

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

The effect of an 8-week aerobic training at home and vitamin D supplementation on serum values of Brain-derived neurotrophic factor (BDNF), Nerve growth factor (NGF), fatigue level and quality of life in patients with Multiple Sclerosis During Covid-19 quarantine

Protocol summary

Study aim

The aim of this study was to evaluate the effect of 8-weeks of aerobic training at home and vitamin D supplementation on serum levels of BDNF, NGF, fatigue and quality of life in patients with multiple sclerosis during Covid-19 quarantine.

Design

For this purpose, 36 women with multiple sclerosis will be randomly divided into 4 groups: aerobic training + vitamin supplementation, aerobic training, vitamin D supplementation and control, as well as vitamin D intake (about 50,000 IU= 1/25 mg per week for eight weeks); Or it will be a placebo. The aerobic training protocol includes 25 to 40 minutes of aerobic exercise with an intensity of 50 to 70% of the maximum heart rate, 3 times a week for eight weeks and online.

Settings and conduct

This study was a clinical trial on the effect of 8-weeks of aerobic training at home and vitamin D supplementation on serum levels of BDNF, NGF, fatigue and quality of life in patients with multiple sclerosis during coronary quarantine under the supervision of Razi University of Kermanshah. Pre-test and post-test will be performed.

Participants/Inclusion and exclusion criteria

At least 2 years of disease history Expanded Disability Status Scale (3-5) Lack of regular exercise No smoking Do not take immunosuppressive drugs Heart disease High blood pressure Orthopedic disorders Use of other drugs in addition to MS drugs

Intervention groups

Aerobic training (placebo); Vitamin D supplementation (no AT); Aerobic training with vitamin D supplements (AT+Vit D); and Control (placebo+no AT)

Main outcome variables

Brain-derived neurotrophic factor (BDNF)- Nerve growth factor (NGF)- Fatigue- quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049525N1**

Registration date: **2021-05-16, 1400/02/26**

Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**

Update count: **0**

Registration date

2021-05-16, 1400/02/26

Registrant information

Name

Elahe Bahmani Meianrodi

Name of organization / entity

Razi University of Kermanshah

Country

Iran (Islamic Republic of)

Phone

+98 83 3429 7186

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an 8-week aerobic training at home and vitamin D supplementation on serum values of Brain-derived neurotrophic factor (BDNF), Nerve growth factor (NGF), fatigue level and quality of life in patients with Multiple Sclerosis During Covid-19 quarantine

Public title

The effect of aerobic training at home and vitamin D supplementation in MS During Covid-19 quarantine

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with Multiple sclerosis (MS) with at least 2 years of history Lack of regular exercise Do not take immunosuppressive drug No smoking Expanded Disability Status Scale (3-5)

Exclusion criteria:

Heart disease High blood pressure Orthopedic disorders Use of other drugs in addition to MS drugs

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Razi University of Kermanshah

Street address

No. 8, University Blvd, Kermanshah Province, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2021-04-03, 1400/01/14

Ethics committee reference number

IR.RAZI.REC.1400.002

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**

Vitamin D

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By Blood sampling

2**Description**

Brain-derived neurotrophic factor

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By Blood sampling

3**Description**

Nerve growth factor

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By Blood sampling

4**Description**

IL-10

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By Blood sampling

5**Description**

TNF-Alpha

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By Blood sampling

6

Description

Fatigue

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By questionnaire

7

Description

Quality of life

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Aerobic training + vitamin D supplementation group: The aerobic training + vitamin D supplementation Intervention will be consists of 25-40 minutes of aerobic exercise at 50% - 70% of HRmax, 3 times a week for eight weeks online and vitamin D supplementation will be receiving vitamin D (~50000 IU • week for eight weeks) receiving vitamin D (about 50,000 IU per week for 8-weeks).

Category

Lifestyle

2

Description

Intervention group 2: aerobic training group: Aerobic training consists of 25 to 40 minutes of aerobic exercise with an intensity of 50 to 70% of maximum heart rate, 3 times a week for eight weeks online.

Category

Lifestyle

3

Description

Intervention group 3: Vitamin D supplementation group: Vitamin D supplementation includes receiving vitamin D (~50000 IU • week for eight weeks).

Category

Lifestyle

4

Description

Control group: Control group: receiving placebo and no aerobic training for eight weeks.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah MS Clinic

Full name of responsible person

Elahe Bahmani mianroudi

Street address

No. 9, Razi University Blvd: Taq Bostan, Faculty of Physical Education and Sports Sciences.

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Email

elbahmani74@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Razi University of Kermanshah

Full name of responsible person

Dr. Farzad Veysi

Street address

No.9, Taqh-Bostan Ave, University Blvd, Razi University.

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R.Hoseini@razi.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The Razi University of Kermanshah

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**

Razi University

Full name of responsible person

Rastegar Hoseini

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Elahe Bahmani mianroudi

Position

Master

Latest degree

Bachelor

Other areas of specialty/work

Others

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be record in the SPSS software and will be available

When the data will become available and for how long

Availability will start nine months after publishing all papers

To whom data/document is available

Only available for researchers in academic and scientific institutions

Under which criteria data/document could be used

All data can be used as reference

From where data/document is obtainable

elbahmani74@gmail.com R.hoseini@razi.ac.ir

What processes are involved for a request to access

data/document

If the explanation for data request would be convincing it will be given in 3 days.

Comments