

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The Effect Of Six Week Modified FIFA 11+ On Proprioception, Balance, Strength And Range Of Motion of Ankle In Male Adolescent Volleyball Players.

#### Protocol summary

##### Study aim

prevention of ankle sprain

##### Design

Semi-experimental and prospective study. With the control group, parallel design single blind, 24 patients, 12 experimental group and 12 control group.

##### Settings and conduct

Subjects will refer to the laboratory of Shahid Beheshti University for pre-test. After performing strength and proprioception tests (isokinetic device system 4), balance (biodex balance system) and ankle range of motion (Seahan goniometer), the experimental group performed FIFA + 11 warm-up exercises for 6 weeks and the control group Continue their routine training for 6 weeks. Then the post-test will be performed in the laboratory of Shahid Beheshti University.

##### Participants/Inclusion and exclusion criteria

Male gender; age range 14-18 years; exercise at least two sessions per week; semi-skilled level; no chronic ankle sprain.

##### Intervention groups

The 12 members of the experimental group will perform 6 weeks of FIFA 11+ adjusted warm-up exercises for 20 minutes at the beginning of their volleyball training. The 12 members of the control group will also practice their volleyball routine during these 6 weeks.

##### Main outcome variables

proprioception; balance; range of motion; strength of ankle

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210801052047N1**

Registration date: **2021-08-11, 1400/05/20**

Registration timing: **prospective**

Last update: **2021-08-11, 1400/05/20**

Update count: **0**

##### Registration date

2021-08-11, 1400/05/20

##### Registrant information

###### Name

sepide moradi nasab

###### Name of organization / entity

Shahid beheshti university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 4242 8477

###### Email address

sepidemoradi75@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-14, 1400/05/23

##### Expected recruitment end date

2021-09-25, 1400/07/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect Of Six Week Modified FIFA 11+ On Proprioception, Balance, Strength And Range Of Motion of Ankle In Male Adolescent Volleyball Players.

##### Public title

The Effect Of Six Week Modified FIFA 11+ On Proprioception, Balance, Strength And Range Of Motion of Ankle In Male Adolescent Volleyball Players.

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

only males age between 14 to 18 have exercise at least 2 days in a week semi skilled level have no chronic sprain in ankle in 6 month before participate in investigation having no underlying disease

##### **Exclusion criteria:**

Dissatisfaction with the continuation of activities in the present study Not participating in training sessions as two consecutive sessions per week and three non-consecutive sessions. Occurrence of any acute injury to the ankle during the present study

#### **Age**

From **14 years** old to **18 years** old

#### **Gender**

Male

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **24**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

After being called to the teams in region one of Tehran, 24 qualified people will enter the study after obtaining their consent and will be randomly divided into two groups: control and experimental. The block randomization method will be used to create a random sequence. Which uses random allocation software.

Allocation software (allocation concealment) is used to hide the group before the person is placed in the group. In this method, 4 blocks of all possible combinations (6 possible modes AABB, ABAB, ABBA, BBAA: BABA, BAAB) are created, then these blocks are inserted on opaque and sealed envelopes and randomly selected and back The heads will be placed in a box and the participants will take each envelope and thus divide it into two groups A (intervention) and B (control).

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

#### **Secondary Ids**

empty

#### **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of shahid beheshti university

##### **Street address**

no. 10, golestan ave., vahed street. dezfool city

##### **City**

dezfool

##### **Province**

Khouzestan

##### **Postal code**

64616-57514

#### **Approval date**

2021-03-13, 1399/12/23

#### **Ethics committee reference number**

IR.SBU.REC.1400.047

#### **Health conditions studied**

### 1

#### **Description of health condition studied**

none

#### **ICD-10 code**

#### **ICD-10 code description**

#### **Primary outcomes**

### 1

#### **Description**

proprioception

#### **Timepoint**

Beginning and end of the study

#### **Method of measurement**

isokinetic system 4

### 2

#### **Description**

balance

#### **Timepoint**

Beginning and end of the study

#### **Method of measurement**

biodex balance system

### 3

#### **Description**

range of motion

#### **Timepoint**

Beginning and end of the study

#### **Method of measurement**

ceahan goniometer

### 4

#### **Description**

strenght

#### **Timepoint**

Beginning and end of the study

#### **Method of measurement**

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: This group performs 6 weeks of FIFA 11+ adjusted warm-up exercises. These exercises were designed by FIFA in 2006. Which consists of 3 main parts. In the present study, these exercises are performed for 6 weeks and two sessions per week in three sections. In the first part, with slow running exercises combined with active stretching movements and controlled collisions, the players perform the correct landing technique and change direction for 8 minutes. In the second part, the focus of the exercises is on balance, strength, explosive power and strengthening the central muscles. Each exercise has three levels from simple to advanced and lasts 10 minutes. In the third part, running exercises are performed with a change of direction at high and medium speeds in two minutes. Balance board exercises have also been added to this protocol in the second part of the exercises.

#### Category

Prevention

### 2

#### Description

Control group: This group follows its 6-week routine volleyball training.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti University- Sport Science Lab

##### Full name of responsible person

Sirous Sheykhl

##### Street address

Shahid Chamran Highway, Yemen St., Shahid Shahriari Square, Daneshjoo Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

19839 69411

##### Phone

+98 21 2990 2233

##### Fax

+98 21 2243 1919

##### Email

#### Web page address

<https://www.sbu.ac.ir/SitePages/Home.aspx>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid beheshti university

##### Full name of responsible person

Mostafa Zarei

##### Street address

Shahid Chamran Highway, Yemen St., Shahid Shahriari Square, Daneshjoo Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

##### Phone

+98 21 2990 2233

##### Fax

+98 21 2243 1919

##### Email

pr.office@mail.sbu.ac.ir

##### Web page address

<https://www.sbu.ac.ir/SitePages/Home.aspx>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid beheshti 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

Shahid beheshti university

##### Full name of responsible person

Sepide Moradi nasab

##### Position

Master student

##### Latest degree

Master

##### Other areas of specialty/work

Sport injury - corrective exercise

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid beheshti university

**Full name of responsible person**

Sepide Moradi nasab

**Position**

Master student

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## Person responsible for updating data

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Shahid beheshti university

**Full name of responsible person**

Sepide Moradi nasab

**Position**

Master student

**Latest degree**

Master

**Other areas of specialty/work**

Sport injury - corrective exercise

**Street address**

no 10, Golestan ave., vahed street. dezfool city

## 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**

We share data files including personal information and data related to pre-test and post-test in a coded folder by the person in charge, Ms. Sepideh Moradi Nasab, on the website of Shahid Beheshti University.

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

Start the access period as soon as the results are printed.

**To whom data/document is available**

It will be available to all research groups as well as all other people who are interested.

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

The data can be used for future studies as well as in all research groups, and any kind of analysis and research use is allowed on the data, and under the conditions that are cited to us, this data will be provided to them.

**From where data/document is obtainable**

To the person responsible for answering Ms. Sepideh Moradi Nasab Contact number 989374078354 + email sepidemoradi75@gmail.com Khuzestan address. Dezful city. Unit 10 - Golestan Alley No. 10

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

The applicant will send his application to the e-mail address of Ms. Sepideh Moradi Nasab (sepidemoradi75@gmail.com) and Ms. Sepideh Moradi nasab will provide information after the necessary checks.

**Comments**