Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Pilates Exercises on Gait Variability in Spatiotemporal and Kinematic Parameters in People with MS Compared to Healthy Individuals

Protocol summary

Study aim

Investigating the effect of Pilates exercises on the variability of spatiotemporal and kinematic gait parameters in individuals with multiple sclerosis and comparing them with healthy individuals.

Design

Study design: A parallel, randomized, assessor-blind trial with three groups (Healthy, MS Control, MS Intervention) in 24 participants (16 with MS, 8 healthy). MS participants were allocated via block randomization after health-based stratification. Phase: Not applicable.

Settings and conduct

This clinical trial was conducted on female members of the MS Association in Hamadan. Participants were divided into three groups (healthy, MS control, MS intervention). The intervention group received a Pilates exercise program (8 weeks, 3 sessions/week) under the supervision of an instructor. The other two groups only underwent assessment. Gait data were collected in the laboratory using a Vicon 3D motion analysis system. Blinding: The study was assessor-blind. The outcome assessor was unaware of the participants' group allocation. Participants and the instructor could not be blinded due to the nature of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion: Adults (>18) with definitive MS (McDonald criteria), able to walk 100m independently, willing to participate. Exclusion: Other neurological diseases, MS relapse in past 3 months, musculoskeletal, cardiopulmonary, or psychiatric/cognitive conditions affecting gait or exercise, recent core-stability exercise (e.g., Pilates).

Intervention groups

1. Healthy Control: No exercise intervention 2. MS Control: Usual care 3. MS Intervention: Pilates exercise program for 8 weeks, 3 sessions/week.

Main outcome variables

Variability of spatiotemporal gait parameters; Variability of kinematic gait parameters.

General information

Reason for update

Acronym

PEG-MS

IRCT registration information

IRCT registration number: **IRCT20251001067458N1**
Registration date: **2026-02-11, 1404/11/22**
Registration timing: **retrospective**

Last update: **2026-02-11, 1404/11/22**
Update count: **0**

Registration date

2026-02-11, 1404/11/22

Registrant information

Name

Mahdi Majlesi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 2454

Email address

m.majlesi@iau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-01-30, 1404/11/10

Actual recruitment start date

2025-12-22, 1404/10/01

Actual recruitment end date

2026-01-30, 1404/11/10

Trial completion date

2026-01-30, 1404/11/10

Scientific title

Effects of Pilates Exercises on Gait Variability in Spatiotemporal and Kinematic Parameters in People with MS Compared to Healthy Individuals

Public title

Pilates Exercises and Gait in MS

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A definite MS diagnosis according to the revised McDonald criteria Age over 20 years Walking 100 meters independently Willingness to participate

Exclusion criteria:

Any neurological disease other than MS Relapse within the past 3 months Orthopedic disorders that could negatively affect gait and balance Cardiopulmonary problems that could prevent performing the exercises Diagnosed psychiatric problems or cognitive decline that renders the individual incapable of performing the tests and exercises Current or recent (within the prior 6 months) participation in a core stability-based exercise program

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **24**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

This study employed a two-stage stratified randomization design. First, participants were divided into two main strata based on their health status (healthy or with MS). Then, only participants in the "with MS" stratum were randomly allocated to two subgroups. Step-by-Step Description: Primary Stratification (Non-Random): Stratum 1 (Healthy Control Group): All eligible healthy participants were assigned to this group non-randomly, based solely on their health status. No randomization process was applied to this stratum. Secondary Stratification and Randomization: Stratum 2 (Participants with MS): All eligible participants diagnosed with MS were placed in this stratum. Randomization Method within this Stratum: Individuals in this stratum were allocated to the following two groups using Block Randomization via the randomization.com website: MS Control Group (no exercise) MS Intervention Group (receiving Pilates exercises) Unit of Randomization: The unit of randomization was individual, but this was applied only to participants in the "with MS" stratum. Sequence Generation: The allocation sequence for the MS stratum was generated by the website using variable block sizes and an equal allocation ratio (1:1) for the "MS Control" and "MS Intervention" groups. Allocation Concealment: To prevent bias in the allocation of participants with MS, the Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) method was used. The generated allocation numbers were placed inside opaque envelopes, which were then sealed and numbered sequentially. After confirming the eligibility and completing the baseline assessment of a participant with MS, the researcher opened the next consecutive envelope and directed the individual to the specified group (control or intervention). Allocation concealment was not applicable for the healthy group.

