# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
**Street address**
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
**City**
shiraz
**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 sampeling

**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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Shiraz University of Medical Sciences,in front of Palestine St,Zand St, Shiraz
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
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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 poursadegh far
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Neurology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Web page address**
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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