Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Title: The effect of a nurse mentoring intervention whit family participation in the management of delirium in ICU patient

Protocol summary

Study aim
Determining the effect of family involvement by nurse mentoring on delirium management in ICU patients

Design
It is a clinical trial in which a blind, randomized Weber strain was used between 61 intervention and control groups on 60patients and a card in an envelope was used for randomization

Settings and conduct
The study was performed in the ICU of Khoy hospitals. First, the control or intervention group was randomly selected with a card in the envelope and sampling was performed by time block method up to 30 samples in each group. Sampling is done for that group for two weeks and continues until the discharge of the last member of the study group. Then sampling is done for the other group. The intervention in the intervention group was done by the nurse mentoring method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: physical and cognitive ability, no dementia, no discharge or death or transfer in the study phase, delirium and score less than 25 according to Neecham criteria Exclusion criteria: transfer of the patient to another medical center, discharge or death of the patient, loss of consciousness and continuous sedation after delirium, cardiopulmonary resuscitation and endotracheal intubation

Intervention groups
In the intervention group, the appropriate caregiver is selected for each patient according to his / her opinion and in coordination with the family, and he / she is given the necessary training on the type of disease and its complications, ways of treatment and management of delirium behaviors. For the control group, only the Richmond and Demographic Questionnaire and the Neecham Questionnaire will be completed.

Main outcome variables
Disease control, cost and length of hospital stay, family education and self-confidence, support for family members

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161116030926N7**
Registration date: **2021-08-20, 1400/05/29**
Registration timing: **retrospective**

Last update: **2021-08-20, 1400/05/29**
Update count: **0**

Registration date
2021-08-20, 1400/05/29

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3275 4961

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alilu@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-24, 1399/11/05

Expected recruitment end date
2021-05-15, 1400/02/25

Actual recruitment start date
2020-12-21, 1399/10/01

Actual recruitment end date
2021-05-13, 1400/02/23

Trial completion date
2021-05-20, 1400/02/30

Scientific title
Title: The effect of a nurse mentoring intervention whit family participation in the management of delirium in ICU patient

Public title
"The management of delirium " & "Nurse mentoring intervention whit family participation "

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The patient or companions have the physical and cognitive ability to provide informed consent The patient has no history of cognitive diseases such as dementia After hospitalization according to Neecham criteria with a score below 25 has delirium and is confirmed by a medical diagnosis The patient or caregiver is not addicted to alcohol Be hospitalized until discharge and completion of 6 interventions A qualified caregiver should be available twice daily for 3 consecutive days after the onset of delirium to visit the patient and participate in the intervention and receive mentoring interventions at the patient's bedside

Exclusion criteria:
Failure to attend the mentoring sessions more than once Transfer of the patient to another medical center, discharge or death of the patient Decreased alertness and sedative intake continuously after delirium No special visitation restrictions due to a specific or transmissible disease Start sedatives by continuous infusion Cardiac resuscitation - pulmonary intubation Severe restlessness that may harm the caregiver and the mentor nurse

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **65**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Instead of randomizing people, random blocks of time will be used to prevent information interference between groups. Two-week blocks will be allocated to one of the intervention or control groups by lottery method. Thus, if the first time block is allocated to the control group, in this block, patients who have inclusion criteria and according to the criteria If Neecham develops delirium, they will be assigned to a control group with their caregiver, and vice versa. Random time block allocation will continue until the sample size reaches the desired level in each group

Blinding (investigator's opinion)
Single blinded

Blinding description
To prevent information interference between groups, caregivers will be committed to preventing information exchange until the end of the study, and the sampling and assignment process for each subgroup will be performed after discharge of all patients in the previous block. Random assignment of patients to intervention and control groups will be done by a person who is not involved in the sampling and data collection process

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences

Street address
Basij Sqr,montazery St,Gamar e Banihashem Hospital

City
Khoy

Province
West Azarbaijan

Postal code
58196-37617

Approval date
2021-01-24, 1399/11/05

Ethics committee reference number
IR.UMSU.REC.1399.328

Health conditions studied

1

Description of health condition studied
Management of Dlirium

ICD-10 code
Code R41.0

ICD-10 code description
ICD-10-CM Diagnosis Code R41.0

Primary outcomes

1

Description
management of delirium in ICU

Timepoint
Before the intervention and twice in the morning at 8 am and 7 pm for three consecutive days

Method of measurement

Richmond Agitation Sedation Scale & Neelon and Champagne (NEECHAM) Confusion Scale&Mini Mental Status Examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Twice in the morning and evening for three days, an outpatient appointment will be made in the presence of the mentor nurse, and the selected family member will sit next to the patient in the presence of the mentor who has experience working in the ICU, holding hands. The patient leaves and talks to him about family issues. During the visit, the patient's delirium-induced behaviors are observed by a family member, and the mentor's nurse explains the adaptation and management of these behaviors to the caregiver.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Gamar e banihashem hospital

Full name of responsible person
Ali- hossein pour asl

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Basij Sq,Montazery St, Gamar e banihashem hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr Rahim. Bagaee

Street address
Emergency Alley ,Resalat Blv,Urmia University of Medical Science

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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
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Dr leyla--- Alilu

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Ph.D.

Other areas of specialty/work
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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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All individual data can be shared after being unidentified

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
Researchers working in academic and scientific institutions and patients admitted to the ICU

Under which criteria data/document could be used
For use in scientific research and patient education

From where data/document is obtainable
Refer to the website of Urmia University of Medical Sciences, School of Nursing and Midwifery

What processes are involved for a request to access data/document
Send request to alililuleyla @ gmail .com and about 2 days after receiving the email

Comments