Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparing the effect of aromatherapy with lavender essential oil and respiratory relaxation on vital signs and anxiety before electroconvulsive therapy in patients with depression

Protocol summary

Study aim
To determine the effect of aromatherapy compared with breathing relaxation on vital signs and anxiety of depressed patients before electroconvulsive therapy

Design
This study was conducted as a single-blinded, three parallel groups clinical trial. Participants were randomly divided into three groups of INT1, INT2, and control.

Settings and conduct
The setting is Avicenna Hospital in Mashhad. After obtaining informed consent, the patient's anxiety level and their vital signs are recorded at baseline. Then the designated intervention will be performed for each group of patients. First intervention group, aromatherapy: A 5×5 pad dipped in two drops of lavender oil will be attached to the patient's cloth. The patient breathes it for 3 to 5 minutes. Second intervention group, breathing relaxation: For 10 minutes, the patient is asked to slowly inhale and exhale while counting the numbers 2, 3, 4. Control group: routine care

Participants/Inclusion and exclusion criteria
Inclusion criteria: the patient's caretaker must voluntarily sign an informed consent form for participation in the study; the patient should have a known diagnosis of depression; the patient should score higher than 7 from the Beck Anxiety Inventory; the patient should be referred for the first session of electroconvulsive therapy; the patient should have the ability to speak and understand Persian language. Exclusion criteria: having any physical illness that leads to cognitive impairment; having a history of known anxiety disease; use of anxiolytic drugs 24 hours before the intervention; having a history of drug abuse

Intervention groups
First intervention group, aromatherapy Second intervention group, breathing relaxation for 10 minutes Control group: Patients in the control group will not receive intervention from the researchers.

Main outcome variables
Patients' anxiety and vital signs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190518043618N1**
Registration date: **2019-05-21, 1398/02/31**
Registration timing: **prospective**

Last update: **2019-05-21, 1398/02/31**
Update count: **0**

Registration date
2019-05-21, 1398/02/31

Registrant information

Name
Farideh Delmoradi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of aromatherapy with lavender essential oil and respiratory relaxation on vital signs and anxiety before electroconvulsive therapy in patients with depression

Public title
Effect of aromatherapy and breathing relaxation on anxiety and vital signs
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient's caretaker must voluntarily sign an informed consent form for participation in the study. The patient should have a known diagnosis of depression. The patient should score higher than 7 from the Beck Anxiety Inventory. The patient should be referred for the first session of electroconvulsive therapy. The patient should have the ability to speak and understand Persian language.
Exclusion criteria:
Having any physical illness that leads to cognitive impairment. Having a history of known anxiety disease Use of anxiolytic drugs 24 hours before the intervention Having a history of drug abuse
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization will be used. Using the random number table, the desired number of sample is selected. The numbers are printed and are placed inside an envelope. Then, randomly, patients are divided into three intervention, one, two, and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants will be unaware of the intervention and control groups. Patients are randomly divided into three groups using the envelope method. In this method, random numbers are printed and placed inside the envelope. The purpose of the study is explained to the patient who met the inclusion criteria. He/she takes a numbered paper from the envelope and then unpacks it. Then, in this way, the specific number for each patient will identify. In the same way, the patient takes a printed letter (A, B, C) randomly to determine the group of patient. Finally, it is randomly determined that each English letter (A-B-C) is related to which group (intervention group one or two or control group).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Avicenna Ave., School of Nursing & Midwifery, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2019-05-15, 1398/02/25
Ethics committee reference number
IR.MUMS.NURSE.REC.1398.013

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The number of patients whose anxiety scores are higher than 7 measured by Beck's anxiety inventory.
Timepoint
Anxiety is measured before intervention and then 30 minutes after intervention.
Method of measurement
Beck Anxiety Inventory

2

Description
Respiratory rate

Timepoint
Before intervention and then 30 minutes after intervention
Method of measurement
Counting the patient's respiratory rate for 1 minutes

3

Description
Blood pressure
Timepoint
Before intervention and then 30 minutes after intervention
Method of measurement
A mercury sphygmomanometer

4

Description
Heart rate
Timepoint
Before intervention and then 30 minutes after intervention
Method of measurement
Reading HR from pulse oximetry attached to patient's finger

5

Description
Arterial oxygen saturation (SaO2 %)
Timepoint
Before intervention and then 30 minutes after intervention
Method of measurement
Reading SiO2 from pulse oximetry device attached to patient's finger

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group, aromatherapy: A 5×5 pad dipped in two drops of lavender oil will be attached to the patient's cloth. The patient breathes it for 3 to 5 minutes.
Category
Treatment - Other

2

Description
Second intervention group, breathing relaxation: For 10 minutes, the patient is asked to slowly inhale and exhale while counting the numbers 2, 3, 4.
Category
Treatment - Other

3

Description
Control group: This group does not receive any intervention. An intervention is not routinely provided in the psychiatric department of Avicenna Hospital to reduce anxiety.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Avicenna Hospital in Mashhad
Full name of responsible person
Farideh Delmoradi
Street address
Hore Amoli Ave., Mashhad
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Razavi Khorasan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
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No. 18, Daneshgah Street, Deputy Director of Research and Technology
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tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Zahra Emami Moghaddam

Position
Instructor, Faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
Disseminating information about patients with mental disorders may endanger their social lives.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not 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
Not applicable

Data Dictionary
Not applicable