

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of music on the agitation on the basis of Richmond in intubated patients admitted to the Medical ICU

Protocol summary

Study aim

The effect of music on the agitation on the basis of Richmond in intubated patients admitted to the Medical Intensive Care Unit(ICU)

Design

Determination of control group and the intervention by random allocation (simple randomization).For both groups, the headphones are placed for 20 minutes each day for 3 days.In the intervention group, music is played but not in the music control group.Richmond is evaluated before and after intervention in each group.At the end of the third day, the results are evaluated and compared

Settings and conduct

Patients admitted to the ICU in Shahid Rajaei Hospital who have criteria for entering the study are in the intervention group and ICU 2 in the control group.For both groups, the headphones are placed for 20 minutes each day for 3 days.In the intervention group,non word music approved by the association will be played but in the control group will not be played.Richmond is evaluated before and after intervention in each group.

Participants/Inclusion and exclusion criteria

Entry Criteria: Having a tracheal tube from entry or on the first day of hospitalization in the unit, mechanical ventilation, Age between 16 and 70 years, Informed consent; Non-entry criteria: Psychological disorder, Hemodynamic disorders, Addiction, Deafness and hearing problems, The ability to communicate verbally

Intervention groups

For both intervention and control groups, the headphones are placed for 20 minutes each day for 3 days.In the intervention group,non word music approved by the association will be played but in the control group will not be played.Richmond is evaluated before and after intervention in each group.

Main outcome variables

Agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180918041060N1**

Registration date: **2019-05-19, 1398/02/29**

Registration timing: **retrospective**

Last update: **2019-05-19, 1398/02/29**

Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

Narges Seyfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3460 0724

Email address

n.seyfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-02, 1397/07/10

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of music on the agitation on the basis of Richmond in intubated patients admitted to the Medical ICU

IR.ABZUMS.REC.1397.063

Public title

Music in agitation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having a tracheal tube from entry or on the first day of hospitalization in the unit mechanical ventilation Age between 16 and 70 years Informed consent

Exclusion criteria:

Psychological disorder Hemodynamic disorders Addiction Deafness and hearing problems The ability to communicate verbally

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

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 Alborz University of Medical Sciences and Health Services

Street address

safariyan estreet, 45 yards of Golshahr

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2018-08-05, 1397/05/14

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Restlessness and agitation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

agitation

Timepoint

before and 20 minutes after intervention

Method of measurement

Richmond

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the headphones are placed for 20 minutes each day for 3 days and non word music approved by the association will be played. The Richmond scale is evaluated before and after intervention.

Category

Treatment - Other

2

Description

Control group: The routine care

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei

Full name of responsible person

Narges Seyfi

Street address

Shahid Rajaei Hospital, Shahid Beheshti, Hesarak

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3457 0030

Fax

Email

narges.seyfi.1986@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

DR Mohammad Noorisepehr

Street address

Shahid Rajaei Hospital, Shahid Behshti Ave, Hesarak

City

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Province

Alborz

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Phone

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+98 26 3455 4484

Email

narges.seyfi.1986@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Narges Seyfi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Rajaei Hospital, Shahid Behshti Ave, Hesarak

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Narges Seyfi

Position

Nurse

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Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Narges Seyfi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable