

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparison of the Effectiveness of Acupuncture with Sham Acupuncture on Cognitive Functioning in Multiple Sclerosis Patients

#### Protocol summary

##### Study aim

To evaluate the effectiveness of acupuncture compared to sham acupuncture on cognitive functioning of relapsing remitting multiple sclerosis (RRMS) patients

##### Design

Block randomized double blind sham controlled clinical trial with a parallel group design of 60 patients. For randomization Excel RAND function will be used

##### Settings and conduct

Study location: Sina Hospital, Tehran University of Medical Sciences Patients are collected from MS Clinic of Sina Hospital . Preliminary assessments are performed at MS Research Center of Sina Hospital, and then participants visit the Sina MS Clinic twice a week for acupuncture treatments. Patients and the psychologist evaluating the primary outcome are blinded to assignment of patients to intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Relapsing remitting multiple sclerosis patients; aged 18 to 55 years; with expanded disability status scale < 5.5. Non-inclusion criteria: History of other severe or malignant disease; Acute relapse or corticosteroid therapy in the last 30 days before inclusion

##### Intervention groups

Intervention group: Acupuncture treatment twice a week for 24 sessions (12 weeks). Control group: sham acupuncture; tiny needles will be inserted very shallow (1-2 mm) at nonspecific locations, with no known acupuncture influence, not on any known meridian at least 2 centimetres away from the actual acupuncture points

##### Main outcome variables

Brief International Cognitive Assessment for multiple sclerosis (BICAMS); Pittsburgh Sleep Quality index (PSQI); Symptom Checklist 90- Revised (SCL-90-R); Fatigue Severity scale (FSS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220101053582N1**

Registration date: **2022-01-04, 1400/10/14**

Registration timing: **prospective**

Last update: **2022-01-04, 1400/10/14**

Update count: **0**

##### Registration date

2022-01-04, 1400/10/14

##### Registrant information

##### Name

Abdorrezza Naser Moghadasi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 937 438 1919

##### Email address

abdorrezamoghadasi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-06-22, 1401/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effectiveness of Acupuncture with Sham Acupuncture on Cognitive Functioning in Multiple Sclerosis Patients

#### Public title

Acupuncture and Cognitive Impairment in MS

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with relapsing-remitting multiple sclerosis  
Expanded disability status scale (EDSS)  $\leq$  5.5 Age 18 to 55 years Sign the written informed consent

##### Exclusion criteria:

History of cognitive impairment caused by other chronic or malignant disease Acute relapse or corticosteroid therapy in the last 30 days before inclusion Previous use of acupuncture or using any herbal or other alternative treatments Pregnancy or breastfeeding

#### Age

From **18 years** old to **55 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Participants will be randomized to acupuncture and sham acupuncture groups by block randomization method. Random blocks with size of four are generated by Excel Rand function. Allocations are placed inside sealed folders. After the researcher has assessed eligibility, obtained the patient's consent, and completed all baseline assessments of the enrolled participants, folders are opened and allocation of treatment for the patients will be determined.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The patients and interviewer who measures the outcomes will be blinded to the randomization status. It is not possible to blind the acupuncturist due to the nature of the intervention. Blinding also will be maintained for data management, outcome assessment and data analysis.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Neuroscience Institute

##### Street address

Room No. 605, 6th floor, Tehran University of Medical Sciences, Keshavarz Blvd. Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2021-12-08, 1400/09/17

#### Ethics committee reference number

IR.TUMS.NI.REC.1400.061

## 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

Score of cognitive functioning assessment test

#### Timepoint

Measurement of cognitive function before the intervention and after 24 sessions of acupuncture during 12 weeks

#### Method of measurement

Brief International Cognitive Assessment for multiple sclerosis (BICAMS) questionnaire

## Secondary outcomes

### 1

#### Description

Score of Sleep Quality index

#### Timepoint

Before the intervention and after 24 sessions of acupuncture during 12 weeks

#### Method of measurement

Pittsburgh Sleep Quality index questionnaire

### 2

#### Description

Score of psychological problems checklist

#### **Timepoint**

Before the intervention and after 24 sessions of acupuncture during 12 weeks

#### **Method of measurement**

Symptom Checklist 90- Revised questionnaire

### **3**

#### **Description**

Score of fatigue severity

#### **Timepoint**

Before the intervention and after 24 sessions of acupuncture during 12 weeks

#### **Method of measurement**

Fatigue severity scale questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The acupuncture group will receive acupuncture treatment 2 times per week for 12 weeks (24 sessions). Patients will receive their routine medications for MS. Major selected acupoints for cognitive dysfunction include Baihui (GV 20), Sishencong (EX-HN 1), Shenting (GV 24), Yintang (GV 29), Fengchi (GB 20), Zhongwan (CV 12), Tianshu (ST 25), Qihai (CV 6), Guanyuan (CV 4), Neiguan (PC 6), Shenmen (HT 7), Zusanli (ST 36), Sanyinjiao (SP 6), Taixi (KI 3) and Taichong (LR 3). Sterile stainless steel acupuncture needles (0.25 x 40 mm, Huan-Qiu, Japan) will be inserted 5-30 mm into selected acupoints with even manipulation method and will be retained for 30 minutes.

#### **Category**

Treatment - Other

### **2**

#### **Description**

Control group: In sham acupuncture group, tiny needles (0.16 x 13 mm) will be inserted very shallow (1-2 mm) without manipulation at nonspecific locations, with no known acupuncture influence, not on any known meridian at least 2 centimetres away from the actual acupuncture points. Patients will receive their routine medications for MS.

#### **Category**

Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Sina Hospital

##### **Full name of responsible person**

Faezeh Khodaie

##### **Street address**

Sina Hospital, Imam Khomeini Ave.

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1136746911

#### **Phone**

+98 21 6634 8571

#### **Email**

faezeh.khodaie@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Mohammad Ali Sahraian

##### **Street address**

6th Floor, Tehran University of Medical Sciences, Keshavarz Blvd.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417653761

##### **Phone**

+98 21 8163 3698

##### **Email**

vcr@tums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Faezeh Khodaie

##### **Position**

Research assistant

##### **Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

MS research center, Sina Hospital, Imam Khomeini Ave.

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**Email**

faezeh.khodaie@gmail.com

**Person responsible for scientific inquiries**

**Contact**

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Tehran University of Medical Sciences

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Medical doctor

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available