

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Guided Imagery on Anxiety & vital signs in patients undergoing Cardiac Electrophysiologic study

#### Protocol summary

##### Study aim

Effect of guided imagery on the anxiety and vital signs of patients candidate for electrophysiologic study

##### Design

Parallel group, single blind, randomized controlled trial

##### Settings and conduct

The study is randomized clinical trial performing on patients undergoing cardiac electrophysiologic study in Dr.Heshmat Hospital in Rasht

##### Participants/Inclusion and exclusion criteria

Entry criteria 1) age between 20-60 ; 2) minimum reading and writing literacy; 3) not having vision and hearing impairment; 4) lack of addiction to opium, sedatives and alcohol; 5)undergoing cardiac electrophysiologic study for the first time, 6) anxiety score less than 64 in the open anxiety scale and anxiety score less than 62 in the hidden anxiety scale Exclusion criteria 1) patient's dissatisfaction for continuation of study; 2)use of sedatives within the last 24 hours, 3) serious complications such as critical arrhythmias ; 4) no experience of relaxation and guided imagery; 5)having degree in psychology and related fields; 6) having bitter memory of sea

##### Intervention groups

For individuals in the intervention group, one day and also one hour before going to the cardiac electrophysiologic study room, a audio CD of guided imagery, which includes imagination of beautiful and pleasant scenery(Seafront) was played for 18 minutes through headphones. To control intruders such as noise in the ward,intervention was performed in the patient's room and without the presence of the researcher,in an enclosed room with folding screen between beds.The control group will receive only routine care and nursing instructions and training during treatment

##### Main outcome variables

Anxiety & vital signs

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180205038626N2**

Registration date: **2018-06-15, 1397/03/25**

Registration timing: **prospective**

Last update: **2018-06-15, 1397/03/25**

Update count: **0**

##### Registration date

2018-06-15, 1397/03/25

##### Registrant information

##### Name

Zahra Ahmadnia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3361 8177

##### Email address

zahmadnia@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-20, 1397/03/30

##### Expected recruitment end date

2018-08-21, 1397/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Guided Imagery on Anxiety & vital signs in patients undergoing Cardiac Electrophysiologic study

#### Public title

Effect of Guided Imagery on Anxiety & vital signs in patients undergoing Cardiac Electrophysiologic study

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

entry criteria 1) age between 20-60 ; 2) minimum reading and writing literacy; 3) not having vision and hearing impairment; 4) lack of addiction to opium, sedatives and alcohol; 5)undergoing cardiac electrophysiologic study for the first time, 6) anxiety score less than 64 in the open anxiety scale and anxiety score less than 62 in the hidden anxiety scale

##### Exclusion criteria:

#### Age

From **20 years** old to **60 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

- Investigator

#### Sample size

Target sample size: **26**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Blocks are made by quadruple random allocation.To determine the alternate selection of blocks,14 different random numbers are generated by randomized numbers table and the sequence of random assignments of the samples are generated by the statistics specialist. Each of the 52 random assignments is written on a card and packaged in a non-transparent closed envelope given to the collaborator researcher, who doesn't interfere in sampling and evaluation of the samples,in the hospital. At the arrival of each patient, the relevant envelope will be opened and the patient allocation group will be informed to the researcher for intervention and basic evaluations

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Principal investigator

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

##### Street address

Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St.

##### City

Rasht

##### Province

Guilan

##### Postal code

419395588

#### Approval date

2018-05-19, 1397/02/29

#### Ethics committee reference number

IR.GUMS.REC.1397.055

#### Health conditions studied

### 1

#### Description of health condition studied

Patients Candidate Heart Electrophysiology Study

#### ICD-10 code

I44

#### ICD-10 code description

Atrioventricular and left bundle-branch block

#### Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

One day and also one hour before going to the cardiac electrophysiologic study room

#### Method of measurement

Spilberger's apparent and hidden anxiety questionnaire

### 2

#### Description

vital signs

#### Timepoint

The effect of audio CD of guided imagery, one day and also one hour before going to the cardiac electrophysiologic study room

#### Method of measurement

vital signs (heart rate, respiratory rate, blood pressure, temperature) are measured by the researcher

#### Secondary outcomes

empty

#### Intervention groups

## 1

### Description

Intervention group: For individuals in the intervention group, one day and also one hour before going to the cardiac electrophysiologic study room, a audio CD of guided imagery, which includes imagination of beautiful and pleasant scenery(Seafont) was played for 18 minutes through headphones.To control intruders such as noise in the ward,intervention was performed in the patient's room and without the presence of the researcher,in an enclosed room with folding screen between beds.The control group will receive only routine care and nursing instructions and training during treatment

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr. Heshmat Rasht Hospital

##### Full name of responsible person

zahra ahmadnia

##### Street address

Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St

##### City

Rasht

##### Province

Guilan

##### Postal code

4193955588

##### Phone

+98 31 3361 8177

##### Fax

+98 31 3361 8177

##### Email

zahmadnia@gums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

shadman nemati

##### Street address

Rasht, Namjoo Ave., Shahid Siadati St., Faced to the 17th Shahrivar Hospital, Old Building, School of Health, University of Technology Research and Technology

##### City

Rasht

##### Province

Guilan

##### Postal code

41446-66949

##### Phone

+98 31 3333 2058

##### Email

zahmadnia@gums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Rasht University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

zahra ahmadnia

##### Position

Nurse

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St

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Rasht

##### Province

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##### Postal code

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##### Phone

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

zahra ahmadnia

##### Position

Nurse

##### Latest degree

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

zahra ahmadnia

**Position**

Nurse

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Phone**

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**Email**

zahmadnia@gums.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

For individuals in the intervention group, one day and also one hour before going to the cardiac electrophysiologic study room, a audio CD of guided imagery, which includes imagination of beautiful and pleasant scenery(Seafront) was played for 18 minutes through headphones. To control intruders such as noise in the ward,intervention was performed in the patient's room and without the presence of the researcher,in an enclosed room with folding screen between beds.The control group will receive only routine care and nursing instructions and training during treatment

**When the data will become available and for how long**

one day and also one hour before going to the cardiac electrophysiologic study room

**To whom data/document is available**

For researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

**From where data/document is obtainable**

Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St

**What processes are involved for a request to access data/document**

Through automation correspondence or email

**Comments**