

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Studying the Effect of Cinnamon Oral Drop on Balance and Fear of Falling in Patients with Multiple Sclerosis Member of MS Association in Isfahan in 2018

#### Protocol summary

##### Study aim

Determining the Effect of Cinnamon Oral Drop on Balance and Fear of Falling in Patients with MS.

##### Design

Controlled Clinical Trial with Parallel and Triple Blind Patterns.

##### Settings and conduct

Patients with multiple sclerosis, members of the MS Society of Isfahan were studied during three months of study using 4 drops of cinnamon extract in three servings, and before the intervention and each month, they were assessed using Berg balance test and the Falls Efficacy Scale-International. In this research, the patients, the researcher, the person in charge of caring the patients and the statistical data analyst were blinded. The drugs and placebo were replicated in a laboratory environment under sterile conditions by a third party. There was no indication of the originality of drugs, and they were indicated by two groups of A and B.

##### Participants/Inclusion and exclusion criteria

The participants had multiple sclerosis (MS) according to the neurologist's diagnosis. The patients' age range was from 18 to 50 years. The patients had relapsing-remitting MS. The recorded disability measurement scale in the patients' file was from 5.1 to 6. Regular treatment was performed 4 weeks before the intervention. Patients agreed not to use alternative medications for 7 days before starting the intervention until the end of the intervention.

##### Intervention groups

The intervention group received 4 drops of cinnamon in three servings (morning, noon, and night) with a glass of tea, water, or milk, and the examinations were done using Berg Balance Scale and the fear of falling questionnaire. In the control group, the protocol was like the placebo group, and they received 4 drops of placebo per serving.

#### Main outcome variables

Consumption of Cinnamon oral drop; Balance; Fear of Falling

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190518043619N1**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **retrospective**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

##### Registration date

2020-01-26, 1398/11/06

##### Registrant information

##### Name

Soheila Moghimisarani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3823 4637

##### Email address

s.moghimisarani@khuisf.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-13, 1397/09/22

##### Expected recruitment end date

2019-07-22, 1398/04/31

##### Actual recruitment start date

2018-12-13, 1397/09/22

**Actual recruitment end date**

2019-07-22, 1398/04/31

**Trial completion date**

2019-07-22, 1398/04/31

**Scientific title**

Studying the Effect of Cinnamon Oral Drop on Balance and Fear of Falling in Patients with Multiple Sclerosis Member of MS Association in Isfahan in 2018

**Public title**

Studying the Effect of Cinnamon Oral Drop on Balance and Fear of Falling in Patients with Multiple Sclerosis (MS)

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient should be with Multiple Sclerosis based on the diagnosis of the neurologist. The patients' age range should be between 18 and 50 years old. The patients should be with relapsing-remitting MS. The recorded disability measuring scale in the patient's medical record should be ranged from 5.1 to 6. The patient should have permanent and regular treatment for 4 weeks before the intervention. The patient should agree not to use any alternative medications for 7 days prior to the intervention until the end of the intervention. The patients should not participate in regular exercises two months before the intervention. The help-seeker should be interested in participating in this research.

**Exclusion criteria:**

Being pregnant or intending to be pregnant or lactate during the intervention. Having liver and kidney dysfunction. Having cardiovascular or infectious diseases. Having allergy to cinnamon. Having neurological diseases in addition to Multiple Sclerosis. Having an experience of consuming alcohol or drug dependence.

