Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of humanistic care on family satisfaction, delirium, and human dignity in patients hospitalized in the intensive care unit

Protocol summary

Study aim
Determining the effect of humanistic care on family satisfaction, delirium, and human dignity of patients admitted to the intensive care unit

Design
Controlled clinical trial, post-test only, with parallel groups, no blinding, non-randomized, on 194 patients and families

Settings and conduct
Research setting: Mahdi Clinic, Imam Khomeini Hospital Complex In the experimental group, interventions based on the 7 components mentioned in the HU-CI model will be implemented for three groups of nurses, patients, and families; the components of the HU-CI model include open ICU, effective communication, patient well-being, staff care, post-ICU syndrome, end-of-life care, and human-centered infrastructure.

Participants/Inclusion and exclusion criteria
Patient inclusion criteria: Age over 18 years, hospitalization for more than 24 hours, absence of delirium, alert and aware of time and place, proficiency in Persian, literacy, no previous history of ICU admission, no underlying cognitive disorders/ Patient exclusion criteria: Unwillingness to continue cooperation, change in level of consciousness and inability to complete the questionnaire, death, sudden discharge or with personal consent, ICU admission for more than one week Family inclusion criteria: Age over 18 years, primary caregiver, proficiency in Persian, literacy, patient not hospitalized in another hospital at the same time./ Family exclusion criteria: Unwillingness to continue cooperation, occurrence of any of the patient exclusion criteria Nurses inclusion criteria: All ICU nurses at General Mehdi Clinic/ Nurses exclusion criteria: Unwillingness to continue cooperation

Intervention groups
Control group: Usual care Test group: Interventions based on the HU-CI model

Main outcome variables
Family satisfaction, Delirium, and Human dignity of patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250727066651N1**
Registration date: **2025-07-30, 1404/05/08**
Registration timing: **prospective**

Last update: **2025-07-30, 1404/05/08**
Update count: **0**

Registration date
2025-07-30, 1404/05/08

Registrant information

Name
Fatemeh Mansoor Samaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2026-08-22, 1405/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of humanistic care on family satisfaction, delirium, and human dignity in patients hospitalized in the intensive care unit

Public title
The effect of humanistic care on family satisfaction, delirium, and human dignity in patients hospitalized in the intensive care unit

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria for patients: Age over 18 years. Inclusion criteria for patients: Patients admitted to the ICU for more than 24 hours. Inclusion criteria for patients: Absence of delirium at the time of study entry. Patient must be conscious (GCS greater than 13) and aware of time and place. Inclusion criteria for patients: The patient must be fluent in Persian and able to communicate. Inclusion criteria for patients: Patients must be literate. Inclusion criteria for patients: No previous history of ICU admission. Inclusion criteria for patients: No underlying cognitive disorders in the patient (dementia, Alzheimer's, etc.) Inclusion criteria for family: Age over 18 years Inclusion criteria for family: Must be the primary family member in patient care. Inclusion criteria for the family: Be fluent in Persian. Inclusion criteria for the family: Must be literate. Inclusion criteria for the family: The family must not have another patient hospitalized at the same time. Inclusion criteria for nurses: All nurses working in the General ICU of Mahdi Clinic, Imam Khomeini Hospital Complex

Exclusion criteria:
Exclusion criteria for patients: Unwillingness to continue cooperation Exclusion criteria for patients: Occurrence of any unexpected conditions such as changes in the level of consciousness that eliminate the patient's ability to complete the questionnaire. Exclusion criteria for patients: Death of the patient Exclusion criteria for patients: The patient is discharged suddenly or with personal consent. Exclusion criteria for patients: The patient's hospitalization in the general ICU exceeds one week. Exclusion criteria for family: Unwillingness to continue cooperation Exclusion criteria for family: If any of the patient's exclusion criteria occur, the patient's family will also be excluded from the study. Exclusion criteria for nurses: Unwillingness to continue cooperation

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **194**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In order to prevent data contamination, sampling will be conducted first from the control group and then from the intervention group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of School of Nursing and midwifery And Rehabilitation- Tehran University

Street address
6th floor. Central Headquarters of Tehran University of Medical Sciences, at the corner of Ghods Street, Keshavarz Boulevard

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Approval date
2025-07-16, 1404/04/25

Ethics committee reference number
IR.TUMS.FNM.REC.1404.086

Health conditions studied

1

Description of health condition studied
Patients admitted to the General ICU

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Delirium of patients

Timepoint
The patient is checked twice a day from the time he or she enters the study until he or she is discharged or transferred to another ward.

