

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of nature-based sounds' intervention on physiological signs of anxiety and agit

Protocol summary

Summary

The purpose of this study was to investigate the effect of nature-based sounds' intervention on physiological signs of anxiety and agitation in patients under mechanical ventilator support in intensive care units of selected hospitals in Tehran. This study is a randomized controlled trial, 60 patients undergoing mechanical ventilator were randomly assigned to the control and experimental groups. All participants were provided with information about the intervention. The patients in the experiment group were given nature-based sounds through an audiotape via fixed earphones. The patients assigned to the control group were asked to wear the foam-lined headphone and rest in silence for a similar time frame as the intervention group. Two groups are assessing without earphones, 30 minutes after finishing the procedure. The intensity of anxiety and agitation expressed by the participants were measured using the visual analogue Richmond Agitation Sedation Scale (RASS) and and Faces Anxiety Scale (FAS) for four times. (after intervention, 30 minutes after intervention, 60 minutes after intervention, 90 minutes after intervention, 30 minutes after finish of the intervention)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207277529N2**

Registration date: **2012-08-17, 1391/05/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-17, 1391/05/27

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2012-01-05, 1390/10/15

Expected recruitment end date

2012-07-05, 1391/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nature-based sounds' intervention on physiological signs of anxiety and agit

Public title

effect of nature-based sounds' intervention on anxiety and agitation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The patients were aged between 18 and 65 years; who were under mechanical ventilation support for 48 hours in an ICU ; had Glasgow Coma Scale Point 9 or above; were able to hear and see ; were not drug-addicted; were not receiving beta blocker and

inotropic support were not taking any neuromuscular blocker agent and antihypertensive drug; had no facial signs of being scared; had no currently using a N-BS intervention; had no psychiatric or neurological illnesses
Exclusion criteria: Subjects were extubations from mechanical ventilation; need emergency dose- stat sedative ; Patient withdraws from study.

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**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahed University

Street address

Opposite to Holy Shrine of Imam Khomeini, Tehran-
Qom Freeway, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-05-08, 1391/02/19

Ethics committee reference number

4/148499

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

agitation

Timepoint

after intervention,30 minutes after intervention, 60 minutes after intervention, 90 minutes after intervention(end intervention), 30 minutes after finish of the intervention

Method of measurement

The visual analog scale Richmond Agitation Sedation Scale(RASS)

Secondary outcomes

1

Description

agitation

Timepoint

after intervention,30 minutes after intervention, 60 minutes after intervention, 90 minutes after intervention(end intervention), 30 minutes after finish of the intervention

Method of measurement

Faces Anxiety Scale (FAS)

Intervention groups

1

Description

In interventional group who received the N-BS intervention consisted of 90 minutes of listening to the N-BS (birds' song, soothing rain sounds, river stream)subjects were assessed in the last thirty minutes without headphones and sounds playing. The nature sounds were played using a MP3 media player (Leono Inc., Guangzhou, China) through disposable foam-lined headphones The average sound pressure level was set to 25-50 dB. For all samples is recording physiological parameters of agitation and anxiety score hemodynamic

Category

Other

2

Description

In the control group which received only The patients assigned to the control group were asked to wear the foam-lined headphone and rest in silence for a similar time frame as the intervention group to minimize unpleasant environmental noises or stimuli. This group is assessed in the last thirty minutes without headphones and sounds playing.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiatallah University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Vice Chancellor for Research of Shahed University

Street address

Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty