Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of aromatherapy with rose essential oil on depression in patients referred to neurology clinics

Protocol summary

Study aim

So far, no specific complications have been observed in connection with the use of rose essential oil. Similarly, this drug has been used to reduce the symptoms of depression in animal models (21), but it has not been used to reduce the symptoms of depression in patients. Therefore, this study will be conducted with the aim of investigating the effect of rose essential oil on reducing depression symptoms in patients referred to the clinics of Arak University of Medical Sciences.

Design

This research is a double-blind randomized clinical trial with a parallel control group, which will use a coin toss for randomization

Settings and conduct

Patients referred to the neuropsychiatric clinic affiliated to Arak University of Medical Sciences, whose depression disorder has been determined based on DSMVITR diagnostic criteria and after examination by a psychiatrist, are randomly assigned to two groups. And in two stages (day 0-30) their depression is measured.

Participants/Inclusion and exclusion criteria

 Age 18-70 years Not having a psychotic phase Absence of suicidal thoughts No history of mental disorder Not taking antidepressants Absence of olfactory disorders No history of allergy and eczema to rose Being able to understand and write Persian language

Intervention groups

The people of the control and intervention groups are taught to perform aromatherapy for one month, in this way, 2 drops of 2% rose essence produced by Barij Essence Company for the intervention group and the same amount of distilled water for the control group, with The dropper is poured on a 10 x 10 cm gas and it is connected to a distance of 20 cm from the subject's nose and on their shirt, and the patients inhale it for 20 minutes. They do this twice a day. The recovery rate will be evaluated after the intervention

Main outcome variables

Depression, age, sex, marriage, education, job

General information

Reason for update

The request to update this protocol has various reasons, one of the most important of which is the disruption in sampling, which means that due to the long duration of the entire intervention, many participants did not finish the intervention at the beginning, and for this reason, the authors, citing Previous studies based on shorter intervention length (one month duration) decided to sample for the second time and with shorter intervention length. Therefore, please update the changes included in the method. The protocols with one month intervention and almost similar to the present study: IRCTID: IRCT20190305042936N1 IRCTID: IRCT20230702058649N1

Acronym

IRCT registration information

IRCT registration number: **IRCT20220703055351N2**
Registration date: **2023-04-21, 1402/02/01**
Registration timing: **prospective**

Last update: **2024-12-09, 1403/09/19**
Update count: **2**

Registration date

2023-04-21, 1402/02/01

Registrant information

Name
Mahsa Hosseini
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-22, 1402/03/01
Expected recruitment end date
2024-01-21, 1402/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of aromatherapy with rose essential oil on depression in patients referred to neurology clinics

Public title
Investigating the effect of aromatherapy with rose essential oil on depression in patients referred to neurology clinics
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-70 years, no psychotic phase, no suicidal thoughts, no history of mental disorders, no use of antidepressants, no olfactory disorders, no history of rose allergy and eczema, able to understand and write Persian language.
Exclusion criteria:
Pregnancy, postpartum depression, reluctance to continue studying, olfactory disorders and complications caused by essential oil consumption, allergies
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, coin tossing will be used for randomization. In this way, the first participant is placed randomly (coin toss) in one of the two intervention or control groups. In the next step, the participants will be distributed evenly between the two groups. In such a way that if the line comes for the first time and the researcher considers the line to be the entry into the control group, the subjects will be entered into the intervention group first and then the control group according to the order of entry into the study
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding in this study will be double blind. In order to reduce the error and bias in this clinical study, the intervention and control group (participants) will be blinded to the type of intervention using a placebo. Also, the plan executives are not included in the process of intervention by conducting the intervention by a researcher other than the people who prepare the draft of the article.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak Medical Sciences
Street address
Arak University of Medical Sciences, Basij Square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3813944438
Approval date
2023-04-19, 1402/01/30
Ethics committee reference number
IR.ARAKMU.REC.1402.021

Health conditions studied

1

Description of health condition studied
Patients with depression
ICD-10 code
F33.0
ICD-10 code description
Major depressive disorder, recurrent, mild

Primary outcomes

1

Description
depression
Timepoint
Before the intervention, after one month,
Method of measurement

"Beck Depression Questionnaire"

Secondary outcomes

1

Description
Age, gender, marital status, occupation
Timepoint
Before the intervention, one month after the intervention
Method of measurement
Ask people

Intervention groups

1

Description
Intervention group: The intervention group is taught to perform aromatherapy for one month, in this way that 2 drops of 2% rose essential oil, a product of Barij Essential Oil Company, is poured with a dropper on a 10 x 10 cm gas. It is connected to a distance of 20 cm from the subject's nose and on their shirt, and the patients inhale it for 20 minutes. They do this twice a day. The recovery rate of depression will be evaluated based on the Beck questionnaire in 30 days after the intervention
Category
Treatment - Other

2

Description
Control group: The control group is taught to perform aromatherapy for one month, in this way, by pouring 2 drops of 2% rose water distilled from Barij Essense Company with a dropper on a 10 x 10 cm gas. It is connected to a distance of 20 cm from the subject's nose and on their shirt, and the patients inhale it for 20 minutes. They do this twice a day. The recovery rate of depression will be evaluated based on the Beck questionnaire in 30 day after the intervention
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuropsychological clinics of Arak University of Medical Sciences
Full name of responsible person
Ali jadidi
Street address
Faculty of Nursing and Midwifery.Basij Square.Taleghani Street.Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak 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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Ali jadidi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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Masters student

Latest degree
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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
There is no further information."

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

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable