

# 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

##### Street address

Arak University of Medical Sciences, Basij Square, Sardasht

##### City

Arak

##### Province

Markazi

##### Postal code

6941-7-38481

##### Phone

+98 86 3417 3505

##### Email

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,

Sardasht

##### City

Arak

##### Province

Markazi

##### Postal code

6941-7-38481

##### Phone

+98 86 3417 3505

##### Email

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

Arak University of Medical Sciences

**Full name of responsible person**

Fahimeh Davodabady

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**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**

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