

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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	

<u>1</u>	
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	4193955588
Approval date	2018-05-19, 1397/02/29
Ethics committee reference number	IR.GUMS.REC.1397.055
Health conditions studied	
<u>1</u>	
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	
<u>1</u>	
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
<u>2</u>	
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(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

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

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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

City

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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

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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