

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of balance training with and without stroboscopic vision on kinesiophobia, proprioception and timing of muscle activity of selected muscles in people with chronic ankle instability

Protocol summary

Study aim

Comparing the effect of balance training with and without stroboscopic vision on kinesiophobia, proprioception, and timing of muscle activity of selected muscles in people with chronic ankle instability

Design

A randomized clinical trial study, single-blind, parallel-group, 45 elderly randomized to 3 intervention groups and a control group through web-based randomization

Settings and conduct

After evaluation by a physician, and inclusion-exclusion criteria, the researcher records the personal information of patients among with the signed consent form. Participants are divided into two groups intervention and control groups. This study was single-blind and the outcome assessor is blind to interventions and groups. This study will be conducted in the laboratory of movement analysis, faculty of physical education at Kharazmi University. The protocols are 8 weeks and three 60-minute sessions per week

Participants/Inclusion and exclusion criteria

Inclusion criteria: A score of less than 27 on the Cumberland Ankle Functional Instability Test, A history of at least two acute sprains in the last 6 months, Exclusion criteria: History of any ankle fracture, History of ankle joint surgery, Acute ankle sprain in the last 6 weeks, Vestibular or balance dysfunction

Intervention groups

Intervention group 1: includes balance exercises three sessions a week for 6 weeks. The duration of each session is 60 minutes and 10 minutes of warm-up and cooling-down program is considered for each session. Intervention group 2: balance exercises with stroboscopic glasses, three weekly sessions for 6 weeks. Each session lasts 60 minutes, and 10 minutes of warm-up and cool-down program is considered for each session. The control group, no exercise program only

performs daily activities during this time.

Main outcome variables

Ankle Proprioception, Ankle Instability Electromyography of lower limb muscles, Kinesiophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180627040251N8**

Registration date: **2024-07-08, 1403/04/18**

Registration timing: **prospective**

Last update: **2024-07-08, 1403/04/18**

Update count: **0**

Registration date

2024-07-08, 1403/04/18

Registrant information

Name

Hassan Sadeghi

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-10, 1403/04/20

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of balance training with and without stroboscopic vision on kinesiophobia, proprioception and timing of muscle activity of selected muscles in people with chronic ankle instability

Public title

Effect of balance training with and without stroboscopic vision on functional performance in athletes with chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A score of less than 27 on the Cumberland Ankle Functional Instability Test A history of at least two acute sprains in the last 6 months Ability to bear weight on the affected limb Not receiving exercise therapy and physiotherapy in the last year

Exclusion criteria:

History of any ankle fracture History of ankle joint surgery Acute ankle sprain in the last 6 weeks Vestibular or balance dysfunction Disability of the athlete during training due to severe pain, fatigue, muscle cramps, and limited movement in the ankle joint

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using simple randomization individually and random sequence allocation through a computer program aided by a web-based program (randomizer.org). It will be determined by a non-involved research team member when selecting samples from opaque, sequentially numbered sealed envelopes for allocation concealment. Participants will be allocated to two intervention groups and one control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blind to the groups' randomization and interventions receiving by participants. In this way, during the evaluation before and after the intervention protocol, they do not make mistakes in their judgments in favor of a specific

therapeutic intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Kharazmi University-Iran

Street address

Enghlab- Mofateh St. Tehran

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Postal code

۱۳۹۱۱-۱۵۷۱۹

Approval date

2024-05-05, 1403/02/16

Ethics committee reference number

IR.KHU.REC.1403.023

Health conditions studied**1****Description of health condition studied**

Sprain of Ankle

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

2**Description of health condition studied**

Balance Exercise

ICD-10 code

Y93.B9

ICD-10 code description

Activity, other involving muscle strengthening exercises

Primary outcomes**1****Description**

Ankle Proprioception

Timepoint

immediately before intervention; immediately after intervention

Method of measurement

Biodex Isokinetic Dynamometer

Secondary outcomes

1

Description

Ankle Instability

Timepoint

immediately before intervention; immediately after intervention

Method of measurement

Cumberland ankle instability questionnaire

2

Description

Electromyography of lower limb muscles

Timepoint

immediately before intervention; immediately after intervention

Method of measurement

Electromyography

3

Description

Kinesiophobia

Timepoint

immediately before intervention; immediately after intervention

Method of measurement

kinesiophobia Questioner

Intervention groups

1

Description

Intervention group1 : Includes static and dynamic balance exercises for the injured ankle. The program consists of 6 exercises, which start from an easy level and gradually become more difficult according to the way of execution and the person's ability. It should be noted that the intensity, duration, type of movements and level of exercises in this protocol are controlled by the examiner and are changed according to the principle of overload. All participants do 18 training sessions for 6 weeks

Category

Rehabilitation

2

Description

Intervention group 2: Includes balance exercises with stroboscopic vision. This exercise protocol includes static and dynamic balance for the injured ankle. The program consists of 6 exercises, which start from an easy level and gradually become more difficult according to the way of execution and the ability of the person. It should be noted that the intensity, duration, type of movements and level of exercises in this protocol are controlled by the examiner and are changed according to the principle

of overload. The exercises are done in a circle for 20 minutes and all participants do 18 training sessions for 6 weeks. The participants perform the above-mentioned balance exercises by adding glasses in the form of alternating vision between opaque and transparent phases during the intervention. The glasses are on the eyes of the participants during the entire training, and the glasses are completely transparent during rest.

Category

Rehabilitation

3

Description

Control group: In the control group, there is no intervention and only pre-test and post-test are taken. They are asked not to exercise during this time.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Sport Sciences. Kharazmi University

Full name of responsible person

Azam Ahmadi

Street address

Faculty of Physical Education and Sports Sciences, Kharazmi University,, University Square, at the end of Shahid Beheshti St. Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Dr Mohammad Delnavaz

Street address

Vice-Chancellor for Research and Technology. No. 43. South Mofatteh Ave., Tehran, Iran

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Fax**Email**

Delnavaz@khu.ac.ir

Web page address

https://research.khu.ac.ir/en

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kharazmi 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**

Kharazmi University

Full name of responsible person

Hassan Sadeghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Latest degree

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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