

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of hip muscle strengthening on postural control in subjects with functional ankle instability: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of hip muscle strengthening on postural control in people with functional ankle instability

Design

Clinical trial with control group, with parallel groups, double-blind. Random assignment of patients to two groups is done by permutation block stratified randomization method. First, fligible patients are classified according to age, sex and BMI, respectively. These blocks were ceated using statistical software R version 4.0.2. People will be randomly divided into two groups, including the group of routine exercises(B) and the group of hip strengthening exercises(A).Initially, 10 patients will be selected as a pilot sample in each group.

Settings and conduct

Razmjoghaddam physiotherapy clinic in zahedan, iran. Three sets of ten exercises will be performed, with a 60-second break between each exercise. In This research, the double-blind method is used. So that patients and statisticians will not be aware of the Intervention

Participants/Inclusion and exclusion criteria

Inclusion: People between the ages of 18 and 45 with unilateral functional ankle instability with at least one sprain in a recent year and a feeling of frequent giving way
Exclusion: Existence of mechanical functional instability in the affected ankle by performing anterior drawer test

Intervention groups

Ankle strengthening group exercises(routine group):strengthening dorsiflexion and plantar flexion with theraband, weight bearing on heel and toe, maintaining balance on tilt board and leg reaches
exercise hip strengthening group exercises:In addition to ankle exercises, strengthening exercises to abduction, extention and external rotation of the hip, clam shell exercises and lateral step exercises.

Main outcome variables

Overall, anterior-posterior and medial-lateral dynamic instability index (two legs and one leg) Overall, anterior-

posterior and medial-lateral static instability index (two legs and one leg)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211113053047N1**

Registration date: **2021-12-27, 1400/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-27, 1400/10/06**

Update count: **0**

Registration date

2021-12-27, 1400/10/06

Registrant information

Name

Iran Khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3328 0777

Email address

soheil.khalili@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hip muscle strengthening on postural control in subjects with functional ankle instability: a randomized controlled clinical trial

Public title

The effect of hip muscle strengthening on postural control in subjects with functional ankle instability

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 45 years Unilateral functional instability of the ankle. At least one sprain in a recent year and a feeling of frequent giving way Conscious and informed consent to participate in the study

Exclusion criteria:

Existence of mechanical functional instability in the affected ankle by performing anterior drawer test and talar displacement History of fracture, dislocation and structural abnormality in the lower limb Ankle injury in the last three months History of severe low back pain in the last six months History of dizziness and fainting History of head trauma History of numbness and tingling in the lower extremities Take painkillers, sedatives and alcohol 48 hours before the test

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of patients to two groups is done by permutation block stratified randomization method. First, eligible patients are classified according to age, sex and BMI, respectively. Then, based on 4 blocks (Consisting of two groups A and B and two repetitions for each) which are randomly selected from all possible modes of permutations, They are assigned to the desired group. These blocks were ceated using statistical software R version 4.0.2

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, the one-blind method is used. So that the statistician will not be aware of 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 zahedan university of medical sciences

Street address

no. 15, Sadra Ave., Zibashahr

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817917997

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

IR.ZAUMS.REC.1400.258

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

Recurrent ankle sprain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Overall, anterior-posterior and medial-lateral dynamic instability index (two legs and one leg)

Timepoint

Dynamic index measurement before the start of the study and 4 weeks after the start of training

Method of measurement

Biodex SD balance system (Balance System SD 950-304 Model SW45-30D-E6N, Biodex Medical System, Inc., New York, USA)

2**Description**

Overall, anterior-posterior and medial-lateral static instability index (two legs and one leg)

Timepoint

Static index measurement before the start of the study and 4 weeks after the start of training

Method of measurement

Biodex SD balance system (Balance System SD 950-304 Model SW45-30D-E6N, Biodex Medical System, Inc., New York, USA)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Exercises of the control group included: Theraband strengthening exercises for dorsiflexor and plantarflexor muscles, Weight bearing on heels and toes, Maintain balance on the tilt board and leg reaches exercise. Three sets of ten exercises will be performed, with a 60-second break between each exercise. The load applied during the exercise was determined based on 70% of a maximum repetition. The maximum load is determined during the first evaluation session and re-examined every week to make changes if necessary based on the ability of each subject. Individuals will perform exercises three times a week for 4 weeks under the supervision of a physiotherapist at the physiotherapy clinic.

Category

Rehabilitation

2

Description

Intervention group: Exercises of the intervention group included: hip abduction with weights in the side position, hip abduction with theraband in standing position, hip extension in prone position, hip external rotation with theraband in sitting position, clam shell exercise in side position, lateral stepping with theraband and ankle routine exercises (control group exercises). Three sets of ten exercises will be performed, with a 60-second break between each exercise. The load applied during the exercise was determined based on 70% of a maximum repetition. The maximum load is determined during the first evaluation session and re-examined every week to make changes if necessary based on the ability of each subject. Individuals will perform exercises three times a week for 4 weeks under the supervision of a physiotherapist at the physiotherapy clinic.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razmjoo moghaddam rehabilitation center

Full name of responsible person

Mohadeseh gholamian arefi

Street address

Kafami Blvd

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Email

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Web page address

<http://razmjoo.zaums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

Street address

Headquarters Building, Campus of Medical Sciences,
Dr. Hesabi Square, Persian Gulf Blvd

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Email

zaums.research@gmail.com

Web page address

<https://research.zaums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Soheil Khalili

Position
Physiotherapist
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Soheil Khalili
Position

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data can be shared

When the data will become available and for how long

6 Months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers and experts in this field It must ensure that data will not be misused

From where data/document is obtainable

soheilkhalili.aban@yahoo.com

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

The Applicant must state himself / herself fully and clearly and state his / her Intention to apply. About 2 to 4 Weeks after the test, he will receive the data

Comments