Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of implementing a family-centered collaborative care program on the level of restlessness in patients hospitalized in the intensive care unit

Protocol summary

Study aim
Investigating the effect of implementing a family-centered collaborative care program on the level of restlessness in patients hospitalized in the intensive care unit

Design
The present study is a randomized clinical trial without blinding.

Settings and conduct
This clinical trial study will be conducted in the special wards of Peymaniyeh Jahrom Hospital in southern Fars Province.

Participants/Inclusion and exclusion criteria
In this study, 120 patients in intensive care units will participate. Inclusion criteria will be willingness to participate in the study and being literate, and exclusion criteria will include having mental and cognitive disorders and worsening of the patient's clinical condition.

Intervention groups
In the intervention group, the first-degree family member who has the most emotional relationship with the patient will be selected. After selecting a close family member, the family member will be present at the patient's bedside for 30 minutes every day for three days from the beginning of admission and twice a day at 10 am and 3 pm. In all the researcher's sessions, the first-degree family member will be accompanied and supported. To ensure the correctness of the intervention by the family and to help the family member if needed. Family-centered care includes: how to communicate with the patient, how to care for the patient's skin, changing positions, etc.

Main outcome variables
Agitation level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190917044802N15**
Registration date: **2026-02-13, 1404/11/24**
Registration timing: **prospective**

Last update: **2026-02-13, 1404/11/24**
Update count: **0**

Registration date
2026-02-13, 1404/11/24

Registrant information

Name
Mostafa Bijani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5331 5012

Email address
bizhani_mostafa@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2026-03-21, 1405/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of implementing a family-centered collaborative care program on the level of restlessness in patients hospitalized in the intensive care unit

Public title
The effect of family-centered collaborative care program on the level of restlessness of patients admitted to the intensive care unit

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Being literate
Exclusion criteria:
Having mental and cognitive disorders Participation in educational classes related to the study topic in the past three months

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
120 cards are placed in a sealed envelope. 60 cards are labeled A and 60 cards are labeled B. Participants are asked to pick one of the cards from the envelope. If they pick the card labeled A, they will be placed in the intervention group, and if they pick the card labeled B, they will be placed in the control group.

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 Fasa University of Medical Sciences
Street address
Fasa University of Medical Sciences, Ibn Sina Square, Fasa, Fars, Iran.
City
Fasa
Province
Fars
Postal code
7461686688

Approval date
2025-11-30, 1404/09/09

Ethics committee reference number
IR.FUMS.REC.1404.184

Health conditions studied

1

Description of health condition studied
Other specified disorders of nervous system in diseases classified elsewhere

ICD-10 code
G99.8

ICD-10 code description
Other specified disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description
Agitation level

Timepoint
Before the intervention and three days after the intervention

Method of measurement
Richmond agitations scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, the first-degree family member who has the most emotional relationship with the patient will be selected. After selecting a close family member, the family member will be present at the patient's bedside for 30 minutes every day for three days from the beginning of admission and twice a day at 10 am and 3 pm. In all the researcher's sessions, the first-degree family member will be accompanied and supported. To ensure the correctness of the intervention by the family and to help the family member if needed. Family-centered care includes: how to communicate with the patient, how to care for the patient's skin, changing positions, etc.

Category
Lifestyle

2

Description
Control group: There will be no educational intervention in the control group. This group will only receive routine ward education. In order to comply with ethical principles, an educational package will be given to the patients in the intervention group after the end of the study.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Intensive care unit

Full name of responsible person
Mojtaba Farjam

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Fasa University of Medical Sciences, Ibn Sina Square, Fasa, Fars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Mojtaba Farjam

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Fasa 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
Fasa University of Medical Sciences

Full name of responsible person
Mostafa Bijani

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All the questionnaires used in this study as well as the content of the training program will be provided to the applicants.
When the data will become available and for how long
The time frame for accessing the data will be after the end of the study.
To whom data/document is available
Researchers can submit their request in writing to the project manager.
Under which criteria data/document could be used
Researchers can submit their request in writing to the project manager.
From where data/document is obtainable
Send a request to the project manager, Mr. Mostafa Bijani. Phone number : 09173308451 Email: bizhani_mostafa@yahoo.com
What processes are involved for a request to access data/document
Send a request to the project manager, Mr. Mostafa Bijani. Phone number : 09173308451 Email: bizhani_mostafa@yahoo.com
Comments