

# 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)

##### 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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3321 7006

##### 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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3337 2116

##### Fax

+98 54 3337 2116

##### 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

**Street address**

No. 6, 15 sadra Ave, Zibashahr

**City**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Soheil Khalili

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Physiotherapist

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Fax****Email**

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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 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**