

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of virtual reality with two approaches of distraction and educational film on anxiety and hemodynamic parameters in patients undergoing cardiac angiography

Protocol summary

Study aim

Comparison of the effect of virtual reality with two approaches of distraction and educational film on anxiety and hemodynamic parameters in patients undergoing cardiac angiography

Design

Clinical trial with control group, with parallel group;
Double blind, randomized

Settings and conduct

This study is being performed at Razi Hospital in Birjand, South Khorasan Province. 90 patients are randomly divided into three groups of candidates for angiographic surgery of the control group and the group receiving the video of deviance and educational video. Then, the level of anxiety and hemodynamics of patients in the three groups before and after angiography will be examined by the nurse without knowing the patient's group.

Participants/Inclusion and exclusion criteria

Criteria for entering the study will include a candidate for angiography, a willingness to participate in the study, an age range of 35 to 70 years, and the necessary visual and auditory health to participate in the study. The criteria for leaving the study include incomplete completion of the questionnaire by patients and patients' refusal to continue participating in the study, phobia of natural landscapes and wildlife, use of anti-anxiety drugs, neurological disorders, and patients with variable and critical hemodynamic conditions.

Intervention groups

Patients will be randomly assigned to be divided into one of three groups: intervention one (educational video), intervention two (including mental deviation film), or control group.

Main outcome variables

Anxiety Patients' hemodynamics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N6**

Registration date: **2020-07-20, 1399/04/30**

Registration timing: **retrospective**

Last update: **2020-07-20, 1399/04/30**

Update count: **0**

Registration date

2020-07-20, 1399/04/30

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of virtual reality with two approaches of distraction and educational film on anxiety and hemodynamic parameters in patients undergoing cardiac angiography

Public title

The Impact of Virtual Reality on Anxiety and Hemodynamic Indicators Patients Candidate for Cardiac Angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for angiography Having a conscious consent to participate in the study Age range 35 to 70 years Having visual and auditory health

Exclusion criteria:

Incomplete completion of the questionnaire by patients The patient refuses to continue studying Fear of natural landscapes and wildlife Taking anti-anxiety medications Suffering from neurological diseases Patients with variable and critical hemodynamic conditions

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The placement of individuals in each group will be randomly simple and blocked. In one of the three groups, intervention A (educational video), intervention B (including deviant film) or control group C will be placed. First, various triple blocks are created on different cards (ABC, CAB, CBA, BCA, BAC and ACB). One of these blocks is randomly selected and patients will be divided into one of three groups A, B or C. Then randomization is performed for other patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Data Analyzer: Without knowing the type of video shown to patients Outcome Assessor: The ward nurse asks patients questions without knowing the type of medication received and records them in the relevant checklist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari BLV

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2020-02-10, 1398/11/21

Ethics committee reference number

IR.BUMS.REC.1398.360

Health conditions studied

1

Description of health condition studied

cardiovascular disease

ICD-10 code

A52.0

ICD-10 code description

Cardiovascular and cerebrovascular syphilis

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after angiography

Method of measurement

Spielberger Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 30 patients are candidates for angiography who are not shown a film.

Category

Rehabilitation

2

Description

Thirty patients are candidates for angiography for whom a virtual film with entertaining content and nature documentaries is shown to them through three-dimensional glasses, which is similar to the length of the patient film (5 minutes in Persian) in the intervention group.

Category

Rehabilitation

3

Description

30 patients are candidates for angiography surgery. The 3D educational video about the process of angiography surgery, which is the source of this video, is a valid medical books, authoritative articles and cardiologists. This video will be for 5 minutes in Persian. Regarding the environment for performing angiography and the equipment that will be encountered at the beginning of the patient's arrival and after work.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital in Birjand

Full name of responsible person

Mohammad Ali Sadeghi

Street address

Ghaffari Str

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaghegh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Davoud Oudi

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Person responsible for updating data

Contact

Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Zabihullah Mohaghegh
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no need to publish individual patient information

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

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