

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effect of mental exercise and routine occupational therapy on balance and walking performance among patients suffering from multiple sclerosis (MS)

Protocol summary

Study aim

Investigation of the validity of the BESTest with Tinetti test, and laboratory tests of force plate and motion camera and evaluation the effect of mental practice on the balance and walking in patients with MS.

Design

A double-blind, randomized clinical trial with community-based and pragmatic control group and parallel group design

Settings and conduct

Twenty-two MS patients are randomly assigned into two experimental and control groups after completing the consent form and gathering data. All patients in both groups are evaluated in 3 stages. 1) The before the intervention, 2) after the intervention, 3) two weeks after the last intervention session. Everyone receives common practice for 3 sessions per week for 6 weeks. Also, the interventions group receives mental practice for 20 minutes in addition to the usual exercises. The method of the second phase (evaluation the validity of BESTest): 17 MS patients and 17 healthy people will be evaluated using Tinetti test, BESTest, force plate (static Balance) and motion camera (Dynamic Balance).

Participants/Inclusion and exclusion criteria

Inclusion criterion: MS diagnosis by specialist physician; EDSS = 1-5; People aged 18-18; Satisfaction to participate in the research. Exclusion criteria: Pregnancy; mental problems; fractures, presence of implants in the body, a history of attack and recurrence within the last 2 months.

Intervention groups

Intervention group includes 11 MS patients who receive 20 minutes of mental training in addition to common practice. Control group includes 11 MS patients who receive the only common practice of occupational therapy.

Main outcome variables

Walking; Independence in activity of daily living ; balance.

General information

Reason for update

Acronym

MS

IRCT registration information

IRCT registration number: **IRCT20181107041588N1**

Registration date: **2019-04-13, 1398/01/24**

Registration timing: **retrospective**

Last update: **2019-04-13, 1398/01/24**

Update count: **0**

Registration date

2019-04-13, 1398/01/24

Registrant information

Name

Fatemeh Hoseinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of mental exercise and routine occupational therapy on balance and walking performance among patients suffering from multiple sclerosis (MS)

Public title

Balance in MS patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of MS by an specialist physician People with mild to moderate disability scale (EDSS = 1-5) Age range of 18-65 years old At least 2 years after the onset of MS Voluntarily participation in the research Ability to perform exercises MMSE scores above 23 to ensure required cognitive function

Exclusion criteria:

Pregnancy having mental problems as well as fractures and the presence of implants in the body (according to patient records) having a history of attack and recurrence within the last 2 months (according to patient records) history of other neurological diseases (according to patient records) previous history of the epilepsy, tumors, osteoporosis, diabetes, etc. according to the physician diagnosis corticosteroid medication till 28 days before the evaluation visual and/or auditory problems that may interfere with the tests Failure to have mental retardation previous history of psychiatric illness that interferes with the examination process previous history of addiction and using psychoactive substances

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **56****Randomization (investigator's opinion)**

Randomized

Randomization description

Via simple randomization method using number box, the subjects will be individually assigned to two groups. Using random allocation rule (RAR), a bog box is provided for all samples, i. e., each subject is allocated a code number between one to last number, after final sample allocation. All codes are placed in a non-transparent envelope, and then, some numbers are transferred blindly from the first envelope to second,

until half of the code numbers are been transferred. Then, each envelope will be allocated to experimental and control groups via dropping coin. Finally, the numbers in each envelope are matched to the name of the subjects and will refer to receiving relevant interventions.

Blinding (investigator's opinion)

Double blinded

Blinding description

1- The researcher encodes patients after compliance with the entry criteria (each patient receives a code) 2. the assessor is Blind to the subjects assignment to the intervention group. He/she Assesses patients, refer them to rehabilitation services. 3. The subject's blindness to the intervention group: The patient receives special care for the group by providing a card containing the code without informing or communicating with other patients. 4. Blindness of the occupational therapist to the subjects assignment to the intervention group. The therapist provides occupational therapy services according to the protocol to each patient-code. 5. Patients with code belonging to the experimental group will refer to the special training site and receive the relevant services. 6. Blindness of the information analyzer on the subjects' assignment to the intervention group. Data will be evaluated and compared in three steps (before and after intervention and follow up). Then, two groups with different codes (blind to assigning code to the intervention group) are also compared.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of The University of Social welfare and Rehabilitation Sciences

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Koodak Yar Street, Daneshjoo Boulevard,Evin

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Approval date

2018-03-11, 1396/12/20

Ethics committee reference number

IR.USWR.REC.1396.300

Health conditions studied

1

Description of health condition studied

patients with MS

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

walking function

Timepoint

Before receiving interventions, after the last intervention session and two weeks after the intervention

Method of measurement

Using the questionnaire and patient records

Secondary outcomes

1

Description

Independence in activities of daily living performances (ADL)

Timepoint

Pretest, post test, two weeks follow-up

Method of measurement

Barthel Index

Intervention groups

1

Description

Intervention group 1: 11 patients with MS are selected as the intervention group. These subjects will receive mental practice for 20 minutes, in addition to the common occupational therapy exercises. The intervention will be conducted for 3 sessions per week and for 6 weeks. Individuals are evaluated in three times (1) before interventions (2) after interventions (3) 2 weeks after the last session of the intervention.

Category

Rehabilitation

2

Description

Control group 1: 11 patients with MS will be assigned as control group 1 and will receive common occupational therapy exercises for 3 45-minute sessions per week for 6 weeks. The participants will be evaluated in three times (1) before intervention (2) after intervention (3) 2 weeks after the last session of the intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofaideh Rehabilitation Hospital

Full name of responsible person

Nazila Akbar Fahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

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Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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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