

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluate of the impact Yoga and Pilates Training on Serum Prolactin and Cortisol, Selected Psychological, and Physical Indicators in Female Patients with Multiple Sclerosis

Protocol summary

Study aim

Effects of Yoga vs. Pilates Training on PRL and Cortisol Serum Levels, as well as physical and psychological indicators in females with MS

Design

Study 1: Fifteen participants in this study will be volunteers from the MS Center that will randomly be separated into three groups: yoga group (n=5), Pilates group (n=5), and control group (n=5). The intervention groups will engage in 4-week yoga and Pilates exercises, while the control group will maintain their current lifestyle, without doing any regular physical activity or exercise. Study 2: Forty-eight voluntary (48) patients fulfilling the inclusion criteria mentioned in study one will be randomized the three same groups, Yoga (n=16), Pilates (n=16), and control (n=16) group).

Settings and conduct

Participants in this study will be volunteers from the MS Center. The intervention will be for 4 weeks in the first study and 8 weeks in the main study of yoga and Pilates exercises and the control group without exercise.

Participants/Inclusion and exclusion criteria

inclusion criteria: EDSS (0-5.5), BMI (range 20-32), and age (range 18-65) and exclusion criteria: Lack of physical exercise, no relapse of the disease in the previous three months, no pregnancy, no history of cardiovascular, metabolic, emotional, cancer, or orthopedic disorders were among the inclusion requirements. Relapse of illness and failure to function were also grounds for exclusion. For the last three months prior to the start of the study, the participants would not have relapses involving the use of corticosteroid medications or cortisone injections

Intervention groups

Three yoga group (n=5), Pilates group (n=5), and control group (n=5) in a pilot study and 48 that will randomize to the three same groups, Yoga (n=16), Pilates (n=16),

and control (n=16) group) in the main study.

Main outcome variables

PRL and cortisol level, QOL, IPAQ, Beck, GHQ12, 25ft walking test

General information

Reason for update

Acronym

patients with MS= pwMS

IRCT registration information

IRCT registration number: **IRCT20211122053145N1**

Registration date: **2022-02-08, 1400/11/19**

Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**

Update count: **0**

Registration date

2022-02-08, 1400/11/19

Registrant information

Name

Maryam Poursadeghfard

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate of the impact Yoga and Pilates Training on Serum Prolactin and Cortisol, Selected Psychological, and Physical Indicators in Female Patients with Multiple Sclerosis

Public title

The effect of exercise on biochemical, psychological, and physical factors of women with MS

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

with inclusion criteria including EDSS (0-5.5), BMI (range 20-32), and age(range 18-65)

Exclusion criteria:**Age**

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **63****Randomization (investigator's opinion)**

Randomized

Randomization description

participants in this study will be volunteers from the MS Center that will randomly be separated into three groups: yoga group (n=21), Pilates group (n=21), and control group (n=21). The randomization sequence will be generated using a computer-generated list of random numbers to create a series of sequentially numbered envelopes containing equal assignments to Pilates and yoga, and waitlist. Recruited participants will be enrolled and assigned a three-digit number in chronological order by a person not involved in the study. Participants will then be randomized to one of the three groups by blocking the stratified sampling method according to age and EDSS.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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Province

Fars

Postal code

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Approval date

2021-11-23, 1400/09/02

Ethics committee reference number

IR.SUMS.MED.REC.1400.586

Health conditions studied**1****Description of health condition studied**

multiple sclerosis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

prolactin

Timepoint

before and after intervention

Method of measurement

blood sampling

2**Description**

cortisol

Timepoint

before and after intervention

Method of measurement

blood sampling

Secondary outcomes**1****Description**

Score of MS QOL questioner

Timepoint

Before and after intervention

Method of measurement

Questioner

2

Description

Score of IPAQ questioners

Timepoint

Before and after intervention

Method of measurement

Questioner

3

Description

Score of Beck depression questioner

Timepoint

Before and after intervention

Method of measurement

Questioner

4

Description

Score of GHQ

Timepoint

Before and after intervention

Method of measurement

Questioner

5

Description

25ft walking test

Timepoint

Before and after intervention

Method of measurement

Timer

Intervention groups

1

Description

Intervention group: yoga exercise

Category

Rehabilitation

2

Description

Intervention group: Pilates exercise

Category

Rehabilitation

3

Description

Control group: they will not regular exercise or physical activity

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Poursadeghfard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

مریم پورصادق فر

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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

maryam porsadeh far

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Specialist

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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 plan to publish

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable