Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of repetitive tactile stimulation on upper limb sensory - motor function, hand motor imagery and cognitive function in multiple sclerosis patients

Protocol summary

Study aim
Determining the effect of tactile stimulation on the sensory and motor function of the upper extremity, the hand motor imagery ability and the cognitive function of multiple sclerosis patients
Design
Quasi randomized,single- blinded, sham controlled clinical trial with a parallel group
Settings and conduct
Rafsanjan cohort studies center
Participants/Inclusion and exclusion criteria
1-They were right-handed according to Edinburg Handedness Inventory; 2. Their disease had remained stable in the last three months before the examination; 3. They were not affected with other brain diseases such as stroke, traumatic brain injury, seizure, and mental retardation; 4. Patients' scores in the cognitive assessment based on Mini Mental State Examination were above 24; 5. Patients' disability according to the Kurtzke Expanded Disability Status Scale (EDSS) was less than 3.5
Intervention groups
Intervention group: implementation of tactile stimulation for 30 minutes Control group: The tactile stimulation device have was turned off.
Main outcome variables
1-Manual dexterity 2-Motor imagery ability 3-cognitive functions

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180902040927N3**
Registration date: **2018-10-08, 1397/07/16**
Registration timing: **registered_while_recruiting**
Last update: **2018-10-08, 1397/07/16**
Update count: **0**
Registration date
2018-10-08, 1397/07/16

Registrant information
Name
Mahdieh Azin
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-05-22, 1397/03/01
Expected recruitment end date
2019-01-21, 1397/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of repetitive tactile stimulation on upper limb sensory - motor function, hand motor imagery and cognitive function in multiple sclerosis patients

Public title
The effect of tactile stimulation on multiple sclerosis patients
Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

They were definitely diagnosed with MS according to neurological examinations by a specialist based on the international revised McDonald's Criteria. These individuals belonged to relapsing remitting MS sub-group based on the National MS Society division

Exclusion criteria:

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

single blinds:Participants were unaware of the intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of rafsanjan university of medical sciences

Street address

Rafsanjan University of Medical Sciences, School of Medicine, Pistachio Street, Gulf Blvd., Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718175911

Approval date

2017-07-16, 1396/04/25

Ethics committee reference number

IR.RUMS.REC.1396.140

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

Two-point discrimination threshold

Timepoint

Before and after tactile stimulation

Method of measurement

A self-made Two-point threshold detection device

2

Description

The upper extremity function by 9HPT

Timepoint

Before and after tactile stimulation

Method of measurement

Nine hole peg test

3

Description

The upper extremity function by BBT

Timepoint

Before and after tactile stimulation

Method of measurement

Box and block test

4

Description

Reaction time of hand mental rotation

Timepoint

Before and after tactile stimulation

Method of measurement

Hand mental rotation task

5

Description

Response accuracy rate of hand mental rotation

Timepoint

Before and after tactile stimulation

Method of measurement

Hand mental rotation task

6

Description

PASAT score

Timepoint

Before and after tactile stimulation

Method of measurement

Paced Auditory Serial Addition Test (PASAT)

7

Description

Score of SDMT

Timepoint

Before and after tactile stimulation

Method of measurement

Symbol Digit Modalities Test (SDMT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 minutes of tactile stimulation of the right index finger was applied

Category

Rehabilitation

2

Description

Control group: the tactile stimulation device was turned off.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Patients Clinic in Rafsanjan

Full name of responsible person

Dr. Ranjbar

Street address

Special Patients Clinic in Rafsanjan, opposite Tarehbar Square, Pistachio Street, Persian Gulf Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Ali Shamsizadeh

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Mahdieh Azin

Position

Assistant Professor of Neuroscience

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable