

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Insoles With Different Wedge on Balance control With and Without Visual input before and after fatigue In healthy people

Protocol summary

Study aim

The main purpose of this study was to study The effect of Insoles with different Wedge on balance control with and without visual input before and after fatigue in healthy individuals

Design

This research was carried out at the Bu-Ali Sina University Rehabilitation Research Laboratory. Which includes pre-test and post-test in one session. Twenty female volunteers from the University who had normal navicular elevations participated in the study and performed equilibrium tests with three different insoles.

Settings and conduct

The Present study is a semi-experimental research based on the desing, the method os selecting the subject,the measurment tools and the intervention, and the research design was pre-test and post- test on one Sesión

Participants/Inclusion and exclusion criteria

no history of surgery, fracture, burn, musculoskeletal problems, back pain or severe trauma in the lower extremity during the last six months of the study and dominance of the right foot, as well as having normal navicular height the criteria for entering the research.Having lower limb damage, having a history of lower limb surgery, balance disorders such as Atrial System disorders, lower extremity abnormalities, spine and legs.

Intervention groups

A group of 20 people performed equilibrium tests using three types of insoles

Main outcome variables

Prevention of injury,Improved static and Dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171225038072N1**

Registration date: **2018-09-02, 1397/06/11**

Registration timing: **retrospective**

Last update: **2018-09-02, 1397/06/11**

Update count: **0**

Registration date

2018-09-02, 1397/06/11

Registrant information

Name

Azadeh Asgarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3436 7105

Email address

azadehasgarpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-05, 1395/08/15

Expected recruitment end date

2017-01-10, 1395/10/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Insoles With Different Wedge on Balance control With and Without Visual input before and after fatigue In healthy people

Public title

The effect of the insoles on the Proprioception of the floor and ankle in balance control

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
no history of surgery fracture burn musculoskeletal problems back pain or severe trauma in the lower extremity during the last six months of the study and dominance of the right foot as well as having normal navicular height
Exclusion criteria:
Having lower limb damage having a history of lower limb surgery balance disorders such as Atrial System disorders , lower extremity abnormalities, spine and legs

Age
From **20 years** old to **24 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher has by no means interfered in test neither in pre-test and post-test.the tests were given by individuals who had not clue about the plan.the participants were not alter of test application as well and just acted to instruction.the person who analyzed the data did know about the study and generally looked at the data.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Pajohesh Intersection, Mahdiah Street

City

Hamedan

Province

Hamadan

Postal code

65178

Approval date

2017-11-11, 1396/08/20

Ethics committee reference number

IR.UMSHA.REC.1396.652

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

در یک balance the

Timepoint

At the beginning of the study, when using the Insoles and at the same time after the fatigue

Method of measurement

Boyd System Balance

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Performing equilibrium tests using three types of insoles

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

The University Bu Ali Sina

Full name of responsible person

Ali Yalfani

Street address

Pajohesh Intersection,Mahdiah stereet

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Hamedan

Province

Hamadan

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38695_65178

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Ali_Yalfani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Bu-Ali Sina

Full name of responsible person

Gholam Hossein Majzoobi

Street address

University of Bu-Ali Sina , Pajohesh intersection,
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Phone

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Email

gh_majzoobi@basu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Bu-Ali Sina

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

The University of Bu-Ali Sina

Full name of responsible person

Azadeh Asgarpoor

Position

Masters Student

Latest degree

Master

Other areas of specialty/work

Corrective Exercises and Sport Injuries

Street address

No. 4, Alley 44., Saadi east Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Bu-Alh Sina

Full name of responsible person

Azadeh Asgarpoor

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Person responsible for updating data

Contact

Name of organization / entity

The University Bu-Ali Sina

Full name of responsible person

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Phone

+98 32252809

Email

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

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

No - There is not a plan to make this available

Title and more details about the data/document

Data and documentation can be shared, but with the

unidentifiable individuals and the private information of the subjects

When the data will become available and for how long

Starting data access 1 year after printing results

To whom data/document is available

Researchers in this field are allowed to act for documentation

Under which criteria data/document could be used

Only the type of analysis that can be done in the research can be redefined

From where data/document is obtainable

azadehasgarpoor@gmail.com

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

When an applicant submits a document for his / her work area in relation to the subject matter of the thesis and, if reasonable request, and the commitment not to misuse the data of this research , the data will be sent to him within1 week' of work

Comments

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