Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of transcranial direct current stimulation(tDCS) on attention, working memory and information processing speed in people with MS

Protocol summary

Study aim
The effect of transcranial direct current stimulation on cognition in people with multiple sclerosis in three groups before and after the intervention.

Design
Clinical trial with one intervention group and 2 control groups with factorial groups, randomized, on 36 patients.

Settings and conduct
Place: Rofeideh hospital in Tehran. Subjects were randomly divided into three groups of intervention, control one and control two. Cognitive Rehabilitation Program in addition to tDCS for intervention group, rehabilitation programin addition to shame tDCS was for Control Group one and just rehabilitation program for Control Group Two. The evaluator will be blind to the groups.

Participants/Inclusion and exclusion criteria
People between the ages of 20 and 50 years old who have received a definitive diagnosis of MS from a specialist and have no history of other comorbid psychological and neurological diseases.

Intervention groups
Cognitive rehabilitation program (including routine rehabilitation exercises in occupational therapy clinics) in addition to tDCS (application of 20 minutes of 2 mA current through the anode electrode on the scalp to the prefrontal dorsolateral region and the cathode electrode above the right eyebrow) presented on the intervention group. In the control group 1, shame tDCS is used (placing anode and cathode electrodes on the scalp for 20 minutes, establishing a current of 2 mA for 10 seconds and then cutting off the current for the next 10 seconds) with a rehabilitation program and in Control group 2 only runs the rehabilitation program.

Main outcome variables
Attention, working memory and information processing speed in people with MS

General information

Reason for update

Acronym
tDCS, MS

IRCT registration information
IRCT registration number: **IRCT20210819052231N1**
Registration date: **2022-04-04, 1401/01/15**
Registration timing: **prospective**

Last update: **2022-04-04, 1401/01/15**
Update count: **0**

Registration date
2022-04-04, 1401/01/15

Registrant information

Name
Hamide Aghachavoshi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7730 3532

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hm.aghachavoshi@uswr.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-20, 1401/03/30

Expected recruitment end date
2022-08-21, 1401/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of transcranial direct current stimulation(tDCS) on attention, working memory and information processing speed in people with MS

Public title
The effect of transcranial direct current stimulation (tDCS) on cognition in people with MS

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willing to participate in research Have a definitive diagnosis of MS by a specialist doctor EDSS score should be from 1 to 6 The person has no history of dementia and other psychotic illnesses There is no Recurrence of relapsing while doing the study Do not take corticosteroids for 28 days before the intervention Have no history of other neurological diseases

Exclusion criteria:
Do not complete the intervention Recurrence of relapsing occurs during the intervention

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting all samples for dividing them into groups as intervention experimental, control 1 and control 2 we will use the SAS application and the PROC SURVEYSELECT process, which is for generating a random sequence for experiments with more complex designs, including factorial experiments.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, outcome assessors and data analysts will be unaware of how people are grouped.

Placebo
Used

Assignment
Factorial

Other design features
In this study, three groups will be examined. A group called the intervention group will receive the intervention along with tDCS. The control group one will receive intended intervention with sham tDCS. Control group two will only receive the intervention without any stimulation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation

Street address
University of Rehabilitation Sciences and Socia Health, Koodkiar St., Daneshjoo Blvd., Evin,

City
Tehran

Province
Tehran

Postal code
1985713871

Approval date
2022-02-19, 1400/11/30

Ethics committee reference number
IR.USWR.REC.1400.303

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 obtained for attention in the Paired Associate Learning test

Timepoint
Measurement of attention at the beginning of the study and after three weeks and 2 months after the intervention

Method of measurement
Paired Associate Learning test

2

Description
Score obtained for working memory in the Spatial Span test

Timepoint
Measurement of working memory at the beginning of the study and after three weeks and 2 months after the intervention

Method of measurement
Spatial Span test

3

Description
Score obtained for data processing speed in Paced Auditory Serial Addition Test
Timepoint
Measurement of information processing speed at the beginning of the study and after three weeks and 2 months after the intervention
Method of measurement
Paced Auditory Serial Addition Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group first: Cognitive rehabilitation program (including routine rehabilitation exercises in occupational therapy clinics) in addition to tDCS stimulation (20 minutes of two milliampere current applied through the anode electrode on the scalp of the prefrontal dorsultral region and the cathode electrode upper of right eyebrow) 4 times a week for three weeks. The duration of each session will be 45 minutes.
Category
Rehabilitation

2

Description
Intervention group second: The tDCS is used artificially (placing the anode and cathode electrodes on the scalp for 20 minutes, establishing a 2 mA current for 10 seconds, and then cutting off the current for the next 10 seconds) with a cognitive rehabilitation program. 4 times a week for three weeks and the duration of each session will be 45 minutes.
Category
Rehabilitation

3

Description
Control group: Only the cognitive rehabilitation program runs. They will receive 4 times a week for three weeks and the duration of each session will be 45 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rofeideh hospital
Full name of responsible person
Nazila Akbarfahimi
Street address
Shahid Nemati St, south Salimi Ave., Anarzgoo Blv., Gheitariyeh
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Province
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Postal code
1935973476
Phone
+98 21 2220 5326
Email
rofeideh.hospital@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Masoud Fallahi Khoshknab
Street address
Koodakyar, Daneshjoo Blvd., Evin
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Postal code
1985713834
Phone
+98 21 7173 2000
Email
webmaster@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Hamide Aghachavoshi
Position

Masters student
Latest degree
Master
Other areas of specialty/work
Occupational Therapy
Street address
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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
Not applicable
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 data is potentially shareable after unidentifiable individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
All individuals, including researchers working in academic and scientific institutions and those working in the clinic, can apply for the data.
Under which criteria data/document could be used
The data will be provided to researchers for further studies or to use this data for related research.
From where data/document is obtainable
Hamideh Aghachavoshi Email Address: aghachavoshi_hamide@yahoo.com Address: Unit 4, Block 33/2, Eram Dead End, Besharat St., Hakimieh, Tehran Phone: 09137729652 Dr. Hojjatullah Haghgoo Email Address: H.haghgoo@yahoo.com Address: Department of Occupational Therapy, University of Rehabilitation and Social Health, Koodakiar St., Daneshjoo Blvd., Evin, Tehran Phone: 02122180063
What processes are involved for a request to access data/document
Files and documents will be provided to the applicant through correspondence and application to the Department of Occupational Therapy of the University of Rehabilitation Sciences and Social Welfare and the approval of the director and deputy director of the Department of Occupational Therapy.
Comments