# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

**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

**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

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**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 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**

## Secondary Ids

empty

## Ethics committees

### 1

**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

**Approval date**

2023-08-07, 1402/05/16

**Ethics committee reference number**

IR.TBZMED.REC.1402.352

## Health conditions studied

### 1

**Description of health condition studied**

delirium

**ICD-10 code**

F05

**ICD-10 code description**

Delirium due to known physiological condition

## Primary outcomes

### 1

**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
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Golgasht St, Imam Reza Educational and Medical Center of Tabriz, Tabriz, Iran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Dr Parviz Shahabi
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Golgasht St, Central Building No. 2, Research and Technology Vice-Chancellor, Tabriz University of Medical Sciences, Tabriz, Iran.
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**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

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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)**

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**