Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of sounds therapy on agitation and anxiety in patients undergoing coronary artery bypass graft during the weaning of mechanical ventilation

Protocol summary

Summary

The purpose of this study was to investigate the effect of nature-based sounds' intervention on agitation and anxiety in patients undergoing coronary artery bypass graft during the weaning of mechanical ventilation in intensive care units in Jamaran hospital in Tehran. This study is a randomized controlled trial, 120 patients undergoing coronary artery bypass graft during the weaning of 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. The intensity of agitation and anxiety expressed by the participants in two groups were measured using the Richmond Agitation Sedation Scale (RASS) , Faces Anxiety Scale (FAS) and hemodynamic changes for ten times. In the intervention group, nature-based sounds will be played for 20 minutes intervals on according to patients' preference but in the control group wear the foam-lined headphone without sounds. Before and then at intervals of 20 minutes applying technique the indicators to be measured and recorded. This is done until extubation and then after 20 min and 30 min after extubation and continued.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304027529N3**
Registration date: **2013-05-04, 1392/02/14**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-05-04, 1392/02/14

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Shahed university

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sounds therapy on agitation and anxiety in patients undergoing coronary artery bypass graft during the weaning of mechanical ventilation

Public title

The effect of sound therapy on agitation and anxiety

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: The patients were aged between 18 and 65 years; who were under weaning of mechanical ventilation and undergoing coronary artery bypass graft Exclusion criteria:drugs and alcohol abuse , hearing problem. Past heart surgery. mental illness are recognized and recorded in the medical record, Severe hemodynamic impairment (inotrope dependence of postoperative, active drainage and what prevents weaning). emergency surgery or re-operation to be performed for any reason. During the intervention, the use of any cause that requires dose-stat of common protocol tranquilizers and sedative medication is needed.changes ASV mode mechanical ventilation to the other modes. high dependence of the positive inotropics, delayed weaning process, unstable vital signs during weaning
Age
From **45 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
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
City
Tehran
Postal code
Approval date
2012-12-15, 1391/09/25
Ethics committee reference number
4/158116

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 level
Timepoint
before intervention,at intervals of 20 minutes applying technique, after extubation ,after 20 min and 30 min after extubation
Method of measurement
Richmond Agitation Sedation Scale (RASS)

Secondary outcomes

1

Description
anxiety
Timepoint
before intervention,at intervals of 20 minutes applying technique, after extubation ,after 20 min and 30 min after extubation
Method of measurement
Face anxiety scale (FAS)

2

Description
Systolic blood pressure
Timepoint
before intervention,at intervals of 20 minutes applying technique, after extubation ,after 20 min and 30 min after extubation
Method of measurement
observation of Monitoring

3

Description
diastolic blood pressure
Timepoint
before intervention,at intervals of 20 minutes applying technique, after extubation ,after 20 min and 30 min after extubation
Method of measurement
observation of Monitoring

4

Description

Arterial oxygen saturation(sao2)

Timepoint

before intervention,at intervals of 20 minutes applying technique, after extubation ,after 20 min and 30 min after extubation

Method of measurement

pulse oximeter

5

Description

heart rate

Timepoint

before intervention,at intervals of 20 minutes applying technique, after extubation ,after 20 min and 30 min after extubation

Method of measurement

observation of Monitoring

6

Description

Mean arterial pressure

Timepoint

before intervention,at intervals of 20 minutes applying technique, after extubation ,after 20 min and 30 min after extubation

Method of measurement

observation of Monitoring

7

Description

Rrespiratory Rate

Timepoint

before intervention,at intervals of 20 minutes applying technique, after extubation ,after 20 min and 30 min after extubation

Method of measurement

observation of Monitoring

Intervention groups

1

Description

The patients in the experimental group were given nature-based sounds (birds' song, soothing rain sounds, river stream) through an audiotape via fixed earphones, then 20 min rest. This is done until extubation. 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 anxiety and agitation score

Category

Other

2

Description

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.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiatallah University

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Baghiatallah University

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

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

City

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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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