

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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

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Iran (Islamic Republic of)

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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