

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

investigating the effect of aromatherapy with lavender extract on fatigue and working memory in women with multiple sclerosis referred to the Multiple Sclerosis Society of Rafsanjan 2018

Protocol summary

Study aim

Determining the effect of aromatherapy with lavender extract on fatigue and work memory in women with multiple sclerosis referred to the Multiple Sclerosis Society of Rafsanjan in 2018

Design

Clinical trial with a control group, single-blind. Simple randomization by random-number table and random assignment by minimization method .With a sample size of 60 patients. with parallel groups

Settings and conduct

This study is done on the fatigue and working memory of women with multiple sclerosis referred to hospital of Rafsanjan University of Medical Science.

Participants/Inclusion and exclusion criteria

desire to participate in the study; age range is between 20-40 years; Education: diploma or more; MS history for at least 1 year; No history of using the aromatherapy program during the past 6 months; No prohibition for aromatherapy ; No chronic illness (except for MS); No allergy, migraines, asthma and other respiratory diseases; Have a healthy sense of smelling

Intervention groups

In the intervention group, in addition to routine therapies, aromatherapy with lavender essential oil is used by patients. Patients use 2 drops of 100% lavender essential oil (Barij essence, Kashan), using a droplet on a cotton ball then keep it at a distance of 5 cm and inhale for 10 minutes and do this for 14 days and mark the check list. In the control group, distilled water is used as placebo.

Main outcome variables

fatigue and working memory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170122032111N4**

Registration date: **2019-01-20, 1397/10/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-20, 1397/10/30**

Update count: **0**

Registration date

2019-01-20, 1397/10/30

Registrant information

Name

Maryame Shahabi nejad

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

m_shahabi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-16, 1397/10/26

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigating the effect of aromatherapy with lavender extract on fatigue and working memory in women with multiple sclerosis referred to the Multiple Sclerosis Society of Rafsanjan 2018	
Public title	investigating the effect of aromatherapy with lavender extract on fatigue and working memory in women with multiple sclerosis
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Desire to participate in the study age range of 20-40 years; Education: at least diploma; MS history for at least 1 year; no history of using the aromatherapy program during the past 6 months; no prohibition on aromatherapy; no other chronic diseases; lack of allergies, migraines, asthma and other respiratory diseases; have a healthy sense of smelling that is measured using coffee.
Exclusion criteria:	Women who are pregnant; Smell problem found after coffee smell testing; allergy, migraine, asthma and other respiratory diseases; other chronic diseases except multiple sclerosis.
Age	From 20 years old to 40 years old
Gender	Female
Phase	3
Groups that have been masked	Data analyser
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization by random-number table and random assignment by minimization method
Blinding (investigator's opinion)	Single blinded
Blinding description	This study is a single-blind clinical trial. Those who evaluate the outcome and analyze the data will be blind.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	Name of ethics committee Ethics Committee of Rafsanjan University of Medical Sciences Street address Imam Ali Blvd Rafsanjan University of Medical Sciences City Rafsanjan Province Kerman Postal code 7717932777 Approval date 2018-05-06, 1397/02/16 Ethics committee reference number IR.RUMS.REC.1397.047
Health conditions studied	
1	
Description of health condition studied	Fatigue, Working Memory of Patients with Multiple Sclerosis
ICD-10 code	G35
ICD-10 code description	Multiple sclerosis
Primary outcomes	
1	
Description	Fatigue severity score
Timepoint	Before and two weeks after the intervention
Method of measurement	Fatigue severity scale
2	
Description	working memory
Timepoint	Before and two weeks after the intervention
Method of measurement	Active Dunnyman and Carpenter Memory test
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: Lavender extract, 2 drops, twice a day, inhalation for 10 minutes, for 14 days, Kashan barij Essence company
Category	

Other

2

Description

Control group: Distilled water, 2 drops, twice a day, inhalation for 10 minutes, for 14 days

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The Center for Specific Diseases of Ali Ibn Abi Talib Hospital

Full name of responsible person

Maryam Shahabi Nejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan 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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Maryam Shahabi Nejad

Position

MSN

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data is shared.

When the data will become available and for how long

Get started 6 months after results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Scientific use

From where data/document is obtainable

Email address

What processes are involved for a request to access data/document

All potential data is shared.

Comments