

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of multifaceted nursing interventions on clinical outcomes and quality of life of patients with delirium admitted to the intensive care unit

Protocol summary

Study aim

This study aims to determine the impact of multifaceted nursing interventions on clinical outcomes and quality of life of patients with delirium hospitalized in the intensive care unit.

Design

A controlled clinical trial with parallel groups will be conducted on 52 patients.

Settings and conduct

This study will be conducted in Golestan and Imam Khomeini teaching hospitals in Ahvaz on delirium patients admitted to the intensive care unit. In the intervention group, the intervention will be done in three stages. The first stage of training, the second stage will be creating changes in the ward environment and the third stage will be the installation of educational posters on how to deal with patients at risk of delirium.

Participants/Inclusion and exclusion criteria

inclusion criteria: • Hospitalization in the ICU Having a state of restlessness, sleepiness and hallucinations after being hospitalized in the ICU and suffering from delirium according to the RASS criteria and confirmed by a doctor
Non-inclusion criteria: • Having a history of previous psycho-cognitive illness through medical history

Intervention groups

Intervention group: In this group, training , interventions in the environment of the department and installed educational posters will be performed. Control group: In this group, routine interventions will be performed.

Main outcome variables

Glasgow coma scale (GCS), agitation and sedation, quality of life, duration of hospitalization, severity of delirium and mortality rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221121056568N1**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **prospective**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

noushin Rostami monjezi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 3839

Email address

rostami.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multifaceted nursing interventions on clinical outcomes and quality of life of patients with delirium admitted to the intensive care unit

Public title

The effect of multifaceted nursing interventions on patients admitted to the intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalization in the ICU Having restlessness, sleepiness and hallucinations after being hospitalized in the ICU and suffering from delirium according to the RASS criteria and confirmed by a doctor

Exclusion criteria:

Having a history of previous psycho-cognitive illness through medical history

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2022-09-10, 1401/06/19

Ethics committee reference number

IR.AJUMS.REC.1401.244

Health conditions studied

1

Description of health condition studied

Patients with delirium admitted to the intensive care unit

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

level of consciousness

Timepoint

Before and after the intervention

Method of measurement

Glasgow scale

2

Description

Agitation and sedation of patients

Timepoint

Before and after the intervention

Method of measurement

Richmond Criterion

3

Description

Quality of Life

Timepoint

Before and after the intervention

Method of measurement

World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the intervention is done in three stages. In the first stage, training of employees will be done in the form of holding educational workshops and pamphlets. The second stage is creating environmental interventions in the department, which includes installing clocks and calendars in front of the patient, allowing the patient to meet with family members, using appropriate light during the day and night, providing glasses and hearing aids to the patient, using optical alarms to Instead of sound alarms, encouraging the staff to interact more with the patient, encouraging the patient to drink fluids in case of dehydration and leaving the bed. The third stage will

include the installation of an educational poster on how to deal with patients at risk of delirium and a step-by-step guide for dealing with delirium patients in the department.

Category

Other

2**Description**

Control group: Routine interventions will be performed in this group.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital

Full name of responsible person

Davoud Shalil-ahmadi

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golestanjpspital@yahoo.com

2**Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Ahmadreza Mohtadi

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Azadegan Ave.

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6135715797

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imam-hospitalajums@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zaker kish

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Marziyeh Asadi-zaker

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Noushin Rostami monjezi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Fax**Email**

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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

There is no further information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable