

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Compare the effectiveness of virtual reality and rhythmic breathing on anxiety and physiologic indices of patients candidate for coronary angiography

Protocol summary

Study aim

Determination and comparison of the effect of sedative images based on virtual reality and rhythmic breathing on anxiety and physiological indices of candidates for coronary angiography

Design

Clinical trial with three intervention and parallel groups, single blind and randomized with a sample size of 60 people

Settings and conduct

This single-blind clinical trial will be performed on patients undergoing coronary angiography in the cardiac care. After applying the inclusion criteria and purposive Sampling, Patients will be divided into three groups by simple random sampling. Group 1: Respiratory technique by the Suha Pranayama method, Group 2: Relaxation images using virtual reality and Group III: Control group. The intensity of anxiety will be measured using a Spielberger standard questionnaire and physiological indicators using a monitoring device. Variables will be measured in each of the three groups before intervention, half an hour after intervention. Measurement of anxiety intensity and physiological indicators will be done by the uninformed researcher of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hemodynamic status stability Age over 18 years No history of previous coronary angiography
Non-inclusion criteria: Hearing and visual impairment Presence of mental disorders The use of sedatives or anti-anxiety medications within 72 hours prior to the intervention Drug addiction
Exclusion criteria: Disturbance and instability in vital signs during the study Patient's deterioration during the study

Intervention groups

Patients will be divided into three groups. The first group will receive respiratory intervention. The second group

will receive virtual reality intervention. The third group will be considered as the control group.

Main outcome variables

Anxiety intensity Physiological Indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150106020581N3**

Registration date: **2019-04-26, 1398/02/06**

Registration timing: **retrospective**

Last update: **2019-04-26, 1398/02/06**

Update count: **0**

Registration date

2019-04-26, 1398/02/06

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3028

Email address

abbasi.ali@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effectiveness of virtual reality and rhythmic breathing on anxiety and physiologic indices of patients candidate for coronary angiography

Public title

Compare the effectiveness of virtual reality and rhythmic breathing on anxiety and physiologic indices of patients candidate for coronary angiography

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Stable hemodynamic status Be alert The first time performing coronary artery angiography

Exclusion criteria:

Opioid addiction Psychopathy Hyperthyroidism and respiratory problems Hearing and vision defects

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation of patients to the three groups of virtual reality, breathing techniques and control will be performed using permutation block.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data collection will be conducted by other researchers (researcher blinding)

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zahedan university of medical

sciences

Street address

Administrative complex of University of Medical Sciences, Khalij Fars blvd, Dr Hesabi square, Zahedan city

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.ZAUMS.REC.1397.435

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Physiologic indices

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety intensity

Timepoint

Before intervention.Half an hour after intervention.

Method of measurement

State-Trait Anxiety Inventory

2**Description**

Systolic blood pressure

Timepoint

Before intervention.Half an hour after intervention.

Method of measurement

CardioSet LX110 monitoring device

3**Description**

Diastolic blood pressure

Timepoint

Before intervention.Half an hour after intervention.

Method of measurement

CardioSet LX110 monitoring device

4

Description

Heart rate

Timepoint

Before intervention.Half an hour after intervention.

Method of measurement

CardioSet LX110 monitoring device

5

Description

Respiratory rate

Timepoint

Before intervention.Half an hour after intervention.

Method of measurement

CardioSet LX110 monitoring device

6

Description

Percentage of saturated oxygen in the blood

Timepoint

Before intervention.Half an hour after intervention.

Method of measurement

CardioSet LX110 monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The respiratory technique will be performed by the Sukha Pranayama method.In this method, the subjects sit on the chair and perfectly relax themselves.Then they close their eyes and ask them to think nothing but the process of breathing.We ask the patient to inhale and exhale slowly and regularly do.Inhale and exhale through the nostrils will be done.The patient will be asked to bring energy into the lungs during the inhalation and expel tension, stress and illness during exhalation.Each breathing phase will last for 5 seconds, and a total respiratory cycle will last 10 seconds.6 breaths per minute will be implemented.This breathing technique will run for 5 consecutive minutes.

Category

Rehabilitation

2

Description

Intervention group: In this group virtual reality intervention will be implemented.For patients, sedation images will be displayed for 5 minutes using the virtual reality camera.

Category

Rehabilitation

3

Description

Control group: Patients in the control group will receive routine care prior to angiography.Measurement of variables such as patients in the intervention group will be done in the control group.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ali ebn abitaleb hospital

Full name of responsible person

Faezeh Pouryousef

Street address

Ali ebn abitaleb hospital, Slamati Blvd, Persian Gulf Highway, Zahedan city

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Dr noormuhammad bakhshani

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Zahedan University of Medical Sciences, Khalije Fars Blvd, Dr Hesabi Square, Zahedan city

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bakhshani@zaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Faezeh Pouryousef

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street addressBehdasht blvd, Faculty of Nursing and Midwifery,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Faezeh Pouryousef

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Nurse

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Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

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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