

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effectiveness of Scheduled Visits of Family Caregivers on incidence and severity of Delirium among Patients admitted to ICU and their caregivers' anxiety

Protocol summary

Study aim

Determining the effect of scheduled visit of family caregivers on incidence and severity of delirium among patients admitted in ICU and their caregivers anxiety

Design

A Randomized Controlled Clinical Trial

Settings and conduct

20 participants will be randomly assigned to the intervention group and 20 to the control group. The data will be collected by NEECHAM scale and Spielberger anxiety questionnaire. The place of study is the Intensive care units

Participants/Inclusion and exclusion criteria

Conscious patients with Glasgow Coma Index score <13
Willingness and consent to participate in the study
Patients who are not completely isolated No delirium and cognitive disorders in the patient before entering the study
Not taking anti-anxiety drugs at the time of starting the intervention by the caregiver

Intervention groups

Intervention group: In the first session, the anxiety level of family caregivers will be assessed using the Beck Anxiety Inventory. Family caregivers will be present at the patient's bedside for 15 minutes from 16:00 to 17:00 and 21:00 to 22:00 and will communicate with the patient according to the defined protocol. In the fifth day, their anxiety level will be checked. Before the presence of the caregiver, immediately after leaving the patient's bed, 60, 120 and 180 minutes after the presence of the caregiver, the patient is checked with the NeeCham scale in terms of the incidence and severity of delirium. Control group: In the first session, the anxiety level of the patient's family caregivers will be assessed. Meetings are done according to the routine of the educational-therapeutic center. The sequence of checking the incidence and severity of delirium will be performed using the NeeCham scale as in the intervention group.

The anxiety level of caregivers is measured On the fifth day.

Main outcome variables

1-Incidence and severity of delirium 2- Caregivers anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111210008359N3**

Registration date: **2023-09-05, 1402/06/14**

Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**

Update count: **0**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name

Farnaz Rrahmani

Name of organization / entity

Tabriz nursing and midwifery school

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

frahmani@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-12-06, 1402/09/15 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty Scientific title Comparison of the Effectiveness of Scheduled Visits of Family Caregivers on incidence and severity of Delirium among Patients admitted to ICU and their caregivers' anxiety	patient's main caregiver to participate in the intervention. Then, the communication protocol and meeting schedule will be taught face-to-face and in writing to the family caregivers of the intervention group. Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features
Public title The effect of scheduled visit of family caregivers on incidence and severity of delirium among patients admitted in ICU and their caregivers anxiety	Secondary Ids empty
Purpose Prevention Inclusion/Exclusion criteria Inclusion criteria: Conscious patients with Glasgow Coma Index score <13 Willingness and consent to participate in the study Patients who are not completely isolated No delirium and cognitive disorders in the patient before entering the study Not taking anti-anxiety drugs at the time of starting the intervention by the caregiver Exclusion criteria: Unavailability of primary caregiver	Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics Committee of Tabriz University of Medical Sciences, Vice chancellor for research Street address Sought shariatee street, Tabriz nursing and midwifery school, Tabriz University of Medical Sciences City Tabriz Province East Azarbaijan Postal code 347-51745
Age From 18 years old to 80 years old Gender Both Phase N/A	Approval date 2023-08-07, 1402/05/16
Groups that have been masked <i>No information</i>	Ethics committee reference number IR.TBZMED.REC.1402.352
Sample size Target sample size: 40	
Randomization (investigator's opinion) Randomized	
Randomization description The participants will be 40 male and female conscious patients hospitalized in Intensive care units and will be selected through convenience sampling. At the beginning of each work shift, the researcher will be informed about the availability of beds and the possible admission of new patients by visiting in person or by calling the officials of the special departments. The participants in the groups will be assigned to the intervention and control groups using the random block method with 4 and 6 blocks and with a ratio of 1:1. Stratification will be done based on the sampling location (Imam Reza, Sinai and Razi Hospital). In order to hide the allocation, the type of allocation will be written on paper and placed in opaque envelopes that are numbered consecutively (Allocation Concealment). The envelopes will be opened in order and by a person not involved in sampling. If the participant is included in the intervention group, a member of the patient's family who meets the family caregiver entry criteria will be selected as the	Health conditions studied <u>1</u> Description of health condition studied delirium ICD-10 code F05 ICD-10 code description Delirium due to known physiological condition Primary outcomes <u>1</u> Description Incidence and severity of Delirium Timepoint Before the intervention, 60, 120 and 180 minutes after the intervention for 5 consecutive days Method of measurement The Neelon and Champagne Confusion Scale(NeeCham)

