# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of gluteal muscle strengthening on performance and balance in adolescent basketball players with functional ankle instability

### Protocol summary


**Study aim**
To determine the effect of eight weeks of gluteal muscle strengthening exercises on performance and balance in adolescent basketball players with functional ankle instability.

**Design**
This study is a randomized controlled trial with a parallel-group design conducted on 40 participants. Allocation will be performed using block randomization generated by the RAND function in Microsoft Excel. Outcome assessors and the data analyst will be blinded.

**Settings and conduct**
This randomized controlled trial will be conducted in Shiraz, Iran, at Mehrsam Basketball Club. Participants will be allocated by block randomization to exercise or control groups. The exercise group will perform an eight-week gluteal strengthening program, while the control group continues regular training. The study is single-blind, with outcome assessors and the data analyst blinded.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age 10–17 years; female active basketball players; history of ankle giving way in the past 6 months; IdFAI score >11; history of ankle sprain; no medical contraindication to exercise; informed consent obtained. Exclusion criteria: Acute lower-limb injury, fracture, or surgery in the past 3 months; acute ankle pain or inflammation at baseline; neurological or systemic diseases affecting balance.

**Intervention groups**
Control group: Participants in the control group will continue their regular and routine basketball training without receiving any additional exercise intervention during the study period. Exercise group: Participants in the exercise group will perform a comprehensive gluteal muscle strengthening exercise program for eight weeks, in addition to their regular basketball training.

**Main outcome variables**
Dynamic balance; vertical jump; agility; 10-m sprint speed with and without the ball; functional ankle instability.


### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180521039762N6**
Registration date: **2026-02-07, 1404/11/18**
Registration timing: **prospective**

Last update: **2026-02-07, 1404/11/18**
Update count: **0**

**Registration date**
2026-02-07, 1404/11/18


**Registrant information**
**Name**
Afshin Moghadasi
**Name of organization / entity**
University of Isfahan
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-02-20, 1404/12/01

**Expected recruitment end date**
2026-03-13, 1404/12/22

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of gluteal muscle strengthening on performance and balance in adolescent basketball players with functional ankle instability

**Public title**

Effect of Gluteal Muscle Strengthening on Balance and Athletic Performance

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 10 and 17 years Female active basketball players Subjective feeling of ankle giving way during the past six months IdFAI score greater than 11 History of ankle sprain No medical contraindication for participation in physical activity and completion of written informed consent

**Exclusion criteria:**

Presence of acute musculoskeletal injury, fracture, or surgery in the lower limbs Presence of pain, inflammation, or signs of acute ankle injury at baseline Presence of neurological or systemic diseases affecting balance or motor performance

**Age**

From **10 years** old to **17 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible participants will be randomly allocated to the study groups after baseline assessment and before the start of the intervention. Block randomization with an individual unit of randomization will be used to ensure balanced allocation between groups. The random allocation sequence will be generated using the RAND function in Microsoft Excel. Allocation concealment will be ensured by using sequentially numbered, opaque, sealed envelopes, which will be opened only after the final enrollment of each participant.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Due to the nature of the exercise intervention, blinding of participants and intervention providers will not be feasible, as participants must be informed about the general study objectives and training procedures. However, participants will not be informed about the type of intervention received by the other group. To minimize bias, outcome assessors and the statistical data analyst will be blinded to group allocation and will not be involved in the randomization or intervention procedures. Blinding will therefore be applied at the level of outcome assessment and data analysis.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of Payame Noor University

**Street address**

Payame Noor University, Nakhl St., Artesh Blvd., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

193954697

**Approval date**

2025-07-15, 1404/04/24

**Ethics committee reference number**

IR.PNU.REC.1404.364

## Health conditions studied

### 1

**Description of health condition studied**

Functional Ankle Instability

**ICD-10 code**

S93.4

**ICD-10 code description**

Sprain of ankle

## Primary outcomes

### 1

**Description**

Dynamic balance

**Timepoint**

Before the intervention and eight weeks after the intervention

**Method of measurement**

Y Balance Test

**2**

**Description**
Explosive power of the lower limb muscles
**Timepoint**
Before the intervention and eight weeks after the intervention
**Method of measurement**
Vertical jump test

**3**

**Description**
Agility
**Timepoint**
Before the intervention and eight weeks after the intervention
**Method of measurement**
Illinois agility test

**4**

**Description**
Running speed over a ten-meter distance with and without the ball
**Timepoint**
Before the intervention and eight weeks after the intervention
**Method of measurement**
Ten-meter sprint test with and without the ball

## Secondary outcomes

**1**

**Description**
Severity of functional ankle instability
**Timepoint**
Before the intervention and eight weeks after the intervention
**Method of measurement**
Identification of Functional Ankle Instability questionnaire

