Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effects of mental fatigue on cognitive-motor interference during walking in people with multiple sclerosis and healthy

Protocol summary

Study aim

Investigating effects of mental fatigue on cognitive-motor interference during walking in people with multiple sclerosis and healthy

Design

A randomized, controlled, double-blind, parallel-group study with a pretest–posttest design in 30 healthy and 30 individuals with MS. Computer-generated block randomization will be used.

Settings and conduct

This study will be conducted at the Rehabilitation Research Center located in the Faculty of Rehabilitation Sciences, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. After the healthy and MS participants were classified into two fatigue and control groups, walking performance will be assessed on a treadmill at a preferred speed in the single walking and walking with concurrent consecutive subtraction of 7 numbers from a randomly selected number. Gait assessment will be performed using Vicon.Gait assessment will be conducted before and after fatigue induction and watching the documentary film. This study is double-blind and participants and outcome assessor will not be aware of type of grouping (mental fatigue induction or control).

Participants/Inclusion and exclusion criteria

Inclusion criteria: MMSE score >24, EDSS score <6
Exclusion criteria: Recurrence of the disease in the past 1 month, Visual involvement

Intervention groups

Participants in healthy and MS group will be randomly assigned to two groups of mental fatigue and control. Mental fatigue protocol: In this study, mental fatigue will be induced using a modified version of 100% incongruent visual Stroop task(color-word). Control: In this condition, participants will choose their favorite film from 3 suggested documentaries.

Main outcome variables

Dual task cost of double support phase; step width; cadence; stride length; stride time; swing phase; dual task cost of the coefficient of variation for double support phase; step width; stride length; stride time; swing phase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240111060675N2**
Registration date: **2026-10-18, 1405/07/26**
Registration timing: **prospective**

Last update: **2026-10-18, 1405/07/26**
Update count: **0**

Registration date

2026-10-18, 1405/07/26

Registrant information

Name
Razieh Mofateh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 3374 3101
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-19, 1405/07/27

Expected recruitment end date

2026-12-26, 1405/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of mental fatigue on cognitive-motor interference during walking in people with multiple sclerosis and healthy

Public title

Investigating the effects of mental fatigue on cognitive-motor interference during walking in people with multiple sclerosis and healthy

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of multiple sclerosis by a neurologist Ability to read and write in Persian Avoid alcohol, nicotine, and caffeinated beverages 24 hours before the study. MMSE Score > 24 Expanded Disability Status Scale (EDSS) > 6 Ability to walk without resting using an assistive device for 3 minutes No balance and gait disorders in healthy individuals

Exclusion criteria:

Recurrence of the disease in the past 1 month Visual involvement

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants in each group of healthy and MS will be assigned 1:1 to either the mental fatigue or control groups using a computerized block randomization method. Randomization will be performed using alternating blocks of variable size to maintain balanced allocation. The randomization sequence will be performed by an independent investigator who is not involved in the current research project. The groups will then be concealed by opaque envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind. As such, the participants and outcome assessors will not be aware of the type of grouping (mental fatigue group or control group) in people with MS and healthy

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan street, Department of Physiotherapy, School of Rehabilitation Sciences, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-33133

Approval date

2024-11-02, 1403/08/12

Ethics committee reference number

IR.AJUMS.REC.1403.423

Health conditions studied

1

Description of health condition studied

MS

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Dual task cost of gait variables

Timepoint

Before and after mental fatigue induction and watching a documentary film

Method of measurement

The dual task cost is the mean of the stance phase variables, stride width, cadence, stride length, stride time, and swing phase, and the dual task cost is the coefficient of variance of the stance phase variables, stride width, stride length, stride time, and swing phase. The dual task cost is calculated by subtracting the value of the variable in the dual task condition from its value in the single task condition, divided by its value in the single task condition, multiplied by 100.

Secondary outcomes

1

Description
Dual task cost of cognitive performance
Timepoint
Before and after inducing mental fatigue and watching a documentary film
Method of measurement
DDual task cost for cognitive task performance (percentage of correct responses) was calculated by subtracting the percentage of correct responses in the dual task condition from its value in the sitting condition divided by its value in the sitting condition multiplied by 100.

Intervention groups

1

Description
Intervention group: mental fatigue protocol: In this study, mental fatigue will be induced using a modified version of the 100% incongruent visual Stroop task (color-word).
Category
Rehabilitation

2

Description
Control group: In this group, participants will choose their favorite film from the 3 suggested documentaries.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation Research Center located in the Faculty of Rehabilitation Sciences, Ahvaz Jundishapur
Full name of responsible person
Razieh Mofateh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz 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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Razieh Mofateh
Position
Associate professor
Latest degree
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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
According to the research team's decision, there are no plans to publish it.
Study Protocol
No - There is not 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
Most data is shareable.
When the data will become available and for how long
Access period begins after results are published.
To whom data/document is available
The data will be available to physiotherapist
Under which criteria data/document could be used
Researchers and physiotherapists
From where data/document is obtainable
Applications can contact the following email for more information: mofatehr@yahoo.com
What processes are involved for a request to access data/document
After authentication and if approved by the people participating in the study, the individual can receive the information.
Comments