Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation and comparison of gait pattern of patients with multiple sclerosis before and after an aerobic exercise course by fixed bicycle plus direct brain stimulation (tDCS)

Protocol summary

Study aim
Evaluation and comparison of gait pattern of patients with multiple sclerosis before and after an aerobic exercise course by fixed bicycle plus direct brain stimulation (tDCS)

Design
Ten patients with multiple sclerosis with Expanded Disability Status Scale (EDSS) score of less than 6 were included in the study. Initially demographic information and quality of life questionnaire will be filled for them. Gait analysis is then performed for them, after that the patient undergoes 12 sessions of fixed-bike exercise and brain stimulation, and again the questionnaires are filled and re-analyzed.

Settings and conduct
Imam khomeini hospital, Tehran university of medical science.

Participants/Inclusion and exclusion criteria
Inclusion criteria:the patients with multiple sclerosis; with mild to moderate involvement; with Expanded Disability Status Scale (EDSS)<6, Exclusion criteria: history of convulsion and major disease ;History of other major disease;history of head trauma

Intervention groups
12 session exercise with fixed bicycle with brain stimulation(TDCS), 2 times in week, 6 week

Main outcome variables
gait analysis variables include: walking velocity; cadence number, step number, cadence length, cadence angels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180703040321N2**
Registration date: **2020-02-29, 1398/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-29, 1398/12/10**
Update count: **0**

Registration date
2020-02-29, 1398/12/10

Registrant information

Name
mohaddeseh Azadvari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6119 2291

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m-azadvari@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-05, 1398/10/15

Expected recruitment end date
2020-03-18, 1398/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison of gait pattern of patients with multiple sclerosis before and after an aerobic exercise course by fixed bicycle plus direct brain stimulation (tDCS)

Public title

Evaluation of exercise plus brain stimulation on gait of patients with multiple sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
multiple sclerosis patient mild to moderate involvement, EDSS< 6

Exclusion criteria:
history of convulsion hisory of other major disease such as stroke and ...

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address
Imam Khomeini hospital, at the end of Keshavarz Blvd, Tehran

City
Tehran

Province
Tehran

Postal code
1419733141

Approval date
2020-01-04, 1398/10/14

Ethics committee reference number
IR.TUMS.IKHC.REC.1398.241

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
gait velocity

Timepoint
Before and after intervention

Method of measurement
according gait analysis results

2

Description
steps number

Timepoint
Before and after intervention

Method of measurement
According gait analysis results

3

Description
Cadance number

Timepoint
Before and after intervention

Method of measurement
According gait analysis results

4

Description
Step length

Timepoint
Before and after intervention

Method of measurement
According gait analysis results

5

Description
cadance Length

Timepoint
Before and after intervention

Method of measurement
According gait analysis results

6

Description
gait angels

Timepoint
Before and after intervention

Method of measurement

According gait analysis results

Secondary outcomes

1

Description
evaluation of quality of life
Timepoint
befor and after intervention
Method of measurement
MSQL-54 questionare

Intervention groups

1

Description
Intervention group: multiple sclerosis patients, at first we analysis gait of the patients, after that the patients will doing exercsie with TDCS for 12 session, after that we will analysis the patients gait again and will compare before and after gait analysis results.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Mohaddeseh Azadvari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran
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Phone
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Email
sahraian1350@yahoo.com
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
Mohaddeseh Azadvari
Position
1. Assistant professor of physical medicine and rehabilitation
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
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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
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
after finishing study, without name
When the data will become available and for how long
six months after publishing results
To whom data/document is available
all researchers
Under which criteria data/document could be used
for study
From where data/document is obtainable
send emaill for Dr Azadvari
What processes are involved for a request to access data/document
request by email
Comments