

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of guided imagery with diaphragmatic breathing on anxiety in patients scheduled for coronary angiography

#### Protocol summary

##### Study aim

Determining and comparing the effects of guided imagery and diaphragmatic breathing on anxiety in patients candidate for coronary angiography

##### Design

This is a randomized clinical trial with a control group and parallel group design, without blinding, using block randomization, with a total sample size of 90 patients.

##### Settings and conduct

This study will be conducted at Shahid Rajaie Cardiovascular Institute on patients who are candidates for coronary angiography, including two intervention groups and one control group. A demographic questionnaire will be completed by all three groups prior to angiography. The Hospital Anxiety and Depression Scale (HADS-Anxiety) questionnaire will be completed by the three groups before and after the intervention. In addition, heart rate and blood pressure will be measured before and after the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years; willingness to cooperate; full consciousness; ability to read and write; being a candidate for coronary angiography. Exclusion criteria: Hearing problem; Use of anti-anxiety medications in the past 6 months; History of psychiatric illness; Substance addiction; Use of stress reduction methods before the start of this study; Patients with moderate to severe anxiety.

##### Intervention groups

Intervention group 1: The diaphragmatic breathing group will listen to an audio file teaching diaphragmatic breathing one hour prior to angiography. Intervention group 2: The guided imagery group will listen to a guided imagery audio file one hour prior to angiography. Control group: The control group will receive routine care.

##### Main outcome variables

Anxiety, heart rate, blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250715066498N1**

Registration date: **2025-09-14, 1404/06/23**

Registration timing: **prospective**

Last update: **2025-09-14, 1404/06/23**

Update count: **0**

##### Registration date

2025-09-14, 1404/06/23

##### Registrant information

##### Name

Zeinab Khorshidi Nikbin

##### Name of organization / entity

Shaheed Rajaie Cardiovascular, Medical & Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8800 2416

##### Email address

f.shabani@rhi.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-09-23, 1404/07/01

##### Expected recruitment end date

2025-11-21, 1404/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of guided imagery with diaphragmatic breathing on anxiety in patients scheduled for coronary angiography

## Public title

Comparison of guided imagery and diaphragmatic breathing on anxiety

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over 18 years Willingness to cooperate Full alertness Literacy in reading and writing Candidate for coronary angiography

### Exclusion criteria:

Hearing problem Use of anti-anxiety medications in the past 6 months History of psychiatric illness Substance addiction Use of stress reduction methods before the start of this study Patients with moderate to severe anxiety

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The block randomization method with blocks of size three was applied, with a total sample size of 30 participants in each of the three groups (Diaphragmatic Breathing [A], Guided Imagery [B], and Control [C]), resulting in 90 participants overall. A total of 30 blocks of three participants each were used. Within each block, the three participants were randomly assigned to the three groups so that each group received exactly one participant per block. The possible allocations for each block were the six permutations: (A, B, C), (A, C, B), (B, A, C), (B, C, A), (C, A, B), and (C, B, A). One of these permutations was then randomly selected using a random number table.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Shahid Rajaei Cardiovascular Medical and Research Center

##### Street address

Ministry of Health and Medical Education, Central Headquarters, Block A, 13th Floor, Simaye Iran St., Shahrak-e Gharb (Qods), Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1995614331

##### Approval date

2025-07-07, 1404/04/16

##### Ethics committee reference number

IR.RHC.REC.1404.067

## Health conditions studied

### 1

#### Description of health condition studied

Patients who are candidates for coronary angiography

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Anxiety is measured before and after the intervention of diaphragmatic breathing and guided imagery. It is also measured before and after routine care in the control group

#### Method of measurement

Anxiety is evaluated through the Hospital Anxiety and Depression Scale (HADS) questionnaire.

### 2

#### Description

Blood pressure measurement

#### Timepoint

Blood pressure will be measured before and after the interventions of diaphragmatic breathing and guided imagery. It will also be measured before and after routine care in the control group.

#### Method of measurement

using manual blood pressure monitor

### 3

#### Description

Heart rate

### Timepoint

Heart rate will be measured before and after the interventions of diaphragmatic breathing and guided imagery. It will also be measured before and after routine care in the control group.

### Method of measurement

Pulse oximeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: The diaphragmatic breathing group, one hour prior to angiography, after obtaining informed consent, completing the demographic questionnaire and the HADS anxiety questionnaire, and measuring heart rate and blood pressure, will listen for approximately 20 minutes to an audio file containing the psychologist's guided instructions, soothing music, and step-by-step diaphragmatic breathing training. After the intervention, the anxiety questionnaire will be completed again, and heart rate and blood pressure will be re-measured.

#### Category

Other

### 2

#### Description

Intervention group 2: The guided imagery group, one hour prior to angiography, after obtaining informed consent, completing the demographic questionnaire and the HADS anxiety questionnaire, and measuring heart rate and blood pressure, will listen for approximately 20 minutes to an audio file containing the psychologist's guided instructions, soothing music, and step-by-step guided imagery training. Following the intervention, the anxiety questionnaire will be completed again, and heart rate and blood pressure will be re-measured.

#### Category

Other

### 3

#### Description

Control group: The control group, one hour prior to angiography, after obtaining informed consent, completing the demographic questionnaire and the HADS anxiety questionnaire, and measuring heart rate and blood pressure, will receive routine care. Following the routine care, the anxiety questionnaire, heart rate, and blood pressure will be measured again.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shaheed Rajaie Cardiovascular, Medical & Research Center

##### Full name of responsible person

Zeynab Khorshidi Nikbin

##### Street address

Shahid Rajaei Medical, Research, and Educational Cardiovascular Center; Corner of Niayesh and Vali Asr (A.S.) Street; Next to Mellat Park; Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1995614331

##### Phone

+98 21 23921

##### Email

khbehnaz1996@gmail.com

##### Web page address

<https://www.rhc.ac.ir/fa>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Rajaei Cardiovascular Medical, Research, and Educational Center

##### Full name of responsible person

Dr. Saeedeh Mazloumzadeh

##### Street address

Shahid Rajaei Medical, Research, and Educational Cardiovascular Center; Corner of Niayesh and Vali Asr (A.S.) Street; Next to Mellat Park; Tehran

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+98 21 23921

##### Email

info@rhi.ac.ir

##### Web page address

<https://www.rhc.ac.ir/fa>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Rajaei Cardiovascular Medical, Research, and Educational Center

#### 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**

Shahid Rajaei Cardiovascular Medical, Research, and Educational Center

**Full name of responsible person**

Zeynab Khorshidi Nikbin

**Position**

Master's student in Critical Care Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Rajaei Cardiovascular Medical, Research, and Educational Center Corner of Niayesh and Vali Asr (A.S.) Street, Next to Mellat Park, Tehran, Iran

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Rajaei Cardiovascular Medical, Research, and Educational Center

**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Rajaei Cardiovascular Medical, Research, and Educational Center

**Full name of responsible person**

Zeynab Khorshidi Nikbin

**Position**

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**Latest degree**

Bachelor

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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