Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of teach-back and distraction with virtual reality on patients' anxiety before coronary angiography

Protocol summary

Study aim
Determining the effect of teach-back combined with virtual reality distraction on anxiety in patients undergoing coronary angiography

Design
Clinical trial with factorial design and parallel groups, four groups: virtual reality, teach-back, combined and control, randomized by block method, sample size includes 112 people (28 people in each group), single-blind

Settings and conduct
Reducing anxiety before angiography, Post-angiology Department, Razi Hospital, Birjand Informed consent was obtained and inclusion criteria were met, and participants were assigned to four groups (virtual reality,teach-back combined, and control). Educational interventions were administered before angiography and under identical conditions. Pre- and post-intervention anxiety was assessed with a standardized questionnaire. The assessor and data analyst were blinded to group assignment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 25 to 85 years, first-time angiography , non-emergency , ability to communicate verbally, no vision or hearing problems, no drug addiction, no use of sedatives, no epilepsy or obvious mental illness, not part of the treatment team. Exclusion criteria: patient death, procedure cancellation , change to emergency, unwillingness to continue cooperation, waiting time less than 20 minutes

Intervention groups
Virtual Reality (VR) : A 3D video of the nature is shown to the patient for 20 minutes through virtual reality glasses before angiography. teach-back : Participants receive teach-back, which includes information, preparations before, during, and after angiography. Combined (VR +teach-back): Participants receive virtual reality education and teach-back simultaneously. Control Group: Receive usual ward care

Main outcome variables
Anxiety before angiography; change in anxiety level after the intervention

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260121068627N1**
Registration date: **2026-02-13, 1404/11/24**
Registration timing: **prospective**

Last update: **2026-02-13, 1404/11/24**
Update count: **0**

Registration date
2026-02-13, 1404/11/24

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-02-20, 1404/12/01
Expected recruitment end date
2026-04-21, 1405/02/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of teach-back and distraction with virtual reality on patients’ anxiety before coronary angiography

Public title

The effect of training and virtual reality glasses on patients' anxiety before cardiac angiography

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study and completing the written informed consent form Age 25 to 85 years The patient's angiography is not an emergency Ability to communicate verbally Candidate for the angiography procedure for the first time No vision or hearing problems No drug addiction No use of sedatives No epilepsy or obvious mental illness (based on the patient's self-report) No anti-anxiety medication before the procedure The patient is not part of the treatment team

Exclusion criteria:

Death of the patient Cancellation of the procedure during the intervention Change of the patient's condition to emergency for any reason (e.g., arrhythmia) Unwillingness to continue cooperation Short waiting time (less than 20 minutes).

Age

From **25 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be designed as a randomized clinical trial with four parallel groups. After identifying eligible patients and obtaining written informed consent, participants will be assigned to one of four study groups. Randomization Method (Time-Block Randomization) This study will use a time-block randomization method. In this way, the study period will be divided into predetermined time blocks (for example, weekly or monthly), and in each time block, only one of the four study groups will be considered as the assigned group. At the end of each time block, the group assignment will change, and this process will continue until the desired sample size is completed in all four groups. The order of group assignment to time blocks will be determined randomly. This method will be used to facilitate the implementation of the intervention, prevent interference between interventions, and reduce information contamination between groups, and is classified as a quasi-randomized method. Randomization unit The randomization unit in this study will be the individual; however, the allocation of individuals will be based on time blocks, meaning that all patients admitted in any given time period will be placed in the same group assigned to that time block. Randomization strata In this study, stratified randomization will not be performed, and background variables such as age, gender, or baseline anxiety severity will not be considered in the group allocation process. Randomization tool The order of allocation of the four study groups to time blocks will be determined using a random number table or statistical software (such as SPSS). This process will be performed by a researcher independent of the intervention implementation team. How to construct a random sequence First, the time blocks of the study will be defined. Then, using random numbers, the sequence of allocation of the four study groups to these time blocks will be randomly generated. Patients will be assigned to the assigned group in the order they enter the study and based on the relevant time block. Allocation Concealment Given the nature of time randomization, complete concealment of allocation at the individual level will not be possible; however, the sequence of allocation of groups to time blocks will be prepared in advance and maintained by the researcher responsible for randomization, and the interventionists will not be aware of the group allocation for that interval until the beginning of each time block. This will be done to reduce selection bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be designed as a single-blind study with blinding of the outcome assessor and data analyst. Participants (patients): Participants will be aware of their inclusion in the study and their allocation to one of the four study groups, and written informed consent will be obtained from all of them. The knowledge of participation in the study will not be hidden from the patients, as this is not ethically permissible. Given the nature of the intervention (feedback-based training and/or virtual reality), it will not be possible to blind the patients to the type of intervention they receive. However, patients will not be informed of the research hypotheses, comparisons between groups, and expected outcomes, and they will be asked to refrain from disclosing details of the intervention when completing the research instruments. Principal Investigator: The principal investigator will be aware of the group allocation of patients due to his/her direct role in the design, organization, and implementation of the interventions; however, he/she will not participate in the process of collecting outcome data and statistical analysis to avoid bias. Healthcare personnel: Therapeutic personnel (physicians and nurses in the angiography department) who will be responsible for routine patient care will not be involved in the randomization process and allocation of patients to the four study groups and will not be aware of the type of educational intervention received by the patients. Routine care will be provided to all patients in

