Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effects of Short Foot Exercises Combined with Tibialis Posterior Strengthening, With and Without Custom-Made Insoles, on Lower Limb Structural Indices, Balance, and Ankle and Lumbar Joint Position Sense in Males with Pronated Foot and Chronic Low Back Pain.

Protocol summary

Study aim

Comparison of the effects of 6 weeks of short-foot exercises combined with tibialis posterior strengthening alone versus the combination of these exercises with custom-made insoles on Q-angle, low back pain, navicular drop, static and dynamic balance, and ankle and lumbar joint position sense in Males aged 18 to 45 years with Pronated Foot and chronic low back pain.

Design

Applied and semi-experimental with a control group using a pretest-posttest design, single-blind, conducted on 51 patients

Settings and conduct

Selected orthotics and prosthetics centers and rehabilitation centers in Tehran, with convenience and purposive sampling, followed by random allocation of subjects into three groups

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Men aged 18–45 years with bilateral foot pronation, chronic low back pain (more than 3 months, VAS more than 3), navicular drop more than 10 mm, normal BMI (19–24), no history of orthosis, extremity/spine surgery, or severe injury, no independent limb pain or diseases affecting balance and joint position sense, along with informed consent and a commitment to the protocol. Exclusion Criteria: New pain/injury, absence from 2 consecutive or 3 non-consecutive sessions, improper orthosis use, influential neuromuscular/orthopedic disorders, balance-affecting medications, concurrent interventions, or study withdrawal.

Intervention groups

'Short Foot exercises combined with tibialis posterior strengthening', 'Short Foot exercises and tibialis posterior strengthening combined with custom insoles', and a 'control' group

Main outcome variables

Q-angle; navicular drop; chronic low back pain intensity; static balance; dynamic balance; ankle joint position sense; lumbar joint position sense

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261015071442N1**
Registration date: **2026-11-13, 1405/08/22**
Registration timing: **prospective**

Last update: **2026-11-13, 1405/08/22**
Update count: **0**

Registration date

2026-11-13, 1405/08/22

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date
2027-06-22, 1406/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Short Foot Exercises Combined with Tibialis Posterior Strengthening, With and Without Custom-Made Insoles, on Lower Limb Structural Indices, Balance, and Ankle and Lumbar Joint Position Sense in Males with Pronated Foot and Chronic Low Back Pain.

Public title
Comparison of the Effects of Foot Muscle Exercises, With and Without Special Insoles, on the alignment of the feet and Low Back Pain, Balance, and Ankle and Lumbar Joint Position Sense in Men With inward-turning feet and Chronic Low Back Pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Male gender Age range of 18 to 45 years Bilateral ankle pronation Chronic non-specific low back pain with a history of at least 3 months and an intensity greater than 3 on the Visual Analog Scale (VAS) Navicular drop of at least 10 mm in both feet Body Mass Index (BMI) between 19 and 24 kg/m² Ability to perform activities of daily living and participate in corrective exercises No history of using custom foot orthoses (insoles) over the past two years No history of musculoskeletal surgery of the lower extremities or spine No history of severe lower extremity injury in the past six months No independent lower extremity pain No neuromuscular, systemic, or inflammatory diseases, or disorders affecting balance, joint position sense, and lower extremity muscle function Readiness for regular attendance in exercises and wearing the insoles Commitment to performing the assessments Signing the written informed consent form
Exclusion criteria:
Onset or aggravation of new pain, inflammation, or injury in the back or lower extremities Absence from 2 consecutive exercise sessions Absence from 3 non-consecutive exercise sessions Non-compliance with the insole usage protocol Diagnosis of an affecting neuromuscular or orthopedic disorder Initiation of medications affecting balance, motor control, or proprioception Participation in concurrent interventions Refusal to perform the assessments Request for voluntary withdrawal from the study
Age
From **18 years** old to **45 years** old
Gender
Male

