Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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Imam Ali Blvd, Rafsanjan University of Medical Sciences
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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
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Other areas of specialty/work
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Person responsible for updating data

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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