Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effectiveness of Virtual Reality Therapy on Hospital Anxiety and Depression and Patient's Stress Before Open Heart Surgery

Protocol summary

Study aim
Effectiveness of Virtual Reality Therapy on Hospital Anxiety and Depression and Patients' Stress Before Open Heart Surgery

Design
This clinical trial is a single-blind intervention and control group.

Settings and conduct
Content of treatment sessions Introduction to Virtual Reality Therapy / Relaxation Training / Presentation and Pre-Test Running forest and mountain virtual reality software Run the sea virtual reality software Running nature's virtual reality software Re-run forest and mountain virtual reality software Reboot Virtual Reality Software Re-run nature's virtual reality software The test will be carried out at the Specialty Heart Center of Martyr Dr. Chamran Isfahan.

Participants/Inclusion and exclusion criteria
Entry criteria: Waiting for open heart surgery - Age 40 - 50 - Reading and writing skills Exit Criteria: - The patient is diagnosed with acute psychiatric disorders - unwillingness to attend treatment sessions - Missing more than two sessions

Intervention groups
Sample size In the sampling, 30 people were selected by available sampling and randomly assigned into two experimental (n = 15) and control (n = 15) groups. After assigning the subjects to the two experimental and control groups, the experimental group will receive 8-minute virtual reality therapy sessions while the control group will receive no intervention. All subjects will complete the research questionnaires once before the intervention, once thereafter and once after 7 days. The summary of the Virtual Reality Therapy content is given in the table below.

Main outcome variables
Stress Hospital anxiety Hospital Depression Virtual Reality Therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191230045953N1**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **prospective**

Last update: **2020-02-01, 1398/11/12**
Update count: **0**

Registration date
2020-02-01, 1398/11/12

Registrant information

Name
sanaz ahmadi

Name of organization / entity
The university of Eslamic Isfahan(Khurasgan)

Country
Iran (Islamic Republic of)

Phone
+98 31 3661 0668

Email address
sanaz.ahmadi.psychology@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-04, 1398/11/15

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effectiveness of Virtual Reality Therapy on Hospital Anxiety and Depression and Patient's Stress Before Open Heart Surgery

Public title
The Effectiveness of Virtual Reality Therapy on Hospital Anxiety and Depression and Patient's Stress Before Open Heart Surgery

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age 40-50 years Reading and writing skills Waiting for open heart surgery

Exclusion criteria:
Out of age 40-50 years Illiteracy Acute mental disorders diagnosed by a psychiatrist or psychologist Absence in medical sessions more than 2 times

Age
From **40 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomized selection of the intervention and control groups is simple random.This random selection is obtained from the list of patients available at the hospital admission.

Blinding (investigator's opinion)
Single blinded

Blinding description
For this process, the patient's name is not mentioned on the questionnaire and the other person collects the data except the researcher who does the treatment.

Placebo
Not used

Assignment
Other

Other design features
Using Virtual Reality Technology in the Treatment of Stress, Anxiety and Depression

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University - Isfahan (Khorasgan) Branch

Street address
Sheikh Mofid Street. Alley 20. Plate 34

City
Isfahan

Province
Isfehan

Postal code
9164960858

Approval date
2020-01-08, 1398/10/18

Ethics committee reference number
IR.IAU.KHUISF.REC.1398.255

Health conditions studied

1

Description of health condition studied
Hospital Depression - Hospital Anxiety - Stress

ICD-10 code

ICD-10 code description
F40

Primary outcomes

1

Description
Hospital Anxiety-Hospital Depression-Stress

Timepoint
All subjects will complete the follow-up questionnaires once before the intervention, once after the intervention and once after 7 days after open heart surgery.

Method of measurement
The method of measurement is done by questionnaire. Two questionnaires are DASS-21 and HADS.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: 15 patients are waiting for open heart surgery with 7 sessions of treatment.

Category
Treatment - Devices

2

Description
Control group: Fifteen patients are awaiting open heart

surgery with no cure.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Chamran Specialty Heart Hospital

Full name of responsible person
Sanaz Ahmadi

Street address
Sheikh Mofid Street. Alley 20. No. 34

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
gholamreza manshaee

Street address
Khorasgan area. Arghavaniyreh Street. Isfahan Islamic Azad University (Khorasgan)

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Phone
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Fax
+98 31 3535 4060

Email
info@khuisf.ac.ir

Web page address
http://new.khuisf.ac.ir/index.aspx?tempname=newmain&lang=1&sub=1

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Isfahan University of Medical Sciences

Proportion provided by this source
20

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
Islamic Azad University

Full name of responsible person
Sanaz Ahmadi

Position
Postgraduate student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

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Position
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Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for updating data

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Email

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
Not applicable

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