

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of a sand training on the kinetics, amplitude of muscular electrical activity and body image in individuals with pronated feet

Protocol summary

Study aim

Effect of a sand training on the kinetics, amplitude of muscular electrical activity and body image in individuals with pronated feet

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Subjects' familiarity with the method of testing is carried out in the health center of Mohaghegh Ardabili University, in two stages of pre-test and post-test. Installing surface electrodes on the lower extremities of the modules and performing the process of walking and running on the force plate. How to double-blind which neither the tester nor the Subject is aware of this process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: A navicular drop of more than 10 mm, a foot posture index of greater than 10, and age range between 18-30 years old. Exclusion criteria: The presence of limb length discrepancies of more than 5 mm, muscle spasm, neuromuscular disorders, orthopedic-related diseases or any previous surgeries in the lower limbs and trunk.

Intervention groups

Intervention group: Pronation complication group (barefoot walking and running before and after training sessions) Control group: Pronation complication group (walking and running barefoot before and after eight weeks without intervention)

Main outcome variables

Electric activity of the muscle, co-contraction and ground reaction force

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191211045704N1**

Registration date: **2020-02-25, 1398/12/06**

Registration timing: **prospective**

Last update: **2020-02-25, 1398/12/06**

Update count: **0**

Registration date

2020-02-25, 1398/12/06

Registrant information

Name

Amir Fatollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3582 2100

Email address

amir.af@student.uma.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2641-03-01, 2019/12/10

Expected recruitment end date

2641-05-10, 2020/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a sand training on the kinetics, amplitude of muscular electrical activity and body image in individuals with pronated feet

Public title

Effect of a sand training in individuals with flat foot

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

pronated foot male No history of surgery

Exclusion criteria:

People with knee injuries Elderly and children

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method will be used to allocate study participants into experimental and control groups. Of note, participants will be blinded to group allocation. During the randomization process, a set of sealed, opaque envelopes will be used to ensure the concealment of allocation. Each envelope will be contained a card indicating to which group the subject would be allocated.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, the main researcher and the evaluator, do not interfere in the process of data recording and analysis. The participant will not be aware of the respective group they will be allocated to. A naïve person that will not have a role in this study will be responsible for the allocation process. One examiner will determine whether a participant will be eligible for inclusion in the trial, while the other will carry out gait analyses of the eligible participants. Both examiners will be unaware of group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical

Sciences

Street address

Daneshgah Ave, University of Mohaghegh Ardebili

City

Ardabil

Province

Ardabil

Postal code

4551733411

Approval date

2640-07-03, 2019/04/12

Ethics committee reference number

IR.ARUMS.REC.1398.484

Health conditions studied

1

Description of health condition studied

over pronation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pronated foot

Timepoint

8 week

Method of measurement

force plate Bertec and surface EMG Bio-system

Secondary outcomes

1

Description

flat foot

Timepoint

8 week

Method of measurement

force plate Bertec and surface EMG Bio-system

Intervention groups

1

Description

Intervention group: During the eight weeks (3 sessions per week) of the intervention, the intervention group will be performed sand running training program that is continuous jogging, striding, and bounding, galloping, short sprints. Every session will be started with a warm-up and stretching session for five minutes and will be ended with a warm-down session for five minutes. Total training duration is 50 minutes per session.

Category

Rehabilitation

2

Description

Control group: The control group will not perform any exercise and will be re-evaluated after 8 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Mohaghegh Ardabili

Full name of responsible person

Amir Fatollahi

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Daneshghah Ave., University of Mohaghegh Ardabili

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Abolfazl Bezaat pour

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

Yes

Title of funding source

Ardabil University of Medical Sciences

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

Ardabil University of Medical Sciences

Full name of responsible person

AmirAli Jafarnezhadgero

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate professor Biomechanics

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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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