Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 2026

Comparison of the effects of an 8-week combined intrinsic foot muscle strengthening and neuromuscular training program versus usual care on lower extremity kinetics and kinematics during single-leg landing and running in men with anterior cruciate ligament reconstruction and functional foot pronation: a randomized controlled trial

Protocol summary

Study aim

To compare an eight week combined intrinsic foot muscle strengthening and neuromuscular training program with usual care on lower extremity kinematics and kinetics during single leg landing and running in men with unilateral anterior cruciate ligament reconstruction and functional foot pronation.

Design

Single centre, parallel group, randomized controlled clinical trial with pre- and post-testing. Forty participants will be randomly allocated 1:1 to intervention or control using computer-generated simple randomization with concealed allocation; trial phase is not applicable.

Settings and conduct

Participants will be recruited from orthopedic and physiotherapy clinics in Hamedan. Testing is in lab and training in sports facility; assessors and analysts are blinded

Participants/Inclusion and exclusion criteria

Men aged 18–40 years with unilateral anterior cruciate ligament reconstruction (hamstring autograft, 12–24 months post-surgery), at least six months standard rehabilitation, functional foot pronation, and ability to run and jump pain-free will be included. Those with other major lower limb injuries, neurological disorders, recurrent ligament injury, or specific foot or lower limb training in the previous six months will be excluded.

Intervention groups

The intervention group will receive an eight week supervised program, three sessions per week, including intrinsic foot muscle strengthening and neuromuscular training in addition to usual activities. The control group will continue usual care without extra structured exercise and will be offered the program after post-intervention assessments.

Main outcome variables

Main outcomes are hip, knee and ankle joint angles and ground reaction forces and joint moments during single leg landing and running. Selected functional performance tests will be assessed as secondary outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170806035517N9**
Registration date: **2026-04-26, 1405/02/06**
Registration timing: **prospective**

Last update: **2026-04-26, 1405/02/06**
Update count: **0**

Registration date

2026-04-26, 1405/02/06

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-05-10, 1405/02/20
Expected recruitment end date
2026-09-01, 1405/06/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of an 8-week combined intrinsic foot muscle strengthening and neuromuscular training program versus usual care on lower extremity kinetics and kinematics during single-leg landing and running in men with anterior cruciate ligament reconstruction and functional foot pronation: a randomized controlled trial

Public title
Effects of an 8-week foot and neuromuscular exercise program on leg movement and forces during landing and running in men after ACL reconstruction with pronated-footed posture
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Male participants aged 18 to 40 years. History of unilateral anterior cruciate ligament reconstruction using hamstring autograft. Time elapsed since surgery between 12 and 24 months. Completion of at least 6 months of standard postoperative rehabilitation. Ability to run and jump without significant pain in the operated limb. Presence of functional foot pronation based on navicular drop test above the predefined threshold. No pain, swelling, or functional limitation that prevents participation in the exercise program. Willingness to participate and signing written informed consent.
Exclusion criteria:
History of previous major surgery or fracture in the lower extremities other than the index ACL reconstruction. History of other significant ligamentous injuries of the knee (e.g. PCL, MCL, LCL) requiring surgery. Presence of neurological, neuromuscular, or vestibular disorders affecting balance or gait. Presence of severe flatfoot or foot deformities requiring orthotic or surgical management. Current acute musculoskeletal injury or pain in the lower extremities that limits participation. Systemic diseases such as uncontrolled diabetes, rheumatoid arthritis, or other inflammatory joint diseases. Participation in other structured lower extremity or neuromuscular training programs during the study period. Use of assistive devices for ambulation. Inability to follow instructions or complete the testing protocol.
Age
From **18 years** old to **40 years** old
Gender
Male
Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed at the individual level using a computer-generated simple randomization procedure. First, a list of eligible participants was prepared. Then, an independent researcher who was not involved in participant recruitment, assessment, or intervention delivery generated the random allocation sequence in Microsoft Excel using the RAND() function. Each participant was assigned a unique code, and codes were randomly allocated in a 1:1 ratio to the intervention group (combined intrinsic foot muscle strengthening and neuromuscular training) or the control group (usual care). The random sequence was created before the start of recruitment and was transferred to a series of sequentially numbered, opaque, sealed envelopes. For each newly enrolled participant, the next envelope in numerical order was opened by a person not involved in outcome assessment, and the group assignment inside was implemented. No stratification factors were used (i.e., no stratified randomization). Allocation concealment was ensured by using the opaque sealed envelopes and by keeping the randomization list inaccessible to the investigators and outcome assessors until the moment of assignment.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this randomized controlled trial, blinding is implemented at the level of outcome assessors and data analysts. Participants: All participants are fully informed that they are taking part in a randomized controlled trial with two different exercise programs. They provide written informed consent prior to randomization. Participants are not told which program is considered the primary experimental intervention in order to reduce expectation bias, but due to the differences in content and intensity between the exercise protocols, full participant blinding is not feasible. Care providers: The exercise trainers/physiotherapists who deliver the intervention necessarily know which exercise program they are administering to each participant. Therefore, care providers are not blinded to group allocation. Investigators: The principal investigator and co-investigators are responsible for protocol development, supervision of recruitment, and safety monitoring, and thus inevitably have access to information about the intervention protocols. Although they are not involved in the day-to-day outcome measurements, they cannot be considered fully blinded in all their roles. Outcome assessors: Outcome assessors who perform biomechanical and functional assessments (e.g.

