Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of eight weeks Outdoor and Home-Based Pilates Training on sirtuin1, Chemokine CC ligand 20, serum vitamin D, physical function and some psychological factors in women with multiple sclerosis

Protocol summary

Study aim

The main purpose of this study was to evaluate the effect of eight weeks of Pilates training at home and outdoors on Sirtuin , Chemokine CC ligand 20, serum vitamin D, physical function and some psychological factors in women with multiple sclerosis.

Design

Clinical trial with control group, with parallel groups, double-blind, phase 2 on 44 patients. Excel software rand function will be used for randomization.

Settings and conduct

First, 44 people will selected from all women with multiple sclerosis in Fasa. They will then be divided into three groups. The written consent will be received from the subjects based on their voluntary and conscious participation in the training sessions. Before starting the training, two or three sessions of introduction, information about the benefits and possible side effects, as well as how to participate for patients and the required factors (height, weight, BMI, etc.) are measured. Anthropometric characteristics of . Also, cardiorespiratory endurance, muscular endurance, balance and flexibility, endurance, stress, anxiety and sleep quality, as well as blood indicators including sirt1, ccl20 And serum vitamin D will be measured before and after eight weeks of fasting exercise. The place of blood sampling and analysis of the results of Fasa Medical Sciences Laboratory will be.

Participants/Inclusion and exclusion criteria

No smoking, no regular exercise and at least two years of history of the Cardiac and respiratory disease

Intervention groups

In this study, subjects will divided into three groups: Pilates training at home (15 people), Pilates training outdoors (15 people) and control group (14 people).

Main outcome variables

Sirtuin1 Serum Chemokine CC ligand 20 Serum Serum Vitamin D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220316054315N1**
Registration date: **2022-03-29, 1401/01/09**
Registration timing: **prospective**

Last update: **2022-03-29, 1401/01/09**
Update count: **0**

Registration date

2022-03-29, 1401/01/09

Registrant information

Name

halimeh vahdatpoor

Name of organization / entity

Hakim sabavari

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 2592

Email address

hvahdatpoor.114@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-15, 1401/02/25

Expected recruitment end date

2022-07-16, 1401/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks Outdoor and Home-Based Pilates Training on sirtuin1, Chemokine CC ligand 20, serum vitamin D, physical function and some psychological factors in women with multiple sclerosis

Public title

The effect Pilates Training on multiple sclerosis

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria included no smoking, no regular exercise at least two years of history

Exclusion criteria:

Muscle injuries, inability to perform exercise severe recurrence of the disease participation in a training program other than the training protocol of research pregnancy recurrence of MS in the last 12 weeks change in MS medication or steroid treatment in 12 weeks Past and period of practice non-cooperation until the end of the research process severe recurrence of the disease

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sabzevar Hakim University Code of Ethics Committee

Street address

Tohid Town, University Street

City

Sabzavar

Province

Razavi Khorasan

Postal code

9617976487

Approval date

2021-11-14, 1400/08/23

Ethics committee reference number

IR.HSU.REC.1400.019

Health conditions studied

1

Description of health condition studied

Patients with MS

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Physical function based on 6 minutes walking time

Timepoint

Periods of this study before the intervention and 2 days after the intervention

Method of measurement

Measurement of physical function (cardiorespiratory endurance) by 6-minute walking test

2

Description

Investigation of inflammatory status

Timepoint

Measurement of serum cysteine 1 and chemokine 20

Method of measurement

Before intervention and 2 days after intervention

3

Description

Check serum vitamin D status

Timepoint

Before intervention and 2 days after intervention

Method of measurement

Examination of blood serum vitamin D by the kit

Secondary outcomes

1

Description

Assess stress and anxiety

Timepoint

Before the intervention and 2 days after the intervention

Method of measurement

By means of the DASS-21 Stress-Anxiety Questionnaire

2

Description
Evaluation of resilience
Timepoint
Before the intervention and 2 days after the intervention
Method of measurement
By Connor-Davidson Resilience Questionnaire

3

Description
Evaluation of sleep quality
Timepoint
Before the intervention and 2 days after the intervention
Method of measurement
By Sleep Quality Questionnaire

Intervention groups

1

Description
Intervention group1: Pilates Exercise Group Outdoors Intervention.15 people will perform an exercise program for eight weeks (three sessions per hour).
Category
Diagnosis

2

Description
Intervention group2: group. Pilates practice at home. 15 people will perform an exercise program for eight weeks (three sessions per hour).
Category
Diagnosis

3

Description
Control group: 14 people will participate in the study for eight weeks and will not run any exercise program.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Fasa Neuroscience Center
Full name of responsible person
Dr. Kaveh Kashani
Street address
Tohid Town, University Street
City
Sabzavar
Province
Razavi Khorasan
Postal code
9617976487
Phone
+98 51 4401 2765
Email
vahdatpoor.114@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hakim Sabzevari University
Full name of responsible person
dr roya askari
Street address
Tohid Town, University Street
City
sabzavar
Province
Razavi Khorasan
Postal code
9617976487
Phone
+98 51 4401 2765
Email
vahdatpoor.114@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
This research work does not have a sponsor or sponsor.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
the Hakim Sabzevari University
Full name of responsible person
dr roya askari
Position
University professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport physiology
Street address
Tohid Town, University Street
City
sabzavar

Province
Razavi Khorasan
Postal code
9617976487
Phone
+98 51 4401 2763
Email
vahdatpoor.114@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
the Hakim Sabzevari University
Full name of responsible person
halimeh vahdatpoor
Position
PhD student in sports physiology
Latest degree
Ph.D.
Other areas of specialty/work
Sport physiology
Street address
Tohid Town, Hakim Sabzevari University
City
sabzavar
Province
Razavi Khorasan
Postal code
9617976487
Phone
+98 51 4401 2763
Email
hvahdatpoor.114@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
the university of hakim sabevari
Full name of responsible person
halimeh vahdarpoor
Position
PhD student in sports physiology
Latest degree
Ph.D.
Other areas of specialty/work
sports physiology
Street address
no.8, west.Tohid Town, University Street
City
sabavar
Province
Razavi Khorasan
Postal code
9617976487
Phone
+98 51 4401 2763
Email
hvahdatpoor.114@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available