## Intervention groups

**1**

**Description**
Intervention group: Participants in this group will receive a comprehensive gluteal muscle strengthening exercise program for eight weeks. The program will be performed three sessions per week, with each session lasting approximately 30 to 45 minutes in the initial weeks, progressively increasing to 60 to 75 minutes in the final weeks.The training program will include a combination of the following components: 1. Gluteal strengthening exercises under non-weight-bearing conditions 2. Strengthening exercises targeting local and global stabilizing muscles of the pelvis and lower extremity 3. Isolated activation and strengthening exercises for the gluteal muscles 4. Weight-bearing strengthening exercises integrated into fundamental movement patterns 5. Reactive neuromuscular training exercises aimed at improving motor control and functional stability of the lower extremity. The exercise program will be conducted in addition to regular basketball training and will be supervised by the researcher.
**Category**
Rehabilitation

**2**

**Description**
Control group: Participants in this group will continue their regular basketball training program throughout the study period and will not receive any specific gluteal muscle strengthening exercises or additional rehabilitation interventions.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Mehrsam Basketball Club
**Full name of responsible person**
Darya Farhadpour
**Street address**
Parvaresh Sports Club, Marefat St., Rahmat Blvd.
**City**
Shiraz
**Province**
Fars
**Postal code**
7396173751
**Phone**
+98 71 4221 3302
**Email**
mehrsam.basketball@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Payame Noor University
**Full name of responsible person**
Dr. Majid Zamahni
**Street address**
Payame Noor University, Nakhl St, Artesh Blvd, Tehran
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zamahani@pnu.ac.ir

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Payame Noor University
**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**
Payame Noor University
**Full name of responsible person**
Afshin Moghadasi
**Position**
Assistant professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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**Phone**
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**Email**
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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**
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**
Not applicable
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Title: De-identified individual participant data, study protocol, statistical analysis plan, clinical study report, and data dictionary Details: De-identified individual participant data (IPD), the study protocol, statistical analysis plan, clinical study report, and data dictionary will be available upon completion of the study and main

publication. Access is granted to qualified researchers via a formal request and is subject to approval and commitment to confidentiality.

**When the data will become available and for how long**

Access to the documents and de-identified data will commence immediately following the final completion of the study and publication of the main results (primary manuscript). This access will be maintained for a period of at least 5 years from the publication date.

**To whom data/document is available**

The data will be accessible to all academic and non-academic researchers from scientific and medical institutions. Requests must be submitted by a formal Principal Investigator (PI). The main condition for access is the submission of a scientifically sound analysis plan, signing of a Data Use Agreement (DUA), and a commitment to maintaining participant confidentiality and using the data strictly for research purposes.

**Under which criteria data/document could be used**

Purpose of Use: The primary purpose of data sharing is to enable complementary scientific analyses, replication of primary findings, and re-analysis of the data by independent researchers. Mandatory Conditions: 1. Valid Research Plan: The applicant must submit a scientifically sound research proposal or protocol detailing the intended use of the requested data. 2. Non-Commercial and Research Use: Use of the data and documents must be strictly for research and educational purposes. Any commercial or proprietary use is prohibited. 3. Agreement Signing: The applicant must sign a Data Use Agreement (DUA), committing to the complete confidentiality of participants and explicitly agreeing not to attempt re-identification. 4. Attribution (Citation): If any results are published, the researcher receiving the data must cite the original study (IRCT) and the primary publication.

**From where data/document is obtainable**

Applicants must submit a formal request containing a detailed scientific analysis plan, along with their full contact information, to the email address of Dr. Afshin Moghadasi (moghadasi@pnu.ac.ir). Following the review and approval of the proposal by the research team, and upon meeting the required criteria, a Data Use Agreement (DUA) will be issued for signature. Subsequently, the de-identified data will be shared with the applicant.

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

The process for accessing the data and documentation of the “Effect of Gluteal Muscle Strengthening on Balance and Athletic Performance” study involves four main stages: 1. Formal Application: The applicant must submit a formal request including a detailed scientific analysis plan, full contact details, and a commitment to research-only use, to the email address of the primary contact (Dr. Afshin Moghadasi: moghadasi@pnu.ac.ir). 2. Proposal Review (Estimated Time: 1 to 3 working weeks): The applicant’s request will be reviewed by the study’s research team for scientific merit, alignment with the primary publication objective, and adherence to ethical standards. 3. DUA Execution (Estimated Time: 2 to 4 working weeks): If the proposal is approved, a Data Use Agreement (DUA) will be sent to the applicant. The applicant is required to sign this document and return it to the research team. This agreement mandates a commitment to maintaining confidentiality and not attempting to re-identify participants. 4. Data Provision (Estimated Time: 1 to 3 working days): Upon receipt of the fully executed DUA and finalization of administrative procedures, the de-identified data and approved documentation (protocol, analysis plan, etc.) will be provided to the applicant in electronic files. Overall Time Estimation: The estimated time to complete the entire process, from receiving the initial request to the final provision of data, assuming the applicant provides complete documentation and the proposal is quickly approved, is approximately 3 to 7 working weeks.

**Comments**