

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of familiar voice on the patient and the use of sedatives in patients with mechanical ventilation in the ICU trauma wards of the Madani hospital

Protocol summary

Study aim

Determining the effect of family members' voices on anxiety and the use of sedatives in patients admitted to the intensive care unit

Design

This clinical trial has a control group with two parallel, double-blind randomized intervention groups. There is no precedent for the study phase and no drug combination is tested. This study will be conducted on 99 patients, which was used for randomization using the method of dividing blocks with 6 blocks. In each group, 33 samples and a total of 99 samples will be included in the study.

Settings and conduct

This study will be done in the ICU department. At first, based on random assignment, patients are divided into 3 groups (2 intervention groups, one control group). The person who performs the intervention for the patient and the person who registers the patient's information is also blind. In the two intervention groups, auditory stimulation is done twice a day for 15-30 minutes during two weeks. one group with the voice of the nurse and the other with the voice of family members).

Participants/Inclusion and exclusion criteria

Concussion patients admitted to the ward with any cerebral hemorrhage, including Subdural, epidural, intracerebral, ventricles, and subarachnoid bleeding. Patients with a level of consciousness of 8-11 (according to the Glasgow Coma Scale) and 10-16 according to the Fore criterion

Intervention groups

Intervention group one: recipient of a familiar voice (first degree relatives of the patient are asked to repeat the message written by the researcher and their voice is recorded) In the second intervention group, the nurse records a message and plays it to the patient.

Main outcome variables

The level of anxiety - the level of use of sedatives

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220924056030N1**

Registration date: **2022-11-18, 1401/08/27**

Registration timing: **prospective**

Last update: **2022-11-18, 1401/08/27**

Update count: **0**

Registration date

2022-11-18, 1401/08/27

Registrant information

Name

iran tayebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

tayebi.medical@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of familiar voice on the patient and the use of sedatives in patients with mechanical ventilation in the ICU trauma wards of the Madani hospital

Public title

Investigating the effect of sound on reducing the anxiety level of patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The age of the patient is 18 to 65 years The level of consciousness should be 8 to 11 according to the Glasgow Trauma Coma Scale, and 10 to 16 according to the Faure Scale. The patient has been admitted to the ward with a diagnosis of concussion. Concussion includes subdural, epidural, intracerebral, ventricular, and subarachnoid hemorrhages. Sedation should be in the range of +2 to -2 based on the Richmond criteria. 48 hours have passed since hospitalization According to the opinion of the attending physician or ENT consultation, patients should have healthy hearing on at least one side. Don't have bandages in their ears No history of depression and other mental disorders Family availability and cooperation for audio recording Not using tobacco, alcohol and highly addictive drugs before the accident according to the family's statement

Exclusion criteria:

Having an underlying disease Have a previous history of hearing loss according to family statements Any illness except head injury

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

For the purpose of random allocation, the method of dividing blocks of six is used. In this way, two test groups of letter A and B were assigned a control group of letter C, And in blocks of six with letters A, B, and C, ninety states such as ABABCC, AABBC were written on sheets and thrown into a container Randomly one of these sheets was taken out of the container and the composition written on it was written down and that sheet was placed outside the container, The sample size in this study was estimated to be 99 patients; Therefore, this process was repeated 17 times ($102 \times 6 = 17$) and each time the extracted combination was written on the sheet following the previous combination. Then, each letter from the beginning of the blocks was assigned a number from 1 to 102. Then the letter was put inside the

envelope and the number of that letter was written on the envelope. Each time a patient was admitted, one of the envelopes was opened in the order of the numbers written on the envelope, and it was determined whether the patient should be in the test group or the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person performing the intervention for the patient as well as the person recording the patient's information are blinded to which study patient is in which study group (intervention 1 or 2 and control).

Placebo

Not used

Assignment

Parallel

Other design features

non

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Alborz University of Medical Sciences

Street address

Alborz Nursing School, Golestan 1st, Golestan 1st, Sobhamati St., Baghistan, Karaj

City

Karaj

Province

Alborz

Postal code

3146883411

Approval date

2022-09-18, 1401/06/27

Ethics committee reference number

IR.ABZUMS.REC.1401.151

Health conditions studied**1****Description of health condition studied**

head injury

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

The level of anxiety: an emotional state that is associated with a feeling of tension, anger, changes in vital signs and increased need for oxygen and increased mortality in patients.س

Timepoint

After the audio is played, it is recorded daily

Method of measurement

Anxiety facial scale

2

Description

Dosage of drugs taken in mg during the day of hospitalization

Timepoint

Daily

Method of measurement

According to the amount of daily prescription and the amount of medicine received through case review and nursing report

3

Description

The type of sedative drugs, which are divided into 4 categories: barbiturates, benzodiazepines, and narcotics.

Timepoint

Daily

Method of measurement

According to the order prescribed through the patient file and nursing report

4

Description

Duration of taking sedatives

Timepoint

Daily

Method of measurement

Daily

5

Description

Mechanical ventilation status

Timepoint

Daily

Method of measurement

View and insert in the checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group that receives a familiar voice, First-degree relatives are asked who had a stronger emotional relationship with the patient, then the person who had a stronger emotional relationship according to

the patient's relatives is asked to repeat the message written by the researcher and their voice is recorded. Yes, this sound is played twice a day for 15 to 30 minutes.

Category

Other

2

Description

Intervention group: The second group is the group that receives the nurse's voice so that the nurse repeats the message that the researcher says and this message is recorded, the recorded message every day and every time for 15 to 30 minutes during two weeks. It is distributed to patients.

Category

Other

3

Description

Control group: Patients in the control group have headphones placed on their ears for 15-30 minutes, but no sound is played for them (putting headphones without sound on the ears to reduce the volume of sounds and not hear false sounds by the patient)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Madany Hospital

Full name of responsible person

Zahra Tayebi Myaneh

Street address

Mahan Blvd. Taleghani st. Alborz

City

Alborz

Province

Alborz

Postal code

0000000000

Phone

+98 26 3442 7001

Fax

+98 26 3442 7001

Email

Tayebi.medical@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Faculty of Nursing, Alborz University of Medical Sciences

Street address

Safari Street, Beheshti Street, Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3774

Email

research@abzums.ac.ir

Web page address

<https://research.abzums.ac.ir/fa-IR/research.abzums.ac/9132/page/%D8%AE%D8%A7%D9%86%D9%87>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz 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

Karaj University of Medical Sciences

Full name of responsible person

Zahra Tayebi Myaneh

Position

Professor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Baghestan Blvd. Nursing School

City

Karaj

Province

Alborz

Postal code

314683811

Phone

+98 26 3433 6007

Email

Nursing@abzums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Zahra Tayebi

Position

University faculty

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

.

City

Karaj

Province

Alborz

Postal code

3146883811

Phone

+98 912 882 2421

Email

Tayebi.medical@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Samira Irani

Position

University student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

Street address

.

City

Karaj

Province

Alborz

Postal code

3195648811

Phone

+98 991 441 5702

Email

Samirairani@gmail.com

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	Since the termination of the plan
Clinical Study Report	To whom data/document is available
Yes - There is a plan to make this available	All people and applicants
Analytic Code	Under which criteria data/document could be used
No - There is not a plan to make this available	In the form of an article
Data Dictionary	From where data/document is obtainable
Yes - There is a plan to make this available	To the email of the author responsible for the plan
Title and more details about the data/document	What processes are involved for a request to access data/document
Information related to the main design variables will be disclosed	Just sending an email to the author responsible for the project is enough
When the data will become available and for how long	Comments