

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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No. 18, Daneshgah Street, Deputy Director of Research and Technology

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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

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

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Person responsible for updating data

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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City

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Province

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