

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparative study of the effect of aromatherapy with lavender and Benson relaxation technique on anxiety in patients with acute coronary syndrome

Protocol summary

Study aim

Compare the effect of aromatherapy with lavender and Benson relaxation technique on anxiety in patients with acute coronary syndrome

Design

Three groups clinical trials, With a control group, Randomized by senary random block with no permutations with 66 patient

Settings and conduct

96 Patients referring to the cardiac care units of the Rasoul-e-Akram hospitals in Tehran and 15 khordad in Varamin, through continuous sampling will enter to study. Aromatherapy group individuals will inhale the fragrance of two drops of lavender, 2% smeared on 10-10 g of gas for 20 minutes at a distance of 5 cm from the nose. The Benson relaxation method will be performed by the patient on the day after the training. Interventions will take place for two consecutive days. All groups will receive regular care of the unit. The Spielberger anxiety inventory questionnaire will be completed before and immediately after each intervention by the researcher's assistance and by interviewing the participant samples.. Finally, the data collected will be analyzed.

Participants/Inclusion and exclusion criteria

Entrance criteria: 1- Diagnosis of acute coronary syndrome 2- 24-48 hours passed from the time they began to be hospitalized 3- Understanding and speaking in Farsi 4- 18 years of age or older Non entrance criteria: 1- history of allergies, Eczema and allergy to herbal medicines and essential oils according 2- olfactory defects and respiratory illnesses 3- having known psychiatric or anxiety disorders 4-perform Surgical or therapeutic interventions on the day of intervention 5- hearing problems 6-having muscle paralysis 7- addiction to drugs and alcohol 8-Patient expression from having anxiety

Intervention groups

Three groups of aromatherapy, Benson's muscle relaxation and control

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160704028781N3**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **prospective**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

Registration date

2018-04-28, 1397/02/08

Registrant information

Name

Farshad Heidari Beni

Name of organization / entity

Iran University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of aromatherapy with lavender and Benson relaxation technique on anxiety in patients with acute coronary syndrome

Public title
Comparative study of the effect of aromatherapy with lavender and Benson relaxation technique on anxiety in patients with acute coronary syndrome

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of acute coronary syndrome by a cardiologist 24-48 hours from the time they began to be hospitalized
 Understanding and speaking in Farsi to provide contact with the patient 18 years of age or older
 No history of allergies, Eczema and allergy to herbal medicines and essential oils according to the patient's self-report
 No olfactory defects and respiratory illnesses, such as asthma according to patient's self-report
 Failure to have known psychiatric or anxiety disorders according to self-report and examination of the patient's file
 Failure to perform Surgical or therapeutic interventions such as angiography on the day of intervention
 No hearing problems according to patient's self-report
 not having muscle paralysis according to patient's self-report
 non-addiction to drugs and alcohol according to patient's self-report
 expressing patient from having anxiety
Exclusion criteria:
 Patient's death
 Any symptoms of allergy, pain, shortness of breath or disorientation during the intervention
 Transferring the patient from the cardiac care unit to another section

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of allocating samples to the groups will be in a random senary blocked without permutation (16 senary blocks from 96) of each center. In this sampling method, different modes of the three groups using the random numbers table are written on six cards, each card will be placed in an envelopes. These envelopes are placed in a box and the researcher does not know which

groups of research will be selected before choosing the card. The statistician (unaware of the study and the groups) identifies with the removal of one of the envelopes from the box, which of the three patients included in the study will fall into the groups, respectively. The process continues to remove all 6 cards from the box, and again the cards are returned to the box, and this random selection is repeated to provide the desired sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran Medical Sciences University of Medical Sciences

Street address

Iran University of Medical Sciences. Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2018-03-27, 1397/01/07

Ethics committee reference number

IR.IUMS.REC 1396.9511449006

Health conditions studied

1

Description of health condition studied

Acute coronary syndrome

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Anxiety: Anxiety is an unpleasant mental sensation, discomfort and tension. The meaning of anxiety in this

study is a score that patients receive from the Spielberger questionnaire.	
Timepoint	The Spielberger anxiety inventory questionnaire will be completed before and immediately after each intervention by the researcher's assistance and by interviewing the participant samples
Method of measurement	The Spielberger anxiety inventory questionnaire
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group 1:Aromatherapy with lavender:Our point is an aroma of lavender extract in the form of an inhaler, in which people will be asked to smear two drops of 2% lavender smeared on 10-10 cm of gas and inhale it for at least 5 cm distance from the nose for 20 minutes.Patients will do this action Once a day, between 18:00 and 18:00 for two consecutive days.
Category	Rehabilitation
<u>2</u>	
Description	Intervention group 2: Benson relaxation technique: The Benson's muscle relaxation is performed by the patient in six steps. 1- Stay in a comfortable position 2. Close eyes. 3. Expansion the muscles of the body from the tip to the head 4. Performing the inhale through the nose and exhaling through the mouth and whisper the word desired when exhaling. 5- Perform the above steps for 20 minutes, then open the eyes and do not move for a few minutes. 6. Lack of worry and ignoring disturbing thoughts during relaxation. During the intervention, remove the disturbing thoughts from your mind as much as possible and choose a word that has always reminded him of calm, such as (God, love, sea). Instructions for doing these steps will be provided through the MP3 player and headphones. In this audio file, the instructions are set for 20 minutes and there is no need to set the clock to determine the method duration. In this file, 30 seconds before the completion of the technique, a gentle song will be put to inform the patient about the end of the procedure. To perform muscle relaxation by pulling the curtains at the patient's bed, the patient's privacy is observed and the privacy of the person and providing a quiet and silent environment for sitting with the department's officials is coordinated so that nobody gets into the patient's unit. One day after training the procedures In addition to the usual care of the department, Benson's relaxation procedure is performed once a day between the hours (18-20) for two consecutive days by patients and supervised by the researcher.
Category	

Rehabilitation	
<u>3</u>	
Description	Control group: Patients in the control group receive regular care. They are asked to stay on their bed for 20 minutes. Then, the Spielberger Anxiety Inventory will be completed.
Category	N/A
Recruitment centers	
<u>1</u>	
Recruitment center	
Name of recruitment center	Rasoul-e-Akram hospital
Full name of responsible person	Samaneh Sahraei
Street address	Corner of Mansouri Street - Niayesh St. - Sattarkhan - Tehran
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Province	Tehran
Postal code	۱۴۴۵۶۱۳۱۳۱
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<u>2</u>	
Recruitment center	
Name of recruitment center	Shohada 15 khordad
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Sponsors / Funding sources	
<u>1</u>	
Sponsor	
Name of organization / entity	Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Kazem Malakooti

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Samaneh Sahraei

Position

Post Graduate Student in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

General data such as demographic variables and outcomes under study will be published.

When the data will become available and for how long

Get started 6 months after printing results

To whom data/document is available

All researchers working in academic and scientific institutions who want the results of the study will be allowed to receive the data.

Under which criteria data/document could be used

Data can be used to enhance science and use results in research.

From where data/document is obtainable

School of Nursing & Midwifery, Rashid Yasemi St, Vali Asr St, Tehran 00982143651000 nsahraea@gmail.com

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

Once requested, the data will be delivered electronically or in person within one week.

Comments