Blinding (investigator's opinion)

Single blinded

Blinding description

ue to the non-pharmacological and behavioral nature of the intervention (Pilates exercises), it was not possible to blind the participants or the personnel administering the intervention. Individuals who were blinded and the procedure: Primary Outcome Assessor: This study was designed as assessor-blind. The individual responsible for measuring and recording the primary and final data related to the main study variables (spatiotemporal and kinematic gait parameters) was blinded to the participants' group allocation. Method: The assessor was stationed in a separate location and only met with participants for baseline and post-test assessment sessions. The list of participants provided to the assessor contained only a unique identification code with no indication of health status (healthy or with MS) or group allocation (control or intervention). The assessor had no access to participants' medical records or exercise schedules. The assessment protocols were standardized to ensure that conversations with participants did not reveal any information about their intervention type or group. Individuals who were not blinded: (Blinding was not possible due to the nature of the intervention) Participants: All participants were aware of their own group (healthy control, MS control, or MS intervention). Principal Investigator and Executive Personnel: The Pilates instructors and the researcher coordinating the exercise sessions were fully aware of the participants' group allocations. Data Safety and Monitoring Board (if applicable): This committee was fully informed of all study details, including group allocations. Data Analyst: For the statistical analysis, raw data were provided to the analyst using non-identifiable codes (e.g., Group_A, Group_B, Group_C) to allow for blinding during the initial analysis phase. The codes were revealed for the final interpretation of results after the primary analysis was completed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University, Science and Research Branch

Street address
Tehran, Islamic Azad University, Science and Research Branch

City
Tehran

Province
Tehran

Postal code
35879-15864

Approval date
2026-01-04, 1404/10/14

Ethics committee reference number
IR.IAU.SRB.1404.433

Health conditions studied

1

Description of health condition studied
MS

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
1. Primary Outcome Measure #1: Title: Variability of Spatiotemporal Gait Parameters Operational Definition: The degree of fluctuation in time- and space-related parameters of the gait cycle, calculated using the Coefficient of Variation (CV). These parameters include gait speed, step length, double support time, and other listed variables in the protocol, measured using the Vicon 3D motion analysis system.2. Primary Outcome Measure #2: Title: Variability of Kinematic (Angular) Gait Parameters Operational Definition: The degree of fluctuation in the joint angles of the lower limbs (hip, knee, and ankle) in the sagittal plane during the gait cycle, calculated using the Mean Coefficient of Variation (MeanCV). These angles are recorded and analyzed using the Vicon 3D motion analysis system.

Timepoint
First Time Point: Baseline assessment (before the start of any intervention or group allocation)Second Time Point: Final assessment (immediately after completing the 8-week Pilates exercise program for the intervention group, and after the same 8-week period for the two control groups)

Method of measurement
Measurement Tool: Vicon 3D Motion Capture System equipped with optical cameras and a force plate.Measurement Method: Spatiotemporal and kinematic gait parameters are obtained using this system by placing reflective markers on specific anatomical landmarks and recording the individual's movement while walking on a defined pathway. The raw data is processed, and the variability (CV and MeanCV) of the target parameters is then calculated from multiple gait cycles.

Secondary outcomes

empty

Intervention groups

1

Description
1. Healthy Control Group:This group did not receive any structured exercise intervention. They only underwent initial (baseline) and final assessments and continued their usual daily life without any new exercise program or specific supervision during the study period.2. MS Control Group (Disease Control):This group also did not receive any exercise intervention and continued their usual care. They only completed baseline and final assessments to measure the natural effects of time and the disease on gait parameters.3. MS Intervention Group:This group received a structured and supervised Pilates exercise program. Intervention Content: The exercise program included Pilates exercises based on classical methodology, focusing on Core Strengthening, Stability, Motor Control, Flexibility, and Coordination. Dosage and Duration: The exercises were conducted for 8 weeks, 3 sessions per week, each session lasting 60 minutes, under the supervision of a qualified Pilates instructor. Intensity: The exercise intensity was gradually and progressively increased based on each participant's individual ability and tolerance. Supervision: The quality of movement execution and participant safety were supervised by the instructor in all sessions.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital Hamadan, MS Association

