Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity
The University of Hakim Sabzevari

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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

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sabzevar

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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 deppresion

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

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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

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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