Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Healing Aromas: The Effects of Lavender and Rosemary Essential Oils on Sleep Quality and Mental Well-Being in Coronary Artery Disease Patients: a Parallel Arm, Randomized, Controlled Trial

Protocol summary

Study aim
Comparing the Effect of Lavender and Rosemary Essential Oil Inhalation and the Simultaneous Use of These Two Scents on Sleep Quality, Anxiety and Depression in Patients Suffering from Coronary Artery Disease

Design
This single-blind randomised clinical trial study will have three intervention groups (lavender aromatherapy, rosemary aromatherapy and simultaneous aromatherapy with these two aromas) and a control group. The study phase is not applicable here. The randomization method will be block randomization on 148 patients.

Settings and conduct
Amol, Iran. single-blind (the data analyst and researcher will be blinded but the data collector and samples will not be blinded). The samples will be randomly divided into three intervention groups and one control group and will be exposed to the aromatic substance three times a day for 20 minutes by pouring 4 drops of the relevant aromatic oil on a piece of gauze and attaching it to the collar. It is done for 30 consecutive days. In the simultaneous aromatherapy group, two drops of lavender oil and two drops of rosemary oil and in the control group, a saline solution will be used.

Participants/Inclusion and exclusion criteria
Entry conditions: suffering from coronary artery disease, obtaining scores of greater than five from the PSQI sleep quality index, able to read and write, EF above 45%, access to social networks Conditions not to enter: having a history of asthma, active mental illness, taking neuropsychiatric drugs, allergies to plants or any seasonal sensitivity, severe pain causing sleep disturbance, smell disturbance

Intervention groups
Aromatherapy with lavender, rosemary, Simultaneous aromatherapy with these two scents and control.

Main outcome variables
Anxiety, depression and sleep quality

General information

Reason for update
The title of the trial was modified due to an effort to choose a more attractive title for publication in reputable journals. The sample size was reduced to 120 samples due to the lack of financial budget and the time limit in carrying out the project. The timing of sampling was changed according to the changes made in the schedules of the respective universities. The end time of the clinical trial was added. By reviewing more literature, a saline solution (0.9% sodium chloride) was used instead of distilled water in the control group.

Acronym

IRCT registration information
IRCT registration number: **IRCT20230702058649N1**
Registration date: **2024-02-10, 1402/11/21**
Registration timing: **prospective**

Last update: **2024-11-27, 1403/09/07**
Update count: **1**

Registration date
2024-02-10, 1402/11/21

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-06-20, 1403/03/31

Actual recruitment start date
2024-02-20, 1402/12/01

Actual recruitment end date
2024-06-25, 1403/04/05

Trial completion date
2024-07-25, 1403/05/04

Scientific title
Healing Aromas: The Effects of Lavender and Rosemary Essential Oils on Sleep Quality and Mental Well-Being in Coronary Artery Disease Patients: a Parallel Arm, Randomized, Controlled Trial

Public title
Effects of Lavender and Rosemary Essential Oils on Sleep Quality and Mental Well-Being in Coronary Artery Disease Patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being diagnosed with coronary artery Disease Having no history of neuropsychiatric disease by self report Having no history of taking psychiatric medications Normal olfactory function Not using benzodiazepines, sedatives and narcotics No history of asthma No history of allergies to plants or any seasonal allergies Absence of severe pain causes sleep disturbance Obtaining scores of greater than five from the PSQI Sleep quality questionnaire Having an ejection fraction above 45% Being able to read and write Access to social media

Exclusion criteria:
Acute pain at the time of completing the questionnaire Any case that causes olfactory disorders during study Showing an allergic reaction to the smell of essential oils Showing discomfort with the smell of essential oils Occurrence of life-threatening complications such as cardiopulmonary resuscitation