kinematic, kinetic, and performance measurements) are blinded to group allocation. Participants are identified only by a unique study code during assessment sessions, and assessors do not have access to the randomization list or to any information revealing group assignment. Assessment visits are scheduled and coordinated by a study coordinator who is not involved in outcome measurements, to minimize the risk of unblinding. Data analysts: Data are exported in a coded format, with intervention groups labeled as, for example, “Group A” and “Group B” without indication of which is the experimental or control condition. The statistician/data analyst performs all primary analyses using these anonymized group codes and remains blinded to the actual meaning of group labels until the main analyses are completed and the analysis plan is finalized. Data and Safety Monitoring Board: No formal Data and Safety Monitoring Board (DSMB) is established for this investigator-initiated, small-scale exercise trial. Safety monitoring is performed by the investigators, who are not blinded to the overall study design.

Placebo

Not used

Assignment

Parallel

Other design features

Two-arm parallel randomized controlled trial with pre-test and post-test assessments. Participants are randomly allocated to an intervention group (combined intrinsic foot muscle strengthening and neuromuscular training) or a usual care control group. Outcome assessors are intended to be blinded to group allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Hamedan Branch

Street address

Islamic Azad University, Hamedan Branch, Shahid Mofatteh Boulevard, Hamedan, Iran

City

Hamedan

Province

Hamadan

Postal code

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Approval date

2026-04-05, 1405/01/16

Ethics committee reference number

IR.IAU.H.REC.1405.017

Health conditions studied

1

Description of health condition studied

Anterior cruciate ligament (ACL) reconstruction with concomitant functional foot pronation

ICD-10 code

S83.5

ICD-10 code description

Sprain of cruciate ligament of knee

2

Description of health condition studied

Men with unilateral anterior cruciate ligament (ACL) reconstruction and concomitant functional foot pronation

ICD-10 code

M21.40

ICD-10 code description

Flat foot [pes planus] (acquired), unspecified foot

Primary outcomes

1

Description

Knee flexion angle at initial contact during single-leg landing from a standardized height

Timepoint

Baseline (before starting the intervention) and after 8 weeks of the training program

Method of measurement

Three-dimensional motion analysis will be performed using an optical motion capture system with at least four high-speed cameras (sampling frequency 200 Hertz). Reflective markers will be placed on pelvic and lower extremity anatomical landmarks according to a standard biomechanical model. Knee flexion angle at initial contact during single-leg landing from a standardized height will be calculated using biomechanical modeling software.

2

Description

Maximum vertical ground reaction force during single-leg landing from a standardized height

Timepoint

Baseline (before starting the intervention) and after 8 weeks of the training program

Method of measurement

Ground reaction forces will be recorded using a force platform installed flush with the laboratory floor (sampling frequency 1000 Hertz). Participants will perform single-leg landings from a standardized height onto the center of the force platform. Vertical ground reaction force signals will be filtered using an appropriate low-pass filter, and the maximum vertical ground reaction force during the landing phase will be extracted and normalized to body weight.

