

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Distraction Technique Using the Virtual Reality on Cardiopulmonary Parameters, Level of Pain and Anxiety in Patients after Percutaneous Coronary Intervention

#### Protocol summary

##### Study aim

To assess cardiopulmonary parameters, level of pain and anxiety in patients after percutaneous coronary intervention PCI. To determine the effect of distraction technique using the virtual reality on cardiopulmonary parameters, and level of pain and anxiety in patients after percutaneous coronary intervention PCI. To find out the relationship between the effect of distraction technique using the virtual reality on cardiopulmonary parameters, and level of pain and anxiety with patients' demographic and clinical data.

##### Design

interventional

##### Settings and conduct

At the Kerbala Center for Cardiac Diseases and Surgery and AL-Imam AL-Hassan AL-Mujtaba Teaching Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: A patient who was admitted to the hospital following percutaneous coronary intervention. Males and females who are at least eighteen years old. Patients who are open to taking part in the research. Exclusion Criteria: Young children under the age of eighteen. Individuals involved in diagnostic catheterization. Individuals with impaired hearing and vision abilities. Patients who experienced hematoma, hemorrhage, arrhythmia, asystole, or other postoperative complications or postponed. Pilot study participant's.

##### Intervention groups

A study group of 72 patients had to be present, (The trial group received the intervention regimen, which consisted of a 15-minute virtual reality program following percutaneous coronary intervention).

##### Main outcome variables

Pain and Anxiety levels.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241114063711N1**

Registration date: **2024-11-18, 1403/08/28**

Registration timing: **prospective**

Last update: **2024-11-18, 1403/08/28**

Update count: **0**

##### Registration date

2024-11-18, 1403/08/28

##### Registrant information

##### Name

Ali Hassan

##### Name of organization / entity

University of kerbala college of nursing

##### Country

Iraq

##### Phone

+964 782 342 9547

##### Email address

ali.ibrahim@s.uokerbala.edu.iq

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-11-25, 1403/09/05

##### Expected recruitment end date

2025-01-09, 1403/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effect of Distraction Technique Using the Virtual Reality on Cardiopulmonary Parameters, Level of Pain and Anxiety in Patients after Percutaneous Coronary Intervention

### Public title

Effect of Distraction Technique Using the Virtual Reality on Cardiopulmonary Parameters, Level of Pain and Anxiety in Patients after Percutaneous Coronary Intervention

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

A patient who was admitted to the hospital following percutaneous coronary intervention. Males and females who are at least eighteen years old. Patients who are open to taking part in the research. Patients with verbal communication skills and intellectual capacity. Individuals without hearing or vision impairments.

#### Exclusion criteria:

Young children under the age of eighteen. Individuals involved in diagnostic catheterization. Individuals with impaired hearing and vision abilities. Patients who experienced hematoma, hemorrhage, arrhythmia, asystole, or other postoperative complications or postponed. Pilot study participants. Patients decline to take part in the trial.

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **72**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In order to maintain a transparent and scientific-based randomization process, simple randomization will be used in assigning participants (individuals: percutaneous coronary intervention patients), to intervention (virtual reality program) and control groups, patients who received percutaneous coronary intervention at the Kerbala Center for Cardiac Diseases and Surgery and AL-Imam AL-Hassan AL-Mujtaba Teaching Hospital were chosen at random (simple random sampling). A study group of 72 patients had to be present, and a control group of 72 patients was chosen. (The trial group received the intervention regimen, which consisted of a 15-minute virtual reality program following percutaneous coronary intervention).

### 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

Ethics committee in College of Nursing at University of Kerbala

##### Street address

Bab-ALTuareg

##### City

Kerbala City

##### Postal code

56001

#### Approval date

2024-10-27, 1403/08/06

#### Ethics committee reference number

uok.oon.24.050

## Health conditions studied

### 1

#### Description of health condition studied

Cardiac Diseases

#### ICD-10 code

I25.11

#### ICD-10 code description

Atherosclerotic heart disease of native coronary artery with angina pectoris

## Primary outcomes

### 1

#### Description

The primary outcome variable is the level of pain and anxiety that can be changed based on virtual reality.

