

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The “11+ Kids” warm-up programme to prevent injuries in young high-level football players: a cluster randomized controlled trial

Protocol summary

Study aim

To assess the efficacy of the “11+ Kids” warm-up programme regarding injury reduction in high-level children’s football players.

Design

a two-armed cluster-randomized controlled trial, The observation period comprised one football season (9 months) from February 2017 to November 2017. the intervention group was to use the new injury prevention programme (“11+ Kids”) as a warm-up, while the control clubs used their regular warm-up programme.

Settings and conduct

All high-level football schools from five provinces of Iran were randomly allocated to an intervention group and a control group. An automated randomization procedure was conducted by a researcher who had no direct contact with the clubs or team officials and who was not involved in the intervention.

Participants/Inclusion and exclusion criteria

1.teams are competing in the highest league of their province; 2.players are between 7 and 14 years old at the start of the study, and 3.regular training must take place at least twice per week. 4. Teams were excluded from the study if they already used an exercise-based injury prevention measure.

Intervention groups

INT replaced their warm-up by “11+ Kids”. The “11+ Kids” programme consists of seven exercises and takes about 15 to 20 min to be performed. the intervention group was asked to use the “11+ Kids” programme at least twice a week at the beginning of the training session, replacing their usual warm-up. The coaches of the control group were asked to use their usual warm-up routine.

Main outcome variables

incidence of lower extremities injuries

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180526039850N1**

Registration date: **2019-02-03, 1397/11/14**

Registration timing: **prospective**

Last update: **2019-02-03, 1397/11/14**

Update count: **0**

Registration date

2019-02-03, 1397/11/14

Registrant information

Name

Hamed Abbasi

Name of organization / entity

Sports Sciences Research Institute of Iran (SSRII)

Country

Iran (Islamic Republic of)

Phone

+98 21 8874 7884

Email address

h.abbasi@ssrc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-02, 1397/11/13

Expected recruitment end date

2019-11-01, 1398/08/10

Actual recruitment start date

2019-02-11, 1397/11/22

Actual recruitment end date

2019-11-15, 1398/08/24

Trial completion date

2019-12-01, 1398/09/10

Scientific title

The “11+ Kids” warm-up programme to prevent injuries in young high-level football players: a cluster randomized controlled trial

Public title

Investigating the Effect of the 11+ Program on Prevention of Injuries in Football Players

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

teams are competing in the highest league of their province players are between 7 and 14 years old at the start of the study regular training must take place at least twice per week

Exclusion criteria:

If the teams already used an exercise-based injury prevention measure

Age

From **7 years** old to **14 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **1250**

Actual sample size reached: **962**

Randomization (investigator's opinion)

Randomized

Randomization description

all high-level football schools from five provinces of Iran were invited to participate in the study. Participating clubs were randomly allocated to an intervention group and a control group. All teams of the same club were allocated to the same group to minimize the risk of contamination. An automated randomization procedure was conducted by a researcher who had no direct contact with the clubs or team officials and who was not involved in the intervention. The number of participating teams per club and the age group served as strata for the randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

by a researcher who had no direct contact with the clubs or team officials and who was not involved in the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sports Sciences Research Institute

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2019-01-23, 1397/11/03

Ethics committee reference number

IR.SSRC.REC.1397.001

Health conditions studied

1

Description of health condition studied

Dislocation, sprain and strain of joints and ligaments of knee

ICD-10 code

S80

ICD-10 code description

Superficial injury of knee and lower leg

2

Description of health condition studied

Superficial injury of ankle and foot

ICD-10 code

S90

ICD-10 code description

Superficial injury of ankle, foot and toes

3

Description of health condition studied

Superficial injury of hip and thigh

ICD-10 code

S70

ICD-10 code description

Superficial injury of hip and thigh

Primary outcomes

1

Description

football related lower extremity injuries

Timepoint

Through one football season

Method of measurement

Reporting

Secondary outcomes

1

Description

Knee injuries Ankle injuries,

Timepoint

36 weeks

Method of measurement

Sport Injuries Registration Form

Intervention groups

1

Description

Intervention group: used the new injury prevention programme ("11+ Kids") as a warm-up during the season

Category

Prevention

2

Description

Control group: used routine warm-up programme during the season

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports Medicine Center of the National Iranian Football Academy

Full name of responsible person

Tohid Seif Barghi

Street address

After the Olympic Hotel, West Blvd. Azadi Stadium, Tehran

City

Tehran

Province

Tehran

Postal code

1484813111

Phone

+98 21 4473 8641

Email

tohid_seif@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Sports Sciences Research

Institute, Sports Sciences Research Institute

Full name of responsible person

Dr Ali Kashi

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Phone

+98 21 8852 9121

Email

Ssrc.intoffice@gmail.com

Web page address

http://ssrc.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Sports Sciences Research Institute, Sports Sciences Research Institute

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

Sports Sciences Research Institute

Full name of responsible person

Hamed Abbasi

Position

Assitant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Province

Tehran

Postal code

1587958711

Phone

+98 21 8852 9121

Email

h.abbasi@ssrc.ac.ir

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

Sports Sciences Research Institute

Full name of responsible person

Hamed abbasi

Position

Assitant professor

Latest degree

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Sport Medicine

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City

Tehran

Province

Tehran

Postal code

1587958711

Phone

+98 21 8852 9121

Fax

+98 21 8875 0884

Email

h.abbasi@ssrc.ac.ir

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

Sports Sciences Research Institute

Full name of responsible person

Hamed Abbasi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Phone

+98 2188909509454

Fax**Email**

h.abbasi@ssrc.ac.ir

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data relating to the control and intervention group in the pre and post test groups will be shared as unidentified.

When the data will become available and for how long

Six months after the publication of the articles

To whom data/document is available

All the researchers

Under which criteria data/document could be used

data is allowed to use in case of citing the reference

From where data/document is obtainable

hamed abbasi

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

by an email

Comments