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **148**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible people will be selected by the available method and will be placed in three intervention groups and one control group using block randomization method. For this purpose, 37 blocks of 4 will be allocated using www.randomizer.org website, and each block will have 4 random numbers from 1 to 4. Then these blocks will be written on paper and sealed and then randomly one block will be chosen at each turn and people will enter the study in the order written on the paper. In fact, one block of four out of every 37 blocks of four will be randomly selected and the patients, as specified in the block, will divided into these groups: aromatherapy with lavender (1), aromatherapy with rosemary (2), simultaneous aromatherapy with these two aromas (3) and control (4). In this way, four patients (one patient in each group) will be examined each time. For the next time, another block is randomly selected and the patients are divided into one of the four study groups based on the selected block. Some blocks of four will be facing as follows: 2341, 1342, 1234.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the data analyst and the researcher who evaluates the results will be blinded and unaware of the nature of the groups, but the nurse assessor (data collector) will not be blinded. For this purpose, first of all, bottles containing essential oils and distilled water, which are completely similar in appearance, will be provided to the nurse evaluator, and she will randomly give them to the samples. without the researcher and data analyst knowing the nature of the groupings. It should be noted that the distinctive smell of essential oils makes it difficult to blind the study participants.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Science

Street address
No.8 Keshavarz Alley, Keshavarz Blvd, Babol

City
Babol

Province
Mazandaran

Postal code
4716141776

Approval date
2023-10-25, 1402/08/03

Ethics committee reference number

IR.MAZUMS.REC.1402.441

Health conditions studied

1

Description of health condition studied
Coronary Artery disease
ICD-10 code
I20-I25
ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1

Description
Depression score in Cardiac Depression Scale (CDS)
Timepoint
Before the intervention, 14 and 30 days after the start of the intervention
Method of measurement
Cardiac Depression Scale (CDS)

2

Description
Anxiety score in Hospital Anxiety and Depression Scale (HADS)
Timepoint
Before the intervention, 14 and 30 days after the start of the intervention
Method of measurement
Hospital Anxiety and Depression Scale (HADS)

3

Description
Sleep quality score in Pittsburgh Sleep Quality Index (PSQI)
Timepoint
Before the intervention, 14 and 30 days after the start of the intervention
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Aromatherapy with lavender, samples will be exposed to the aromatic substance three times a day at 8 am, 3 pm and 10 pm for 20 minutes by pouring 4 drops of the relevant aromatic oil (provided by Barijesans Company) on a piece of gauze and attaching it to the patient's collar. This will be done for 30 consecutive days.
Category
N/A

2

Description
second intervention group: Aromatherapy with rosemary, samples will be exposed to the aromatic substance three times a day at 8 am, 3 pm and 10 pm for 20 minutes by pouring 4 drops of the relevant aromatic oil (provided by Barijesans Company) on a piece of gauze attached to the patient's collar. This will be done for 30 consecutive days.
Category
N/A

3

Description
The third intervention group: Simultaneous aromatherapy with rosemary and lavender, samples will be exposed to the aromatic substance three times a day at 8 am, 3 pm and 10 pm for 20 minutes by pouring 2 drops of lavender essential oil and 2 drops of rosemary essential oil (provided by Barijesans Company) on a piece of gauze attached to the patient's collar and this will be done for 30 consecutive days.
Category
N/A

4

Description
Control group: Samples will be exposed to the placebo substance three times a day at 8 am, 3 pm and 10 pm for 20 minutes by pouring 4 drops of saline solution on a piece of gauze and attaching it to the patient's collar and this will be done for 30 consecutive days.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiologist doctor's clinic
Full name of responsible person
Dr. Safoura Salehi
Street address
Nikan Building, 15/1 Aftab Alley, Imam Khomeini Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Province
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48157-33971
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+98 11 3304 4000
Email
pajhoheshi@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Fatemeh Ahmadjani
Position
Nursing graduate student
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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
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

Title and more details about the data/document
All demographic information, sleep quality, depression and anxiety of the samples

When the data will become available and for how long
accessible from 2024

To whom data/document is available
The data will be accessible to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data will be used in secondary data analysis or meta-analysis studies.

From where data/document is obtainable
Address of the University: The Headquarters of Mazandaran University of Medical Sciences and Health Services, the beginning of ValiAsr Highway (AJ), Sari Postal code: 48157-33971 Contact phone numbers: 09811-33044000 and 09811-33044001 Contact number of Research and Technology Unit: 09811-34484800 Email of Research and Technology Unit: pajhoheshi@mazums.ac.ir Assistant of Research and Technology Unit: Dr. Pedram Ebrahimnejad

What processes are involved for a request to access data/document
At first, official request will be sent from the applicant organization to Mazandaran University of Medical Sciences, and if there is no legal prohibition, the information will be provided to the researcher with the coordination and permission of the university's Research and Technology Unit.

Comments