

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Isfahan

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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Email

sanaz.ahmadi.psychology@gmail.com

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)

City

Isfahan

Province

Isfahan

Postal code

81551-39998

Phone

+98 31 3535 4001

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

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

sanaz ahmadi

Position

University student

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