

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison the effect of two methods of virtual reality and multimedia on the anxiety and stress in companions of patients underlying angiography

Protocol summary

Study aim

Comparison of the effectiveness of the world's top two technologies on reducing the level of anxiety and stress of patients

Design

Clinical trial with control group with randomized double-blind blind groups in 3 groups of 70 people

Settings and conduct

The patient's family in the cardiac ward will complete the questionnaires the night before the operation and receive routine training. They will be placed before the patient leaves the operating room and then by a constant but unfamiliar nurse with people before the patient leaves the stress and anxiety questionnaires will be completed and then the data will be processed by an unfamiliar analyzer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: first-degree relativity with the patient. Having informed consent. Age 18-60. Be on the next day's operation list. ! Non-entry conditions: Causing neurological complications of headache and dizziness. vision or hearing problems . neurological and motion sickness.

Intervention groups

The first study group underwent virtual reality and routine training the night before surgery The second study group underwent multimedia and routine training the night before surgery The third study group as a control did only routine training the night before surgery

Main outcome variables

Determining the anxiety and stress of companions. Determining the effect of Multi Media on reducing anxiety and stress. Determining the effect of virtual reality on reducing anxiety and stress.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051552N1**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **prospective**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

Registration date

2022-01-29, 1400/11/09

Registrant information

Name

roshanak efekhar ardebili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3371 9148

Email address

r.efekhar@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-04-04, 1401/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two methods of virtual reality and multimedia on the anxiety and stress in companions of patients underlying angiography

Public title

Comparison of the effect of virtual reality and multimedia methods on anxiety and stress

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

First class patient family Having conscious satisfaction
Age over 18 and under 60 Families of patients on the operation list the next day

Exclusion criteria:

Having effective vision and hearing problems in communication Join the treatment team Having neurological illnesses (for at least 6 months) and motion sickness

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population is randomly divided into 6 groups by triple blocking method. How to arrange the groups as ABC ACB BAC BCA CAB CBA by assigning each letter to each study group. These makeups will be placed inside a container. At each sampling, they will be randomly selected from inside the container and will be placed in a group according to the letter arrangement of each sample with the priority of the letters.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, a regular nurse will be used to complete the questionnaires of the subjects who are not aware of the study group and also the data analyzer is not aware of the type of groups of individuals.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

Street address

Administrative complex of Ardabil University of Medical Sciences.,End of Daneshgah St.

City

Ardabil

Province

Ardabil

Postal code

5618985991

Approval date

2021-08-23, 1400/06/01

Ethics committee reference number

IR.ARUMS.REC.1400.166

Health conditions studied

1

Description of health condition studied

Stress and anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stress score in Harry Stress Questionnaire

Timepoint

The sections of completing the questionnaire are the night before the operation and then tomorrow (the day of the operation) after the intervention with virtual reality and multimedia in the intervention groups before the patient leaves the operating room.

Method of measurement

Harry Stress Inventory Standard Questionnaire

2

Description

anxiety score in Speilberger Questionnaire

Timepoint

The sections of completing the questionnaire are the night before the operation and then tomorrow (the day of the operation) after the intervention with virtual reality and multimedia in the intervention groups before the patient leaves the operating room.

Method of measurement

The State-Trait Anxiety Inventory (Spielberger)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Virtual reality (people in this group received routine training by a regular nurse the night before the operation and the day of the operation after the patient enters the operating room will be under virtual reality with sedative content for 10 minutes and before The patient will leave the operating room and the questionnaires will be completed.)

Category

Prevention

2

Description

Intervention group 2: under multimedia (people in this group received routine training by a regular nurse the night before the operation and the day of the operation after the patient enters the operating room will be under multimedia with sedative content for 10 minutes and before The patient will leave the operating room to complete the questionnaires.)

Category

Prevention

3

Description

Control group: Control group: People in this group will receive routine training by a regular nurse the night before the operation and the day of the operation will be without intervention and the questionnaires will be completed before the patient leaves the operating room.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Roshanak Eftekhari Ardebili

Street address

Imam Khomeini Hospital.,Atai St.

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<https://www.arums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Farhad Pourfarzi

Street address

School of Nursing and Midwifery., between Hafez and Saadi Bridge intersections.,Highway shohada.

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fnm-ardabil@arums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Roshanak Eftekhari ardebili

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Latest degree

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Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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 data, such as information about the main outcome, can be shared after people are not identified. زمان

When the data will become available and for how long

The access period starts 1 year after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Can be requested for academic studies as well as for use in clinical treatment

From where data/document is obtainable

Applicants can apply for documentation by sending an e-mail to the main researcher of the study, Dr. Nasser Mozaffari, at naser.m51@gmail.com

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

In order to receive the documents, a written letter must be sent from the place of application as well as the full details of the requesting person or university by email to the main researcher, and after review, it must be answered within 2-3 weeks.

Comments