

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8164960858

**Phone**

+98 31 3661 0668

**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

sanaz.ahmadi.psychology@gmail.com

### Contact

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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