

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 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)

##### Phone

+98 21 5121 3071

##### 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

##### Street address

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

##### City

Tehran

##### Postal code

##### Phone

+98 21 5121 3071

##### Fax

##### Email

nreh@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahed University

##### Full name of responsible person

Dr. Nahid Rejeh

##### Position

Associate Professor

##### Other areas of specialty/work

##### Street address

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

##### City

Tehran

##### Postal code

##### Phone

+98 912 370 6378

**Fax**  
**Email**  
nrekeh@yahoo.co  
**Web page address**

**Fax**  
**Email**  
nrekeh@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahed University

**Full name of responsible person**

Dr. Nahid Rekeh

**Position**

**Other areas of specialty/work**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

## 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*