

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The Effect of Aerobic-cognitive Combined Training on Inflammatory factors and Mental fatigue in Multiple Sclerosis Patients

Protocol summary

Study aim

Determining the effect of Brighton training on plasma levels of interleukin-17 (IL17), interleukin-4 (IL4), ratio of interleukin-17 to interleukin-4, Dual Task and functional test, PVT cognitive test, cognitive profile questionnaire of POMS mood modification, fatigue correction MFIS, St. Petersburg Sleep Quality and Vickery Quality of Life for MS Patients

Design

The research project will have 3 training and control groups, with parallel groups, blinded, randomized, on 45 patients. Simple randomization and toss throwing will be used for randomization.

Settings and conduct

The full implementation of this research project in the pre-test and post-test period will be done in the MS clinic of Imam Hossein hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with recurrent and clinically stable MS, a minimum disability (EDSS) below 3, the age range of 20 to 50 years. Exclusion criteria: cardiovascular disease, diabetes, thyroid disorders, gout, orthopedic restrictions, patients who have an attack 4 weeks before or during the project.

Intervention groups

Patients will be randomly divided into 3 groups: aerobic-cognitive training, aerobic training and control.

Main outcome variables

Brighton training on plasma levels of interleukin-17 (IL17), interleukin-4 (IL4), interleukin-17 to interleukin-4 ratio, Dual Task and TUG functional test, PVT cognitive test, POMS mood profile cognitive questionnaire tests, modified fatigue MFIS will affect the quality of sleep in St. Petersburg and the quality of life of Vicky patients with MS.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211214053407N1**

Registration date: **2021-12-28, 1400/10/07**

Registration timing: **prospective**

Last update: **2021-12-28, 1400/10/07**

Update count: **0**

Registration date

2021-12-28, 1400/10/07

Registrant information

Name

sara farajnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-01, 1400/10/11

Expected recruitment end date

2022-03-02, 1400/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aerobic-cognitive Combined Training on Inflammatory factors and Mental fatigue in Multiple Sclerosis Patients

Public title

The effect of exercise on fatigue in MS

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The subjects used in this study will be patients with MS and all of them will use interferon. People with recurrent and clinically stable MS with a minimum of disability (EDSS) below 3 will be selected for this study. The age range of the subjects will be 20 to 50 years (based on the average age of the patients).

Exclusion criteria:

People with cardiovascular disease, diabetes, thyroid disorders, gout, and orthopedic restrictions Patients who have an attack 4 weeks before or during the project. No signing the consent form approved by the Research Ethics Committee

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in this study will be divided into 3 groups of aerobic-cognitive training, aerobic training, and control by simple randomization method and by throwing baldness. The division is such that the names of all the candidates will be written on a piece of paper and the names of each bald person will be placed in front of it. 5 and 6 are also considered for the division of the control group. It should also be noted that if the quorum of each group reaches the quorum, the numbers belonging to that group will be awarded equally to the other two groups. For example, if 14 people in the first group are completed, the number 1 will be assigned to the second group and the number 2 to the third group, and henceforth the numbers 1, 3, and 4 for the second group and the numbers 2, 5 and 6 will be for the third one.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

National Committee for Ethics in Biomedical Research

Street address

Ghods Town (West) - Between South Flamek and Zarafshan, Iran TV Street - Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th Floor

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2021-12-19, 1400/09/28

Ethics committee reference number

IR.SBU.REC.1400.177

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**

Determining the effect of Brightonic training on mental fatigue in patients with MS

Timepoint

Pre-test and post-test

Method of measurement

Mental fatigue will be assessed by the MFIS Modified Fatigue Effect Questionnaire.

2**Description**

Determining the effect of Brightonic training on inflammatory factors in patients with MS

Timepoint

Pre-test and post-test

Method of measurement

Inflammatory factors will be assessed by measuring the plasma levels of interleukin 17 and interleukin 4 and their ratios.

Secondary outcomes**1****Description**

Determining the effect of Brightonic training on sleep quality in patients with MS

Timepoint
Pre-test and post-test

Method of measurement
By the Petersburg Sleep Quality Questionnaire

2

Description
Determining the effect of Brightonic training on quality of life in patients with MS

Timepoint
Pre-test and post-test

Method of measurement
By Vickery Quality of Life Questionnaire

Intervention groups

1

Description
Intervention group 1: Performing 8 weeks of aerobic-cognitive training called Brightonic training, which includes 2 sessions of approximately 40 minutes each week.

Category
N/A

2

Description
Intervention group 2: Perform 8 weeks of aerobic exercise called isotonic exercise, which includes 2 sessions of approximately 40 minutes each week.

Category
N/A

3

Description
Control group: 8 weeks without any activity and exercise.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
MS Clinic of Imam Hossein Hospital, Tehran

Full name of responsible person
Dr. Nahid Baladi Moghadam and Dr. Mehran Ghaffari

Street address
Tehran, Imam Hossein Square, at the beginning of Shahid Madani Street, Imam Hossein Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Faculty of Physical Education and Sport Sciences, Shahid Beheshti University, Tehran

Full name of responsible person
Dr. Rana Fayaz Milani

Street address
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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
Faculty of Physical Education and Sport Sciences, Shahid Beheshti University, 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
Faculty of Physical Education and Sport Sciences, Shahid Beheshti University, Tehran

Full name of responsible person

Sara Farajnia
Position
PhD student in sports physiology
Latest degree
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Other areas of specialty/work
Physiology
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Plasma levels of interleukin-17 and interleukin-4 and mental fatigue Some of the data that will be related to the main consequences of the work will be shared after the people are not identified.

When the data will become available and for how long

Access period starts 1 year before the results are published

To whom data/document is available

Researchers related to MS

Under which criteria data/document could be used

To study in patients with multiple sclerosis

From where data/document is obtainable

1. Department of Sports Physiology, Faculty of Physical Education and Sport Sciences, Shahid Beheshti University, Tehran 2. MS Clinic of Imam Hossein Hospital, Tehran

What processes are involved for a request to access data/document

1. Request via email Dr. Rana Fayyaz Milani 2. Request via e-mail Dr. Mehran Ghaffari

Comments