Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Six weeks Selected Ankle Sprain Prevention Exercise Program on Ankle Range of Motion, Proprioception, Ankle Muscle Strength, and Trunk Muscle Endurance in Female Karate Athletes Aged 10 to 13 Years

Protocol summary

Study aim

The aim of this study was to investigate the effect of six weeks of selected ankle sprain prevention exercise program on ankle range of motion, ankle proprioception, ankle muscle strength, and trunk muscle endurance in female karate athletes aged 10 to 13 years.

Design

This randomized controlled trial with 36 participants will use the RAND function in Microsoft Excel for group allocation.

Settings and conduct

This study will be conducted in Mashhad. The procedure will involve: (1) registering interested participants; (2) initial screening and invitation of eligible individuals; (3) familiarizing participants with the research process and obtaining informed consent; (4) randomly dividing participants into training and control groups; (5) measuring dependent variables at baseline, 3 weeks, and 6 weeks; and (6) performing statistical data analysis.

Participants/Inclusion and exclusion criteria

In the present study, participants will be female karate athletes aged 10 to 13 years with at least three years of competitive training experience. The inclusion criteria will be: no history of injury or surgery in the ankle region, absence of musculoskeletal abnormalities in the lower limbs, and general good health as confirmed by a physician.

Intervention groups

This study will include 36 female karate athletes (aged 10–13 years) purposively selected and randomly assigned to either an ankle injury prevention program or standard warm-up exercises.

Main outcome variables

Ankle range of motion ankle, angle proprioception, ankle muscle strength, and trunk muscle endurance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241221064122N1**
Registration date: **2026-02-23, 1404/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-23, 1404/12/04**
Update count: **0**

Registration date

2026-02-23, 1404/12/04

Registrant information

Name

Negin Nosrati Khoreshbari

Name of organization / entity

Ferdowsi University of Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 915 233 1275

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2026-05-20, 1405/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Six weeks Selected Ankle Sprain Prevention Exercise Program on Ankle Range of Motion, Proprioception, Ankle Muscle Strength, and Trunk Muscle Endurance in Female Karate Athletes Aged 10 to 13 Years

Public title
Ankle sprain prevention strategy in 10-13 year old female karate athletes: An exercise-based approach

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The subjects were girls aged 10 to 13 who practiced karate regularly Absence of musculoskeletal injury or abnormality in the lower extremities, especially the ankle General health clearance by a doctor

Exclusion criteria:
People with musculoskeletal injuries or abnormalities in the lower extremities, especially the ankle People with a specific disease

Age
From **10 years** old to **13 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, each participant is assigned independently and with equal chance to one of two intervention or control groups. This simple randomization method was chosen for its simplicity, transparency, and the lack of need to consider specific variables to ensure that no known or unknown factors, such as demographic or clinical characteristics, affect the allocation of groups. The required randomization sequence is generated using the RAND function in Excel software. This function generates a random number between 0 and 1 for each individual. Then, based on a predetermined threshold, numbers less than 0.5 are assigned to the control group and numbers equal to or greater than 0.5 are assigned to the intervention group. This randomization sequence is recorded and archived as evidence of the study so that, if necessary, the process can be reviewed and verified.To maintain impartiality and avoid any bias, the allocation process is carried out by an independent observer who has no role or knowledge of the details of the study design, implementation or analysis. Although it is not possible to conceal the grouping from participants and administrative personnel due to the nature of the intervention, both outcome assessors and data analysts are kept unaware of the group allocation until the end of the data collection and analysis phase to reduce bias in the assessment of outcomes

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ferdowsi University of Mashhad

Street address
Azadi Square, Ferdowsi University of Mashhad, Central Administration Building

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۷۴

Approval date
2026-01-20, 1404/10/30

Ethics committee reference number
IR.UM.REC.1404.455

Health conditions studied

1

Description of health condition studied
Ankle Injuries

ICD-10 code
S90

ICD-10 code description
Superficial injury of ankle, foot and toes

Primary outcomes

1

Description
Ankle range of motion

Timepoint
Assessments will be conducted at three time points: prior to the intervention, at the end of week three, and following the completion of the six-week protocol.

Method of measurement
Inclinometer

2

Description
Ankle proprioception
Timepoint
Assessments will be conducted at three time points: prior to the intervention, at the end of week three, and following the completion of the six-week protocol.
Method of measurement
Inclinometer

3

Description
Ankle muscle strength
Timepoint
Assessments will be conducted at three time points: prior to the intervention, at the end of week three, and following the completion of the six-week protocol.
Method of measurement
Active force 2 digital dynamometer

4

Description
Trunk muscle endurance
Timepoint
Assessments will be conducted at three time points: prior to the intervention, at the end of week three, and following the completion of the six-week protocol.
Method of measurement
McGill's Torso Muscular Endurance Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will perform the selected ankle sprain prevention exercises for six weeks, three sessions per week, with each session lasting 20 minutes.
Category
Prevention

2

Description
Control group: Participants in the control group will continue performing standard karate warm-up exercises for six weeks.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ferdowsi University of Mashhad
Full name of responsible person
Negin Nosrati Khoreshbari
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Azadi Square, Ferdowsi University of Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ferdowsi University of Mashhad
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
Ferdowsi University of Mashhad
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
Ferdowsi University of Mashhad

Full name of responsible person
Negin Nosrati Khoreshbari
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Karate, Gymnastics, Children's sports coach
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Azadi Square, Ferdowsi University of Mashhad
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Person responsible for scientific inquiries

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Person responsible for updating data

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Negin Nosrati Khoreshbari
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Karate, Gymnastics, Children's sports coach
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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