all four groups according to the department's standard protocol. Data collectors and outcome assessors: Data collection related to study outcomes, including patient anxiety, will be performed by an individual or individuals who will not be aware of the group allocation of participants to the four study groups. Outcome assessment will be performed based on standard instruments and using anonymous codes for the groups to maintain blinding of the assessors. Data analysts: Statistical analysis of the data will be performed by a researcher who will not be aware of the type of intervention and allocation of patients to the four study groups and the data will be provided to him/her in coded form. Data Safety and Monitoring Committee (DSMC): Due to the non-invasive and low-risk nature of educational and virtual reality interventions, an independent data safety and monitoring committee will not be formed; however, any potential complications will be recorded and monitored continuously during the study. Drafters of the article: A draft of the article will be prepared based on the coded data after data collection and statistical analysis are completed to avoid bias in the interpretation of the results.

Placebo

Not used

Assignment

Factorial

Other design features

This study is conducted as a randomized clinical trial with a factorial design. Participants are allocated into four groups: virtual reality, feedback-oriented education, combined intervention, and control. Block randomization is used, and both the outcome assessor and data analyst are blinded to group allocation. All interventions are delivered under similar conditions prior to coronary angiography.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of birjand University of Medical Sciences

Street address

No. 78, between Nasrin 5 and 7, Ghafari St.

City

Birjand

Province

South Khorasan

Postal code

9717916717

Approval date

2025-08-26, 1404/06/04

Ethics committee reference number

IR.BUMS.REC.1404.165

Health conditions studied

1

Description of health condition studied

Patients who are candidates for angiography

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score on the Spielberger Situational Anxiety Inventory

Timepoint

Anxiety was measured at the beginning of the study (before the intervention) and 5 minutes before entering the lab coat room, in 4 groups.

Method of measurement

Spielberger Situational Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: We converted a 20-minute nature film from YouTube into a 3D format that can be played on virtual reality glasses using programming. We submitted the film to the approval of the cardiologist of the hospital under study. For patients who are candidates for angiography, we will show the film with special glasses for one session, 5 minutes before entering the angiography room, with their consent.Training content:video from nature

Category

N/A

2

Description

Second intervention group: Educational materials including care before, during, and after angiography that are understandable to patients were prepared by the researcher and approved by the professors and cardiologists of the studied hospital. During a 30-45 minute session, 1 hour before entering the angiography room, the researcher will provide training using a feedback-based training method and the patient will be asked questions until he/she answers 80% of the questions correctly. The training will be repeated.Training content:Educating patients who are candidates for coronary angiography• What is cardiac angiography?Angiography is only a diagnostic method, not a treatment, that provides complete information about the patient's cardiac condition and is considered a

