Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of distraction through virtual reality glasses and aromatherapy during angiography on patients' pain and anxiety

Protocol summary

Study aim
Determining and comparing the effects of distraction through virtual reality glasses with aromatherapy during angiography on patients' pain and anxiety

Design
A randomized, double-blind clinical trial with two intervention groups and one control group.

Settings and conduct
The location of this study is the Angiography Department of Ali Ibn Abi Taleb Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the study, stable hemodynamic status (no cardiac dysrhythmias and MI, arterial blood oxygen saturation greater than 80%), age range 25 to 60 years, first-time angiography. Exclusion criteria: hearing, vision, and smell impairment, mental disorders, use of sedatives.

Intervention groups
Demographic and Spielberger Anxiety Questionnaires will be completed 15 minutes before the patient enters the angiography room. In the virtual reality group, patients will wear virtual reality goggles 10 minutes before and during the angiography. The displayed content will include a relaxing environment with soft music. In the aromatherapy group, patients will inhale the scent of lavender oil through a pad soaked in 3 drops of lavender oil that is attached to the patient's collar 10 minutes before and during the angiography. In the control group, patients will not receive any intervention and will undergo angiography according to the usual hospital procedure, except that the goggles without the film will be used as a placebo. Immediately after the angiography is completed, the Spielberger Anxiety Questionnaire will be completed again, and the patient's pain will also be measured with a numerical pain scale.

Main outcome variables
Pain Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131228015965N26**
Registration date: **2025-05-20, 1404/02/30**
Registration timing: **prospective**

Last update: **2025-05-20, 1404/02/30**
Update count: **0**

Registration date
2025-05-20, 1404/02/30

Registrant information

Name
Majid Kazemi

Name of organization / entity
Rafsanjan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-20, 1404/03/30

Expected recruitment end date
2025-09-21, 1404/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effects of distraction through virtual reality glasses and aromatherapy during angiography on patients' pain and anxiety

Public title
Comparing the effects of distraction through virtual reality glasses and aromatherapy during angiography on patients' pain and anxiety

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Performing angiography for the first time Stable hemodynamic status (no cardiac dysrhythmias or MI, arterial blood oxygen saturation greater than 80%) Age range 25 to 60 years

Exclusion criteria:
Hearing, vision, or smell impairment Mental disorders Taking sedatives

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were selected by convenience sampling, and then eligible patients meeting the inclusion criteria were divided into one of three groups: virtual reality, aromatherapy, or control through block random assignment.

Blinding (investigator's opinion)
Double blinded

Blinding description
It is impossible to completely blind the participants in the study due to the specific scents of the oils used in aromatherapy and the use of glasses. In this study, to ensure the accuracy and precision of the assessments, the pain and anxiety assessor will be completely blinded. This person will have no knowledge of the type of treatment each patient receives and his only task will be to assess the level of pain and anxiety of the patients based on their reports. The assessments will be carried out using standard pain and anxiety questionnaires that will be completed anonymously and without any reference to the type of treatment. Also, the data analyst will not know the names of the groups because the names of the groups in the SPSS software will be written from number 1 to 3 and the original names of the groups will not be written.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Rafsanjan University of Medical Sciences

Street address
Imam Ali Blvd

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2025-05-14, 1404/02/24

Ethics committee reference number
1404.016.IR.RUMS.REC

Health conditions studied

1

Description of health condition studied
Pain and anxiety caused by angiography

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Anxiety

Timepoint
15 minutes before and immediately after completion of angiography

Method of measurement
Spielberger Anxiety Questionnaire

2

Description
Pain

Timepoint
immediately after completion of angiography

Method of measurement
Numeric Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the virtual reality group, patients wore virtual reality goggles 10 minutes before and during the angiography. The content displayed included a relaxing environment with soft music.
Category
Treatment - Other

2

Description
Intervention group: In the aromatherapy group, patients inhale the scent of lavender oil 10 minutes before and during the angiography through a pad soaked in 3 drops of lavender oil that is attached to the patient's collar.
Category
Treatment - Other

3

Description
Control group: In the control group, patients do not receive any intervention and undergo angiography according to the hospital's usual procedure, with the difference that glasses without a film will be used as a placebo.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abitalib Rafsanjan Hospital
Full name of responsible person
Majid Kazemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Reza Vaziri nejad
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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
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Majid Kazemi
Position
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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
No more information available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available