Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Optimizing motor learning in people with Multiple Sclerosis

Protocol summary

Study aim
Examine the impact of the optimized condition on motor learning in MS patients

Design
According to baseline assessments (e.g., walking speed, balance, and, cognitive assessments), patients were randomized into either the optimized or control groups. Following this, all patients participated in the acquisition phase, comprising three blocks of four trials. The instructions for these three blocks were contingent upon the assigned patient group. For the optimal group, patients practiced under EE, AS, or EF conditions in a counterbalanced order

Settings and conduct
The sample of this research included 30 MS patients (male and female) with an age range of 30 to 50 years and a physical disability scale (EDSS) between 2 and 5, who were selected from the patients referred to the MS center in Isfahan. First, in a briefing session, the steps of the exercise program and the duration of its implementation were explained to the participants. Then, in an interview using the sports medicine information questionnaire, the researcher examined the medical records including the attending physician, the drugs used by the patient, and in general their clinical, health and physical activity conditions. The patients were aware that they were participating in a research project, but due to one-way blinding, none of them know about the goals of the researcher and the specific protocol.

Participants/Inclusion and exclusion criteria
1) clinically definitive diagnosis of MS, 2) age > 18, 3) Expanded Disability Status Scale: 2.0–5.0, 4) ability to walk without aid (e.g., cane), 5) Timed Twenty-Five-Foot Walk Test (T25-FW) > 5 seconds, 6) normal cognitive status or absence of dementia was determined through the Mini-Mental State Exam

Intervention groups
optimal group Control group

Main outcome variables
Motor learning, Intrinsic Motivation, Mental effort, Movement-Specific Reinvestment, Positive Affect

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240709062370N2**
Registration date: **2024-08-10, 1403/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-10, 1403/05/20**
Update count: **0**

Registration date
2024-08-10, 1403/05/20

Registrant information

Name
Hamid Salehi

Name of organization / entity
The university of Isfahan

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Iran (Islamic Republic of)

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+98 31 3793 2577

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salehi@spr.ui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-03, 1403/05/13

Expected recruitment end date
2024-08-22, 1403/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Optimizing motor learning in people with Multiple Sclerosis

Public title
Optimizing motor learning in people with Multiple Sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
: 1) clinically definitive diagnosis of MS 2) age > 30 3) Expanded Disability Status Scale (EDSS): 2.0–5.0, 4) ability to walk without aid (e.g., cane), 5) Timed Twenty-Five-Foot Walk Test (T25-FW) > 5 seconds 6) normal cognitive status or absence of dementia was determined through the Mini-Mental State Exam (MMSE)

Exclusion criteria:
No modification has been made to disease-modifying medications or medications influencing walk performance and spasticity in the preceding 4 weeks.

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization method. For this purpose, the participants were listed alphabetically and each participant was assigned numbers one and two from this list. The unit of randomization was individual, and randomization was produced and applied using Excel software and the combination of two commands, SORTBY and ARRAYRAND. By applying this method, each participant will be randomly replaced in the control or optimal group, and the role of all related/unrelated variables in selecting participants in the two groups will be randomly neutralized.

Blinding (investigator's opinion)
Single blinded

Blinding description
Written informed consent document was obtained before participating in the experiment. They had not informed about the purpose of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics committees of University of Isfahan

Street address
The university of Isfahan, Hezar Jarib Ave

City
Isfahan

Province
Isfehan

Postal code
8174673444

Approval date
2023-11-12, 1402/08/21

Ethics committee reference number
IR.UI.REC.1402.122

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
Motor learning

Timepoint
Pretest (before intervention)

Method of measurement
Stopwatch

Secondary outcomes

1

Description
intrinsic motivation, Positive affect, mental effort

Timepoint
End of the practice

Method of measurement
Intrinsic Motivation Inventory (IMI), The Movement-Specific Reinvestment Scale (MSRS), The Rating Scale for Mental Effort (RSME), Positive Affect and Negative Affect Scales

Intervention groups

1

Description
Intervention group: one training session including 30 minutes of stepping training under optimal conditions (by providing motivational and attentional variables of optimal theory)
Category
Behavior

2

Description
Control group: one training session including 30 minutes of stepping training under natural (non-optimal) conditions.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
The MS Comprehensive Center in Isfahan
Full name of responsible person
Mr. Torabi
Street address
M.S Isfahan Center, Bahonar St, Isfahan, Iran
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isfms.pr@gmail.com
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The university of Isfahan
Full name of responsible person
Dr. Hadi Amiri
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The University of Isfahan, Azadi square, Isfahan, Iran
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info@ui.ac.ir
Web page address
https://www.ui.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The university of Isfahan
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
The University of Isfahan
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Hamid Salehi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Motor behavior
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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