

# 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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9816743111

**Phone**

+98 54 3329 5570

**Email**

fpouryousef@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr noormuhammad bakhshani

**Street address**

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

**City**

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**Phone**

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**Email**

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 address**Behdasht blvd, Faculty of Nursing and Midwifery,  
Zahedan city**City**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

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**Position**

Nurse

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

Zahedan University of Medical Sciences

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**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