Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of lavender (Lavandula angustifolia) inhalation aroma therapy on stress, anxiety and depression of addicts under treatment hospitalized in the addiction wards

Protocol summary

Study aim
Determining the effect of lavender inhalation aromatherapy on stress, anxiety, and depression in addicts undergoing drug treatment

Design
A randomized, controlled clinical trial with parallel groups on 56 addicts. Random allocation software is used for randomization.

Settings and conduct
Addicts hospitalized in the addiction wards of Modares Hospital in Isfahan will be enrolled in the study on a convenience basis and then randomly assigned to two experimental and control groups. Inhaled aromatherapy will be administered to the intervention group. Blinding will not be performed in this study.

Participants/Inclusion and exclusion criteria
Entry requirements: 1. Age 18 years and above 2. Be able to read and write in Persian. 3. Consent to participate in the study. 4. Not be participating in another similar study at the same time as the research. 5. Be under methadone maintenance treatment. Exclusion criteria: 1. History of allergic rhinitis, eczema or known respiratory problems such as asthma 2. Having a cold or any other condition that affects the person's ability to smell. 3. History of lavender allergy (skin or inhalation) as self-reported and tested

Intervention groups
For the intervention group, in addition to receiving drug treatment and routine care, aromatherapy with lavender will be performed. In the intervention group, the samples participating in the study will undergo aromatherapy with lavender essential oil for 3 days at 10 am and 6 pm. Thus, the researcher drops 2 drops of 100% pure lavender essential oil with a dropper onto a 10 x 10 gauze and attaches it to the research subject's collar 20 cm from the nose with a clip. After that, the patient is asked to breathe normally for 20 minutes; their stress, anxiety, and depression levels are measured immediately before and after the end of the intervention.

Main outcome variables
Stress, anxiety, depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141127020108N9**
Registration date: **2025-06-12, 1404/03/22**
Registration timing: **prospective**

Last update: **2025-06-12, 1404/03/22**
Update count: **0**

Registration date
2025-06-12, 1404/03/22

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3778 2856

Email address
musarezaie@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-11, 1404/04/20

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of lavender (Lavandula angustifolia) inhalation aroma therapy on stress, anxiety and depression of addicts under treatment hospitalized in the addiction wards

Public title
Investigating the effect of lavender (Lavandula angustifolia) inhalation aroma therapy on stress, anxiety and depression of addicts
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years and above be able to read and write in Persian. Consent to participate in the study.
Exclusion criteria:
Having a history of allergic rhinitis, eczema, or known respiratory problems such as asthma Having a cold or anything else that affects a person's ability to smell.
Age
From **18 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with size of 4. Randomization unit: individual. Randomization tool: Random allocation software. Random chain concealment is by placing participants' codes in opaque envelopes.
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
Research Ethics Committees of Nursing, Rehabilitation and Management schools- Isfahan
Street address
sfahan University of Medical Sciences, Hezar Jarib St, Isfahan, Isfahan Province, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2025-03-10, 1403/12/20
Ethics committee reference number
IR.MUI.NUREMA.REC.1403.185

Health conditions studied

1

Description of health condition studied
Drug addiction
ICD-10 code
Z63.72
ICD-10 code description
Alcoholism and drug addiction in family

Primary outcomes

1

Description
stress
Timepoint
Immediately before and three days after the start of the intervention
Method of measurement
Stress, Anxiety, Depression Questionnaire (DASS-21)

2

Description
Anxiety
Timepoint
Immediately before and three days after the start of the intervention
Method of measurement
Stress, Anxiety, Depression Questionnaire (DASS-21)

3

Description
Depression
Timepoint
Immediately before and three days after the start of the intervention
Method of measurement
Stress, Anxiety, Depression Questionnaire (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the Intervention group, the samples participating in the study were subjected to aromatherapy with lavender essential oil for 3 days at 10 am and 6 pm. Thus, the researcher drops 2 drops of lavender essential oil (product of Barij Essential Oil Company, Kashan) with a dropper on a sterile cloth measuring 10 cm by 10 cm and attaches it to the collar of the research unit's clothing with a clip at a distance of 20 cm from the nose. Immediately before and after the end of the intervention, their stress, anxiety, and depression levels are measured using a questionnaire.

Category
N/A

2

Description
Control group: The control group will be hospitalized in the ward, receive routine treatments and care, and like the intervention group, their levels of stress, anxiety, and depression will be assessed using questionnaires immediately before the study and three days after the start of the study.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Modares Hospital

Full name of responsible person
Shahid Modares Hospital

Street address
18 km of Isfahan-Najaf Abad road

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 0048

Email
musarezaie@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Gholamreza Asgari

Street address
Building number 4, Isfahan University of Medical Sciences, Hezar Jarib St, Isfahan, Isfahan Province, Iran

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Amir Musarezaie

Position
Nursing faculty instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Hazar Jarib Street, Isfahan University of Medical Sciences

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Isfahan

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Amir Musarezaie

Position
Nursing faculty instructor

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Person responsible for updating data

Contact

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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