

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

#### **Province**

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

#### **Street address**

No. 4, 8th Alley., Sorosh St., Yasin St., Pasdaran Blvd

#### **City**

Yazd

#### **Province**

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#### **Postal code**

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**Phone**

+98 35 3822 9653

**Email**

ms\_kh1994@yahoo.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Maryam Seddighi Khavidak

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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**

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**

It is depended on the request of researcher

**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 send the information to them.

**Comments**