scores is calculated as the overall sleep quality score (0–100); higher scores indicate better sleep quality. Measurement is performed at baseline and then every morning on Days 1–3 of the intervention; if hospitalization continues, it is continued until ICU discharge.

Secondary outcomes

1

Description
Length of ICU stay
Timepoint
From study enrollment until ICU discharge, transfer, or death (single assessment at the end of ICU stay).
Method of measurement
Number of days the patient stays in the ICU from study enrollment until ICU discharge, transfer to another ward, or death. Data are extracted from the medical record and hospital information system and recorded in days.

2

Description
Duration of mechanical ventilation
Timepoint
From initiation of mechanical ventilation until weaning/discontinuation (recorded at the end of the ventilation period).
Method of measurement
Total duration of mechanical ventilation from initiation until successful weaning or discontinuation. Data are extracted from the medical record and mechanical ventilation flow sheet and recorded in days (or hours converted to days). This variable is measured only for patients receiving mechanical ventilation.

3

Description
Sedative drug consumption
Timepoint
Recorded daily and summed at the end of ICU stay (or recorded cumulatively once at ICU discharge).
Method of measurement
Total dose of sedative agents (e.g., midazolam, propofol, morphine, and other prescribed sedatives) administered during ICU stay. Data are extracted from the medication record and hospital pharmacy information system and recorded in milligrams or number of doses. If multiple agents are used, the total equivalent dose or total number of doses can be recorded.

Intervention groups

1

Description
Control group: Patients in the control group receive routine ICU care according to the hospital's current protocols and the treating team's orders. Family presence in this group follows the usual ICU policy, and no structured family participation program is implemented. The family-centered intervention designed

in this study (including regular presence in three shifts, caregiver training, and specific care activities) is not performed in the control group. However, delirium incidence is assessed using CAM-ICU and sleep quality using RCSQ at the same timepoints as the intervention group (baseline, Days 1–3, and continued until ICU discharge if applicable). Other treatments, medications, and clinical care continue as ordered by the treating team.

Category

Other

2

Description

Intervention group: Patients in the intervention group receive routine ICU care plus a structured family participation program. One first-degree family member attends a 30–45 minute training session, then is present at the bedside for 3 consecutive days (or until ICU discharge), 3 times daily (morning, evening, night), about 60 minutes per session. Activities include calm verbal communication, therapeutic touch, talking about positive memories, using hearing aids/glasses, assisting with simple care under nurse supervision, encouraging mobilization, and night presence for relaxation and sleep preparation. Supplementary measures such as reducing light/noise and regulating sleep-wake cycle are also taught. Delirium is assessed with CAM-ICU and sleep quality with RCSQ at the same timepoints as the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Educational and Therapeutic Center, Hamadan, Intensive Care Unit (ICU)

Full name of responsible person

Negin Saadat

Street address

Shahid Beheshti Educational and Therapeutic Center, Qaem Square, Beginning of Eram Blvd., Hamadan, Iran.

City

Hamadan

Province

Hamadan

Postal code

3371565179

Phone

+98 81 3838 0704

Email

Shahidbeheshti@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Soltanian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Boulevard, Pazhohesh Square, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3838 0717

Email

Info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Ali Afshari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Boulevard, Pazhohesh Square, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone
+98 81 3838 0717
Email
afshari777@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Ali Afshari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Boulevard, Pazhohesh Square, Hamadan, Iran
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0717
Email
afshari777@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Ali Afshari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Boulevard, Pazhohesh Square, Hamadan, Iran
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0717
Email
afshari777@gmail.com

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
Due to the confidentiality of participants' medical information and the need to protect patients' privacy, individual participant data will not be made publicly available. Study findings will be reported in aggregated form without identifying individual participants.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The documents available for sharing will include the final study protocol, statistical analysis plan, final clinical study report, and research data dictionary. These documents will contain information regarding study design, intervention procedures, study variables, statistical analysis methods, and definitions and coding of variables. The study investigates the effect of family participation in patient care on the prevention of delirium and sleep quality among patients admitted to intensive care units. No identifiable patient information will be included in the shared documents.
When the data will become available and for how long
The selected documents will be made available to eligible applicants after study completion, data analysis, and preparation of the final study report.
To whom data/document is available
Researchers, academic staff, and qualified investigators with valid scientific and research purposes, subject to approval by the principal investigator.
Under which criteria data/document could be used
The documents may be used solely for scientific, research, and educational purposes. Their use must comply with research ethics principles, maintain patient confidentiality, and prevent disclosure of participants' identities. Any use beyond scientific and research purposes or redistribution without compliance with ethical requirements will not be permitted.
From where data/document is obtainable
Applicants may submit their requests by contacting the principal investigator at Hamadan University of Medical Sciences.
What processes are involved for a request to access data/document
Requests for access to the documents will be reviewed by the principal investigator. Following assessment of the scientific purpose, verification of the applicant's eligibility, and confirmation of compliance with research

ethics and confidentiality requirements, the requested documents will be provided upon approval.

Comments