

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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 physiilogy

**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