Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 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)
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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
۶۷۱۴۴۱۴۹۷۱
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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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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Email
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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Person responsible for updating data

Contact
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Razi University
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