Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effectiveness of Calf and Ankle Myofascial Exercises Versus the Use of Nighttime Ankle-Foot Orthosis on Gait Temporal Parameters, Plantar Pressure, and Balance in Skater Children with Achilles Tendon Shortening

Protocol summary

Study aim

Comparison of the Effectiveness of Calf and Ankle Myofascial Release Exercises Versus Night Ankle-Foot Orthosis on Spatiotemporal Gait Parameters, Plantar Pressure Distribution, and Balance in Young Skaters with Achilles Tendon Tightness

Design

A single-blind, randomized, parallel-group, controlled clinical trial was conducted involving 36 patients. Randomization was performed using the RAND function in Microsoft Excel

Settings and conduct

Skiter swith achill tendon stiffness who refer to Akhtar Hospital in Tehran will be enrolled if eligible and randomly allocated to intervention and control groups using block randomization. The study will be single-blind, whereby the investigator and participants will be aware of the intervention type, while the outcome assessor and data analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female skaters aged 8–12 years with at least 6 months of skating experience and Achilles tendon tightness. Exclusion criteria: History of surgery, unwillingness to participate in the study, or concurrent participation in other therapeutic interventions outside the study protocol.

Intervention groups

Intervention Group 1 (Myofascial Release Exercise Group): 6-week myofascial release exercise program (3 sessions per week, 30 minutes). The program includes myofascial release techniques using foam rollers, soft massage balls, and manual techniques. Intervention Group 2 (Night AFO Group): Participants will use an AFO during sleep for 6 weeks. Intervention Group 3 (Control Group): Participants will receive no intervention.

Main outcome variables

Spatial-temporal gait parameter, Foot pressure, Balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260321069007N5**
Registration date: **2026-09-11, 1405/06/20**
Registration timing: **prospective**

Last update: **2026-09-11, 1405/06/20**
Update count: **0**

Registration date

2026-09-11, 1405/06/20

Registrant information

Name
Razieh Yousefian Molla
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Email address
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

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 the Effectiveness of Calf and Ankle Myofascial Exercises Versus the Use of Nighttime Ankle-Foot Orthosis on Gait Temporal Parameters, Plantar Pressure, and Balance in Skater Children with Achilles Tendon Shortening

Public title
Comparison of the Effectiveness of Calf and Ankle Myofascial Exercises Versus the Use of Nighttime AFO Brace in Skater Children with Achilles Tendon Shortening
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of Achilles tendon tightness based on the Silfverskiöld test (passive ankle dorsiflexion range of motion less than 10 degrees). A minimum of 6 months of active participation and experience in skating.
Exclusion criteria:
No history of injury or surgery History of other exercise programs or treatment interventions Lack of consent to participate in the study
Age
From **8 years** old to **12 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, eligible participants who meet the inclusion and exclusion criteria and provide written informed consent will be randomly assigned to one of three groups: the Calf and Ankle Myofascial Exercises group, the Use of Nighttime AFO Brace group, or the Control group. The individual participant will serve as the unit of randomization. To ensure balanced group sizes, block randomization with variable block sizes will be employed. The random allocation sequence will be generated using Random Allocation Software with block sizes of six and nine. As the study consists of three groups, these block sizes were selected to maintain balanced allocation across groups within each block. For each block, all possible allocation arrangements among the three groups will be generated by the software, and the sequence of assignments will be determined completely at random. The randomization sequence will be generated by an individual who is not involved in the implementation of the study, and the researcher will have no role in either sequence generation or participant allocation. To maintain allocation concealment, group assignments will be placed in sequentially numbered, opaque, sealed envelopes according to the randomization sequence. Following participant enrollment and completion of baseline assessments, the appropriate envelope will be opened by the designated staff member, and the participant will be assigned to the corresponding study group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding in this study is limited to the outcome assessment level. Due to the nature of the interventions, participants are aware of the exercise program and orthosis they receive; therefore, participant blinding is not feasible. Likewise, the principal investigator, the therapist responsible for supervising the exercise program, and the clinician prescribing the orthosis are aware of group allocation and are actively involved in delivering the interventions. Consequently, blinding is not possible for these personnel. In contrast, all outcome assessments are performed by an independent assessor who has no access to participants' group allocation. Assessment data are provided using numerical identification codes only. During data collection and entry, coded identifiers are used, and no information regarding treatment allocation is disclosed to the outcome assessor. Data analysis is also conducted using coded datasets. No independent Data and Safety Monitoring Committee (DSMC) is established for this study. The investigators perform the primary data analysis using coded group labels, and treatment allocation remains concealed until completion of the primary 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 Islamic Azad University- Central Tehran Branch
Street address
Velayat University Complex, Salman Street, Khandan Street, Qaem Square, Artesh Boulevard, Sohanak.
City
Tehran
Province
Tehran
Postal code

1955847781

Approval date

2026-04-07, 1405/01/18

Ethics committee reference number

IR.IAU.CTB.REC.1405.024

Health conditions studied

1

Description of health condition studied

Achill Tendon Tightness

ICD-10 code

M67.0

ICD-10 code description

Short Achilles tendon (acquired)

Primary outcomes

1

Description

Foot Pressure

Timepoint

Outcome measures will assess in two stages: a pre-test conducted before the start of the intervention and a post-test administered immediately after the completion of the 6-week training program.