Method of measurement
Confusion Assessment Method for the Intensive Care Unit

(CAM- ICU)

Secondary outcomes

1

Description
Family satisfaction
Timepoint
After discharge or transfer of the patient to another ward
Method of measurement
Family Satisfaction in the Intensive Care Units (FS-ICU-24)

2

Description
Human dignity of patients
Timepoint
After discharge or transfer of the patient to another ward
Method of measurement
Patient Dignity Inventory (PDI)

Intervention groups

1

Description
Control group: The control group receives usual care.
Category
N/A

2

Description
Intervention group: In the experimental group, measures based on the 7 components mentioned in the HU-CI model will be implemented for three groups of nurses, patients, and families. Nurses: The HELLO protocol will be implemented for nurses, which will promote mutual respect among staff, improve the moral atmosphere in the ward, and increase the quality of patient care. This protocol consists of six key components:1- Hello posters: Hello posters are designed as visual cues and constant reminders of the desired behaviors and will be displayed in the staff’s training board and break room;2- Reminder messages: Reminder messages will be sent to nurses twice a week by the research team through a group formed in one of the messengers (given the greater frequency of use of a software among staff, such as Telegram or WhatsApp); Greetings will be done at the beginning of the shift with the aim of strengthening and uniting the team and creating a positive tone throughout the day. The goal is to create a regular flow of supportive and positive messages that will encourage team collaboration;3- Integrate greetings into the team: Starting each shift with a simple but effective greeting can have a big impact on the morale of the team and its members. The goal is to create a more friendly and supportive atmosphere during the shift;4- HELLO Box: A box that allows employees to leave messages of gratitude and appreciation for their colleagues. The goal is to motivate and motivate team members by recognizing and appreciating the daily efforts of colleagues;5- Leadership Role Modeling: Nursing and medical leaders will set a positive behavioral model for others by using positive communication behavior and greeting colleagues; the goal is to improve the workplace by creating a clear and positive role model for all team members;6- HELLO Board: Employees write positive sentences daily on the Hello Board, which is placed in the break room. This board can include positive comments from patients or families, recognition of good performance by team members, or general encouragement. The intervention will last four weeks. /Family (primary caregiver): A brochure titled "Welcome Guide" will be provided to the families of patients admitted to the ICU, which will include information about the ICU, visiting hours, expectations from the family, and other important points related to the patient's treatment and care process. The ICU physician will also explain the patient's condition and treatment process to the patient's family./ Patients: Patients who are included in the study based on the established criteria will receive the necessary interventions. Before any action, the staff will introduce themselves to the patient and provide the necessary explanations about the measures to be taken. The necessary equipment, including hearing aids, glasses, dentures, eye patches, and earplugs, will be provided to the patients if they wish and need them. Given the arrangement of the beds in the ward and the patients' visibility, a number of times and dates will be displayed to the patients. To reduce the extra light and noise in the environment, appropriate measures such as turning off the light above the patients' beds at night, optimally adjusting the alarm sound of the devices, and using similar methods will be taken to provide more peace and comfort to the patients. Also, the meeting time in the intervention group will be increased compared to the control group and will be twice a day and a maximum of 30 minutes each meeting. (While in the control group, the meeting is once a day and a maximum of 30 minutes each meeting)./ Also, all measures are divided according to the HU-CI stages: 1. ICU with open doors: Increased visit time (twice a day and a maximum of 30 minutes per visit)2. Effective communication: Nurses will introduce themselves to the patient before each action and will also explain the said action. Explain the patient's condition and treatment process to the family. Give the family a brochure titled "Welcome Guide" at the time of admission. Implement the HELLO protocol for ward staff3. Patient welfare: Make available the patient's necessary equipment such as hearing aids, glasses, dentures. Make eyepatches and earplugs available to the patient if desired4. Care for ICU staff: Implement the HELLO protocol for ward staff5. Post-ICU syndrome: Measures mentioned in steps 1, 3, and 7. 6. End-of-life care: Since patients' consciousness is one of the inclusion criteria, and with impaired consciousness or death of the patient, the sample is excluded from the study, it is not possible to implement this step in the design of interventions.7. Human-centered infrastructure: Reduce light and excess noise in the environment. Place the time and date in patients'

sight

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdi Clinic, Imam Khomeini Hospital Complex

Full name of responsible person

Fatemeh Mansoor Samaei

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Sponsors / Funding sources

1

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Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

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Latest degree

Ph.D.

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after anonymizing individuals.
When the data will become available and for how long
The access period will begin 6 months after the publication of the results.
To whom data/document is available
The data will not only be available to researchers working at academic and scientific institutions, but individuals employed in industry can also apply to access them.
Under which criteria data/document could be used
No other specific condition is required.
From where data/document is obtainable
They can refer to the person who is conducting the sampling.
What processes are involved for a request to access data/document
They can send a message to the mentioned number, and it will be sent to them within a week.
Comments