Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Brightonic 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
Brightonic 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)

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+98 21 2641 6337

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

Tehran, Evin, Shahid Shahriari Square

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Email

pr-office@sbu.ac.ir

Web page address

https://www.sbu.ac.ir

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 tudent in sports physiology

Latest degree
Master

Other areas of specialty/work
Physiology

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Tehran - Saadat Abad - Mohammad Ali Keshavarz Boulevard - East East Corner - No. 35 - Viva Yuka Tower - West West Unit

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Shahid Beheshti University of Medical Sciences

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Full name of responsible person
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Position
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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