

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison of implementing nature based sounds with placebo on anxiety patients undergoing gastrointestinal endoscopy

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of nature-based sounds on the level of anxiety and satisfaction of patient before undergoing gastrointestinal endoscopy. This quasi- experimental study will be conducted in Mostafa Khomeini hospital in Tehran, Iran with the participation of 124 patients who are scheduled to undergo upper gastrointestinal endoscopy. The patients are randomly allocated to the experiment and control groups (60 patients per each group). Random allocation will be conducted by using the randomization list. The patients in the experiment group will receive the intervention of 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 15 minutes, between 25 - 50 decibel (dB) before the procedure , while the control group will wear the foam-lined headphone without sounds for a similar time frame as the intervention group. The level of anxiety (measured by using spielburger questionnaire) and vital signs (recorded in a checklist) are used in both groups before the intervention, before the endoscopy (immediately before the procedure) and after endoscopy. Finally, the level of satisfaction of patients is measured by using the visual analogue scale after endoscopy. 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: **IRCT201304137529N4**

Registration date: **2014-01-25, 1392/11/05**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-01-25, 1392/11/05

##### 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 , Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way,Tehran, Iran.

##### Expected recruitment start date

2013-04-15, 1392/01/26

##### Expected recruitment end date

2014-03-17, 1392/12/26

##### 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 patients undergoing gastrointestinal endoscopy

##### Public title

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

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Having the order of upper gastrointestinal endoscopy at least one day before the procedure; age over 18 years old; ability to speak and understand Persian language; having no visual and hearing disorders; Having no previous history of endoscopy; Having no order of emergency endoscopy; Having no history of psychological diseases or anxiety disorders; no consuming opium or sedative drugs; not experiencing severe pain due to nature of disease; not receiving hypertension or anti hypertensive drugs.  
Exclusion criteria: Cancellation of endoscopy due to any reason except patient's anxiety; Not willingness to participate in this study

## Age

From **60 years** old to **80 years** old

## Gender

Both

## Phase

1

## Groups that have been masked

*No information*

## Sample size

Target sample size: **62**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## 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

2013-03-09, 1391/12/19

#### Ethics committee reference number

41/166426

## Health conditions studied

### 1

#### Description of health condition studied

Upper Gastrointestinal Endoscopy

#### ICD-10 code

K20, K31

#### ICD-10 code description

Diseases of Oesophagus, Stomach and Duodenum

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Before nature-based sounds therapy , before endoscopy , and after endoscopy

#### Method of measurement

Spielberger questionnaire

### 2

#### Description

Blood pressure

#### Timepoint

Before nature-based sounds therapy , before endoscopy , and after endoscopy

#### Method of measurement

Sphygmomanometer

### 3

#### Description

Respiratory rate

#### Timepoint

Before nature-based sounds therapy , before endoscopy , and after endoscopy

#### Method of measurement

Checklist

### 4

#### Description

Pulse rate

#### Timepoint

before nature based sounds therapy , before endoscopy , and after endoscopy

#### Method of measurement

Checklist

### 5

#### Description

Patient's satisfaction

#### Timepoint

After endoscopy

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

empty

## Intervention groups

1

### Description

In the control group, except for listening to nature-based sounds, all routine activities will be performed before endoscopy

### Category

Other

2

### Description

The patients are randomly allocated to the experiment and control groups (60 patients per each group). Random allocation will be conducted by using the randomization list. The patients in the experiment group will receive the intervention of 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 15 minutes, between 25 - 50 decibel (dB) before the procedure , while the control group will wear the foam-lined headphone without sounds for a similar time frame as the intervention group. The level of anxiety (measured by using spielburger questionnaire) and vital signs (recorded in a checklist) are used in both groups before the intervention, before the endoscopy (immediately before the procedure) and after endoscopy.

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Endoscopy Unit in Mostafa Khomeini Hospital, Tehran, Iran.

#### Full name of responsible person

Ms. Ali Mohammadi

#### Street address

Mostafa Khomeini Hospital , Italia Street, Tehran

#### 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, Islamic Republic Of

### 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

Assistant 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*

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Dr. Nahid Rejeh

**Position**

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**Other areas of specialty/work**

**Street address**

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