Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target 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
Street address
Koodak Yar Street, Daneshjoo Boulevard,Evin
City
Tehran
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Tehran
Postal code
۱۹۸۵۷۱۳۸۷۱
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 whit 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 Reahabilitation 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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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
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
Fatemeh Hoseinpour
Position
MSc student
Latest degree
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Other areas of specialty/work
Occupational Therapy
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Person responsible for updating data

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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