Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 diabets Heart and fat diseases History of addiction Fractures in the four limbs
Age
From **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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr leyli yekke fallah
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22 Bahman Boulevard
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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
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
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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)
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