Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of combined training protocol on postural control, motor function, fatigue and quality of life of individuals with multiple sclerosis

Protocol summary

Study aim

Main goal: Study of the effect of combined training protocol on postural control, motor function, fatigue and quality of life of individuals with multiple sclerosis.

Design

The present study is an applied and semi experimental research, including pretest and post test of two-blinded intervention and control group that studies the effect of combined training protocol on postural control, motor function, fatigue and quality of life of individuals with multiple sclerosis. Statistical population: Individuals with MS who had enrolled in Zanjan MS Association until 1396. Sample size: 60 subjects

Settings and conduct

This research will be conducted under the supervision of the professors of Tehran University and Zanjan University of Medical Sciences in collaboration with the MS Association of Zanjan Province.The main researcher and subjects have been blinded to the process described in previous section.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Relapsing Remitting Multiple Sclerosis diagnosed by neurologist - Expanded disability severity scale between 1 to 4 diagnosed by neurologist -History of disease for more than one year - Signed consent form for voluntarily attendance Exclusion criteria: -History of other diseases and neurological disorders such as stroke -Relapse of the disease in last three months -History of cardiovascular and respiratory diseases - Abnormal BMI - Presence of musculoskeletal deformities in spine and lower extremities -Use of auxiliary equipment for walking and other daily activities.-Etc

Intervention groups

The intervention group will conduct a combined training protocol for 8 weeks and each week 3 sessions.The control group will not attend in any intervention during the research.

Main outcome variables

Main outcomes: management and control of MS disorders, improvement of postural control, motor function, fatigue and quality of life in MS patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170115031954N1**
Registration date: **2018-10-22, 1397/07/30**
Registration timing: **retrospective**

Last update: **2018-10-22, 1397/07/30**
Update count: **0**

Registration date

2018-10-22, 1397/07/30

Registrant information

Name

Behzad Najafi

Name of organization / entity

University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 6212 8209

Email address

behzad.najafi@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

2018-06-10, 1397/03/20

Actual recruitment end date

2018-09-11, 1397/06/20

Trial completion date

empty

Scientific title

The effect of combined training protocol on postural control, motor function, fatigue and quality of life of individuals with multiple sclerosis

Public title

The effect of training protocol on multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Relapsing Remitting Multiple Sclerosis diagnosed by neurologist Expanded disability severity scale (EDSS) between 1 to 4 diagnosed by neurologist Diagnosed multiple sclerosis More than one year Signed consent form for voluntarily attendance

Exclusion criteria:

History of other diseases and neurological disorders such as stroke etc Relapse of the disease in the last three months History of cardiovascular and respiratory diseases Abnormal body mass index Presence of musculoskeletal disorders and deformities in the spine and lower extremities Use of auxiliary equipment for walking and other daily activities Severe cognitive impairment

Age

From **30 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

One of researcher assistants will be responsible for dividing randomly the subjects into two intervention and control groups and the other assistants and researcher will not be aware of this trend. After selecting the research subjects, this assistant will write the subjects name in similar form and size cards. Then, by specifying the position of a coin, a coin performs random assignments to each of the groups. It should be noted that after selecting any subject in the intervention or control group, his name is recorded on the sheet and the card of the subject is returned to the pot to draw the same chance and chance of the subjects.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, some assistants will help the main researcher. After selecting subjects, one of the assistants will divide subjects randomly into two groups of intervention and control. This assistant does not have any duty in the pretest, posttest and intervention procedure. None of the subjects know that he/she belongs to which group and the researcher will say that all of them attend in the intervention protocol but the date of intervention start is different.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Physical Education and Sport Sciences of University of Tehran Committee for Ethics in Bio

Street address

Faculty of physical education and sport sciences of university of Tehran, between avenue 15 and 16, North Karegar Avenue

City

Tehran

Province

Tehran

Postal code

1439813117

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.UT.SPORT.REC.1397.001

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

Postural control

Timepoint

Before and after 8 weeks intervention

Method of measurement

Zebris Force Distribution Measuring System (FDM-s),

Berg balance scale, Activities balance confidence scale

2

Description
Motor function
Timepoint
Before and after 8 weeks intervention
Method of measurement
Timed 25 Feet Walk Test (T25FW), Timed up and Go Test (TUG)

3

Description
Fatigue
Timepoint
Before and after 8 weeks intervention
Method of measurement
Fatigue severity scale (FSS)

4

Description
Quality of life
Timepoint
Before and after 8 weeks intervention
Method of measurement
Multiple Sclerosis Quality of Life (MSQOL-54)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will attend in combined training protocol consist of postural control (balance) training and Core stabilization training for 8 weeks according 24 sessions.
Category
Rehabilitation

2

Description
Control group:This group will not attend in any interventions in 8 weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan Multiple Sclerosis Association
Full name of responsible person
Behzad Najafi
Street address
No 47, Shahid Ganjkhanloo Alley, Safa Ave
City
Zanjan
Province
Zanjan
Postal code
4513654163
Phone
+98 45 1367 6154
Email
info@mscharity.ir
Web page address
http://mscharity.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Affairs of Physical Education and Sport Sciences Faculty of University of Tehran
Full name of responsible person
Dr Foad Seidi, Research vice president of faculty
Street address
Faculty of Physical Education and Sport Sciences of University of Tehran, between avenue 15 and 16, North Karegar Avenue
City
Tehran
Province
Tehran
Postal code
1439813117
Phone
+98 21 6111 8812
Email
foadseidi@ut.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Affairs of Physical Education and Sport Sciences Faculty of University of Tehran
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 Tehran
Full name of responsible person
Behzad Najafi
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Physical Education and Sport Sciences
Street address
Faculty of physical education and sport sciences of university of Tehran, between avenue 15 and 16, North Karegar Avenue
City
Tehran
Province
Tehran
Postal code
1439813117
Phone
+98 912 241 3821
Email
behzad.najafi@ut.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Tehran
Full name of responsible person
Behzad Najafi
Position
PhD student
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Physical Education and Sport Sciences
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City
Tehran
Province
Tehran
Postal code
1439813117
Phone
+98 912 241 3821
Email
behzad.najafi@ut.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
University of Tehran
Full name of responsible person
Behzad Najafi
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Physical education and sport sciences
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City
Tehran
Province
Tehran
Postal code
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behzad.najafi@ut.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All information and data to be provided after identification and any information relevant to this research, including the protocol of intervention, statistical method, etc., in the form of research papers through valid and approved publications by the Ministry of Science or the Ministry Health or foreign journals will be available to interested hobbyists and researchers in this area.
When the data will become available and for how long
After 2 years of publishing results
To whom data/document is available
The research data will be available to researchers working in academic association, specialists, doctors and any one research on MS.
Under which criteria data/document could be used
The research data will be available to researchers working in academic association, specialists, doctors and any one research on MS after publishing the relevant articles extracted this research.
From where data/document is obtainable
Researcher via email: behzad.najafi@ut.ac.ir
What processes are involved for a request to access data/document

After publishing the research results in the form of internal and international articles, the applicant can submit his/ her application by email to the researcher.

Comments