Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 randimized 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
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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) ≤ 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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

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

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Person responsible for updating data

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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