

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of foot intrinsic muscles strengthening on postural control in subjects with functional ankle instability

Protocol summary

Study aim

The effect of foot intrinsic muscles strengthening on postural control in subjects with functional ankle instability

Design

The study will be a clinical trial type with 3 groups of control, routine and intrinsic muscles, single blinded, randomized by permutation blocks method on 50 patients.

Settings and conduct

This study will be conducted on volunteer patients with functional ankle instability in Zahedan, Razmjoo moghaddam physiotherapy clinic of university of medical sciences. Patients will be entered randomly to one of the control, routine or intrinsic muscles groups. The patients will only be informed of their group.

Participants/Inclusion and exclusion criteria

Entry criteria: 1) Ladies and gentlemen aged 18-45 years
2) Unilateral functional ankle instability with at least one sprain in 1 recent year and feeling recurrent giving way
3) Not being mechanical instability in unstable ankle with doing anterior drawer test and talar tilt test
4) Not existing fracture, dislocation and structural disorders in lower limb
5) Not existing vertigo, faint and head trauma
6) No ankle injury in the last 3 months
No entry criteria:
1) Receive other treatment
2) Unwillingness to enter research
3) Taking painkillers, sedatives and alcohol

Intervention groups

The study consists of three groups of intrinsic muscles exercises, routine exercises and control group. In routine group, routine physiotherapy exercises in functional ankle instability and in intrinsic muscles strengthening group, special exercises of this muscles will be performed in 12 sessions for 4 weeks every other day. The control group will not be received any intervention.

Main outcome variables

Dynamic balance index for single leg and double legs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040466N2**

Registration date: **2020-12-26, 1399/10/06**

Registration timing: **retrospective**

Last update: **2020-12-26, 1399/10/06**

Update count: **0**

Registration date

2020-12-26, 1399/10/06

Registrant information

Name

Fateme Ghiasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 6708

Email address

f_ghiasi_p@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot intrinsic muscles strengthening on postural control in subjects with functional ankle instability

Public title

The effect of physiotherapy in functional ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Unilateral functional ankle instability with at least one sprain in recent year and recurrent giving way Not being mechanical instability in unstable ankle with doing anterior drawer test and talar tilt test Not existing fracture, dislocation and structural disorders in lower limb Not existing vertigo, faint and head trauma No ankle injury in the last 3 months

Exclusion criteria:

Receive other treatment Unwillingness to enter research Taking painkillers, sedatives and alcohol

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected by available sampling method. then by randomization permutation blocks method will enter the groups: A: intrinsic exercises group B: routine exercises group C: control group In this method, after determining the age and sex, patients will enter the research in the following order: CCCBBAA ABCABB ACCABCAA ACBCCAB BCACABA CCAABA CCABCBB BBCAABBCCBAB According to this randomization, for example patient number 1 will enter group C and patient number 4 will enter group B and so on it will continue.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are considered blind regardless of the difference in treatment methods of the groups. In this research, patient will be blinded from other research groups.

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

Dr. Hesabi Street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.ZAUMS.REC.1398.174

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

functional ankle instability

ICD-10 code

S93.40

ICD-10 code description

Sprain of unspecified ligament of ankle

Primary outcomes**1****Description**

Dynamic balance indexes for single leg

Timepoint

The beginning of research and after of 4 week intervention

Method of measurement

Biodex system

2**Description**

Dynamic balance indexes for double legs

Timepoint

The beginning of research and after of 4 week intervention

Method of measurement

Biodex system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The patient will perform foot intrinsic muscles exercises for 12 sessions. Patients in intrinsic muscles exercise group will perform the following exercises: scrunching towel with toes: the patient sitting on a chair, then puts his foot on top a towel and with toes flexion scrunches the towel. By putting weight at the end of the towel will progress the exercise. Short foot exercise: While the patient sitting on a chair, increase and decrease medial longitudinal arch. By doing in standing position, the exercise is progressed. Toes abduction and adduction: while sitting on a chair, the patient abduct and adduct the toes. By using elastic band, exercise is progressed. Piano key exercise: while sitting on a chair, alternately extend toes and big toe. Stretching big toe: in sitting position, he stretches his big toe toward extension. Passive exercises include mobilization of sub talar, midfoot and forefoot joints. These techniques are performed according to Maitland method. Exercises are done 3 sets with 10 repetitions. There is 30-60 seconds rest between each set. Exercises are conducted in physiotherapy clinic 3 times per week for 4 weeks.

Category

Rehabilitation

2

Description

Intervention group 2: The patient will perform routine exercises in functional ankle instability for 12 sessions. Patients in routine group will perform the following exercises: strengthening exercises with theraband for dorsi and plantar flexor muscles: in sitting position with extended knee, the exercise will be performed in both dorsi and plantar directions. Plantar flexor muscles stretching: in sitting position with extended knee, stretching is applied in the dorsi flexion direction with theraband or rope. Weight bearing on the heel and toe exercise: in standing position, the patient alternately shifts the weight on the heel and toe. Tilt board balance exercise: the patient preserves his balance on the affected foot on the tilt board. Leg reaches exercise: the sun is designed on the ground and then the patient stands on one foot in the middle point and moves the other foot in the directions of the sun's rays. This exercise will be performed for both feet. Jump: the patient will practice jumping on the ground. Exercises will be done 3 sets with 10 repetitions. There is 30-60 seconds rest between each set. Exercises are conducted in physiotherapy clinic 3 times per week for 4 weeks.

Category

Rehabilitation

3

Description

Control group: There is no intervention in control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Razmjo Moghadam Physiotherapy Clinic

Full name of responsible person

Mohammad Reza Arab Kangan

Street address

Razmejo Moghadam Laboratory, Ayatoallah Kafami St.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9813664855

Phone

+98 54 3342 4675

Email

mohamadreza_arab@icloud.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Noormohammad Bakhshani

Street address

Zahedan University of Medical Sciences, Dr.Hesabi sq.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5796

Email

f_ghiasi_p@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

f_ghiasi_p@zaums.ac.ir

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Fateme Ghiasi
Position
Assistance Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Khatam al anbia Hosp, Jame jam Blvd
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 54 3322 0501
Email
f_ghiasi_p@zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Fateme Ghiasi
Position
Assistance professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Khatam al anbia Hosp, Jame jam Blvd
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 54 3322 0501
Email

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Fateme Ghiasi
Position
Assistance professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Khatam al anbia Hosp, Jame jam Blvd
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Phone
+98 54 3322 0501
Email
f_ghiasi_p@zaums.ac.ir

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