

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 Mazlounzadeh

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

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Province

Tehran

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1995614331

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+98 21 23921

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info@rhi.ac.ir

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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

City

Tehran

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1995614331

Phone

+98 21 23921

Email

khbehnaz1996@gmail.com

Person responsible for scientific 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

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khbehnaz1996@gmail.com

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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

Master's student in Critical Care Nursing

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Email

khbehnaz1996@gmail.com

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