3

Description

Peak knee abduction moment during single-leg landing from a standardized height

Timepoint

Baseline (before starting the intervention) and after 8 weeks of the training program

Method of measurement

Three-dimensional inverse dynamics analysis will be used to calculate knee joint moments. Kinematic data of the pelvis and lower extremity will be collected using an optical motion capture system with at least four high-speed cameras (sampling frequency 200 Hertz), and ground reaction forces will be recorded using a force platform (sampling frequency 1000 Hertz). Reflective markers will be placed on anatomical landmarks of the pelvis and lower extremity according to a standard biomechanical model. Using synchronized kinematic and kinetic data, the peak knee abduction moment during the landing phase of single-leg landing from a standardized height will be calculated and normalized to body weight and height.

4

Description

Knee valgus angle at the time of peak vertical ground reaction force during single-leg landing from a standardized height

Timepoint

Baseline (before starting the intervention) and after 8 weeks of the training program

Method of measurement

Three-dimensional motion analysis of the lower extremity will be performed using an optical motion capture system with at least four high-speed cameras (sampling frequency 200 Hertz), synchronized with a force platform (sampling frequency 1000 Hertz). Reflective markers will be placed on anatomical landmarks of the pelvis and lower extremity according to a standard biomechanical model. Knee valgus angle in the frontal plane at the time of peak vertical ground reaction force during single-leg landing from a standardized height will be calculated using biomechanical modeling software.

Secondary outcomes

1

Description

Performance on the Star Excursion Balance Test to assess dynamic balance and lower limb function.

Timepoint

Baseline (before starting the intervention) and after 8 weeks of the training program.

Method of measurement

Performance on the Star Excursion Balance Test will be measured by recording the maximum reach distance in eight directions while the participant maintains single-leg stance on the tested limb. The composite score will be calculated by summing the reach distances in all directions and normalizing the total reach distance to the limb length. The test will be performed by trained outcome assessors according to a standardized protocol.

2

Description

Self-reported intensity of knee pain.

Timepoint

Baseline (before starting the intervention) and after 8 weeks of the training program.

Method of measurement

Knee pain intensity will be assessed using the Numeric Pain Rating Scale, which is an eleven point scale from zero to ten, where zero indicates no pain and ten indicates the worst pain imaginable. Participants will be asked to rate their average knee pain during functional activities over the previous week on this scale.

3

Description

Subjective knee function score based on the International Knee Documentation Committee subjective knee form.

Timepoint

Baseline (before starting the intervention) and after 8 weeks of the training program.

Method of measurement

Subjective knee function will be assessed using the International Knee Documentation Committee subjective knee form, which is a standardized questionnaire evaluating symptoms, function, and sports activity related to the knee. The responses to all items will be converted to a total score ranging from zero to one hundred, where higher scores indicate better knee function and fewer symptoms. Participants will complete the questionnaire independently, and trained research staff will check the forms for missing responses.

Intervention groups

1

Description

Intervention group: participants in the intervention group will receive an 8-week combined exercise program consisting of intrinsic foot muscle strengthening exercises and neuromuscular training in addition to their usual post-reconstruction care. The training program will be performed 3 sessions per week, on non-consecutive days, for approximately 60 minutes per session, under the supervision of a trained exercise specialist.Each session will start with a 5 to 10 minute warm-up including light aerobic activity such as stationary cycling or brisk walking and dynamic stretching of the lower extremity. Then, approximately 15 minutes of intrinsic foot muscle strengthening exercises will be performed, including exercises such as towel curls, short-foot exercises, toe spreading, and resisted toe flexion and extension using elastic bands, with progressive increases in difficulty based on the participant’s tolerance.After that, approximately 30 minutes of neuromuscular training will be carried out, focusing on dynamic postural

control and lower limb alignment. This part will include single-leg balance exercises on stable and unstable surfaces, step-downs, squats and lunges with emphasis on proper knee and hip alignment, single-leg landing and jump-landing drills from a standardized height, and perturbation or balance exercises as appropriate. Exercise intensity and complexity will be progressed during the 8-week period according to a predefined progression protocol and the participant's clinical status and pain response.Each session will end with 5 to 10 minutes of cool-down including stretching of the lower extremity muscles. Participants will be monitored continuously during the sessions for pain, swelling, or any adverse events, and exercises will be modified or stopped if necessary. Adherence to the program will be recorded for each participant by documenting attendance at all scheduled sessions.

