Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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)

Phone

+98 71 3726 9793

Email address

maryam.kiali2016@gmail.com

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

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

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
City
Shiraz
Province
Fars
Postal code
7164954937
Phone
+98 71 3735 5032
Fax
Email
Maryam.kiali2016@gmail.com
Web page address
https://hfhc.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpour
Street address
Zand St. - Next to the Red Crescent - Central Building of Shiraz University of Medical Sciences - Seventh Floor
City
Shiraz
Province
Fars
Postal code
7164954937
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
Web page address
https://research.sums.ac.ir
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
Street address
No,22,West Kalantari ,Modares Blvd ,Parvaz Town
City

Shiraz
Province
Fars
Postal code
7155674455
Phone
+98 71 3726 9793
Fax
Email
maryam.kiali2016@gmail.com

Person responsible for scientific 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
Street address
No,22,West Kalantari ,Modares Blvd ,Parvaz Town
City
Shiraz
Province
Fars
Postal code
7155674455
Phone
+98 71 3726 9793
Fax
Email
maryam.kiali2016@gmail.com

Person responsible for updating data

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
Street address
No,22,West Kalantari ,Modares Blvd ,Parvaz Town
City
Shiraz
Province
Fars
Postal code
7155674455
Phone
+98 71 3726 9793
Fax
Email
maryam.kiali2016@gmail.com

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