Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of lavender as olfactory stimulus on balance and ADL of persons with multiple sclerosis: (Randomized clinical trial)

Protocol summary

Study aim

The effect of lavender as olfactory stimulus on balance and ADL of persons with multiple sclerosis

Design

Two-arm parallel group, ten-session treatment, randomized clinical trial.

Settings and conduct

Thirty six ambulatory MS patients are selected from among the patients who will be referred to the physiotherapy departments of Iran MS Society in 2019. Using a block randomization, participants are randomly assigned to an Experimental Group (EG) or Control Group (CG). EG received program based Vestibular Rehabilitation exercise protocol along with olfactory stimulus. CG received Vestibular Rehabilitation exercise protocol without olfactory stimulation.

Participants/Inclusion and exclusion criteria

patients with relapsing–remitting or secondary-progressive types of MS, clinically definite MS, being in remission period, being between the ages of 18 and 60 years, ability to stand for 30 seconds and to walk a distance of 6 m without any assistance, to have a Berg Balance Scale (BBS) score of 21–44, had normal olfactory function diagnosed with an olfactory identification test, no allergy to lavender, did not have any disease in musculoskeletal and cardiovascular system, not suffering from any other neurological diseases other than MS, showed no problem in communication, and agreed to voluntarily participate in the present research. unwilling or unable to participate in the research

Intervention groups

Experimental Group : received a standardized program based on Vestibular Rehabilitation (VR) exercise protocol along with olfactory stimulus (through a mask containing 3 drops of lavender essential oil (2% concentration)). Control Group: received a standardized program based on Vestibular Rehabilitation (VR) exercise protocol without olfactory stimulation.

Main outcome variables

FES-I questionnaire, MSIS-29 questionnaire, Berg Balance Scale, Time Up and Go Test.

General information

Reason for update

1- Increasing the sample size due to insufficient intergroup differences 2- The start date of the study was done after the registration date.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190902044672N1**
Registration date: **2019-10-23, 1398/08/01**
Registration timing: **prospective**

Last update: **2020-05-18, 1399/02/29**
Update count: **1**

Registration date

2019-10-23, 1398/08/01

Registrant information

Name

Maryam Seddighi Khavidak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 9653

Email address

seddighi.m24@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-30, 1398/08/08

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lavender as olfactory stimulus on balance and ADL of persons with multiple sclerosis: (Randomized clinical trial)

Public title

The effect of lavender on balance a persons with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

clinically definite multiple sclerosis the ages between 18 and 60 years ability to stand for 30 seconds and to walk a distance of 6 m without any assistance have a Berg Balance Scale score of 21–44 being in remission period did not have any disease in cognitive, musculoskeletal and cardiovascular system, not suffering from any other neurological diseases other than MS had normal olfactory function no allergy to lavender

Exclusion criteria:

unwilling or unable to participate in the research disease relapse during the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a block randomization, participants are randomly assigned to a experimental or control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

3th Floor, Medical School, Evin Blvd., Shahid Chamran Hwy., Tehran

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2019-01-20, 1397/10/30

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1004

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

balance

Timepoint

balance measurement at the beginning of the study and after 10 sessions.

Method of measurement

Balance measurement are performed using the berg balance scale.

2

Description

Dynamic balance

Timepoint

dynamic balance measurement at the beginning of the study and after 10 sessions.

Method of measurement

dynamic Balance measurement are performed using the Time Up and Go Test.

Secondary outcomes

1

Description

fear of fall

Timepoint

Measurement of fear of falling before the beginning of the study and after 10 sessions.

Method of measurement

Fear of falling is measured using the Falling Efficiency Scale questionnaire.

2

Description
Independence in activity of daily living
Timepoint
Measurement of Independence in activity of daily living before the beginning of the study and after 10 sessions.
Method of measurement
Independence in activity of daily living is measured using the Multiple Sclerosis Impact Scale-29 questionnaire.

Intervention groups

1

Description
Intervention group: Vestibular Rehabilitation exercise protocol are carried out during three exercise sessions, alternate days, with a total of 10 sessions while the olfactory stimulus is applied to the nose of the patients through a mask containing 3 drops of lavender essential oil.
Category
Rehabilitation

2

Description
Control group: Vestibular Rehabilitation exercise protocol are carried out during three exercise sessions, alternate days, with a total of 10 sessions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran MS society
Full name of responsible person
Abolqhasem Najafi
Street address
No. 35, Shams Alley, Vesal Shirazi Ave., Engelab Ave., Tehran
City
Tehran
Province
Tehran
Postal code
1416864731
Phone
+98 21 6695 3907
Email
iranmsociety@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran MS society
Full name of responsible person
Seyed Khosro-sadegh Mosavi
Street address
No. 35, Shams Alley., Vesal Shirazi Ave., Enghelab Ave., Tehran
City
Tehran
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Tehran
Postal code
1416864731
Phone
+98 21 6695 3907
Email
iranmsociety@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran MS society
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Seddighi Khavidak
Position
MSc student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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Person responsible for scientific inquiries

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Person responsible for updating data

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Email
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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
Individual data of subjects in relevant to outcome measured
When the data will become available and for how long
Start of access period 3 months after printing results
To whom data/document is available
All researchers studying neurological diseases
Under which criteria data/document could be used
Itis depended on the request of resurcher
From where data/document is obtainable
Maryam Seddighi Khavidak. Phone number: 09135195444 Email: ms_kh1994@yahoo.com Address: No. 4, 8th Alley., Sorosh St., Yasin St., Pasdaran Blvd
What processes are involved for a request to access data/document
The researchers have to e-mail a request to the responder. After reviewing and identifying the researcher's purpose, the responder will be sended the information to them.
Comments