

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Survey effect of Guided Imagery and music therapy on Anxiety in patients before Coronary Artery Bypass Grafting

#### Protocol summary

##### Study aim

Comparison of the Effect of Music Therapy and Guided Imagination on Anxiety in Patients Before Coronary Artery Bypass Grafting in Heshmat Hospital in Rasht;

##### Design

Clinical trial with control group, with parallel groups, one blinded, randomized

##### Settings and conduct

For patients before coronary artery bypass grafting hospitalized in surgery wards of heshmat hospital in rasht ,7 days prior to cardiac surgery will be listened to bach nonverbal music CD and guided imagery CD for 7 session during 18-20 mintutes.7 days before CABG and immediately at the end of listening to CDs, the apparent and hidden anxiety scores of the subjects under study will be measured by the Spielberger questionnaire. The present study design is one blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : 1) having an age of 20-65 years; 2) having a minimum reading and writing literacy; 3) not having hearing impairment; 4) lack of addiction to alcohol and drugs; 5) having undergone cardiac surgery for the first time; Non-compliance criteria: 1) the patient's dissatisfaction with the continuation of the study, 2) receiving sedation drugs within the last 24 hours, 3) having arrhythmias (Atrial fibrillation, etc.), 4) lack of experience in the use of relaxation and guided imagery classes and music therapy 5) having a degree in psychology and related fields; 6) having a bitter memory of the sea;

##### Intervention groups

Eligible individuals are randomly assigned to the 3 groups according to block randomized allocation.The first group, the group that is undergoing music therapy;The second group, the group being guided imagery and the third group, a group that receives routin nursing care without interventions.

##### Main outcome variables

Anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180205038626N3**

Registration date: **2019-06-11, 1398/03/21**

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

Last update: **2019-06-11, 1398/03/21**

Update count: **0**

##### Registration date

2019-06-11, 1398/03/21

##### 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

2019-06-08, 1398/03/18

##### Expected recruitment end date

2019-07-09, 1398/04/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Survey effect of Guided Imagery and music therapy on Anxiety in patients before Coronary Artery Bypass Grafting

#### **Public title**

The Effect of Music Therapy and Guided Imaging on Anxiety in Coronary Artery Bypass Grafting patients

#### **Purpose**

Education/Guidance

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Having the age of 20-65 years 2) having the least reading and writing skills 3) not having hearing impairment 4) lack of drug and alcohol addiction 5) undergoing cardiac surgery for the first time 6) having anxiety Less than 64 on anxiety scale and anxiety less than 62 in the hidden anxiety scale;

##### **Exclusion criteria:**

Patient's dissatisfaction with the continuation of the study 2) Receiving sedation drugs within 24 hours ago 3) Having dangerous arrhythmias (atrial fibrillation, etc 4) No history of using relaxation and guided visualization classes and music therapy 5) Having a degree in psychology and related courses 6) having a bitter memory of the sea 7) any pain and calmness or calmness habit 8) a history of participation in training courses on stress and yoga control at the previous 6 months 9 ) The history of a new crisis, such as the death of a first-degree relative, a self-divorce or his/her parent`s at the previous 6 months

#### **Age**

From **20 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

2

#### **Groups that have been masked**

- Investigator

#### **Sample size**

Target sample size: **84**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Eligible individuals are randomly assigned to the 3 groups according to block randomized allocation. Random sequences will be generated using the Random Generator program. Based on the random block method and considering the six blocks, 14 blocks will be generated for 84 patients. To hide the randomization process from sealed envelopes, which are numbered sequentially will be used and the envelope related to each person will be opened only after the verification of the inclusion criteria eligible and sign in the consent form.

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

Registration and sequencing of random allocation is done by the collaborator of the methodology of the project and the assignment of interventions by the collaborator of the project, which is blinded to the control and

intervention group.

#### **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**

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

##### **Approval date**

2019-05-29, 1398/03/08

##### **Ethics committee reference number**

IR.GUMS.REC.1398.084

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Patients before cardiac bypass surgery

##### **ICD-10 code**

I97.1

##### **ICD-10 code description**

Other functional disturbances following cardiac surgery

### **Primary outcomes**

#### **1**

##### **Description**

Anxiety

##### **Timepoint**

7 days before the operation and immediately at the end of listening to Bach nonverbal music CD and guided imagery CD auditory

##### **Method of measurement**

Spielberger questionnaire

### **Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: 7days prior to cardiac surgery will be listened to Bach nonverbal music CD for 7 sessions during 18-20 mintutes.

#### Category

Other

### 2

#### Description

Intervention group:7days prior to cardiac surgery will be listened to guided imagery CD for 7 sessions during 18-20 mintutes.

#### Category

Other

### 3

#### Description

Control group: A group that receives routin nursing care without intervention and just get training during treatment by nurse .

#### Category

Other

## 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

Namjoo Ave., Shahid Siadati St., Rasht., Technology & Research Vice-chancellor of University

#### City

Rasht

#### Province

Guilan

#### Postal code

41446-66949

#### Phone

+98 31 3333 2058

#### Fax

+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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## 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

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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**

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available