# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**
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**Postal code**
6941-7-38481
**Phone**
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**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
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**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
**Street address**
Arak University of Medical Sciences, Basij Square, Sardasht
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## Person responsible for scientific inquiries

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**Position**
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**Latest degree**
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**Other areas of specialty/work**
Nursery

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## Person responsible for updating data

**Contact**

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**Position**
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**Latest degree**
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**Other areas of specialty/work**
Nursery

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**Email**
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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