

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

#### **Street address**

Azadi Square, Ferdowsi University of Mashhad

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9177948974

#### **Phone**

+98 51 3880 2000

#### **Email**

nn0sratikhoresbarin@mail.um.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ferdowsi University of Mashhad

##### **Full name of responsible person**

Negin Nosrati Khoreshbari

##### **Street address**

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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**

Sport Medicine

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

Ferdowsi University of Mashhad

**Full name of responsible person**

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**Position**

Master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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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