

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of aromatherapy with lavender on sleep quality, fatigue and anxiety in patients with Multiple sclerosis

Protocol summary

Study aim

Determine the effect of aromatherapy on sleep quality, fatigue and anxiety in patients with MS

Design

In the control group, one hour before bed, the sweet almond extract was put on a cotton ball for 2 to 3 drops every night for 4 weeks and placed at a distance of 10 to 15 centimeters (the cotton ball is attached to the cloth by a pin) And smell for 5-10 minutes.

Settings and conduct

Clinical trial with control group, Blind, randomized, with 60 patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 50 years; informed consent, EDSS Expanded Disability Status Scale that measures the severity of MS patient disability less or equal to 4 .
Exclusion criteria: use of hypnotic and antipyretic drugs, use of other complementary and alternative methods during the study, History of asthma or respiratory diseases, History of smoking

Intervention groups

In the intervention group, one hour before bedtime, the lavender extract was put on a cotton ball for 2 to 3 drops every night for 4 weeks and placed at a distance of 10 to 15 centimeters (the cotton ball is attached to the clothes by a pin) And smell for 5-10 minutes.

Main outcome variables

Quality of sleep; fatigue; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038211N8**

Registration date: **2019-04-26, 1398/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-26, 1398/02/06**

Update count: **0**

Registration date

2019-04-26, 1398/02/06

Registrant information

Name

Fahime Davodabady

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3226 7610

Email address

F_davodabady@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of aromatherapy with lavender on sleep quality, fatigue and anxiety in patients with Multiple sclerosis

Public title

Aromatherapy Effects on Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with MS who have Expanded Disability Status Scale (EDSS) equal or less than 4. Patients with MS aged 18 to 50 years old Informed consent

Exclusion criteria:

Use of other complementary and alternative methods during the study Sleeping and sedative medications, antidepressants and analgesics during the study History of asthma or respiratory diseases

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are entered with accessible method in the study. Blocks randomly divide into intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Individuals with entry criteria are divided into intervention and control groups according to the random numbers table. One of the groups is A and the other is called B. Before and after the intervention, the information is collected by the evaluator of the outcome that is unaware of the Classification of the groups. Data analysis is also done by someone who is unaware of the allocation of groups. The control group also receive similar (but not effective) intervention so containers containing essential oils are of a single form and color, so are unaware of the allocation to the intervention 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 Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Approval date

2018-11-04, 1397/08/13

Ethics committee reference number

IR.ARAKMU.REC.1397.196

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35-G37

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

Sleep quality with Pittsburgh Sleep Quality Questionnaire

Timepoint

Measurement of sleep quality at the beginning of the study and the end of the fourth week after the intervention began

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2

Description

Fatigue with Fatigue Impact Scale MS

Timepoint

Measurement of fatigue at the beginning of the study and the end of the fourth week after the intervention began

Method of measurement

Fatigue Impact Scale MS

3

Description

Anxiety with State-Trait Anxiety Inventory (STAI)

Timepoint

Measurement of anxiety at the beginning of the study and the end of the fourth week after the intervention began

Method of measurement

State-Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: one hour before bedtime, the lavender extract was put on a cotton ball for 2 to 3 drops every night for 4 weeks and placed at a distance of 10 to 15 centimeters (the cotton ball is attached to the clothes by a pin) And smell for 5-10 minutes.

Category

Treatment - Other

2

Description

Control group: one hour before bed, the sweet almond extract was put on a cotton ball for 2 to 3 drops every night for 4 weeks and placed at a distance of 10 to 15 centimeters (the cotton ball is attached to the cloth by a pin) And smell for 5-10 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Multiple Sclerosis Association of Arak

Full name of responsible person

Fahimeh Davodabady

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Arak University of Medical Sciences, Basij Square, Sardasht

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fahimedavodabady@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

Arak University of Medical Sciences, Basij Square,

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arjomandzadegan@arakmu.ac.ir

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

Fahimeh Davodabady

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Instructor

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Person responsible for updating data

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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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available