

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the Effect of Nature Sound and Family Voice on Physiological Indicators and Level of Consciousness (LOC) of Patients Admitted to Intensive Care Units (ICU)

Protocol summary

Study aim

Comparison of the Effect of Nature Sound and Family Voice on Physiological Indicators and Level of Consciousness (LOC) of Patients Admitted to Intensive Care Units (ICU)

Design

Randomized controlled clinical trial Determining the exact sample size using a statistical formula with a 95% confidence level and a 5% error Sampling by Easy Access Method Randomly in 3 groups

Settings and conduct

Shahid Rajaei Hospital and Razi Social Security Hospital in Qazvin

Participants/Inclusion and exclusion criteria

Age group 15-60 years Of both sexes 5< Glasgow Coma Scale Score <8 The Patient's Guardian should read and sign the Informed Consent

Intervention groups

Intervention Group 1: In addition to routine care, play a set of nature sounds (night, wind, rain, sea, waterfall, birds, river and crickets) with an intensity of 60 to 70 decibels for 5 days, twice a day in the morning shift and Evening for 30 minutes with MP3 player and ambient soundproof headphones The second group of intervention: playing a tape of the patient's favorite person in the family for 10 minutes with the content (informing the patient of the person, time and place, brief description of what happened to the patient, expressing sweet memories of the past and phrases From the recovery of the patient and his return to the family) by MP3 Player Control group: Receiving routine ward care for all patients admitted to intensive care units

Main outcome variables

Auditory stimulation Level of consciousness Age Gender marital status Education level Underlying diseases Cause of coma Duration of coma Mechanical ventilation Drugs Systolic blood pressure Diastolic blood pressure Number

of breaths Pulse count Tympanic temperature Arterial blood oxygen saturation SPO2 Family member ratio Average arterial blood pressure MAP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201016049038N1**

Registration date: **2020-12-08, 1399/09/18**

Registration timing: **prospective**

Last update: **2020-12-08, 1399/09/18**

Update count: **0**

Registration date

2020-12-08, 1399/09/18

Registrant information

Name

Reyhaneh Rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3366 6412

Email address

r.rahmani@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-20, 1399/09/30

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Nature Sound and Family Voice on Physiological Indicators and Level of Consciousness (LOC) of Patients Admitted to Intensive Care Units (ICU)

Public title

Effect of Nature Sound on Physiological Indicators and Level of Consciousness (LOC) Effect of Family Voice on Physiological Indicators and Level of Consciousness (LOC)

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between 15 and 60 years old Both sexes
5<Glassco Coma Score<8 Hospitalization in the intensive care unit

Exclusion criteria:

Unknown Patients Having a history of brain injury
Hearing imparment or loss Fractures of the skull in the temporo mandibular area and bleeding Having diabetis
Heart and fat diseases History of addiction Fractures in the four limbs

AgeFrom **15 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Not randomized

Randomization description**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 Qazvin University of Medical

Sciences

Street address

No. 37, Sanaye Dasti Alley., Mulla Sadra Street

City

QAZVIN

Province

Qazvin

Postal code

3418854134

Approval date

2020-10-26, 1399/08/05

Ethics committee reference number

IR.QUMS.REC.1399.297

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

Patients with Brain Injury Coma Patients

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

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

The level of consciousness of stroke patients

Timepoint

Before, during and 2 minutes after each auditory stimulation

Method of measurement

Glasgow Coma Scale score (GCS)

Secondary outcomes**1****Description**

Physiological indicators of stroke patients

Timepoint

Before and during and two minutes after the intervention

Method of measurement

Devices for control of blood pressure, respiratory rate
view, touch the heart rate, pulse oximetry and mercury
thermometer

Intervention groups**1****Description**

Intervention group: In addition to routine care, the group
broadcasts a collection of nature sounds (night, wind,
rain, sea, waterfall, birds, river and crickets) with an
intensity of 60 to 70 decibels for 3 days, twice a day in
the morning and evening shifts for 30 minutes with MP3
player and soundproof headphones Interference

Category

Treatment - Devices

2**Description**

Intervention group: The second group of intervention: playing a tape of the patient's favorite person in the family for 10 minutes with the content (informing the patient of the person, time and place, brief description of what happened to the patient, expressing sweet memories of the past and phrases From the recovery of the patient and his return to the family) by MP3 Player

Category

Treatment - Devices

3**Description**

Control group: Control group: receiving routine care in the intensive care unit

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rajai Hospital

Full name of responsible person

Leyli Yekke Fallah

Street address

Shahid Safdari Alley, Padegan Street

City

QAZVIN

Province

Qazvin

Postal code

3413996134

Phone

+98 28 3333 5800

Email

rehi_rahmani@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr leyli yekke fallah

Street address

22 Bahman Boulevard

City

Qazvin

Province

Qazvin

Postal code

3418854134

Phone

+98 28 3366 4001

Email

rehi_rahmani@yahoo.com

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

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**

Qazvin University of Medical Sciences

Full name of responsible person

Reyhane Rahmani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Babaei Street., Razi Hospital

City

Qazvin

Province

Qazvin

Postal code

3418854134

Phone

+98 28 3386 0179

Email

rehi_rahmani@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Reyhaneh Rahmani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 14, West KHAKALI 29., Noruziyan Town

City

Ghazvin

Province

Qazvin

Postal code

3418854134

Phone

+98 28 3366 6412

Email

rehi_rahmani@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Reyhane Rahmani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 14, West 29., Parastar Blvd., Noruziyan Town

City

Ghazvin

Province

Qazvin

Postal code

3418854134

Phone

+98 28 3366 6412

Email

rehi_rahmani@yahoo.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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data used in the research can be shared after the intervening people have not been identified and after the end of the study. Including participants, data, data analysis, attachments, informed consent and other documents

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Everyone

Under which criteria data/document could be used

If the researcher is a member of the medical staff or a student, the use of documents is unrestricted and all analyzes will be provided to them for use in their research.

From where data/document is obtainable

Refer to me Reyhaneh Rahmani, the author and executor of the project, through the following communication channels: Email address: rehi_rahmani@yahoo.com
Phone number: 09128403680

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

Finally, over the next year and fall, 1,400 documents or data files can reach applicants.

Comments