Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effect of aromatherapy with lavender essential oil on sleep quality and fatigue of major depressed patients.

Protocol summary

Study aim

Determination the effect of lavender essential oil on the quality sleep and fatigue in patients with major depression Special goals: Determining the quality sleep and fatigue in the intervention group before and after intervention. Determination sleep quality and fatigue in the control group before and after the intervention

Design

A single blind randomized clinical trial with a pretest-post test design with a placebo controlled group. The statistical population included all patients referring to the specialized clinic of Yahyanezhad Hospital Babol, who have a mild to moderate depression. The sample size is calculated on the basis of the study of Lee et al. 34 person. Because of the 10% Probability of sample Falling out, 40 people will be calculated per group. Sampling method in this research was available. Patients are blocked by random blocking method based on age variables.

Settings and conduct

Eligible patients were selected from patients referring to the psychiatric clinic of Yahyanezhad Hospital. This is a single-blind study and only patients do not know Which group to enter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 18-60 years,Literacy reading and writing, having a healthy sense of smell, Exclusion criteria: alcohol and cigarettes and opiate material, taking hypnotic drugs, asthma and respiratory diseases, history of allergy to aromatic substances, pregnancy, history of migraine and chronic headaches, having a night shift job

Intervention groups

The intervention group will use the aromatherapy for 14 Continuous nights with 2 drops of lavender essential oil at a Density 10%. Patients in the control group will use the placebo.

Main outcome variables

sleep quality, Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180924041109N2**
Registration date: **2019-05-05, 1398/02/15**
Registration timing: **retrospective**

Last update: **2019-05-05, 1398/02/15**
Update count: **0**

Registration date

2019-05-05, 1398/02/15

Registrant information

Name

Yadollah Jannati

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with lavender essential oil on sleep quality and fatigue of major depressed patients.

Public title

Effect aromatherapy with lavender essential oil on sleep quality and fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18-60 Having Complete consciousness Have reading and writing skills Having a healthy sense of smell (examining the nerve pair 1) If you take antidepressants, you are less than 3 weeks old after taking antidepressants Earn score 5 and above Pittsburgh Sleep Quality Questionnaire A score of 7-24 Hamilton questionnaires Obtain 21 and higher Multidimensional Fatigue Inventory Questionnaire (MFI)

Exclusion criteria:

Drinking alcohol and cigarettes and drugs Taking hypnotic drugs and antihistamines Allergic rhenitis, asthma and respiratory diseases The use of known methods of complementary and traditional medicine that affects the quality of sleep coincident with this intervention. Gain score higher than 2 based on the title of suicide from the Hamilton Measurement Scale for depression History of allergy to aromatic substances and lavender oil Intolerance to lavender smell Failure to intervene for more than three continues days Crisis or accidental events Hospitalized during intervention A fetus and appearance physical or psychological disorder that diagnosed by a psychiatrist based on DSM5 that causes sleep disturbance during the intervention. Pregnancy History of migraine and chronic headaches Having a night shift job indisposition to continue the intervention and non-cooperation during the study

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: **95**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are blocked by random blocking method based on age variables. 80 qualifier depressed patients with 10% probability of loss of case will be selected and 40 person will be allocation randomly blocking to either one intervention and control group. For random selection, this will be done in the first in form blocks of 4 person, include each block 4 person in 6 states (four can take six different modes, AABB1, BBAA2, ABAB3, BABA4, ABBA5 BAAB6) And 20 blocks of 4 person. In each group, the number of people will be equal to the intervention and control. Based on the random number table, according to the sample size, 20 blocks of 4 person are selected based on each of the 6 modes and will be arranged in serial. The method of allocation samples to each of the blocks is define by this pattern. Blocking with code A and B is define, A indicative the allocation to the aromatherapy group and B is allocation to the placebo group, then the patients will be placed in blocks according to the Respectively, entering the study

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a blind one. Participants are unaware of how they are in the intervention and control group, but the researcher and the rest of the people in the research team are aware.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Teachers 'Street, Deputy of Research and Technology of Mazandaran University of Medical Sciences

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4815733971

Approval date

2018-09-26, 1397/07/04

Ethics committee reference number

IR.MAZUMS.REC.1397.164

Health conditions studied

1

Description of health condition studied

major depression

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

Primary outcomes

1

Description

sleep quality and fatigue

Timepoint

before intervention and 15 days after starting to use lavender essential oil

Method of measurement

Pittsburgh sleep quality questionnaire and Multidimensional Fatigue Inventory questionnaire MFI

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: aromatherapy with Lavender essential oil

Category

Treatment - Drugs

2

Description

Control group: Aromatherapy with sweet almond oil

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanezhad hospital babool

Full name of responsible person

Yadollah Jannati

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Shahid Yahyanezhad Hospital, Shahid Mostafa Khomeini St, Modarres Ave, babool town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Yadollah Jannati

Position

Associate professor

Latest degree

Ph.D.

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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