Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of dual task training on somatosensory, balance, activity of daily living and Community participation in patient with relapsing-remitting Multiple sclerosis: Double Blind Clinical Trial

Protocol summary

Study aim

Effect of cognitive-motor dual task training on somatosensory, balance, activity of daily living and community integration in patient with relapsing-remitting Multiple sclerosis

Design

A prospective study of a blind clinical trial with two parallel, randomized groups

Settings and conduct

The samples are selected from the clients of the Multiple Sclerosis Society of Isfahan and randomly divided into two groups. Before the randomization, patients are described, which will be divided into two groups with two different programs. After obtaining patient consent and collecting demographic data, EDSS will be used to diagnose patients' incapacity. Clients, the person who evaluates, and the person who performs the rehab program do not know the type of group (intervention, control).

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of multiple sclerosis, EDSS 2-5/5, Ability to stand without any support, Having a sensory problem on the soles of the foot ,Remitting during the last 30 days, Having the ability to read and write, The doctor confirmed to participate in research Exclusion criteria: People with diseases such as diabetes, epilepsy and with any problem in the musculo-skeletal system: History of surgery, History of fractures, and ... that disturbs the balance, Receive corticosteroid treatment one month before the study, MMSE-less than 24, Uncorrected visual disorders, Relapsing, Inability to walk a distance of 25 feet with or without assistive device

Intervention groups

Intervention group: cognitive-motor dual task training control group: balance training

Main outcome variables

Intervention(cognitive-motor dual task training): independent variable Somatosensory: dependent variable Balance: dependent Community integration: dependent Instrumental activity of daily living: dependent Activity of daily living: dependent

General information

Reason for update

Acronym

Dual Task Training DTT

IRCT registration information

IRCT registration number: **IRCT20180523039792N1**
Registration date: **2019-06-13, 1398/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-13, 1398/03/23**
Update count: **0**

Registration date

2019-06-13, 1398/03/23

Registrant information

Name

Shirin Saberimobarake

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5229

Email address

shirin.saberi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dual task training on somatosensory, balance, activity of daily living and Community participation in patient with relapsing-remitting Multiple sclerosis: Double Blind Clinical Trial

Public title

Effect of dual task training on somatosensory, balance, Community participation and activity of daily living in Multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Neurologist EDSS Score 2-5/5(To be able to complete walking tests) Ability to stand without any support Having a sensory problem on the soles of the foot relapsing During the last 30 days Having the ability to read and write The doctor confirmed to participate in research

Exclusion criteria:

Diseases such as diabetes, epilepsy and ... Any problem in the musculoskeletal system: history of surgery, history of fractures, etc., which disturbs the balance. Corticosteroid treatment one month before the study MMSE less than 24 Uncorrected visual disorders Exacerbation of symptoms Inability to walk 25 ft with or without assisstive device Major depression

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Method: Restricted Randomization by random allocation rule method: first, a sample size determine and then randomly assign a set of them to Group A and assign the remainder to Group B. Random unit: Individual Non-transparent envelopes are used to hide random assignments In this method, first, a random sequence is created using the above method. Then, based on the sample size of the research, a number of envelopes with an aluminum wrapper (in order to avoid the clarity of the contents of the envelopes) are prepared and each random sequence created on a card is recorded and the cards is placed inside the envelopes. At the time of the start of the registration of the participants, one of the envelopes shall be opened in accordance with the order of entry of the eligible participants, and the group allocated to that participant shall be revealed. Process execution:One person will create a random sequence, the other will examine the participants in terms of inclusion and exclusion criteria and enroll them in the study, and the third person will assign the participants to the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant will be notified in two groups whose programs are different. Practitioners who train the intervention program do not know about the intervention and control group program.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan university of medical sciences

Street address

Isfahan university of medical sciences, Hezarjrib Ave.

City

Isfahan

Province

Isfehan

Postal code

81745-164

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.314

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
Somatosensory
Timepoint
Before the intervention, immediately after the intervention, one week after the end of the intervention
Method of measurement
monofilament

2

Description
Balance
Timepoint
Before the intervention, immediately after the intervention, one week after the end of the intervention
Method of measurement
Berg balance scale

3

Description
Balance
Timepoint
Before the intervention, immediately after the intervention, one week after the end of the intervention
Method of measurement
Force plate

Secondary outcomes

1

Description
Activities of daily living (basic, instrumental)
Timepoint
Before the intervention, immediately after the intervention, one month after the end of the intervention
Method of measurement
Barthel index score Lawton instrumental activity of daily living

2

Description
Community integration
Timepoint
Before the intervention, immediately after the intervention, one month after the intervention
Method of measurement
Community integration Questionnaire

Intervention groups

1

Description
Intervention group: Dual cognitive-motor exercises. At the beginning of the session, warm-up exercises are performed for 10 minutes, then balanced exercises begin. Each exercise consists of 2 courses, depending on the person's level of ability, each course performed one to two minutes and for repetitive exercises 10 to 15 repetitions. The rest time between each period is also 1 to 2 minutes. The intervention group performs the second cycle exercises with cognitive activity. At the end, the cooling exercises will take about 10 minutes.
Category
Rehabilitation

2

Description
Control group: Dual cognitive-motor exercises. At the beginning of the session, warm-up exercises are performed for 10 minutes, then balanced exercises begin. Each exercise consists of 2 courses, depending on the person's level of ability, each course performed one to two minutes and for repetitive exercises 10 to 15 repetitions. The rest time between each period is also 1 to 2 minutes. At the end, the cooling exercises will take about 10 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan MS Society
Full name of responsible person
Shirin Saberimobarake
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Yousef Gheysari
Street address
Faculty of Rehabilitation Sciences., Isfahan University of Medical Sciences., Hezarjrib Street
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Shirin Saberimobarake
Position
Researcher
Latest degree
Master
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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