Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Adding Motor Skill Retraining Versus Adding Balance Training to a Standard Core Stabilization Program on Pain and Function in Adults With Chronic Non-Radicular Low Back Pain: Randomized Controlled Trial

Protocol summary

Study aim

To compare motor skill retraining and balance training, each added to core stabilization, for pain and disability in adults with chronic non radicular low back pain.

Design

Randomized trial with parallel groups, equal allocation in blocks of four, 25 per group.

Settings and conduct

Consecutive recruitment at the Sports Medicine Clinic, Hazrat Rasoul Hospital, Iran University of Medical Sciences, Tehran, over 12 months; assessments at weeks zero, four and eight. blinded outcome assessment where feasible.

Participants/Inclusion and exclusion criteria

Sixty adults aged 18 to 60 with non radicular low back pain diagnosed by a sports medicine specialist, lasting at least three months or recurrent episodes within six months, pain at least 3 out of 10 in the preceding week, independent walking and exercise ability, and written consent. Exclusions: red flags, radiculopathy, spinal surgery in the past year or surgical candidacy, epidural injections within six months, major neurological, vestibular or musculoskeletal impairment, pregnancy, active back rehabilitation within three months, sustained strong opioid use or major analgesic changes within four weeks, and disc sequestration or severe spinal stenosis on magnetic resonance imaging.

Intervention groups

Group one receives core stabilization and motor skill retraining; group two receives core stabilization and balance training. Each receives 12 supervised sessions over four weeks, three weekly sessions lasting 45 to 60 minutes, with sham lumbar high intensity laser treatment before exercise.

Main outcome variables

Pain intensity using the Visual Analogue Scale and disability using the Oswestry Disability Index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230416057919N1**
Registration date: **2026-11-06, 1405/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-06, 1405/08/15**
Update count: **0**

Registration date

2026-11-06, 1405/08/15

Registrant information

Name

Ahmad Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-15, 1405/02/25

Expected recruitment end date

2027-05-15, 1406/02/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Adding Motor Skill Retraining Versus Adding Balance Training to a Standard Core Stabilization Program on Pain and Function in Adults With Chronic Non-Radicular Low Back Pain: Randomized Controlled Trial

Public title
Exercise therapy in low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of non-radicular low back pain by a sports medicine specialist, based on clinical examination and the absence of clear signs of nerve root involvement (radiating pain along a dermatomal distribution, focal muscle weakness, diminished reflexes, or localized neurological deficits). Duration of pain ≥ 3 months (chronic low back pain) or recurrent episodes of low back pain over the past ≥ 6 months. Low back pain intensity of at least 3 out of 10 on the Visual Analog Scale (VAS) during the preceding week. Ability to walk independently and perform the prescribed exercises. Provision of written informed consent.
Exclusion criteria:
Presence of red flags or indications for urgent imaging, including trauma associated with a risk of fracture, fever or suspected infection, known or suspected malignancy, cauda equina syndrome, unexplained weight loss, high-risk osteoporosis, progressive spinal deformity, or progressive neurological deficits. Clinical evidence of radiculopathy or nerve root involvement, including dermatomal radiating pain extending below the knee and reproduced by the Straight Leg Raise (SLR) or Slump test; myotomal weakness, dermatomal sensory deficits, or diminished reflexes consistent with a specific nerve root; or a positive Crossed Straight Leg Raise test. Recent spinal surgery within the past 12 months, being scheduled for surgical intervention during the study period, or receiving epidural or spinal injections within the past 6 months. Other significant neurological, vestibular, or musculoskeletal disorders that substantially impair balance or functional performance. Pregnancy. Participation in another active rehabilitation program for low back pain within the past 3 months. Regular use of strong opioid medications or major changes in the analgesic medication regimen within the past 4 weeks. Presence of evidence of severe spinal canal stenosis or disc sequestration on lumbar magnetic resonance imaging (MRI). Unwillingness to continue participation in the study. Absence from more than 20% of the scheduled exercise sessions.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomized using a permuted block randomization method with a block size of four and a 1:1 allocation ratio to maintain a balanced number of participants between the two groups throughout the recruitment process. For this purpose, all possible allocation sequences within blocks of four (AABB, ABAB, ABBA, BAAB, BABA, BBAA) will be generated. In these sequences, A represents the core stability exercise group combined with motor skill retraining, and B represents the core stability exercise group combined with balance exercises. The order of the blocks will then be determined randomly using a random number table or computer software. Eligible participants will be allocated to one of the two groups according to their order of enrollment in the study and the predefined allocation sequence. This randomization method will help maintain numerical balance between the two groups and reduce selection bias throughout the study. The assigned intervention will be documented in the randomization record form and kept confidential in the research file.
Blinding (investigator's opinion)
Single blinded
Blinding description
Since the types of exercises differ between the two groups, blinding the therapist is not feasible. However, the outcome assessor (responsible for conducting functional tests, recording questionnaires, and performing ultrasound measurements) will be kept blinded to group allocation as much as possible. For this purpose, assessment sessions will be conducted separately from exercise sessions by an individual who is not involved in administering the exercises or laser treatment. Participants will be instructed not to disclose details of the exercises they received in the presence of the assessor. This approach will help reduce assessor bias and improve the internal validity of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Tehran - Sattar Khan St. - Niayesh St. - Hazrat Rasool Akram Hospital (PBUH)
City
Tehran
Province
Tehran
Postal code
14456 13131
Approval date
2026-05-15, 1405/02/25
Ethics committee reference number
IR.IUMS.FMD.REC.1405.110