low-risk method.Angiography is basically the injection of contrast material into the veins and cavities of the heart and simultaneous X-ray imaging to create an image of the same vessel or cavity in the angiography images. In this way, if there is a stenosis or blockage in the path of the vein or cavities of the heart, the contrast material will not reach those areas and therefore an image of these areas will not be created.To perform angiography, one of the available peripheral veins, such as the femoral artery in the groin or the radial artery in the wrist, is used. Through this vein, long, hollow tubes called "catheters" are guided to the heart, and the rest of the angiography work is performed through these catheters.Possible complications include:Damage to blood vessels, including rupture or bleedingInfection or bruising at the catheter siteAllergic reaction to the dye or contrast usedKidney damage from the dye or contrast usedBlood clots that can lead to stroke or heart attack• Reason for angiographyDiagnosis of coronary artery disease (blockage or narrowing of the arteries)Assess the severity and location of the blockage to decide on treatment (medication, stent, bypass surgery)Investigate the cause of chest pain, shortness of breath, or abnormal heart test resultsEvaluate the condition of the arteries in patients with acute coronary syndrome (ACS) or unstable angina• Preparations before angiographyFasting: Avoid eating solid and heavy foods for at least 4 hours before the procedure. Fluids and liquid foods such as soup are not contraindicated.Medications: Tell your doctor a complete list of medications you are taking (dose and name).Anticoagulants (blood thinners): Your doctor will give you specific instructions on how to stop or adjust your medication before surgery. Never stop your medication without consulting your doctor.Your doctor will adjust your dose of warfarin depending on the reason for taking it.Do not take zaleplon the day before surgery or apixaban the day of surgery.Oral anticoagulants such as aspirin and Plavix are not contraindicated.Metformin (for diabetes): Usually must be stopped 24 to 48 hours before surgery as directed by your doctor (due to the risk of kidney failure after injection of the contrast agent).Currently, depending on the type of contrast agent, metformin does not need to be stopped.If you have diabetes and are taking insulin, you may need to adjust your insulin dose on the day of surgery. Your primary care doctor can help you with this adjustment.Blood pressure and thyroid medications: You can usually take them with a small amount of water the morning of surgery, but be sure to check with your doctor.Allergies: Be sure to tell your doctor about any allergies to medications, especially to iodine or contrast media.Tests: CBC, BUN, Cr, coagulation tests (PT, INR, PTT), blood sugar. These tests can help you determine how well your kidneys and liver are working. They can also show how well your blood is clotting.Catheter site preparation: Trim hair from the upper half of both thighs to the navel (do not shave)Be sure to shower on the day of surgery and wash the catheter site with soap and water.Remove any jewelry, glasses, contacts, or hairpins before surgery.• Care and procedure during angiographyLocation: The procedure is performed in the cardiac catheterization room ("cat lab"). The patient lies on a cat lab table. Heart rate, blood pressure, and oxygen are monitored.Awake: You are usually awake during the procedure and may receive a sedative to reduce stress.Catheter insertion: The radial (wrist) or femoral (groin) artery area is numbed and the catheter is inserted through an artery (vein).Common sensations:You may feel some pressure or mild pain where the catheter is inserted.Duration of the procedure: Usually 20–45 minutes.The treatment team constantly monitors the patient's vital signs.During the angiogram, the doctor will ask you to take a deep breath and hold it.During the angiogram, you may feel hot or warm in your body, which is caused by the injection of the contrast material. You may also feel nauseous at times, which is normal for some people, so there is no need to worry.Your doctor may ask you to cough during angiography, which is to increase your heart rate and, as a result, the contrast material will be expelled from your vessels more quickly.• Post-angiography careCatheter insertion site: Keep the catheter insertion area clean and dry.Absolute rest:In the femoral method (leg angiography): After angiography, stay in bed for 8 hours and do not get up. Try to keep your leg straight and motionless. Do not bend the angiographic leg, move slowly to the back with help.Two sandbags are placed, the first bag should be left on the dressing for one hour and the second bag for 4-6 hours.The area is bandaged with pressure.Inform the nurse if the dressing area becomes hot, wet, or painful.Stay in bed for up to 6 hours, and use a bedpan if you need to use the bathroom.For the first 7 days after the operation, do not strain during bowel movements and use the toilet to prevent bleeding from the catheter insertion site.In the radial method (hand angiography): In the angiography room, a special cuff is placed around the patient's arm, and the air inside is reduced every 30 minutes by the nurse. When the air is completely evacuated, the cuff is opened 1 hour later and a dressing is placed, and the dressing is removed after 12 hours.Do not lift heavy weights with the arm that has undergone angiography for up to 1 week.Bath: From the

Category

N/A

3

Description

Third intervention group: Combination group - will receive both interventions one and two

Category

N/A

4

Description

Control group: Will receive routine ward care, including training provided by the shift nurse for pre- and post-angiography care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi hospital
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Sponsors / Funding sources

1

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Full name of responsible person
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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

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Latest degree
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
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
All data is potentially shareable after de-identification
When the data will become available and for how long
Access period starts 6 months after results are published.
To whom data/document is available
The data will only be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Providing a valid code of ethics
From where data/document is obtainable
Email address: hosseinpoorsara53@gmail.com
What processes are involved for a request to access data/document
Send email
Comments