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the present study, available or easy sampling was used since all the samples were not available. Then, the samples with the inclusion criteria, after getting written consent by using a Random Picker Software from Play Store, which was already installed on the cellphone, and telling the help-seeker to hit the specified phone screen,

were placed in Group A or B. 30 individuals were placed in the intervention group, and 30 were placed in the control group. During the intervention, 8 individuals in the intervention group and 5 in the control group were excluded due to the unwillingness to cooperate or relapse of the disease, that the researcher performed further sampling to replace them.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

It was necessary to prepare a 15 ml glass container for making placebo. Since the Cinnamon Drop lid had the logo of the manufacturer, twice of the lids were purchased to replace them. Glassware, cinnamon drops and mineral water were prepared for making placebo and homogenization, and were sent to the laboratory to perform homogenizing and coding without the presence of the researcher. In the laboratory, all the dishes and caps (heads) were washed using dishwashing liquid and water and then were placed in an autoclave at 120°C to ensure the process was sterile. By consulting to the pharmacist consultant and the Research Deputy of Medical Sciences of the University, 14.5 cc of mineral water and 5.5 cc of cinnamon drop were used by a dropper, and then labeled and coded. Labels of the dishes with cinnamon drop were washed and cleaned, and their lids were replaced, labeled and then coded; the placebo-making process was performed by a third party, and the researcher did not know whether the drugs were placebo or origin. Before getting the informed consent, the samples were informed that the probability of being placed in each of the intervention and control group was 50%, and if they were placed in the placebo group, it would be safe for them because placebo is a harmless material. At the end of the research, data analyzer and data evaluator were not aware of which groups A or B was the intervention group, and only the mark of A and B was used in the questionnaire to identify the groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Islamic Azad University, Khurasgan Branch, Isfahan

**Street address**

Islamic Azad University, Khurasgan Branch, Isfahan, University Blvd, East J Avenue., Arghavanieh, Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

39998-81551

**Approval date**

2018-12-12, 1397/09/21

**Ethics committee reference number**

IR.IAU.KHUISF.REC.1397.151

**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**

At the beginning of the research, 1,2, and 3 months after using cinnamon orally.

**Method of measurement**

Berg Balance Scale

**Secondary outcomes****1****Description**

Fear of Falling

**Timepoint**

at the beginning of the study, 1,2, and 3 months after the study.

**Method of measurement**

effectiveness scale questionnaire in falling- international form.

**Intervention groups****1****Description**

Intervention group: Patients in the intervention group consumed 4 drops of cinnamon extract three times in a day (morning, noon, and night) with a glass of tea, water or milk, and examinations were performed using Berg balance scale and by fear of falling questionnaire on the first day, and at the end of the first, second, and third months.

**Category**

Treatment - Drugs

**2****Description**

Control group: Patients in control group consumed four drops of placebo in three servings (morning, noon, and night) with a glass of tea, water or milk, and examinations were done using Berg balance scale and the questionnaire of fear of falling on the first day, and at the end of first, second, and third months.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Isfahan MS Society

**Full name of responsible person**

Masoud Etemadifar

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Isfahan University, Azadi Square, Isfahan, Iran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Sayedali Najj

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Islamic Azad University, Isfahan (Khorasgan) Branch, University Blvd., East J Ave., Arghavanieh, Isfahan, Iran

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info@khuisf.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Sayedali Naji

**Position**

Lecturer

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Soheila Moghimi sarani

**Position**

Master of Nursing Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Soheila Moghimi sarani

**Position**

Master of Nursing Student

**Latest degree**

Master

**Other areas of specialty/work**

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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 the results and final data can be shared except for patient data and personal data with the principle of confidentiality in receiving information

**When the data will become available and for how long**

2019

**To whom data/document is available**

Researchers working in academia, people who are engaged in the industry, students, patients and all the individuals interested in obtaining data and documentation are permitted to request data and documentation.

**Under which criteria data/document could be used**

People are permitted to ask for any data and documentation except patients' personal information, by

observing the principle of confidentiality.

**From where data/document is obtainable**

Dr.Sayedali Naji; Islamic Azad University Isfahan (Khorasgan) Branch, University Blvd, Arqavanieh, Jey Street, Isfahan, Iran; a\_naji@khuisf.ac.ir; 0098 9131150865 Soheila Moghimisarani; Islamic Azad University Isfahan (Khorasgan) Branch, University Blvd,

Arqavanieh, Jey Street, Isfahan, Iran;  
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**What processes are involved for a request to access data/document**

People can receive data and documentation by calling, sending emails, or meeting in person.

**Comments**