

# 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

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717811674

##### Phone

+98 56 3232 3232

##### Email

oabstudent@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Dr. Tooba Kazemi

##### Street address

Ghaffari Str

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717811674

##### Phone

+98 56 3238 1200

##### Email

oabstudent@gmail.com

##### 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

General Practitioner

##### Street address

Moallem Blvd

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717811674

##### Phone

+98 56 3232 3232

##### Email

oabstudent@gmail.com

## Person responsible for scientific inquiries

### Contact

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Davoud Oudi

##### Position

Member of the Faculty

**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Moallem Str  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717811674  
**Phone**  
+98 56 3232 3232  
**Email**  
oabstudent@gmail.com

## Person responsible for updating data

### 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**  
General Practitioner  
**Street address**  
Moallem Str  
**City**

Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717811674  
**Phone**  
+98 56 3232 3232  
**Email**  
oabstudent@gmail.com

## 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