Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of lavender aromatherapy on anxiety and cognitive status of patients undergoing electroconvulsive therapy in 5 Azargargan hospital in2022

Protocol summary

Study aim
The effect of lavender aromatherapy on anxiety and cognitive status of patients undergoing electroconvulsive therapy in 5 Azargargan hospital in2022

Design
Clinical trial with intervention and control group, with parallel groups, single-blind, randomized, phase 3 on 80 patients. Randomization of data analysis will be done using SPSS-16.

Settings and conduct
Method : 80 ECT candidate patients are divided into two groups of test and control and homogenized in terms of number, age, and sex. The data collection tool will include a checklist of demographic characteristics, the Montreal Cognitive Test (MoCA) and Beck's anxiety questionnaire. One hour before ECT, the questionnaires are completed by the intervention and control groups. For 10 to 20 minutes, sterile gas containing five drops of lavender essential oil in the test group, and the same amount of placebo (distilled water) in the control group, will be placed in front of the nose of the samples to inhale. One hour after receiving ECT, when the samples are in a state of consciousness and proper orientation to time, place and person, the questionnaires will be completed again.

Participants/Inclusion and exclusion criteria
inclusion criteria: Hospitalized patients with ECT indication based on DSM-5 criteria, positive smell test, satisfaction with participating in the study, ability to verbally communicate with researchers, age 25-55 years, at least literate exclusion criteria: History of serious medical diseases such as hyperthyroidism, concomitant serious psychiatric diseases. Withdrawal from the study, having an allergy to lavender during the intervention, decreased level of consciousness.

Intervention groups
Intervention and control group

Main outcome variables
Lavender aromatherapy, anxiety, cognitive status, age, gender, level of education, marital status.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220915055965N1**
Registration date: **2022-12-04, 1401/09/13**
Registration timing: **prospective**

Last update: **2022-12-04, 1401/09/13**
Update count: **0**

Registration date
2022-12-04, 1401/09/13

Registrant information

Name
Mohammadzaman Kamkar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3115 3365

Email address
kamkar72@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-06, 1401/09/15

Expected recruitment end date
2023-03-03, 1401/12/12

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of lavender aromatherapy on anxiety and cognitive status of patients undergoing electroconvulsive therapy in 5 Azargargan hospital in2022

Public title
the effect of lavender on anxiety and cognition
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Admitted to the psychiatric department, all patients with ECT indication based on DSM-5 criteria with the diagnosis of a psychiatrist, consent to participate in the study, the ability to verbally communicate with the researchers, aged 25 to 55 years, patients benefit from minimal reading and writing literacy. (Middle or 8th grade), do not have any disease or physical disability such as speech, hearing or vision impairment, a positive smell test (olfactory nerve health test) is taken from them in such a way that the coffee sample is taken under their nose with their eyes closed and smell it), have no history of physical problems that lead to cognitive disorders such as mental retardation, epilepsy, dementia, and head trauma, no physical diseases related to anxiety and cognitive disorders such as pheochromocytoma, thyroid problems, and brain tumors, no bad Consuming alcohol and drugs, not taking anti-anxiety drugs, being aware of the time and place before the electroshock, having the physical and mental ability to answer questions, not having a history of allergies and respiratory diseases, schizophrenic patients who are dominated by negative symptoms and their reality check is impaired. are not eligible to enter the study.
Exclusion criteria:
Patients who have difficulty communicating verbally, withdraw from the study, have an allergy to lavender during the intervention, decrease the level of consciousness of the patient during the study, participate in other studies that affect their anxiety and cognitive status.
Age
From **25 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The present study will be conducted in order to investigate the effect of lavender aroma therapy on the anxiety and cognitive status of patients undergoing electroshock therapy in the fifth hospital of Azargorgan in 1401. After approving and receiving the code of ethics from the University of Medical Sciences, and obtaining permission from the authorities of 5 Azar Gorgan Hospital, the research will begin. This study is a clinical trial study, the number of 80 patients under treatment with ECT was selected using the available sampling method, and then based on simple random assignment, they were divided equally into two test and control groups (40 people in each group) and considering equalization in terms of number, age, and gender. They will be. The samples are equally selected from patients with bipolar disorder. After explaining the objectives of the study and how to complete the questionnaires to the research samples and assuring them about the confidentiality of the answers, the researcher first obtains informed written consent from them and then the questionnaires are completed by them. The data collection tool in this study will include demographic characteristics checklist, Montreal Cognitive Assessment (MoCA) and Beck's anxiety questionnaire. The samples will be selected considering the entry and exit criteria. The method of conducting the intervention will be that one hour before ECT, the Beck questionnaire will be completed to measure anxiety, and the MoCA questionnaire will be completed by the intervention and control groups to measure their cognitive status. Lavender drops made in Iran by Zarband company will be used. In the test group, for 10 to 20 minutes, sterile gas containing five drops of lavender essential oil, and the same amount of placebo (distilled water) in the control group, will be placed in front of the nose of the samples to inhale. One hour after receiving ECT, when the samples are in a state of consciousness and proper orientation to time, place and person, they will complete the questionnaires once again. And finally, the data will be collected and analyzed in different groups. Data analysis will be done using SPSS-16.
Blinding (investigator's opinion)
Double blinded
Blinding description
To avoid bias, neither the researchers nor the patients know which drops are used, and for this purpose, the research colleagues simultaneously and separately, one person in the intervention group and the other in the control group, conduct the research.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Golestan University of Medical Science

