

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of weight bearing exercise with taping in comparison with weight bearing exercise alone in balance and ankle joint proprioception in patients with functional ankle instability

Protocol summary

Study aim

The effects of weight bearing exercise with taping in comparison with weight bearing exercise alone in balance and ankle joint proprioception in patients with functional ankle instability

Design

Clinical trial with control group, community based and pragmatic, with parallel groups, randomized (randomized block design), without control with placebo, single center trial.

Settings and conduct

Neuromuscular Rehabilitation Research Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals should have frequent ankle sprain and feel empty; Patients have not reported any pain at the start of the study; Individuals should have a medical history of ankle sprain due to the inertia mechanism that resulted in functional damage for 24 hours or more; people have experienced instability in the last 12 months between 1 and 3 times. Exclusion criteria: A history of lower limb disorders and any neurological damages; Vestibular system disorders; A history of lower extremity surgery and disorders affecting on balance such as diabetes, neuropathy and etc.

Intervention groups

Intervention group 1: The referral of 20 patients who according to the treatment protocol carry out weight bearing exercise with tape during 6 weeks and then, static balance assessment and dynamic and also deep feelings will be done for them. (Replacing of tape in 3 times a week and lasts for 6 weeks). Intervention group 2: The referral of 20 patients who according to the treatment protocol carry out weight bearing exercise and then, static balance assessment and dynamic and also deep feelings will be done for them. Control group: Only for comparison with intervention group, no treatment is performed.

Main outcome variables

Balance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N35**

Registration date: **2018-08-21, 1397/05/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-21, 1397/05/30**

Update count: **0**

Registration date

2018-08-21, 1397/05/30

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-14, 1396/12/23

Expected recruitment end date

2018-09-14, 1397/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of weight bearing exercise with taping in comparison with weight bearing exercise alone in balance and ankle joint proprioception in patients with functional ankle instability

Public title

Effects of weight bearing exercise with taping in comparison with weight bearing exercise alone in balance and ankle joint proprioception in patients with functional ankle instability

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Individuals should have frequent ankle sprain and feel empty Patients have not reported any pain at the start of the study Individuals should have a medical history of ankle sprain due to the inertia mechanism that resulted in functional damage for 24 hours or more people have experienced instability in the last 12 months between 1 and 3 times

Exclusion criteria:

A history of lower limb disorders and any neurological damages Vestibular system disorders A history of lower extremity surgery and disorders affecting on balance such as diabetes, neuropathy and etc

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 3). Using Excel software to generate random number tables.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

IR.SEUMS.REC.1396.264

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

Ankle injury

ICD-10 code

S90.8

ICD-10 code description

Other superficial injuries of foot

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

Balance

Timepoint

Before and 6 weeks after the intervention

Method of measurement

Biodex balance system SD

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: The referral of 20 patients who according to the treatment protocol carry out weight bearing exercise with tape during 6 weeks and then, static balance assessment and dynamic and also deep feelings will be done for them. (Replacing of tape in 3 times a week and lasts for 6 weeks)

Category

Rehabilitation

2

Description

Intervention group2: The referral of 20 patients who according to the treatment protocol carry out weight bearing exercise and then, static balance assessment and dynamic and also deep feelings will be done for them.

Category

Rehabilitation

3

Description

Control group: Only for comparison with intervention group, no treatment is performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Rozita Hedayati

Street address

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3365 4180

Email

are20935@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Ehsani

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan.

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

fatemehehsani59@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Rozita Hedayati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Neuromuscular Rehabilitation Research Center, Ghods Blvd.

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Rozita Hedayati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Neuromuscular Rehabilitation Research Center,
Ghods Blvd.

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

+98 23 3365 4180

Email

are20935@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

Only available to scholars working in academic institutions.

Under which criteria data/document could be used

In case of relevant studies.

From where data/document is obtainable

Rozita Hedayati. Neuromuscular Rehabilitation Research Center, Ghods Blvd. +98 912 331 1988

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

-

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Binaei

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

City

Semnan

Province

Semnan

Postal code

3513138111

Phone