

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the Effect of Familiar Voice on Decrease of Agitation in Patients in Intensive Care Unit

Protocol summary

Study aim

The aim of this study is to evaluate the effect of playing a familiar voice in reduction of agitation in patients admitted in the Intensive Care Unit.

Design

This is a clinical trial with a control group, with parallel, non-blind, and randomized groups which was randomized by using a computer software for defining the blocks.

Settings and conduct

This study is conducted in Shahid Beheshti Hospitals, including Shohada Tajrish Hospital and Taleghani Hospital, and the intervention is performed as playing a familiar voice for patients (voice record of family members) three times a day in the morning and evening, each time for 30 minutes and totally for 3 days.

Participants/Inclusion and exclusion criteria

The inclusion criteria: Age between 18 and 65; The agitation rate based on the Richmond criterion is between 1+ and 2+; The complete health of the patient's hearing system; The exclusion criteria: History of neurological diseases such as Alzheimer's disease, dementia, stroke; The history of drug addiction; History of mental illness

Intervention groups

In the intervention group, a familiar voice record (the recorded sound of a patient's acquaintance, containing relaxing and hopeful sentences) will be played for them. the control group consists of agitated patients who have been admitted to the same intensive care unit and the usual care will be provided for them.

Main outcome variables

Agitation rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170701034837N2**

Registration date: **2018-03-14, 1396/12/23**

Registration timing: **retrospective**

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

Registration date

2018-03-14, 1396/12/23

Registrant information

Name

hasti ansari ashlaghi

Name of organization / entity

shahid beheshti university

Country

Iran (Islamic Republic of)

Phone

+98 88061058

Email address

h.ansari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

researcher

Expected recruitment start date

2016-09-26, 1395/07/05

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2017-02-08, 1395/11/20

Trial completion date

empty

Scientific title

Evaluating the Effect of Familiar Voice on Decrease of Agitation in Patients in Intensive Care Unit

Public title
Effect of Familiar Voice on Decrease of Patient's Agitation

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 18 and 65 The agitation rate based on the Richmond criterion is between 1+ and 2+ Complete health of the patient's hearing system
Exclusion criteria:
 History of neurological diseases such as Alzheimer's disease, dementia, stroke The history of drug addiction History of mental illness

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: **60**
 Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization method was used which the patient was the randomization unit. For this purpose, computer software was used to define the blocks and the allocation concealment was not applicable in this study.

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Iran, Evin, Tehran, Islamic Republic of Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2016-07-26, 1395/05/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.247

Health conditions studied

1

Description of health condition studied

Agitation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Agitation

Timepoint

Measurements will be done before the intervention in each day and at the end of the study.

Method of measurement

Richmond Agitation Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Familiar voice (the sound of favorite relatives of the patient) for 30 minutes, two times a day in the morning and evening for 3 days

Category

Prevention

2

Description

Control group: common care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Hasti Ansari Ashlaghi

Street address

Tajrish Sq., Tehran, Iran

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56845342
Phone
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pr_shohada@sbmu.ac.ir

2

Recruitment center

Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Hasti Ansari Ashlaghi
Street address
Tabnak St., Velenjak Region, Chamran High Way,
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taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Babak Shokri
Street address
Velenjak, Tehran, Iran
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info.ece@cc.sbu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hasti Ansari Ashlaghi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 2, Ladan alley, shiraz shomali street, Mollasadra
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Person responsible for scientific inquiries

Contact

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hasti Ansari Ashlaghi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 2, Ladan alley, shiraz shomali street, Mollasadra Avenue, Vanak Square, Tehran, Iran

City

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Tehran

Postal code

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Phone

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Fax**Email**

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Web page address**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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is unobtrusive when being unrecognizable

When the data will become available and for how long

The access beginning period is 6 months after printing the results

To whom data/document is available

Only for scholars working in academic institutions

Under which criteria data/document could be used

No statistical analysis is allowed on data.

From where data/document is obtainable

Data request should be sent to the following e-mail: mahdisvakili@gmail.com

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

After sending the email to the person responsible, it takes 7 days to deliver the data to the requester.

Comments