Method of measurement

Foot Scanner Device

Secondary outcomes

1

Description

Achill Tighness

Timepoint

Outcome measures will assess in two stages: a pre-test conducted before the start of the intervention and a post-test administered immediately after the completion of the 6-week training program

Method of measurement

Silverskiold

2

Description

Spatial Temporal Gait Parameters

Timepoint

Outcome measures will be assessed in two stages: a pre-test conducted before the start of the intervention and a post-test administered immediately after the completion of the 6-week training program.

Method of measurement

Foot Scanner Device

3

Description

Balance

Timepoint

Outcome measures will assess in two stages: a pre-test conducted before the start of the intervention and a post-test administered immediately after the completion of the 6-week training program.

Method of measurement

Foot Scanner Device

Intervention groups

1

Description

Intervention group 1: Myofascial Release Exercise Group. Participants in this group will undergo a structured and progressive myofascial release exercise program for 6 weeks. The intervention will be performed three times per week, with each session lasting approximately 30 minutes under the supervision of a rehabilitation specialist. Each session consists of three phases: warm-up, myofascial release exercises, and cool-down. The warm-up includes light walking, ankle mobility exercises, and breathing exercises to increase blood flow and prepare the soft tissues. The myofascial release program targets the gastrocnemius, soleus, Achilles tendon complex, and plantar fascia using foam rollers, soft massage balls, and manual release techniques. The intensity and duration of the exercises are progressively increased throughout the intervention period. During the initial weeks, emphasis is placed on correct technique and reducing fascial tension, whereas in the later weeks the program incorporates active ankle movements, trigger-point release techniques, and functional movement activities. Each session concludes with diaphragmatic breathing and neuromuscular relaxation exercises for the calf muscles.

Category

Rehabilitation

2

Description

Intervention group 2: Night Ankle-Foot Orthosis (AFO) Group. Participants in this group will use a custom-made Night Ankle-Foot Orthosis (AFO) during sleep for 6 consecutive weeks. The orthosis will be individually fabricated according to each child's lower-limb measurements and designed to maintain the ankle in a neutral position, providing a sustained low-load stretch to the posterior calf muscles and the Achilles tendon complex. The nightly wearing time will be progressively increased, beginning with 3–4 hours per night during Weeks 1–2, increasing to 5–6 hours during Weeks 3–4, and reaching the entire sleep period (approximately 6–8 hours) during Weeks 5–6. Parents will record daily orthosis wear time using a monitoring log, and skin condition, comfort, and any adverse events will be monitored throughout the intervention.

Category

Rehabilitation

3

Description
Control group: Participants assigned to the control group will receive no myofascial release exercises or Night AFO intervention during the 6-week study period. They will continue their usual daily activities and regular skating practice without additional therapeutic interventions. Participants will also be instructed to avoid initiating any new rehabilitation exercises or orthotic treatments that could influence lower-limb function or Achilles tendon length during the study period. Pre-intervention and post-intervention assessments will be conducted under the same standardized conditions as those used for the intervention groups.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Akhtar Hospital

Full name of responsible person
Aliasghar Jamebozorgi

Street address
Akhtar Hospital, Shariati St., Rumi Bridge, Sharifi Manesh St., Azar Dead End, Tehran

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mohammadreza Tanhaei Ahari

Street address
Central Administrative Building, Islamic Azad University, Central Tehran Branch, Soheini Street, East Artesh Highway, Tehran, Iran.

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ict@iauctb.ac.ir

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
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
Islamic Azad University

Full name of responsible person
Razieh Yousefian Molla

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
Faculty of Physical Education and Sport Sciences, Velayat University Complex, Salman Street, Khandan Street, Ghaem Square, Artesh Boulevard, Sohanak

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

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

All potential data can be shared after de-identifying individuals

When the data will become available and for how long

Access period starts after publication of results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers at universities, such as faculty members, will be allowed to conduct any statistical and clinical analysis

From where data/document is obtainable

Applicants can contact the responsible researcher by sending an email (razieh.yousefianmolla@iau.ac.ir) or calling (0098 9122022730).

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

The researcher will receive the items within a maximum of two weeks after sending the email or making the phone call

Comments