

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effect of Lavendola Inhalation aroma and Benson relaxation on Anxiety in Patients with Major Depressive Disorder under ECT

Protocol summary

Study aim

Comparison of Inhalation Scent of Lavendola and Benson relaxation for Anxiety in Patients with Major Depressive Disorder under ECT

Design

Clinical trial with two groups of intervention and control group, with parallel groups, blinded, randomized

Settings and conduct

This study was performed on 90 patients with major depression disorder in Ibn -Sina Hospital in Mashhad. They were selected on the basis of available sampling and randomly divided into three groups: control (30) and Benson relaxation intervention (30) Lavendula aroma (30 people) will be placed. The data gathering tool is Spielberger's anxiety questionnaire, which will be done in four stages one day before the intervention and after intervention before the first, third and six sessions of the ECT treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria:1- Mood disorders diagnosed by a psychiatrist 2- Ability of listening, speaking, and acceptable consciousness to answer questions. 3- lack of psychotic disorder at the time of the Electroconvulsive Therapy (ECT). 4- Aged 20 to 60 years and signed a consent form . 5- lack of olfactory disorder and sensitivity to the smell of lavender. Exclusion criteria: 1- Less than four sessions of shock therapy at the time of the study. 2- The use of sedative drugs or any non-pharmacological method to reduce stress and fatigue during the intervention period. 3- Failure to comply with the study plan.

Intervention groups

Benson relaxation groups and groups with aromatherapy Lavendola routine intervention control group

Main outcome variables

anxiety

General information

Reason for update

Acronym

ECT

IRCT registration information

IRCT registration number: **IRCT20181211041922N1**

Registration date: **2019-05-27, 1398/03/06**

Registration timing: **retrospective**

Last update: **2019-05-27, 1398/03/06**

Update count: **0**

Registration date

2019-05-27, 1398/03/06

Registrant information

Name

Reza Hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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hesarir941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Ethics committee of Mashhad University of Medical Sciences
Scientific title	Street address
Comparison of the effect of Lavendola Inhalation aroma and Benson relaxation on Anxiety in Patients with Major Depressive Disorder under ECT	Crossing Doctora, Street Ibn Sina University School of Nursing and Midwifery
Public title	City
Comparison of the effect of Lavendola Inhalation aroma and Benson relaxation on Anxiety in Patients with Major Depressive Disorder under ECT	Mashhad
Purpose	Province
Supportive	Razavi Khorasan
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	9137913199
A definitive diagnosis of major depressive disorder is given by the psychiatrist No history of previous ECT Would like to participate in the study The level of upper secondary education is high Speech and voice noproblems Lack of physical illness leads to cognitive impairment Lack of psychotic disorder during ECT Lack of Mental retardation There are no major medical and medical problems involved in the research Anxiety disorder is not severe and not synchronous	Approval date
Exclusion criteria:	2018-10-04, 1397/07/12
Unwillingness of the family or patient to continue to collaborate and participate in research for any reason If sensitized to the lavender extract	Ethics committee reference number
Age	IR.MUMS.NURSE.REC.1397.033
From 20 years old to 60 years old	Health conditions studied
Gender	<u>1</u>
Both	Description of health condition studied
Phase	Major Depressive disorder
N/A	ICD-10 code
Groups that have been masked	F32
No information	ICD-10 code description
Sample size	Major depressive disorder, single episode
Target sample size: 90	Primary outcomes
Randomization (investigator's opinion)	<u>1</u>
Randomized	Description
Randomization description	Significant anxiety score in patients with major depressive disorder under ECT
Simple randomization with the help of throwing coins	Timepoint
Blinding (investigator's opinion)	The beginning of the study before intervention and after the intervention of the first and the sixth session of shock therapy
Not blinded	Method of measurement
Blinding description	Spielberger Anxiety Inventory
Placebo	Secondary outcomes
Not used	empty
Assignment	Intervention groups
Parallel	<u>1</u>
Other design features	Description
NO	Usual care control group, such as fasting, voiding, and will be carried out jewelry and metals
Secondary Ids	Category
empty	Other
Ethics committees	<u>2</u>
<u>1</u>	Description
Ethics committee	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
Name of ethics committee	

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 (6-8) for six consecutive days by patients and supervised by the researcher.

Category

Other

3

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 6:00 and 8:00 for six consecutive days.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Abne Sina hospital

Full name of responsible person

Reza Hesari

Street address

Hor Amli Street, Bu'ali, Ibn Sina Hospital

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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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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

Reza Hesari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Nursery

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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