2

Description

Anxiety score of the main caregiver

Timepoint

The first day before the intervention, the fifth day after the intervention

Method of measurement

Speilberger State – Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After determining the main caregiver, the objectives and method of the study are explained to them. Then, in a briefing session, the necessary training is provided regarding how to perform the intervention, and then the materials are given to them in the form of a booklet. After the coordination of the researcher with the patient's nurse and the shift manager, the family caregivers of the patients are present at the patient's bedside for 15 minutes from 16:00 to 17:00 and from 21:00 to 22:00 and communicate with the patient according to the defined protocol. During the entire duration of the meeting, the researcher is a non-participant observer of the meeting and examines the caregiver's performance during the meeting. If necessary, after the completion of the intervention, training will be given to the caregiver again so that the method of implementing the intervention can be modified in the next meeting. Also, before the presence of the caregiver at the patient's bedside, immediately after leaving the patient's bedside, 60, 120, and 180 minutes after the presence of the caregiver, the patient is checked with the NeeCham scale in terms of the incidence and severity of delirium.

Category

N/A

2

Description

Control group: meeting in this group is done according to routine meetings. The researcher was present at the patient's bedside at the appointed time for the visit and immediately before and after the presence of the caregiver, 60, 120 and 180 minutes after the presence of the caregiver, as in the intervention group, examines the patient with the NeeCham scale in terms of the incidence and severity of delirium. .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Tabriz

Full name of responsible person

Farnaz Rahmani

Street address

Golgasht St, Imam Reza Educational and Medical Center of Tabriz, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 7059

Fax

Email

imamreza@tbzmed.ac.ir

Web page address

<https://imamreza.tbzmed.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Parviz Shahabi

Street address

Golgasht St, Central Building No. 2, Research and Technology Vice-Chancellor, Tabriz University of Medical Sciences, Tabriz, Iran.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3335 7311

Fax

+98 41 3334 4280

Email

research-vice@tbzmed.ac.ir

Web page address

<https://researchvice.tbzmed.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Farnaz Rrahmani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursing
Street address
Sought shariate street, Tabriz nursing and midwifery school, Tabriz University of Medical Sciences, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 1479 6770
Fax
+98 41 3479 6969
Email
frahmani@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farnaz Rrahmani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursing
Street address
Sought shariate street, Tabriz nursing and midwifery school, Tabriz University of Medical Sciences, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone

+98 41 3479 6770
Fax
+98 41 3479 6969
Email
frahmani@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farnaz Rrahmani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursing
Street address
Sought shariate street, Tabriz nursing and midwifery school, Tabriz University of Medical Sciences, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
347-51745
Phone
+98 41 3479 6770
Fax
+98 41 3479 6969
Email
frahmani@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

Data related to primary (incidence and severity of delirium) and secondary (family caregivers' anxiety) outcomes can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

The researchers working in academic institutions

Under which criteria data/document could be used

The use of documents is allowed only for scientific purposes and the publication of information for the advancement of science.

From where data/document is obtainable

Farnaz Rahmani, Assistant professor in Tabriz Nursing and Midwifery Faculty, Tabriz University of Medical Sciences, Tabriz, Iran. Tell: +984134796770, Cellphone: +989143002439 Email: frahmani@tbzmed.ac.ir

What processes are involved for a request to access data/document

Send the reason for the request to access the data via email.

Comments