

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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	Not used
Scientific title	Assignment
Effect of Distraction Technique Using the Virtual Reality on Cardiopulmonary Parameters, Level of Pain and Anxiety in Patients after Percutaneous Coronary Intervention	Parallel
	Other design features
	Secondary Ids
	empty
Public title	Ethics committees
Effect of Distraction Technique Using the Virtual Reality on Cardiopulmonary Parameters, Level of Pain and Anxiety in Patients after Percutaneous Coronary Intervention	1
Purpose	Ethics committee
Education/Guidance	Name of ethics committee
Inclusion/Exclusion criteria	Ethics committee in College of Nursing at University of Kerbala
Inclusion criteria:	Street address
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.	Bab-AlTuareg
Exclusion criteria:	City
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.	Kerbala City
Age	Postal code
From 18 years old	56001
Gender	Approval date
Both	2024-10-27, 1403/08/06
Phase	Ethics committee reference number
N/A	uok.oon.24.050
Groups that have been masked	Health conditions studied
No information	1
Sample size	Description of health condition studied
Target sample size: 72	Cardiac Diseases
Randomization (investigator's opinion)	ICD-10 code
Randomized	I25.11
Randomization description	ICD-10 code 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).	Atherosclerotic heart disease of native coronary artery with angina pectoris
Blinding (investigator's opinion)	Primary outcomes
Not blinded	1
Blinding description	Description
Placebo	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

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2

Recruitment center

Name of recruitment center

Kerbala Center for Cardiac Diseases and Surgery

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Kerbala

Full name of responsible person

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Email

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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

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Grant name

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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

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

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Person responsible for updating data

Contact

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Position

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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