Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 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)

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+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 extention 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
public@zaums.ac.ir

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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No. 6, 15 sadra Ave, Zibashahr
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 ensured 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