

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing The effect of family members' voice and nurse' voice on restlessness, anxiety, delirium and success in weaning of ventilator in patients admitted to Intensive Care Units

Protocol summary

Study aim

Comparison of the effect of family members and nurses on restlessness, anxiety, delirium and success in ventilator isolation in patients admitted to the intensive care unit of Qazvin University of Medical Sciences

Design

a prospective randomized clinical trial of three groups with a control group.

Settings and conduct

The researcher, after obtaining a license from the Ethics Committee from Qazvin University of Medical Sciences, will refer to the educational and medical centers of Qazvin University of Medical Sciences and after explaining the research and its objectives and obtaining permission from officials.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. The age of patients should be between 18-65 years (18). 2. The level of consciousness according to the Glasgow coma criterion due to trauma should be 11-8 (19). Exclusion criteria: 1. Dissatisfaction of the patient's companions to continue participating in the study 2. A history of hearing, vision, aphasia and limb movement disorders (18,19)

Intervention groups

In one group the voice of a family member and in the other group the voice of a nurse is recorded and played by the headset to the patients and in the other group no sound is played.

Main outcome variables

restlessness, Success weanig, and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201014049029N1**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Fariba Abdollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing The effect of family members' voice and nurse' voice on restlessness, anxiety, delirium and success in weaning of ventilator in patients admitted to Intensive Care Units

Public title

Comparing The effect of family members' voice and nurse' voice on restlessness, anxiety, delirium and success in weaning of ventilator in patients admitted to Intensive Care Units

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

1.The age of patients should be between 18-65 years
2.The level of consciousness according to the Glasgow coma criterion due to trauma should be 11-8
3.The patient has been admitted to the ward with a diagnosis of concussion. Traumatic brain injury includes subdural, epidural, intracerebral, ventricular, and subarachnoid hemorrhages.
4.Sedation should be in the range of +2 to 2- according to Richmond criteria
5.48 hours have elapsed since hospitalization
6.Patients should have at least one healthy hearing position according to the physician or ENT consultation
7.Have no previous history of hearing loss according to family statements
8.Do not have a bandage on the ear
9.No history of depression and other mental disorders
10.Family availability and collaboration to record audio
11.Do not use alcohol and drugs with high dependence before the accident according to family statements

Exclusion criteria:

1.Dissatisfaction of the patient's companions to continue participating in the study
2.A history of hearing, vision, aphasia and limb movement disorders
3.Patients with vegetative status as determined by physician
4.Patients with severe previous head injury
5.Sudden loss of consciousness more than 3 points according to the Glasgow Coma Criterion during the intervention
6.Simultaneous participation of the patient in similar care programs such as massage therapy and the use of relaxation techniques and ...

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients who meet the inclusion criteria will be included in the study by random sampling method of block division method with triple blocks. In this way, the letter A will be assigned to the test group and the letter B to the control group, and in 6 blocks with the letter A, B, C, six states ACB, ABC, CAB, BCA, BAC, CBA will be written on the sheet. The blocks will then be sorted according to a table of random numbers.

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**

Dept of research Qazvin University of Medical Sciences

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qazvin

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Approval date

2020-03-02, 1398/12/12

Ethics committee reference number

IR.QUMS.REC.1398.408

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

Head trauma

ICD-10 code

S07.8XXS

ICD-10 code description

Crushing injury of other parts of head, sequela

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

Restlessness was assessed by the Richmond Restlessness Checklist. The Richmond tool consists of 10 levels, four of which are for restlessness, one for calm and alert, and five for relaxation.

Timepoint

Before and after the intervention

Method of measurement

Richmond Restlessness Checklist

2**Description**

Delirium is assessed with the Neecham Delirium instrument and this questionnaire has a total of 30

points. Based on the overall score obtained by the patient, it is divided into 4 categories; A healthy person with a score of 27-30, prone to confusion with a score of 25-26, mild delirium with a score of 20-24, moderate to severe delirium with a score of 0-19.

Timepoint

Before and after the intervention

Method of measurement

Neecham Delirium questionnaire

3

Description

Anxiety was assessed with the Facial Anxiety Scale. It has a range from 1 to 5, the lowest of which is related to the normal state of the facial state and the highest of which is the number 5 related to the maximum state of anxiety

Timepoint

Before and after the intervention

Method of measurement

Facial Anxiety Scale

4

Description

Weaning success was assessed with the Burn weaning Success Tool. The total score is 26 and after receiving a score of 17 or higher, the separation process begins.

Timepoint

Before and after the intervention

Method of measurement

Burn weaning Success Tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the voice of a family member is recorded and played to patients through a headset. This intervention is performed twice a day for six days for patients. In the intervention group, this sound will be heard by patients with 60 to 80 beats per minute with MP3 PLAYER through headphones.

Category

Other

2

Description

Intervention group: a nurse's voice is recorded and played to patients through a headset. This intervention is performed twice a day for six days for patients. In the intervention group, this sound will be heard by patients with 60 to 80 beats per minute with MP3 PLAYER through headphones.

Category

Other

3

Description

Control group: No sound is played in this group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Trauma ICUs of Qazvin University of Medical Sciences

Full name of responsible person

Fariba Abdollahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Qazvin University of Medical Sciences

Proportion provided by this source

60

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

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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 more information

Study Protocol

No - There is not 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

No - There is not 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

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