#### Timepoint

fifteen minutes after intervention directly

#### Method of measurement

The Visual analogue scale (VAS) for pain aoutcom.

### 2

#### Description

The primary outcome variable is the level of anxiety that can be changed based on virtual reality

#### Timepoint

fifteen minutes after intervention directly

#### Method of measurement

The Visual analogue scale (VAS-A) for anxiety aoutcom.

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: After percutaneous coronary intervention, the virtual reality headset as part of this protocol. After putting the patient in a semi-fowler and sitting position, the virtual reality goggles are worn for fifteen minutes. After that, a variety of soothing 3D videos are shown, including a natural video with soothing music. The patient has the option to stop or switch the chosen video at any moment.

### Category

Other

2

### Description

Control group: For the control group, no interventions will be done.

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

AL-Imam AL-Hassan Al-Mujtaba Teaching Hospital

#### Full name of responsible person

Kerbala Health Directorate

#### Street address

Al-Hur

#### City

Kerbala City

#### Postal code

56001

#### Phone

+964 782 342 9547

#### Email

gen.health@moh.gov.iq

2

### Recruitment center

#### Name of recruitment center

Kerbala Center for Cardiac Diseases and Surgery

#### Full name of responsible person

Kerbala Health Directorate

#### Street address

Seef Saad

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#### Postal code

56001

#### Phone

+964 782 342 9547

### Email

gen.health@moh.gov.iq

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

University of Kerbala

#### Full name of responsible person

Ali Hassan Ibrahim Shutnan

#### Street address

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#### City

Kerbala City

#### Postal code

56001

#### Phone

+964 782 342 9547

#### Email

ali.ibrahim@s.uokerbala.edu.iq

#### Web page address

<https://nursing.uokerbala.edu.iq/wp/en/>

### Grant name

### Grant code / Reference number

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

No

### Title of funding source

The author of the trial is the funding source

### 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

Persons

2

### Sponsor

#### Name of organization / entity

University of Kerbala

#### Full name of responsible person

Ali Hassan Ibrahim Shutnan

#### Street address

Kerbala City

#### City

Kerbala City

#### Postal code

56001

#### Phone

+964 782 342 9547

#### Email

ali.ibrahim@s.uokerbala.edu.iq

### Grant name

### Grant code / Reference number

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

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**Title of funding source**

The author of the trial is the funding source

**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**

Persons

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

University of Kerbala

**Full name of responsible person**

Ali Hassan Ibrahim Shutnan

**Position**

Master Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursing

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**Phone**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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

University of Kerbala

**Full name of responsible person**

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**Position**

Master Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursing

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**Postal code**

56001

**Phone**

+964 782 342 9547

**Email**

ali.ibrahim@s.uokerbala.edu.iq

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Effect of Distraction Technique Using the Virtual Reality on Cardiopulmonary Parameters, Level of Pain and Anxiety in Patients after Percutaneous Coronary Intervention

**When the data will become available and for how long**

God Willing, once the article is published, the data will be available after 6 months of publication. If the article will be published in a subscribed journal, the data will be available after one year because of the policy of the subscribed journals.

**To whom data/document is available**

With academic nurses and any researcher who is interested in the data.

**Under which criteria data/document could be used**

The data could be used after getting the permission via email. Also, users need to acknowledge the owner.

**From where data/document is obtainable**

Users can ask for the data and the permission via email is the corresponding author. He will be in contact with whom ask for the data. His email

ali.ibrahim@s.uokerbala.edu.iq Also, works at University of Kerbala/ College of Nursing. The address is Bab-Tuerag, Kerbala, Iraq.

**What processes are involved for a request to access data/document**

Users can ask for the data and the permission via email. Ali is the corresponding author. He will be in contact with whom ask for the data. His email is ali.ibrahim@s.uokerbala.edu.iq

**Comments**