Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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

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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

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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

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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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Web page address

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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

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Person responsible for updating data

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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