Category

Rehabilitation

2

Description

Control group: participants in the control group will receive only their usual post-operative and rehabilitation care after anterior cruciate ligament reconstruction, according to the routine protocols of their treating orthopedic surgeon and physiotherapist. They will not receive the structured combined exercise program of intrinsic foot muscle strengthening and neuromuscular training that is provided to the intervention group.During the 8-week study period, participants in the control group will be allowed to continue their usual daily activities and any standard physiotherapy or home exercises that have already been prescribed as part of their routine care, but no additional supervised training sessions will be scheduled by the research team. They will be contacted or visited only for baseline and post-intervention assessments, similar to the intervention group. Any changes in medication, additional treatments, or new injuries during the study will be recorded.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Hamedan Branch

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Islamic Azad University

Proportion provided by this source

100

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

Amirali Jafarnezhadgero

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Yes - There is 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
Deidentified individual participant data (IPD) and supporting study documents The following items may be shared with qualified researchers upon reasonable request: – Deidentified individual participant data (IPD) for all enrolled participants, including baseline characteristics, intervention allocation, and all outcome measures related to knee biomechanics, functional performance, pain, and patient-reported outcomes. No directly identifying variables (e.g., name, national ID, phone number, address) will be included. – The final version of the study protocol and, if applicable, the English translation of the ethics committee–approved protocol. – The template of the informed consent form used in this trial, with all identifying information removed. – The analytic code/scripts used for data processing and statistical analysis (e.g., scripts in MATLAB/Python/SPSS/R or other software used in the study). – A data dictionary describing variable names, definitions, units, coding schemes, and valid ranges for all shared variables.
When the data will become available and for how long
Deidentified IPD and supporting documents will be made available after the main results of the trial have been published in a peer-reviewed journal. The anticipated starting time for data availability is within 6 to 12 months after publication of the primary results. Data and documents will remain available for at least 5 years after the date of first publication, or longer if required by journal or funder policies.
To whom data/document is available
Deidentified IPD and supporting documents may be shared with independent researchers affiliated with academic or non-profit research institutions who have a scientifically sound proposal that is consistent with the aims of the original trial and with ethical principles. Requests from researchers working in for-profit or industry settings may also be considered on a case-by-case basis, provided that there is no conflict with participant confidentiality, institutional policies, or

relevant legal/ethical requirements.

Under which criteria data/document could be used

Data and documents will be shared only for non-commercial, ethically sound research purposes, such as meta-analyses, secondary analyses related to musculoskeletal biomechanics, injury prevention, rehabilitation, or other closely related research questions. The following criteria will apply: – The requesting researcher must submit a brief research proposal describing the objectives, methods, planned analyses, and data requirements. – The proposed use of data must be scientifically justified, must not overlap inappropriately with ongoing analyses by the original investigators, and must be consistent with the informed consent obtained from participants and the ethics committee approval. – The requesting institution must provide evidence of local ethics approval or waiver for the proposed secondary analysis, if applicable. – A data use agreement (DUA) must be signed, specifying the conditions for data use, data security, prohibition of re-identification attempts, prohibition of data sharing with third parties, and obligations regarding acknowledgement of the original investigators and citation of the primary publication. – Data will be shared in a secure format (e.g., encrypted files), and only deidentified variables will be included. – Any results derived from the shared data must be reported in an aggregated, non-identifiable form.

From where data/document is obtainable

Interested researchers should send their data-sharing requests by email to the principal investigator.

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

The process for requesting access to deidentified IPD and supporting documents will involve the following steps: Initial contact: The interested researcher sends an email to the principal investigator briefly describing the proposed secondary analysis (research question, main methods, and data needed). Submission of documents: If the proposal is potentially acceptable, the requester will be asked to submit:– A short written proposal (2–5 pages)– A recent curriculum vitae (CV) of the responsible researcher– Evidence of local ethics committee approval or waiver (if applicable) Review of request: The principal investigator (and, if needed, the supervising committee or local ethics committee) will review the request to ensure scientific merit, feasibility, and consistency with the original consent and ethical requirements. This review is expected to take approximately 4 to 8 weeks, depending on the complexity of the request. Data use agreement: If the request is approved, a data use agreement (DUA) will be sent to the requester. Data will be shared only after both parties have signed the DUA. Data transfer: After the DUA is finalized, the deidentified dataset, data dictionary, relevant code/scripts, and agreed supporting documents will be transferred in a secure manner (e.g., encrypted files via secure file transfer or password-protected archive). The overall time from initial request to data access is expected to be approximately 1 to 3 months, depending on the completeness of the applicant’s documents and the complexity of the proposed analysis.

Comments

All data sharing will be conducted in accordance with applicable institutional policies, national regulations, and the conditions specified in the ethics committee approval.