Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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
+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