Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of the effects of showing comedy videos and foot reflexology massage on anxiety and physiological indices in patients undergoing coronary angiography

Protocol summary

Study aim
Determining and comparing the effects of showing a comedy videos and reflexology foot massage on anxiety and physiological indicators of patients who are candidates for coronary angiography

Design
Clinical trial with a humorous film and foot reflexology group and control with parallel groups, single-blinded and randomized with the random block method in the random allocation software, which includes 6 blocks of 24 and the sample size is 144 people. For the phase part of this study, there is no drug combination (not valid)

Settings and conduct
his study will be conducted in the post ccu of the Payambar Aazam Educational, Research, and Therapeutic Center in Bandar Abbas before entering the angiography room and meeting the study entry requirements. After data collection, the results analyst will not be aware of the allocation of groups to intervention and control, and the study is single-blind.

Participants/Inclusion and exclusion criteria
Patients 18 years of age and older, conscious of time, place, and person, willing to participate in the study and provide informed consent, and no symptoms of myocardial infarction and emergency angiography

Intervention groups
The group watches a comedy film (selected from a list of films compiled by the researcher from popular and highly viewed Persian comedy films on social media and excerpts from old Iranian Broadcasting Corporation comedy series that are free of scenes of violence, conflict, and profanity, while preserving human dignity and Islamic decency) and the other intervention group will receive foot reflexology at specific points. The control group will follow the ward routine without intervention.

Main outcome variables
anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251213068317N1**
Registration date: **2025-12-16, 1404/09/25**
Registration timing: **prospective**

Last update: **2025-12-16, 1404/09/25**
Update count: **0**

Registration date
2025-12-16, 1404/09/25

Registrant information

Name
Ali Rezvani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 4244 1427

Email address
alirezvani7030@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-29, 1404/10/08

Expected recruitment end date
2026-07-30, 1405/05/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effects of showing comedy videos and foot reflexology massage on anxiety and physiological indices in patients undergoing coronary angiography

Public title
A comparative study of the effects of showing comedy videos and foot reflexology massage on anxiety and physiological indices in patients undergoing coronary angiography

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 18 years and older Aware of time, place, and person Willingness to participate in the study and informed consent Heart patients waiting for coronary angiography First angiography experience Ability to see and hear Stable hemodynamic status before angiography Ability to communicate verbally and understand Persian language Patients with normal lower limbs (no previous varicose vein surgery, edema, open wounds, bruises, fungus, peripheral neuropathy, deep vein thrombosis, etc.) Spielberger State Anxiety Score equal to or above 43 (moderate and above)

Exclusion criteria:
Presence of symptoms of myocardial infarction and emergency angiography Having severe acute or chronic disorders of the liver, brain, kidney, digestive and respiratory diseases, and other severe physical illnesses Presence of a pacemaker Presence of an obstacle at the site of pressure application (wounds, skin diseases, etc.)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
Each individual will be assigned to one of three intervention and control groups using the random block method, taking into account 6 blocks of 24 (random allocation list) that will be obtained in the random allocation software. The block randomization method will be used to allocate patients to the three groups.A letter (A, comedy group, B, foot reflexology group, C, control group) will be randomly assigned to each block. These letters will be written on slips of paper and placed in a container. One slip of paper will be randomly removed and the new combination will be recorded.This process will be repeated until all patients have been assigned. For each patient, the assignment to groups will be determined using sealed envelopes, and the number assigned to each patient will be consecutively assigned to maintain balance at each stage. In this way, no one, including the researchers or the patients, will know the patient's assignment to groups before the envelope is opened.This allocation concealment method will ensure fair and unbiased patient allocation.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, due to the nature of the interventions (comedy film group, foot reflexology group), blinding of participants and facilitators will not be possible. Patients will be aware of the type of intervention they are receiving, as these interventions are clearly different.However, the results analyst will not be aware of the allocation of patients to different groups to reduce bias in the analysis. The lack of blinding of participants and operators will be considered as a limitation of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
University of Medical Sciences Campus - Vice President for Research and Technology، Beginning of Imam Hossein Blvd، Bandar Abbas

City
Bandar Abbas

Province
Hormozgan

Postal code
0000000000

Approval date
2025-12-13, 1404/09/22

Ethics committee reference number
IR.HUMS.REC.1404.286

Health conditions studied

1

Description of health condition studied
The subject of the study is not the disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety in this study refers to the score obtained from the Spielberger Anxiety Questionnaire (state section), which will be completed by the samples in two sessions. It should be noted that this questionnaire has two sections: state (situational) and trait (personality).
Timepoint
Anxiety with Spielberger Anxiety Questionnaire (state section) on two occasions before the intervention and ten minutes after the intervention.
Method of measurement
Spielberger Anxiety Inventory (State Section)

Secondary outcomes

1

Description
Physiological indicators (heart rate, oxygen saturation)
Timepoint
On three occasions including before, during and ten minutes after the intervention
Method of measurement
Pulse oximetry device

Intervention groups

1

Description
Intervention group: In the comedy video category (selected from a list of films compiled by the researcher from popular and highly viewed Persian comedy video on virtual networks and excerpts from old Iranian Broadcasting Corporation comedy series that are free of scenes of violence, conflict, and profanity, while preserving human dignity and Islamic decency) The video will be shown to the audience for twenty minutes first thing in the morning before the individual enters the coronary angiography department. In this group, the video will be played via a Samsung tablet and hands-free while the subject is lying on the ward bed, with the tablet in the hands of the research sample.
Category
N/A

2

Description
Intervention group: Patients in the reflexology group will receive a twenty-minute massage in a cardiac aftercare room with minimal environmental stimuli (such as light and sound) and privacy for patients, by a female researcher for women and by a male researcher for men. They will be asked to lie down on a comfortable bed with their legs extended on the bed.After washing and warming their hands, the researcher will use olive oil to lubricate their hands and facilitate the reflexology intervention on the patient's feet. The intervention will begin on the left foot for ten minutes, and the massage will be performed at a slow pace, regular rhythm, and at a depth that is tolerable for the patient.The solar plexus, pituitary gland, and heart reflex points will be massaged using the thumb (which, according to reflexology principles, can reduce anxiety), without breaking contact with the skin, and then the same process will be repeated for ten minutes on the right foot.
Category
N/A

3

Description
Control group: In the control group, the operation will be performed without any intervention and according to the ward's routine.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
payambar aazam educational, research, and therapeutic center
Full name of responsible person
Shilan Azizi
Street address
payambar aazam educational, research, and therapeutic center، Islamic Republic Blvd، Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
0000000000
Phone
+98 76 3138 5000
Email
alirezvani7030@agmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Shilan Azizi
Street address
Shahid Chamran Blvd، Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code

0000000000

Phone
+98 76 3333 3280

Email
info@hums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Ali Rezvani

Position
Master's student in internal surgical nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 8, 4th Baharestan Street, Motahari Boulevard, Yazdanshahr, Najafabad

City
Najaf Abad

Province
Isfehan

Postal code
8519738111

Phone
009842441427

Email
alirezvani7030@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Shilan Azizi

Position
Faculty - Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Shahid Chamran Blvd، Bandar Abbas

City
Bandar Abbas

Province
Hormozgan

Postal code
13885-79166

Phone
009876-33333280-4

Email
azizi.sh23@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Ali Rezvani

Position
Master's degree student in internal surgical nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 8, Baharestan 4th Street, Motahari Blvd, Yazdanshahr, Najafabad

City
Najaf Abad

Province
Isfehan

Postal code
8519738111

Phone
009842441427

Email
alirezvani7030@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
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