

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of FIFA 11+ Kids program on kinematic risk factors for ACL in preadolescent girl soccer players during single leg landing

Protocol summary

Study aim

ACL injury prevention in preadolescent girl soccer players is study's main purpose.

Design

A number of 40 young healthy female football players will be invited to the laboratory of the Faculty of Physical Education of Bu Ali Sina University in Hamedan. and will be divided into two control and experimental groups with parallel groups. To conceal the random sequence, the method of opaque envelopes with random sequences will be used. And all the measured factors will be done in two phases before training program and after the training program for both groups.

Settings and conduct

The place of conducting the tests is the laboratory of Bu Ali Sina University in Hamedan. To conceal the random sequence, the method of closed envelopes with random sequences will be used. And only the data evaluator will be blinded

Participants/Inclusion and exclusion criteria

Only preadolescent females in the range of 10-13 years old will recruit for the study.

Intervention groups

The intervention group performs 11+ kids program for 8 weeks and 2 sessions per week. The control group performs warm-up routine program.

Main outcome variables

knee flexion, abduction and internal rotation hip flexion, adduction and internal rotation trunk flexion, lateral flexion and rotation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220814055680N1**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **retrospective**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

Maedeh Taghizadeh Kerman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3523 1441

Email address

maedeh.taghizadeh1988@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-12, 1401/07/20

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of FIFA 11+ Kids program on kinematic risk factors for ACL in preadolescent girl soccer players during single leg landing

Public title

11+ Kids exercises on risk factors for ACL

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All of the players involved in football at least 6 months
All of the players should be 10-13 years old

Exclusion criteria:

Neuromuscular disorders Participation in other sports
injury prevention program at past 6 months

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

To create a simple random sequence, randomization under web such as graphpad.com and for concealment, allocation concealment will be used.

Blinding (investigator's opinion)

Single blinded

Blinding description

For concealment, the method of opaque envelopes with random sequences will be used. Each of the random sequences is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. At the time of starting the registration of the participants, one of the envelopes will be opened based on the order of their arrival and the allocated group of that participant will be revealed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bu-Ali sina university

Street address

No 24, Ahmadi roshan Ave, Pazhuhesh Blvd, Bu ali sina university, Hamadan Town

City

Hamadan

Province

Hamadan

Postal code

6516738695

Approval date

2021-10-13, 1400/07/21

Ethics committee reference number

IR.BASU.REC.1400.035

Health conditions studied

1

Description of health condition studied

Healthy preadolescent girl soccer players

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Knee angles in sagittal, frontal, and horizontal planes

Timepoint

Pretest and posttest after 8 weeks

Method of measurement

Motion analyze system

2

Description

Hip angles in sagittal , frontal and horizontal planes

Timepoint

Before and after 8 weeks

Method of measurement

Motion capture analysis system

3

Description

Trunk angles in sagittal, frontal and horizontal planes

Timepoint

Before and after 8 weeks

Method of measurement

Motion capture analysis system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 11+ kids training performs for 8 weeks and 2 sessions per week. it includes balance, strength, and jumping training. and there are seven difficulty levels for each exercise

Category

Prevention

2

Description

Control group: Warm up routine program performs for 8

weeks and 2 sessions per week. this includes running, stretching and agility training.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina University

Full name of responsible person

Maedeh Taghizadeh Kerman

Street address

No. 24, Ahmadi Roshan Ave, Pazhuhesh Blvd,
Hamadan Town

City

Hamadan

Province

Hamadan

Postal code

6516738695

Phone

+98 81 3838 1601

Email

maedeh.taghizadeh1988@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Bu Ali sina

Full name of responsible person

Ali Yalfani

Street address

No. 24, Ahmadi Roshan Ave, Pazhuhesh Blvd

City

Hamadan

Province

Hamadan

Postal code

6516738695

Phone

+98 81 3838 1016

Email

maedeh.taghizadeh1988@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

The University of Bu Ali sina

Full name of responsible person

maedeh taghizadeh kerman

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Sports injury and corrective exercises

Street address

No 24, Ahmadi Roshan Street, Pazhuhesh Blvd,
Hamadan Town

City

Hamadan

Province

Hamadan

Postal code

6516738695

Phone

+98 51 3523 1441

Email

maedeh.taghizadeh1988@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Bu Ali sina

Full name of responsible person

maedeh taghizadeh

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Sport injury

Street address

No 24, Ahmadi Roshan Street, Pazhuhesh blvd,

City

Hamadan

Province

Hamadan

Postal code

6516738695

Phone

+98 51 3523 1441

Email

maedeh.taghizadeh1988@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The University of Bu Ali sina

Full name of responsible person

maedeh taghizadeh kerman

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Sports injury

Street address

No 24, Ahmadi Roshan Street, Pazhuhesh BLV, Bu ali sina university, Hamadan Town

City

Hamadan

Province

Hamadan

Postal code

6516738695

Phone

+98 51 3523 1441

Email

maedeh.taghizadeh1988@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All of the points without the names of the participants will be available

When the data will become available and for how long

6 months after the result publication

To whom data/document is available

All of the individuals

Under which criteria data/document could be used

Improvement of the situation of the participants

From where data/document is obtainable

Accessible and available in Bu Ali sina library

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

Email to corresponding author

Comments