Full name of responsible person
Dr. Masoud Ghiasian

Street address
Hamadan, Besat Hospital Hamadan, MS Association

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۴۸-۴۵۴۱۱

Phone
+98 81 3826 8511

Email
m.ghiasian@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahdi Majlesi
Street address
Hamadan, Shahid Madani Town, Imam Khomeini Blvd., Professor Musivand Blvd., Islamic Azad University, Hamadan Branch Complex
City
Hamedan
Province
Hamadan
Postal code
6518115743
Phone
+98 81 3448 1200
Email
m.majlesi@iau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
1
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
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahdi Majlesi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Hamadan, Shahid Madani Town, Imam Khomeini Blvd., Professor Musivand Blvd., Islamic Azad University, Hamadan Branch Complex
City
Hamedan
Province
Hamadan
Postal code
6518115743
Phone
+86 813 448 1200
Email
m.majlesi@iau.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahdi Majlesi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Hamadan, Shahid Madani Town, Imam Khomeini Blvd., Professor Musivand Blvd., Islamic Azad University, Hamadan Branch Complex
City
Hamedan
Province
Hamadan
Postal code
6518115743
Phone
+98 81 3448 1200
Email
m.majlesi@iau.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahdi Majlesi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Hamadan, Shahid Madani Town, Imam Khomeini Blvd., Professor Musivand Blvd., Islamic Azad University, Hamadan Branch Complex
City
Hamedan
Province
Hamadan
Postal code

6518115743

Phone

+98 81 3448 1200

Email

m.majlesi@iau.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

(This section is not applicable at this time. Details will be provided if a decision is made to share the data in the future.)

When the data will become available and for how long

If a final decision is made to share the anonymized individual participant data, access will be provided after the final thesis defense and publication of the main study results. The exact date will be announced upon completion of the university's administrative processes.

To whom data/document is available

If shared, de-identified data will be accessible for legitimate research requests from researchers and students affiliated with recognized academic institutions or research centers, following review and approval of the request. Access for commercial purposes is not intended.

Under which criteria data/document could be used

The data may be used solely for legitimate research purposes and for replication or meta-analysis of studies related to the thematic area of this research (e.g., the effects of exercise on gait parameters in neurological disorders). Conditions of Use: Submission of a brief research proposal outlining the objective, methodology, and necessity of using the data. A written commitment to: Use the data for non-commercial purposes. Acknowledge the original source of the data (this study) in any subsequent publication. Not attempt to re-identify participants. Share any manuscript or result derived from this data for final review prior to publication. Approval of the request by a supervisory committee consisting of the main supervisor and principal investigator. Any use outside this framework or without written agreement is not permitted.

From where data/document is obtainable

Respected applicants may submit their request as follows: Primary Contact: Email of the study supervisor Name: Dr. Mehdi Majlesi Email Address: m.majlesi@iau.ac.ir

What processes are involved for a request to access data/document

Submission of Request: The applicant submits a complete request, including the proposal and commitment letter, to the specified email address. Initial Review (Approximately 2 weeks): The request is reviewed for completeness and compliance with initial conditions (research objectives, commitments). If incomplete, the applicant will be asked to provide additional information. Review by Committee (Approximately 4 weeks): The complete request is referred to the supervisory committee (the main supervisor and principal investigator) for a decision based on scientific merit, available resources, and ethical considerations. Notification of Outcome: The result of the review (approval, rejection, or request for modification) is communicated to the applicant via email. Signing Agreement and Data Transfer (Approximately 2 weeks): If approved, a Data Transfer Agreement is sent to the applicant for signature. Upon its signed return, the de-identified data will be provided in a secure format (e.g., via an encrypted download link). Total Time Estimate: From the submission of a complete request to data receipt (if approved), the process typically takes between 6 to 8 weeks. This timeframe may vary depending on the volume of requests and the committee's schedule.

Comments