Street address
5 azar ave., 5 azar hospital

City
Gorgan

Province
Golestan

Postal code
4917763681

Approval date
2022-07-03, 1401/04/12

Ethics committee reference number
IR.GOUMS.REC.1401.155

Health conditions studied

1

Description of health condition studied
Bipolar disorder

ICD-10 code
F31

ICD-10 code description
Bipolar disorder

Primary outcomes

1

Description
Anxiety before and after the intervention

Timepoint
One hour before and one hour after electroconvulsive therapy

Method of measurement
Based on the average scores obtained from Beck Anxiety inventory and Montreal Cognitive Assessment (MOCA)

2

Description
Cognitive status before and after the intervention

Timepoint
One hour before and one hour after electroconvulsive therapy

Method of measurement
Beck Anxiety Questionnaire and Montreal Cognitive Assessment (MOCA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The method of conducting the intervention will be that one hour before ECT, the Beck questionnaire will be completed to measure anxiety, and the MoCA questionnaire will be completed by the intervention group to measure cognitive status. Sterile gas containing five drops of lavender essential oil made in Iran, Zarband company, will be placed in front of the nose of the samples for 10 to 20 minutes to inhale. One hour after receiving ECT, when the patients are in a state of consciousness and proper orientation to time, place and person, they will complete the questionnaires again.

Category
Treatment - Drugs

2

Description
Control group:One hour before ECT, the Beck questionnaire to measure anxiety, and the MoCA questionnaire to measure cognitive status, will be completed by the control group. Gas impregnated with five drops of sterile distilled water (placebo) will be placed in front of the nose of the samples to inhale. One hour after receiving ECT, when the patients are in a state of consciousness and proper orientation to time, place and person, they will complete the questionnaires again.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
5 azar hospital of Gorgan

Full name of responsible person
Mohammad Zaman Kamkar

Street address
5 azar ave., 5 azar hospital

City
Gorgan

Province
Golestan

Postal code
4917763681

Phone
+98 17 3115 3365

Email
kamkar72@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Zaman Kamkar
Street address
5 azar ave., 5 azar hospital
City
Gorgan
Province
Golestan
Postal code
4917763681
Phone
+98 17 3115 3365
Email
kamkar72@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Mohammad Zaman Kamkar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
5 azar ave., 5 azar hospital
City
Gorgan
Province
Golestan
Postal code
4917769681
Phone
+98 17 3115 3365
Email
kamkar72@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Mohammad Zaman Kamkar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
5 azar ave,. 5 azar hospital
City
Gorgan
Province
Golestan
Postal code
4917763681
Phone
+98 17 3115 3365
Email
kamkar72@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Mohammadzaman Kamkar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
5azar Ave., 5azar hospital,
City
Gorgan
Province
Golestan
Postal code
4917763681
Phone
+98 17 3115 3365
Fax
Email
kamkar72@yahoo.com

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The individual data of the participants without mentioning their names, as well as the results of the research, can be made available to researchers after public publication and with the permission of the university's ethics committee.

When the data will become available and for how long

After public release through the article.

To whom data/document is available

All researchers

Under which criteria data/document could be used

For additional research work

From where data/document is obtainable

Conductors of the research

What processes are involved for a request to access data/document

Request from the administrator and the reason for the request, obtaining the permission of the administrator from the ethics committee of the university.Corresponding author's email: kamkar72@yahoo.com

Comments

We have not started sampling, we need to get a code from IRCT to take samples.