Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Pilates, Pelvic Floor Training, and Combined Programs on Pain and Function in Middle-Aged Women with Chronic Low Back Pain

Protocol summary

Study aim
Comparing 8-week Pilates, Pelvic Floor Muscle Training (PFMT), and combined (Pilates+PFMT) effects on pain, disability, trunk endurance, and motor control in middle-aged women with Chronic Nonspecific Low Back Pain (CNSLBP).

Design
Randomized controlled trial, 4 parallel groups (1:1:1:1), 60 participants (15/group). Simple randomization (SPSS table). Allocation concealed (opaque envelopes). Blinded assessor. Pre/post-test after 8 weeks.

Settings and conduct
Kerman sports/rehabilitation centers (2025). Recruited via announcements/referrals. Supervised exercises. Blinded assessor; participants blinded to assessor.

Participants/Inclusion and exclusion criteria
Inclusion: Women 40-65y; CNSLBP >12w; pain ≥3/10 Visual Analog Scale (VAS); able to exercise; consent. Exclusion: Spine/pelvic/leg surgery; specific spinal pathologies; severe neurology; pregnancy/childbirth <6m; concurrent exercise.

Intervention groups
1-Pilates: 8w, 3/wk, 50-60min: mat exercises for core stability. 2-PFMT: 8w, 3/wk, 30-45min: pelvic floor contractions. 3-Combined: 8w, 3/wk, 60min: PFMT integrated into Pilates. 4-Control: No structured exercise; usual activities.

Main outcome variables
Pain (Visual Analog Scale-VAS), disability (Oswestry Disability Index-ODI), trunk endurance (McGill tests), motor control (Active Straight Leg Raise-ASLR).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211201053244N10**
Registration date: **2026-07-12, 1405/04/21**
Registration timing: **prospective**

Last update: **2026-07-12, 1405/04/21**
Update count: **0**

Registration date
2026-07-12, 1405/04/21

Registrant information
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-06, 1405/05/15

Expected recruitment end date
2026-11-22, 1405/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Pilates, Pelvic Floor Training, and Combined Programs on Pain and Function in Middle-Aged Women with Chronic Low Back Pain

Public title
Comparing the Effects of Different Exercise Programs for

Chronic Back Pain in Middle-Aged Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female gender and age between 40 and 65 years. Diagnosis of chronic nonspecific low back pain (CNSLBP) with a history of pain lasting more than 12 weeks. Pain intensity of at least 3 out of 10 on the Visual Analog Scale (VAS) at the time of enrollment. Ability to perform moderate physical activity and no medical contraindication for exercise. Willingness to participate and provide written informed consent.

Exclusion criteria:

History of spinal, pelvic, or lower limb surgery. History of specific spinal pathologies (e.g., tumors, infections, fractures, inflammatory disorders). Presence of severe neurological signs or clinical radiculopathy (e.g., significant muscle weakness, sensory loss). Pregnancy or childbirth in the last 6 months. Concurrent participation in another structured exercise or physical therapy program.

Age

From **40 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to one of four groups (Pilates, Pelvic Floor Muscle Training (PFMT), Combined Program, or Control) using a simple randomization method with a 1:1:1:1 allocation ratio. The randomization sequence will be generated using a random number table created by SPSS software (version 26) prior to the start of the study. The unit of randomization is the individual participant. To ensure allocation concealment, the generated sequence will be placed into opaque, sealed, and sequentially numbered envelopes by an independent researcher who is not involved in the recruitment, assessment, or intervention process. After the baseline assessments (pre-test) are completed, the next envelope in the sequence will be opened by the same independent researcher, who will then inform the participant of their group allocation. Neither the outcome assessor nor the participants will have access to the randomization list or the contents of the unopened envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single Blind (Outcome assessor blinded to group allocation; participants and care providers cannot be blinded due to the nature of exercise interventions). To maintain blinding, the outcome assessor will not be present during the intervention sessions, will have no access to the randomization list, and participants will be instructed not to discuss their group assignment with the assessor during the post-test assessments.

Placebo

Not used

Assignment

Parallel

Other design features

No additional unique design features. Standard parallel-group RCT with supervised interventions and blinded outcome assessment. Control group receives no structured exercise.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Sistan and Baluchestan

Street address

University Blvd., University of Sistan and Baluchestan, Zahedan, Sistan and Baluchestan Province, Iran

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Approval date

2026-06-16, 1405/03/26

Ethics committee reference number

IR.USB.REC.1405.010

Health conditions studied

1

Description of health condition studied

Chronic nonspecific low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain intensity

Timepoint

Baseline (before intervention) and immediately after 8 weeks of intervention (post-test)

Method of measurement
Visual Analogue Scale (VAS) - a 10-centimeter line where 0 indicates no pain and 10 indicates the worst imaginable pain; participants mark their current pain level on the line

2

Description
Functional disability
Timepoint
Baseline (before intervention) and immediately after 8 weeks of intervention (post-test)
Method of measurement
Oswestry Disability Index (ODI) - a validated 10-item questionnaire assessing the impact of low back pain on daily activities, including personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and employment; each item scored 0 to 5; total score converted to percentage (0-100%)

