Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
Phone
+98 21 2222 8001
Email address
hassan.sadeghi81@yahoo.com

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
City
Tehran
Province
Tehran
Postal code
۱۴۹۱۱-۱۵۷۱۹
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
City
karaj
Province
Alborz
Postal code
3755131979
Phone
+98 26 3451 2001
Email
labrotary.pess.khu@gmail.com

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
City
Tehran
Province
Tehran
Postal code
15719-14911

Phone
+98 21 2222 8001
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
Street address
Mirdamad - Shahid Hesari St. - Shahid Keshvari Complex - Faculty of Physical Education and Sports Sciences
City
Tehran
Province
Tehran
Postal code
1544733111
Phone
+98 21 2222 8001
Fax
Email
hassan.sadeghi81@yahoo.com

Person responsible for scientific 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
Street address
Mirdamad - Shahid Hesari St. - Shahid Keshvari Complex - Faculty of Physical Education and Sports Sciences
City
Tehran
Province
Tehran
Postal code
1544733111
Phone
+98 21 2222 8001
Fax
Email
hassan.sadeghi81@yahoo.com

Person responsible for updating data

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
Street address
Mirdamad - Shahid Hesari St. - Shahid Keshvari Complex - Faculty of Physical Education and Sports Sciences
City
Tehran
Province
Tehran
Postal code
1544733111
Phone
+98 21 2222 8001
Fax
Email
hassan.sadeghi81@yahoo.com

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