Phase
N/A
Groups that have been masked
- Data analyser

Sample size
Target sample size: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated into the three study groups (exercise, exercise with insoles, and control) using simple individual randomization. The randomization tool and sequence generation involve using identical paper cards with group names (in equal proportions), which are placed inside sequentially numbered, opaque, and sealed envelopes. To ensure allocation concealment and prevent bias, following the definitive entry of each participant into the study and the completion of baseline assessments, the envelopes are opened sequentially by an independent person, and the participant’s research group is determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the intervention (corrective exercises and insoles), blinding of the participants and the intervention administrator was not feasible. However, data analysis will be performed by a blinded statistician/data analyst who is completely independent of the intervention process and unaware of the group allocations (single-blind design regarding data analysis). Group codes will be anonymized (e.g., Group A and Group B) before being provided to the data analyst.
Placebo
Not used
Assignment
Factorial
Other design features
The interventions will be conducted over a 6-week period, with three sessions per week, totaling 18 sessions. Each session will last 20 to 25 minutes, consisting of a five-minute warm-up, the main exercise phase, and a five-minute cool-down. The program is designed in three two-week phases, progressing gradually from seated to double-leg and single-leg standing positions. Exercises include progressive Short Foot (SF) training and posterior tibialis strengthening using elastic resistance bands, with intensity increased by adjusting band resistance and surface instability. The Short Foot exercises will be implemented based on the protocol by Zarali et al. (2024), and posterior tibialis strengthening will follow the protocol by Da bee Lee et al. (2016), with modifications tailored to the study’s objectives.The second group, in addition to the exercise program, will wear CAD/CAM custom orthotic insoles via CNC milling for at least 6 to 8 hours daily. All sessions will be supervised by a corrective exercise specialist and will incorporate visual, verbal, and tactile feedback.The third group (control) will continue their normal daily activities and will receive no intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Faculty of Sport Sciences and Health, University of Tehran

Street address
Unit 4, No. 16, between Khairi and Mozaffari Intersections, 198th East St. (Tavakol St.), 3rd Square, Tehranspars

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Approval date
2026-09-20, 1405/06/29

Ethics committee reference number
IR.UT.SPORT.REC.1405.096

Health conditions studied

1

Description of health condition studied
Pronated Foot and Chronic Low Back Pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The Q-angle is an indicator of lower limb alignment, representing the angle formed by a line drawn from the anterior superior iliac spine (ASIS) to the center of the patella and a line drawn from the center of the patella to the tibial tuberosity. This angle reflects the direction of the quadriceps muscle force on the patella, and its increase is associated with biomechanical disorders of the knee and lower limb.

Timepoint
at baseline (before the start of the intervention) and 6 weeks after initiation

Method of measurement
2D Video Analysis of the Q-Angle: To measure the Q-angle using Kinovea software, markers will be placed on the tibial tuberosity, the center of the Anterior Superior Iliac Spine (ASIS), and the center of the patella. Participants will maintain a standing position for 10 seconds and an overhead squat position for 7 seconds. The Q-angle in both positions will be calculated based on the mean of three measurements.

2

Description
Navicular drop is a measure used to assess foot pronation, which indicates the change in navicular bone height from a non-weight-bearing sitting position to a weight-bearing standing position, reflecting the function of the medial longitudinal arch of the foot.

Timepoint
at baseline (before the start of the intervention) and 6 weeks after initiation

Method of measurement
Navicular Drop Test: The navicular drop and foot pronation will be evaluated using Brody’s method and a millimeter ruler. The subject will be assessed in a seated position, with 90 degrees of hip and knee flexion and the subtalar joint in a neutral position, and subsequently in a standing position.The difference in navicular height between the non-weight-bearing and weight-bearing conditions will be recorded, and the mean of three measurements for each limb will be used for analysis.

3

Description
Static balance is defined as the ability to maintain a stable body posture over a base of support in a stationary condition without shifting the center of gravity.

Timepoint
at baseline (before the start of the intervention) and 6 weeks after initiation

Method of measurement
Stork Balance Test: Participants will stand barefoot on a level, non-slip surface with eyes open, trunk upright, and hands on their hips. They will balance on one leg, placing the sole of the non-supporting foot against the medial aspect of the supporting knee. The duration of maintaining this position until the first error occurs will be recorded using a stopwatch. Errors are defined as: removing hands from the hips, changing body position, contact of the free foot with the ground, displacement or lifting of the supporting heel, compensatory trunk movements, falling, or requiring external support. Three trials will be performed, and the longest duration will be recorded.