Health conditions studied

1

Description of health condition studied
Non radicular low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain intensity
Timepoint
Before the intervention, and at weeks 4 and 8 after the initiation of the intervention.
Method of measurement
Visual Analogue Scale

2

Description
Disability level
Timepoint
Before the intervention, and at weeks 4 and 8 after the initiation of the intervention.
Method of measurement
Oswestry Disability Index (ODI)

Secondary outcomes

1

Description
Biering–Sorensen Test
Timepoint
Before the intervention, and at weeks 4 and 8 after the initiation of the intervention.
Method of measurement
The Sorensen test will be used to assess lumbar extensor muscle endurance. Participants will lie prone on an examination table with their anterior superior iliac spines positioned approximately at the edge of the table, allowing the trunk to extend beyond the table without support. The pelvis and lower limbs will be secured using three straps placed around the pelvis, thighs, and ankles. The arms will be crossed over the chest or positioned behind the head, with the selected position maintained consistently throughout all assessments. Participants will be instructed to maintain their trunk in a horizontal position, parallel to the floor. The duration of maintaining this position will be measured using a stopwatch. The test will be terminated when the participant can no longer maintain the horizontal position, the trunk drops more than 10 degrees below horizontal, or pain or fatigue prevents continuation. A brief familiarization trial lasting a maximum of 10 to 15 seconds will be performed before the main test, followed by adequate rest. The final result will be recorded in seconds.

2

Description
Timed Up and Go Test (TUG)
Timepoint
Before the intervention, and at weeks 4 and 8 after the initiation of the intervention.
Method of measurement
The Timed Up and Go test will be used to assess functional mobility and dynamic balance. Participants will initially sit in a standard armchair with their backs resting against the backrest. A line will be marked on the floor at a distance of three meters from the chair. At the command to start, participants will be instructed to stand up from the chair, walk at their usual comfortable and safe pace to the marked line, turn around, walk back to the chair, and sit down again. The time will be measured using a stopwatch, starting at the verbal command and ending when the participant is fully seated again. Participants will wear their usual footwear and may use their customary walking aid if necessary. A familiarization trial will be performed before the main assessment. The test will then be performed three times, with adequate rest intervals between trials. The shortest completion time among the three trials will be recorded in seconds as the final test result. A shorter completion time indicates better functional mobility performance.

3

Description
Transversus Abdominis (TrA) Muscle Thickness at Rest
Timepoint
Before the intervention, and at weeks 4 and 8 after the initiation of the intervention.
Method of measurement
Mean transversus abdominis (TrA) muscle thickness measured by ultrasonography at rest, at the end of quiet expiration.

4

Description
Transversus Abdominis (TrA) Muscle Thickness During

Contraction

Timepoint

Before the intervention, and at weeks 4 and 8 after the initiation of the intervention.

Method of measurement

Mean transversus abdominis (TrA) muscle thickness measured by ultrasonography during contraction, at the end of quiet expiration.

Intervention groups

1

Description

Intervention group: Motor skill retraining

Category

Rehabilitation

2

Description

Intervention group: Balance training

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Ahmad Nazari

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Tehran, Sattar Khan St., Niayesh St., corner of Mansouri St., Hazrat Rasool Akram Hospital

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Sponsors / Funding sources

1

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Ahmad Nazari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available