Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of implementing nature based sounds with placebo on anxiety and pain in patients undergoing cardiac catheterization

Protocol summary

Summary

The aim of the study was to investigate the effect of nature-based sound therapy on patients' anxiety and pain undergoing cardiac catheterization. This was a randomized controlled trial. A purposive sample of 130 patients who were undergoing cardiac catheterization was recruited. Patients were randomly allocated to either the control or the experimental groups (65 patients per each group). In the experimental group, patients received a 20 minutes, between 25 - 50 decibel (dB) sound therapy intervention consisted of birds' song, soothing rain sounds, and river stream by using a digital MP3 player and a headphone. While the control group received the usual sound environment. Study data were collected by using a demographic questionnaire, the Spielberger's Anxiety Inventory, Pain scale VAS and a data sheet for documenting hemodynamic parameters. Patients' data monitored and recorded in before and after intervention, and after cardiac catheterization. The researchers and data monitoring committee will not become aware of what sort of intervention the patients receive.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412047529N5**
Registration date: **2014-12-21, 1393/09/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-21, 1393/09/30

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

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Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University Vice chancellor for research, Dr. Zahra Kiasalari

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of implementing nature based sounds with placebo on anxiety and pain in patients undergoing cardiac catheterization

Public title

Effect of nature-based sounds on the level of anxiety and pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : patients with first coronary cardiac catheterization; being able to understand and speak Persian; having age of over 18 years; having no hearing impairment; having no drug or alcohol addiction;

receiving no anxiolytic medication; needing no emergency cardiac catheterization; not receiving hypertension or anti hypertensive drugs; having 20 number anxiety. Exclusion criteria: not willingness to participate in this study; cancellation of cardiac catheterization due to any reason except patient's anxiety.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The patients are randomly allocated to the experiment and control groups (65 patients per each group). Random allocation to intervention and control groups was done by assigning patients to each group every other week.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahed University

Street address
Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express

City
Tehran

Postal code

Approval date
2014-04-19, 1393/01/30

Ethics committee reference number
14/9881

Health conditions studied

1

Description of health condition studied
Diseases of the circulatory system

ICD-10 code
I70, I79

ICD-10 code description
Diseases of arteries, arterioles and capillaries

Primary outcomes

1

Description
Blood pressure

Timepoint
Before and after intervention, and after cardiac catheterization

Method of measurement
Sphygmomanometer

2

Description
Anxiety

Timepoint
Before and after intervention, and after cardiac catheterization

Method of measurement
Spielberger questionnaire

3

Description
Respiratory rate

Timepoint
Before and after intervention, and after cardiac catheterization

Method of measurement
Checklist

4

Description
Pulse rate

Timepoint
Before and after intervention, and after cardiac catheterization

Method of measurement
Checklist

5

Description
Oxygen saturation

Timepoint
Before and after intervention, and after cardiac catheterization

Method of measurement
pulse oximeter

6

Description
Pain

Timepoint

Before and after intervention, and after cardiac catheterization

Method of measurement

Pain Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

The patients in the experiment group will receive the nature- based sounds such as birds' song, soothing rain sounds, and river stream using an audiotape via fixed earphones. The intervention will be conducted in a quiet room. that will last for 20 minutes, between 25 - 50 decibel (dB) before the cardiac catheterization. The level of anxiety (measured by using spielburger questionnaire) and pain (VAS) hemodynamic parameters (recorded in a checklist) are used before and after intervention, while and after cardiac catheterization.

Category

Other

2

Description

In the control group received the usual sound environment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University Vice chancellor for research

Full name of responsible person

Shahed University Vice chancellor for research : Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way Tehran Tehran Iran

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 Vice chancellor for research

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

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work

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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