

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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

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Neuromuscular Rehabilitation Research Center, Ghods Blvd.

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##### Province

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##### Email

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## 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

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**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

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Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

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Semnan

**Province**

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3513138111

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