

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The effect of eight weeks Home-Based and Outdoor Pilates Training on Neurofilament light chain, Kynurenine pathway, serum vitamin D, physical function and some psychological factors in women with multiple sclerosis

#### Protocol summary

##### Study aim

Determining the effect of home-based (HPT) and outdoor (OPT) Pilates training on 1. Improvement of Neurofilament Light Chain 2- Improvement of the Kynurenine pathway 3- Improvement of vitamin D 4- Improvement of physical function 5- Improvement of mental function In women with MS

##### Design

A clinical trial with the control group, with parallel groups, double-blind, phase 2 on 44 patients. Excel software rand function was used for randomization.

##### Settings and conduct

First, 44 people selected from all women with multiple sclerosis in Fasa and divided into three groups. The written consent was 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, agility and muscle strength, and fatigue, quality of life and depression, as well as blood indicators including NfL, Kynp And serum vitamin D were measured before and after eight weeks of fasting exercise. The place of blood sampling and analysis of the results were Fasa Medical Sciences Laboratory.

##### Participants/Inclusion and exclusion criteria

Admission requirements include no smoking, no regular exercise, at least two years of history Exclusion criteria include muscle injuries, severe recurrence of the disease, inability to perform the exercise

##### Intervention groups

Intervention group 1: 8 weeks of home-based and outdoor Pilates training (3 sessions per week, 1hour each

session) Control group: did not do any regular exercise for eight weeks and remained sedentary.

##### Main outcome variables

Neurofilament light chain, Kynurenine pathway, serum Vitamin D, functional ability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220324054348N1**

Registration date: **2022-05-09, 1401/02/19**

Registration timing: **retrospective**

Last update: **2022-05-09, 1401/02/19**

Update count: **0**

##### Registration date

2022-05-09, 1401/02/19

##### Registrant information

##### Name

Faranak Balaghi Inaloo

##### Name of organization / entity

The University of Hakim Sabzevari

##### Country

Iran (Islamic Republic of)

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+98 51 4401 2755

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-09, 1400/11/20  
**Expected recruitment end date**  
2022-04-09, 1401/01/20  
**Actual recruitment start date**  
2022-02-04, 1400/11/15  
**Actual recruitment end date**  
2022-04-09, 1401/01/20  
**Trial completion date**  
2022-04-09, 1401/01/20

#### Scientific title

The effect of eight weeks Home-Based and Outdoor Pilates Training on Neurofilament light chain, Kynurenine pathway, serum vitamin D, physical function and some psychological factors in women with multiple sclerosis

#### Public title

The effect of Pilates exercise on the treatment of multiple sclerosis

#### Purpose

Health service research

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

at least two years of history EDSS between 2 and 5 no smoking, no regular exercise

##### Exclusion criteria:

Muscle injuries Severe relapse of the disease disability to perform sports exercises Lack of regular participation in the training protocol Participate in a training program other than the research training protocol, Pregnancy relapse of MS in the last 12 weeks Change in MS medication or steroid treatment in the last 12 weeks and period of practice Lack of cooperation until the end of the research process

#### 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**

Actual sample size reached: **34**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Among the reasons for this study is the role of home-based exercise in preventing the risk of Covid 19 in sports venues, the benefits of Pilates training and its ability to perform and adjust its intensity at home, its low cost and popularity among these patients, and its impact on improving the condition. Functional and psychological

of these patients and, most importantly, considering the role of sunlight in the absorption of vitamin D and its effect on disease severity and modulation of psychological factors, it is not yet clear whether exercise through the kynurenine pathway or through other mediators can affect the results. Whether it has a psychological effect or not (Lim et al., 2021). Therefore, according to studies conducted so far, no research has been observed on the effect of Pilates exercise at home and outdoors on the structural proteins of neurons and important molecular pathways in the progression of the disease and psychological and physical factors in patients with MS. Therefore, this study is the first study to compare the effect of 8 weeks of Pilates training at home and outdoors on NFL indices, kynurenine pathway (KYN, TRP, KA, QA), serum vitamin D, and some psychological factors (fatigue, depression, quality of life). And physical function (coordination, balance, abdominal muscle endurance, gait endurance, and upper and lower body muscle strength) of women with MS.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Research, Hakim Sabzevari University

##### Street address

Tohid Town

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sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617976487

#### Approval date

2021-10-16, 1400/07/24

#### Ethics committee reference number

IR.HSU.REC.1400.015

## 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

Blood serum vitamin D status

**Timepoint**

48 hours before and 48 hours after the intervention

**Method of measurement**

enzyme-linked immunosorbent assay (ELISA) by the Kit

**2**

**Description**

the inflammatory status of axonal damage (Neurofilament light chain)

**Timepoint**

2 days before the intervention and 2 days after the intervention

**Method of measurement**

enzyme-linked immunosorbent assay (ELISA) by the Kit

**3**

**Description**

Status of neuroprotective metabolites in the kynurenine pathway (kynurenine and kynurenic acid)

**Timepoint**

48 hours before and 48 hours after the intervention

**Method of measurement**

Liquid chromatography-mass spectrometry (LC-MS)

**4**

**Description**

Status of neurodegenerative metabolite in the kynurenine pathway (quinolinic acid)

**Timepoint**

48 hours before and 48 hours after the intervention

**Method of measurement**

Liquid chromatography-mass spectrometry (LC-MS)

**Secondary outcomes**

**1**

**Description**

Assess fatigue status

**Timepoint**

Before the intervention and 2 days after the intervention

**Method of measurement**

By the Fatigue Severity Scale (FSS) Questionnaire

**2**

**Description**

Evaluation of Quality of life

**Timepoint**

48 hours before and 48 hours after the study

**Method of measurement**

By multiple sclerosis Quality of life-54 (MSQOL-54) Questionnaire

**3**

**Description**

evaluation of depression

**Timepoint**

48 hours before and 48 hours after the study

**Method of measurement**

questionnaires Depression, Anxiety, Stress Scales (DASS-21)

**4**

**Description**

Physical function based on 6 minutes walking time

**Timepoint**

48 hours before and 48 hours after the study

**Method of measurement**

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

**Intervention groups**

**1**

**Description**

Intervention group1: Pilates Exercise Group Outdoors Intervention.15 people performed an exercise program for eight weeks (three sessions per week, each session one hour). The exercise consisted of three parts: warming up, the main body of the exercise, and cooling down. The subjects had to perform 7, 14, and 9 Pilates movements in each section, respectively.

**Category**

Diagnosis

**2**

**Description**

Intervention group2: group. Pilates practice at home. 15 people performed an exercise program for eight weeks (three sessions per week, each session one hour). The exercise consisted of three parts: warming up, the main body of the exercise, and cooling down. The subjects had to perform 7, 14, and 9 Pilates movements in each section, respectively.

**Category**

Diagnosis

**3**

**Description**

Control group: 14 people participated in the study for eight weeks and did 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

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## Sponsors / Funding sources

### 1

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**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
The University of Hakim Sabzevari  
**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**  
Academic

## Person responsible for general inquiries

#### Contact

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## 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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available