Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Thought Diversion Intervention using Virtual Reality Glasses on Morphine Consumption and Anxiety in Patients After Cardiac Surgery: A Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of virtual reality glasses on morphine consumption and anxiety in patients undergoing cardiac surgery.

Design
This single-blind randomized clinical trial will include 56 patients undergoing heart valve surgery, randomly assigned to a virtual reality intervention or control group using block randomization.

Settings and conduct
This randomized clinical trial will take place at Shahid Rajaee Cardiovascular Institute in Tehran. Patients will be randomly assigned to either the intervention or control group, both of which will receive identical anesthetic protocols. The study will be single-blind, with data on anxiety, pain, and clinical variables being collected and analyzed.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients aged 18-65, post-heart valve surgery, conscious, able to communicate, fluent in Persian, no chronic pain or impairments, and no psychological disorders or phobias. Exclusion Criteria: Unwillingness to continue, clinical deterioration, death, postoperative delirium, need for intra-aortic balloon pump, surgery cancellation/postponement, adrenal disorders, substance abuse, or uncooperative behavior.

Intervention groups
Intervention Group: Received a distraction intervention using virtual reality goggles. Control Group: Received standard daily care without any additional intervention.

Main outcome variables
Primary outcomes include morphine consumption and anxiety levels.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251121068066N7**
Registration date: **2026-01-13, 1404/10/23**
Registration timing: **prospective**

Last update: **2026-01-13, 1404/10/23**
Update count: **0**

Registration date
2026-01-13, 1404/10/23

Registrant information
Name
Atiyeh Hesari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-30, 1404/11/10

Expected recruitment end date
2026-08-16, 1405/05/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Thought Diversion Intervention using Virtual

Reality Glasses on Morphine Consumption and Anxiety in Patients After Cardiac Surgery: A Randomized Clinical Trial

Public title
The Effect of Thought Diversion Intervention using Virtual Reality Glasses on Morphine Consumption and Anxiety in Patients After Cardiac Surgery: A Randomized Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients admitted to the intensive care unit following heart valve surgery. Age between 18 and 65 years. Conscious and able to communicate verbally. Fluent in Persian. Willingness to cooperate in the study. No chronic pain prior to surgery. No speech, hearing, or vision impairments. No psychological diseases. No claustrophobia or acrophobia.

Exclusion criteria:
Unwillingness to continue cooperation. Clinical deterioration or decreased level of consciousness. Death during the study. Postoperative delirium. Patients undergoing intraaortic balloon pump. Surgery canceled or postponed. Adrenal gland disorder. Substance abuse or addiction. Uncooperative behavior interfering with study procedures.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be conducted continuously and randomly. Eligible patients will be assigned to two groups: the virtual reality group (Group A) and the control group (Group B) using a randomized block allocation method. The randomization list will only be accessible to the person responsible for educating the patients and will not be known to other personnel, including the surgeon, anesthesiologist, data collectors, or statisticians.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will use single-blind or partial blinding, where the surgeon, anesthesiologist, data collectors, and statisticians are blinded to the group assignment. The patient educator is the only individual who will have access to the randomization list. Although patients will be aware of their assigned group, the same anesthetic drug protocol will be applied to both groups to minimize potential confounding factors during the assessment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Specialized Committee on Ethics in Biomedical Research

Street address
Shahid Rajaee Cardiovascular Educational, Research, and Treatment Institute, Corner of Niayesh, Next to Mellat Park, Vali Asr Street (Aj), Tehran

City
Tehran

Province
Tehran

Postal code
۱۹۹۵۶۱۴۳۳۱

Approval date
2025-12-01, 1404/09/10

Ethics committee reference number
IR.RHC.REC.1404.181

Health conditions studied

1

Description of health condition studied
Postoperative anxiety

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Morphine Consumption: The amount of morphine consumed by the patient, recorded via the PCA (Patient-Controlled Analgesia) system, measured and compared before the first and second interventions.

Timepoint
Before the first intervention and before the second intervention (with a 6-hour interval).

Method of measurement
The dose taken via the Patient-Controlled Analgesia (PCA) device will be recorded by the researcher or staff at the designated time points.

2

Description
Anxiety Level: Anxiety is defined as a state of intense and persistent worry or fear about potential future events. It is a common psychological response to changes and new experiences, often characterized by heightened nervousness and apprehension.

Timepoint
Anxiety will be assessed at three time points: before the intervention, immediately after the first intervention, and immediately after the second intervention.

Method of measurement
Anxiety levels were assessed using the Situational Anxiety Inventory (STAI-Y1), consisting of 20 items on a 4-point Likert scale (from very low to very high). The total score ranges from 20 to 80.

3

Description
Pain Level: Pain is defined as “an unpleasant sensory and emotional experience associated with or resembling actual or potential tissue damage,” where sensory perceptions, emotional, and cognitive processes interact in a complex manner.

Timepoint
Pain levels will be assessed at three time points: before the intervention, immediately after the first intervention, and immediately after the second intervention.

Method of measurement
Pain intensity is measured using a Visual Analog Scale (VAS), represented by a 100-mm line, with scores ranging from 0 (no pain) to 100 (worst possible pain).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive two virtual reality intervention sessions in the intensive care unit, starting 24 hours after endotracheal extubation. Each session will last 15 minutes, with a 6-hour interval between sessions. During the intervention, patients will lie in a quiet environment and use virtual reality goggles displaying 3D natural landscapes (e.g., sea and beach) accompanied by relaxing natural sounds (e.g., wind, waves, birds) via headphones. The anesthesia and PCA protocols will be identical to those used in the control group.

Category
Treatment - Other

2

Description
Control group: Patients will receive routine daily care in the intensive care unit without any additional intervention. The anesthesia and PCA protocols will be the same as those used in the intervention group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Intensive Care Units of Shahid Rajaee Cardiovascular Institute, Tehran

Full name of responsible person
Dr. Fereydoun Nouhi

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Shahid Rajaee Cardiovascular Educational, Research, and Treatment Institute, Corner of Niayesh, Next to Mellat Park, Vali Asr Street (Aj), Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Rajaee Cardiovascular Research and Treatment Center

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Shahid Rajaee Cardiovascular Research and Treatment Center

Proportion provided by this source

50

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
Shahid Rajaee Cardiovascular Educational, Research and Treatment Institute

Full name of responsible person
Hamed Jamshidi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Anesthesiology

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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