

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Investigation of long term effect of Ankle Balance Taping method on balance and function of patients with chronic ankle instability

#### Protocol summary

##### Study aim

Investigating the long term effects of ABT procedure on balance and functional status of a patient who suffer from chronic ankle instability

##### Design

Randomized Clinical trial with stratified randomization, Including two parallel interventional groups, Double blind

##### Settings and conduct

After screening CAI patients referred to medical centers affiliated to Shiraz University of Medical Sciences and obtaining informed consent, patients would be evaluated and then randomly assigned to two treatment groups and it will be done in the Faculty of Rehabilitation Sciences of Shiraz University of Medical Sciences. The evaluations will be repeated after the end of the treatment. Assessors will not know how patients are assigned to groups

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: History of sever ankle sprain at least once: History of emptying and twisting again and feeling of instability in the injured ankle: CAIT score equal to or less than 24: Daily activity scale equal to or less than 90% according to FAAM questionnaire: Exercise activity scale equal to or less than 80% according to FAAM questionnaire Exclusion criteria: History of musculoskeletal surgery in each lower limb: History of lower limb fractures which need realignment: Acute musculoskeletal injury of other lower limb joints in last three month which affect joint stability and function : History of neurological disease and ocular and vestibular disorder or any event that is effective on balance : Sensitivity symptoms which are related to taping like skin redness: Pregnancy: Professional athlete

##### Intervention groups

We have three groups include kinsiotape group and sham group and control group. in first group we apply ABT for 4 weeks on every other day and in second group we apply tapes but without stretch and we have no intervene in third group

#### Main outcome variables

Static balance and dynamic balance and function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200909048671N1**

Registration date: **2020-10-26, 1399/08/05**

Registration timing: **prospective**

Last update: **2020-10-26, 1399/08/05**

Update count: **0**

##### Registration date

2020-10-26, 1399/08/05

##### Registrant information

##### Name

Moslem Yousefi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3234 2079

##### Email address

moslemyousefi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-19, 1399/10/30

##### Expected recruitment end date

2023-01-20, 1401/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigation of long term effect of Ankle Balance Taping method on balance and function of patients with chronic ankle instability

**Public title**

Investigation of effect of Ankle Balance Taping on chronic ankle instability

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

A history of at least one significant ankle sprain: The initial sprain must have occurred at least 12 months prior to the study enrolment A history of the previously injured ankle joint 'giving way', and/or recurrent sprain and/or 'feelings of instability': participants should report at least 2 episodes of 'giving way' in the 6 months prior to the study enrolment. Cumberland Ankle Instability Tool (CAIT): score of equal or less than 24 Foot and Ankle Ability Measure (FAAM): ADL scale < 90%; Sport scale < 80%

**Exclusion criteria:**

A history of previous surgeries to the musculoskeletal structures (ie, bones, joint structures and nerves) in either lower extremity A history of a fracture in either lower extremity requiring realignment Acute injury to the musculoskeletal structures of other joints of the lower extremity in the previous 3 months, which impacted joint integrity and function (ie, sprains, fractures) resulting in at least 1 interrupted day of desired physical activity No history of neurological disease, vestibular or visual disturbance, or any other pathology that have negative effect on balance Taping side effects such as skin redness Being professional athlete

**Age**

From **18 years** old to **35 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **63**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients after compliance with inclusion and exclusion criteria and after signing the consent form : they consciously enter the study and they divided into three groups : In order to randomly assign individuals to three groups the permutation block randomized method will be used hexagonal blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The outcome assessor is not aware of the interventions performed on patients also, the data analyzer does not know about the intervention groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

National Committee on Ethics in Biomedical Research

**Street address**

Sheikh Abivardi 1, Chamran Blvd., Shiraz

**City**

shiraz

**Province**

Fars

**Postal code**

33669-71947

**Approval date**

2020-05-20, 1399/02/31

**Ethics committee reference number**

IR.SUMS.REHAB.REC.1399.016

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

Chronic Ankle Instability

**ICD-10 code**

S93.4

**ICD-10 code description**

Sprain of ankle

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

Dynamic balance

**Timepoint**

Initiation of treatment, immediately after and one month after the end of the intervention

**Method of measurement**

Modified star excursion balance test(mSEBT)

**2****Description**

Static balance

**Timepoint**

Initiation of treatment, immediately after and one month

after the end of the intervention

#### Method of measurement

Single leg stance

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#### Description

Function

#### Timepoint

Initiation of treatment, immediately after and one month after the end of the intervention

#### Method of measurement

Single leg hop

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Kinesio type group: People in this group are treated with Ankle Balance Taping for four weeks at intervals of one day. Sham Group: This intervention is inductive. In this method, we use tape without applying tension to the person. Control group: This group of patients do not receive any treatment and are evaluated only like other groups before, immediately after and one month after the treatment interventions of other groups.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

medical centers affiliated to shiraz university of medical sciences

##### Full name of responsible person

samane ebrahimi

##### Street address

Abiverdi 1 Street, Chamran Blvd

##### City

Shiraz

##### Province

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##### Postal code

33669-71947

##### Phone

+98 71 3626 1081

##### Fax

+98 71 3627 2495

##### Email

EbrahimiS@Sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Abbas Rezaianzadeh

##### Street address

Deputy of Research and Technology, 7th Floor, Central Building of Shiraz University of Medical Sciences, Zand St.

##### City

shiraz

##### Province

Fars

##### Postal code

33669-71947

##### Phone

+98 71 3235 7282

##### Fax

+98 71 3212 2430

##### Email

rezaiana@sums.ac.ir

#### Grant name

Vice chancellor of research of Shiraz University of Medical Sciences

#### Grant code / Reference number

99-01-06-22602

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Moslem Yousefi

##### Position

Bachelor student in Physical Therapy

##### Latest degree

A Level or less

##### Other areas of specialty/work

Physiotherapy

##### Street address

Second unit, Fadak Building, Alley7, Shahid moradi

street, South saffir Blvd, Shiraz Town

**City**

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**Postal code**

7178897667

**Phone**

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**Email**

moslemyousefi@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Moslem Yousefi

**Position**

Bachelor student in Physical Therapy

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Not applicable

**Title and more details about the data/document**

All data except personal information would be available.

**When the data will become available and for how long**

The start of the access period is 6 months after the acceptance of the article.

**To whom data/document is available**

In addition to the principal researcher and the supervisor of the project, upon request, access to information can be reviewed by the Ethics Committee.

**Under which criteria data/document could be used**

Researchers can use data for advanced analyses or for meta analysis studies.

**From where data/document is obtainable**

Dr. Samaneh Ebrahimi, Shiraz, Chamran Blv., Sheikh Abivardi 1 ave., School of Rehabilitation Sciences, Mobile:09173070211, E-mail:EbrahimiS@Sums.ac.ir

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

After 6 months from article acceptance, while announcing a written request to the executor of the project to receive information and a precise explanation about how to use the information, an official letter is also requested to obtain permission from the ethics committee to obtain a license, and if the ethics committee approves, emphasizing the confidentiality of the information, the requested information will be provided to the applicant.

**Comments**