3

Description
Trunk muscle endurance
Timepoint
Baseline (before intervention) and immediately after 8 weeks of intervention (post-test)
Method of measurement
McGill Core Endurance Tests - three timed tests including: (1) Trunk flexor endurance test (holding a 60-degree sit-up position); (2) Trunk extensor endurance test (holding a prone position with upper body unsupported); (3) Side-bridge endurance test (holding a side-lying plank position). Holding time in seconds is recorded for each test

4

Description
Motor control
Timepoint
Baseline (before intervention) and immediately after 8 weeks of intervention (post-test)
Method of measurement
Active Straight Leg Raise (ASLR) test - participant lies supine and is asked to actively lift one leg straight up without bending the knee; the quality and ease of movement are scored on a 6-point scale (0-5) where 0 indicates no difficulty and 5 indicates impossible to perform; both legs are assessed separately

Secondary outcomes

1

Description
Health-related quality of life
Timepoint
Baseline (before intervention) and immediately after 8 weeks of intervention (post-test)
Method of measurement
Short Form Health Survey (SF-36) - a 36-item validated questionnaire assessing physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health; each domain scored 0-100, with higher scores indicating better quality of life

2

Description
Fear of movement
Timepoint
Baseline (before intervention) and immediately after 8 weeks of intervention (post-test)
Method of measurement
Tampa Scale for Kinesiophobia (TSK) - a 17-item validated questionnaire assessing fear of movement and (re)injury; each item scored 1-4; total score ranges from 17 to 68, with higher scores indicating greater fear of movement

Intervention groups

1

Description
Intervention group 1: Pilates Exercise Program: An 8-week mat Pilates exercise program consisting of 3 sessions per week, each lasting 50-60 minutes. The program includes a 10-minute warm-up, 30-40 minutes of mat Pilates exercises focusing on deep core muscle activation (transversus abdominis, multifidus, diaphragm, and oblique muscles), spinal stabilization, and controlled breathing, followed by a 5-10 minute cool-down and stretching. Exercise intensity progresses gradually from simple supine and quadruped positions to more challenging sitting and standing positions. All sessions are supervised by a trained Pilates instructor.
Category
Rehabilitation

2

Description
Intervention group 2: Pelvic Floor Muscle Training Program: An 8-week pelvic floor muscle training program consisting of 3 sessions per week, each lasting 30-45 minutes. The program includes voluntary, controlled, and repetitive contractions of the pelvic floor muscles, initially performed in simple positions (supine and sitting) and progressing to more functional positions (standing). Training includes sustained contractions (5-10 seconds), rapid contractions, and breathing coordination exercises. Intensity progresses gradually. Emphasis is placed on preventing compensatory movements by superficial abdominal and gluteal muscles. All sessions are supervised by a trained therapist.
Category
Rehabilitation

3

Description
Intervention group 3: Combined Program (Pilates +

Pelvic Floor Muscle Training): An 8-week combined program integrating Pilates exercises and pelvic floor muscle training, consisting of 3 sessions per week, each lasting 60 minutes. Pelvic floor muscle training is incorporated as part of neuromuscular preparation at the beginning of each session and integrated throughout Pilates movements. The program emphasizes coordination between pelvic floor muscles and deep core muscles, regulation of intra-abdominal pressure, and improvement of lumbopelvic motor control. Exercise intensity and complexity progress gradually from stable to more challenging positions. All sessions are supervised by a trained instructor.

Category
Rehabilitation

4

Description
Control Group: No Structured Exercise: Participants in the control group do not receive any structured exercise intervention during the 8-week study period. They are advised to maintain their usual daily activities and avoid starting any new exercise programs or similar therapeutic interventions during the study period. At the end of the study, an appropriate exercise program will be offered to them educationally upon request.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Sports Clubs and Rehabilitation Centers of Kerman

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Grant name
Not applicable

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
University of Sistan and Baluchistan

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
University of Sistan and Baluchestan

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Other areas of specialty/work
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Person responsible for updating data

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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
The deidentified individual participant data (IPD) collected in this study will not be publicly available due to ethical and privacy considerations. However, the study protocol, statistical analysis plan, informed consent form, and clinical study report will be made available to other researchers upon reasonable request to the corresponding author. Data sharing requests will be reviewed by the research team and the ethics committee of the University of Sistan and Baluchestan to ensure compliance with ethical standards and participant privacy. Access to IPD may be granted for meta-analyses or systematic reviews with a valid scientific rationale, subject to a data sharing agreement. All shared data will be fully anonymized to protect participant identities. The analytic code and data dictionary may be shared upon request after the completion and publication of the study results.

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

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

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Study Protocol - Includes the full research proposal approved by the ethics committee, detailing the study objectives, design, methodology, inclusion/exclusion criteria, intervention protocols, outcome measures, and statistical analysis plan.

When the data will become available and for how long
6 months after completion of the study and publication of the main results

To whom data/document is available
Researchers affiliated with academic and research institutions; also available to clinicians and rehabilitation professionals upon reasonable request

Under which criteria data/document could be used
For non-commercial use only; for systematic reviews, meta-analyses, or methodological evaluations; requests must include a brief research proposal and intended use; requests reviewed by the research team and ethics committee

From where data/document is obtainable
Corresponding author: Mohammadreza Rezaeipour, Email: rezaeipour@ped.usb.ac.ir

What processes are involved for a request to access data/document
Submit request via email; response within 2 weeks; approval by research team and ethics committee;

document sent electronically

Comments

Study protocol will be shared in Persian or English based on the requester's preference