

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

nnosratikhoshbarin@mail.um.ac.ir

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

91177948974

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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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ferdowsi University of Mashhad

Full name of responsible person

Behnaz Shahtahmassebi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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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