4

Description
Dynamic balance is defined as the ability to maintain stability over a base of support during movement or displacement of the center of gravity.

Timepoint
at baseline (before the start of the intervention) and 6 weeks after initiation

Method of measurement
Y-Balance Test (YBT) :Following the viewing of an instructional video and performing six practice trials in each of the three directions, the participant will stand on one leg in the center of the YBT platform and perform reaches with the free limb in the anterior, posteromedial, and posterolateral directions. The maximum reach distance from three successful trials in each direction will be recorded. Trials will be repeated if the participant loses balance, the stance foot moves, weight is borne by the reach limb, or the participant is unable to return to

the starting position. Reach distances will be normalized to the participant's lower limb length. Limb length will be measured from the Anterior Superior Iliac Spine (ASIS) to the medial malleolus; this measurement will be performed three times with one-minute intervals, and the mean value will be recorded.

5

Description

Ankle joint position sense refers to the awareness of the ankle joint position and the ability to reproduce angles following active and passive movement in the joint without the use of vision.

Timepoint

at baseline (before the start of the intervention) and 6 weeks after initiation

Method of measurement

Ankle joint position sense test: In a seated position with eyes closed, following passive movement of the ankle to 10 degrees of dorsiflexion and return to the neutral position, the participant reproduces the target angle. The absolute angular error will be calculated using a manual goniometer in degrees.

6

Description

Lumbar position sense refers to the awareness of lumbar posture and the ability to reproduce angles following active and passive movement in the lumbar spine without the use of vision.

Timepoint

at baseline (before the start of the intervention) and 6 weeks after initiation

Method of measurement

Lumbar position sense test: Proprioception will be assessed using an active joint position reproduction test. To evaluate the lumbar region position sense, the participant stands with feet shoulder-width apart, knees straight, and trunk in neutral. Following two to three familiarization trials with visual feedback, the participant, while blindfolded, reproduces a target angle, such as 30 degrees of lumbar flexion. The angle is measured using a manual goniometer, and the absolute angular error—defined as the difference between the reproduced angle and the target angle—is recorded in degrees.

7

Description

Low back pain intensity represents the level of pain perceived by the individual in the lumbar region and is considered a primary index for evaluating treatment outcomes in individuals with chronic low back pain.

Timepoint

at baseline (before the start of the intervention) and 6 weeks after initiation

Method of measurement

Visual Analogue Scale: Low back pain intensity and its changes are measured using the Visual Analogue Scale, consisting of a 10-cm line ranging from 0 (no pain) to 10 (the worst pain imaginable / worst possible pain)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (short-foot exercises combined with tibialis posterior strengthening): The interventions will be conducted over a 6-week period, with three sessions per week, totaling 18 sessions. Each session will last 20 to 25 minutes, consisting of a five-minute warm-up, the main exercise phase, and a five-minute cool-down. The program is designed in three two-week phases, progressing gradually from seated to double-leg and single-leg standing positions. Exercises include progressive Short Foot (SF) training and posterior tibialis strengthening using elastic resistance bands, with intensity increased by adjusting band resistance and surface instability. The Short Foot exercises will be implemented based on the protocol by Zarali et al. (2024), and posterior tibialis strengthening will follow the protocol by Da bee Lee et al. (2016), with modifications tailored to the study's objectives.

Category

Rehabilitation

2

Description

Intervention group 2 (Short Foot exercises and tibialis posterior strengthening combined with custom insoles): The second intervention group, in addition to the exercise program of intervention group 1, will wear CAD/CAM custom orthotic insoles via CNC milling for at least 6 to 8 hours daily.

Category

Rehabilitation

3

Description

Control group: The third group (control) will continue their normal daily activities and will receive no intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

West Tehran Rehabilitation Clinic

Full name of responsible person

Ehsan Hosseini Sianaki

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Sponsors / Funding sources

1

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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
Faculty of Sport Sciences and Health, University of Tehran
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
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Faculty of Sport Sciences and Health, University of Tehran
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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 data will not be made publicly available due to confidentiality and ethical considerations

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