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

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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 don.
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
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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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Email
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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

Person responsible for general inquiries

Contact
Name of organization / entity
University of Kerbala
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Ali Hassan Ibrahim Shutnan
Position
Master Student
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Person responsible for updating data

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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