

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of virtual reality-based play therapy on pain intensity and anxiety in patients with open heart surgery

Protocol summary

Study aim

Determining and comparing the average pain score and anxiety of open heart surgery patients before and after the intervention in the intervention and control groups

Design

The clinical trial has a control group, with a parallel group, randomized on 100 patients. Blocking of 4 will be used for randomization.

Settings and conduct

In the open heart special care department, the day after the operation, patients who meet the inclusion criteria will be included in the study. For the intervention group, virtual visualization will be performed with the help of special glasses, while the control group will receive routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: full consciousness (relative to place, time and person); RASS +1 to -1; having sinus rhythm during the intervention. Non-entry criteria: receiving anti-anxiety or sedative drugs 24 hours before and after the intervention.

Intervention groups

In the intervention group, a game based on virtual reality will be implemented with the help of glasses for the patients of the intervention group. The control group will receive routine ward care.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111203008286N11**

Registration date: **2022-08-29, 1401/06/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-29, 1401/06/07**

Update count: **0**

Registration date

2022-08-29, 1401/06/07

Registrant information

Name

Fatemeh Bahramnezhad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

fatemeh_bahramnezhad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual reality-based play therapy on pain intensity and anxiety in patients with open heart surgery

Public title

Virtual reality-based play therapy on pain and anxiety in patients with open heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Full awareness (relative to place, time and person) RASS +1 to -1 Having sinus rhythm during intervention

Exclusion criteria:
Occurrence of anxiety symptoms such as fear of closed spaces History of neurological disorders (such as movement, vision and hearing disabilities) Use of respiratory equipment such as artificial respiration Receiving anti-anxiety or sedative drugs 24 hours before and after the intervention Severe dysfunction of non-cardiovascular systems (for example, chronic renal failure)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In the sampling method, samples with inclusion criteria will be divided into two test and control groups by random allocation by block method. In this way, the research samples will be randomly placed in blocks of four, and to form these blocks of four, cards are used that have already been placed in four blocks by the computer randomly into two test and control groups. In this way, in each block of 4, two control samples and two test samples are placed with random permutations. In this study, 33 blocks of 4 blocks will be allocated according to 90 research samples. For example, in the first block of 4, volunteer number one will be in the control group (B) and volunteer number two will be in the control group (A).

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 of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Boulevard, Quds corner

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.TUMS.FNM.REC.1401.025

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Pain

Timepoint

Before, one month after

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Anxiety

Timepoint

Before, one month after

Method of measurement

Spielberger questionnaire

Intervention groups

1

Description

Intervention group: using virtual reality with the help of 3D glasses In this case, the day after the surgery, the patient will put the special glasses on his eyes for 20 minutes and first he will see a forest with the sound of birds. Then he will cross this path and enter a The environment becomes snowy, in this case, you have to put snowballs on top of each other and make a snowman. By making a snowman, if there is no error, his page will become a rain star.

Category

Rehabilitation

2

Description

Control group: In this group, no intervention is done for the patient and the patient will only receive routine ward care.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital (RA) Tehran

Full name of responsible person

FatemehBahramnezhad

Street address

Nosrat st. Tohid sq.

City

Tehran

Province

Tehran

Postal code

141973317

Phone

+98 21 6105 4416

Email

bahramnezhad.f@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotohi

Street address

6th Floor, Research and Technology Vice-Chancellor,
Corner of Qods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4125

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Bahramnezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Dr. Mirkhani Street (Nusrat East), Tohid Square,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4416

Email

bahramnezhad.f@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Bahramnezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Dr. Mirkhani Street (Nusrat East), Tohid Square,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4416

Email

bahramnezhad.f@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Bahramnezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Dr. Mirkhani Street (Nusrat East), Tohid Square,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4416

Email

bahramnezhad.f@gmail.com

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

Yes - There is 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

Title and more details about the data/document

Some information about the primary data is releasable

When the data will become available and for how long

One year after the publication of the article

To whom data/document is available

Researchers working in academic departments

Under which criteria data/document could be used

Secondary analysis

From where data/document is obtainable

E-mail: bahramnezhad.f@gmail.com

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

Send an email and explain why it needs this data

Comments