

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Ganjkhanelo 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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+98 912 241 3821

Email

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