Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of 12-weeks combined exercise training on body composition, disability scale, and NGF, BDNF, and VDBP serum concentrations in women with multiple sclerosis

Protocol summary

Summary

The purpose of this study was to investigate the effect of concurrent training on the Brain-derived Neurotrophic factor, Nerve growth factor and Vitamin D-binding protein serum concentrations in women with multiple sclerosis. Twenty four 20-50-year-old women with EDSS score of 2-5 were randomly divided into control (n=12) and experimental (n=12) groups, using random number function in excel. We didn't have blinding in this study. All participants had regular menstrual cycles and had never participated in any regular exercise training before the beginning of the study. Inclusion criteria: EDSS score of 2 to 5 (approved by neurologist through MS diagnostic tests including MRI or CT scan and functional tests for balance, strength, walking ability, and visual and tactile senses); women aged between 20 and 50 years; regular menstrual cycle, absence of any other acute or chronic diseases; Not participating in any regular exercise training. The training protocol included one resistance exercise session and two aerobic exercise sessions per week for 12 weeks. The main dependent variables of this study were NGF, BDNF, and VDBP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032633146N1**
Registration date: **2017-08-11, 1396/05/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-11, 1396/05/20

Registrant information

Name
Vahid Tadibi
Name of organization / entity
Razi University
Country
Iran (Islamic Republic of)
Phone
+98 83 3427 9265
Email address
vahidtadibi@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 12-weeks combined exercise training on body composition, disability scale, and NGF, BDNF, and VDBP serum concentrations in women with multiple sclerosis

Public title

The effect of exercise training on women with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Inclusion criteria: EDSS score of 2 to 5

(approved by neurologist through MS diagnostic tests including MRI or CT scan and functional tests for balance, strength, walking ability, and visual and tactile senses); women aged between 20 and 50 years; regular menstrual cycle, donot presence of any other acute or chronic diseases; not participating in any regular exercise training. Exclusion criteria: Did not have one of the condition of entry

Age
From **20 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization was performed in the form random categorized and in each class, a simple randomization method was used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences

Street address
Sabzevar University of Medical Sciences, Tehran-Sabzevar road

City
Sabzevar

Postal code

Approval date
2016-02-01, 1394/11/12

Ethics committee reference number
IR.MEDSAB.REC.1394.137

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
Nerve growth factor(NGF)

Timepoint
Before and after training

Method of measurement
ELISA Kit

2

Description
Brain-derived neurotrophic factor(BDNF)

Timepoint
Before and after training

Method of measurement
ELISA Kit

3

Description
Vitamin D-binding protein(VDBP)

Timepoint
Before and after training

Method of measurement
ELISA Kit

4

Description
Disability status scale

Timepoint
Before and after training

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: combined exercise training included aerobic and resistance exercises, three sessions per week (two sessions of aerobic training and one session of resistance training), lasting 12 weeks.

Category
Rehabilitation

2

Description

Control group: had received no exercises and did their normal activities

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Special Disease Center, Vasei Hospital

Full name of responsible person
Maryam Bahram por

Street address
Special Disease Center, Vasei Hospital, Bagh Melli square, Sabzevar

City
Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Razi University

Full name of responsible person
Mohammad Joshaghani

Street address
Central Building of Razi University, Bagh Abrisham, Taq Bostan, Kermanshah

City
Kermanshah

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Vice Chancellor for research of Razi University

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Razi University

Full name of responsible person
Mitra Khademosharie

Position
PhD in Exercise Physiology

Other areas of specialty/work

Street address
In front of oil depot, Shahrbani Square, Sabzevar

City
Sabzevar

Postal code

Phone
+98 51 4465 9021

Fax

Email
m_khadem_un@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Razi University

Full name of responsible person
Vahid Tadibi

Position
Associate Professor of Exercise Physiology

Other areas of specialty/work

Street address
Razi University, Daneshgah Avenue, Taq-e Bostan, Kermanshah

City
Kermanshah

Postal code

Phone
+98 83 3427 7609

Fax

Email
vtadibi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Razi University

Full name of responsible person
Mitra Khademosharie

Position
PhD in Exercise Physiology

Other areas of specialty/work

Street address
In front of oil depot, Shahrbani Square, Sabzevar

City
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+98 51 4465 9021

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m_khadem_un@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty