

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of face-to-face and video-based education on anxiety of patients undergoing Angiography in Alzahra Heart Hospital in Shiraz during 2021

Protocol summary

Study aim

Determining the effectiveness of two methods of training based on video and face-to-face training on patients' anxiety before angiography referred to Alzahra Heart Hospital in Shiraz in 2021

Design

The clinical trial has two intervention groups, with parallel groups, two-way blind, randomized, the first phase is performed on 228 patients. The randomization list is performed based on the random permutation block method.

Settings and conduct

The procedure is as follows: The researcher at Al-Zahra Heart Hospital identifies angiography candidates who have the inclusion criteria. Based on the accident table, the patients are placed in the face-to-face and video-based training groups. Obtains informed written consent. Prior to angiography, patients' demographic characteristics and anxiety scores are first assessed using a Spielberger questionnaire. 5 minutes of questioning and answering between the patient and the researcher. In the second intervention group, all educational content is taught face to face. Then, questions and answers are asked for 5 minutes between the patient and the researcher. People who analyze the results are blind to the study

Participants/Inclusion and exclusion criteria

Admission requirements include full consent to participate in the study, age between 30 and 65 years, literacy, marriage. Exclusion criteria also include reluctance to cooperate and participate in the study, history of psychological problems, use of sedatives and painkillers before angiography, patients who need emergency surgery, and patients with a previous history of angiography.

Intervention groups

Intervention group A: Patients who are trained by video

before angiography. Intervention group B: Patients who are trained in face-to-face angiography before surgery

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220226054131N1**

Registration date: **2022-03-06, 1400/12/15**

Registration timing: **prospective**

Last update: **2022-03-06, 1400/12/15**

Update count: **0**

Registration date

2022-03-06, 1400/12/15

Registrant information

Name

Maryam Kiali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-12, 1400/12/21

Expected recruitment end date

2022-06-11, 1401/03/21

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of face-to-face and video-based education on anxiety of patients undergoing Angiography in Alzahra Heart Hospital in Shiraz during 2021

Public title
Investigating the effect of video education on reducing patients' anxiety before surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients in the age range of 30 to 65 years Patients undergoing angiography for the first time They are literate They are married
Exclusion criteria:
 Patients who need emergency surgery They used sedatives They have psychological problems Patients who have previously had angiography

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **228**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done according to the random permutation block method. According to the randomization table provided by the professor of statistics to the researcher, patients are divided into 10 groups of 24 and in each group 12 people are in group A and 12 people in group B, which is arranged by accident. They arrange the placement of patients in the group with the help of a researcher who is blind to the study. The researcher has no choice in choosing patients in groups A and B. And patients are blind to the study and have no choice in group placement. If necessary, a crash list will be provided to you. And the data analysis will be done step by step until a meaningful result is achieved.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and their caregivers are blind in the study. The placement of patients based on the randomization table is done by the ward secretary, who is blind to the study. And the person analyzing the results is not aware of the intervention and control group.

Placebo
Not used

Assignment
Parallel

Other design features
The sample size is done in a sequential group method. In this method, sampling is done in 10 stages, in each stage, 24 people, 12 people from group A and 12 people from group B, are analyzed and the analyzes are performed analytically. In the first stage, 24 people are analyzed and in the next stage, another 24 people are added and the analysis is performed on 48 people and the fear of the sampling result continues.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Modares Boulevard, Kalantari St., Alley 22

City

Shiaz

Province

Fars

Postal code

7155674455

Approval date

2022-02-20, 1400/12/01

Ethics committee reference number

IR.SUMS.REC.1400.790

2

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7155674455

Approval date

2022-02-20, 1400/12/01

Ethics committee reference number

IR.SUMS.REC.1400.790

Health conditions studied

1

Description of health condition studied

Anxiety of patients before angiography

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of reducing overt and covert anxiety in preoperative patients with video training intervention

Timepoint

Measurement of anxiety the day before the operation before the intervention and on the day of the operation after the educational intervention

Method of measurement

The Spielberger Questionnaire, which measures both latent and overt anxiety.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group is patients who are trained in angiography procedures and care by video method. The second intervention group of patients who are trained in face-to-face angiography procedures and care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Heart Hospital, Shiraz

Full name of responsible person

Maryam.kiali

Street address

Sibouyeh Blvd. Alzahra Heart Hospital Clinic Unit

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Kiali

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The main consequence is the possibility of sharing

When the data will become available and for how long

Start of access period 6 months after printing the results

To whom data/document is available

Available to researchers and health education supervisors

Under which criteria data/document could be used

For use in promoting health education

From where data/document is obtainable

By email to Maryam Kiali Maryam.kiali2016@gmail.com

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

Make your request via email and the information will be provided to them after authentication.

Comments

no