Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effect of ankle joint mobilization and exercise therapy along with dry needling with ankle joint mobilization and exercise therapy on balance, range of motion, pain and function in patients with chronic ankle instability In Hamedan city: Randomized clinical trial

Protocol summary

Study aim
comparing the effect of ankle joint mobilization and exercise therapy along with dry needling with ankle joint mobilization and exercise therapy on balance, range of motion, pain and function in patients with chronic ankle instability In Hamedan

Design
A randomized blinded control and parallel group clinical trial, Randomization was done with randomizer software.

Settings and conduct
In this study, patients aged 18-50 years with a diagnosis of chronic ankle instability who referred to orthopedic clinics in Hamedan city will be selected and will be divided into two intervention and control groups by simple randomization method. The intervention group will receive the combination of ankle joint mobilization and exercise therapy along with dry needling, and in the control group, ankle joint mobilization and exercise therapy will be applied. This study will be done by blinding the evaluator. The person who does the assessment is different from the person who does the treatment. Also, data analysis is done by another person who is unaware of the evaluation and treatment.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 50 with chronic one-sided ankle instability referring to physical medicine and orthopedic clinics of Hamedan University of Medical Sciences were included in the study, among them, patients who had a history of surgery or fracture in any of the lower limbs were excluded from the study. .

Intervention groups
The intervention group receives ankle mobilization and exercise therapy along with dry needling, while the control group receives ankle mobilization and exercise therapy.

Main outcome variables
Dynamic balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230205057336N3**
Registration date: **2024-01-07, 1402/10/17**
Registration timing: **prospective**

Last update: **2024-01-07, 1402/10/17**
Update count: **0**

Registration date
2024-01-07, 1402/10/17

Registrant information

Name
Narges Meftahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3627 1552

Email address
meftahin@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-10-22, 1403/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of ankle joint mobilization and exercise therapy along with dry needling with ankle joint mobilization and exercise therapy on balance, range of motion, pain and function in patients with chronic ankle instability In Hamedan city: Randomized clinical trial

Public title
Comparison of the effect of ankle joint mobilization and exercise therapy along with dry needling with ankle joint mobilization and exercise therapy on balance, range of motion, pain and function in patients with chronic ankle instability In Hamedan city: Randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with unilateral chronic ankle instability aged between 18-50 years A history of at least one ankle sprain in the past 12 months with symptoms of inflammation that prevented activity for at least one day At least three months have passed since the last ankle sprain. People who have a feeling of instability or recurrent ankle sprains (two or more cases in one ankle) or ankle sprains (at least two cases in six months). Trigger points in at least one of the muscles: Peroneus Longus, peroneus brevis, gastrocnemius and anterior tibialis ankle instability scores 25 and less in Cumberland ankle instability tool Foot and Ankle Ability Measurement questionnaire (FAAM) (Home scale<90%, sport scale<80%)
Exclusion criteria:
History of any musculoskeletal surgery in any of the lower limbs History of fractures in any of the lower limbs Having diseases related to imbalance (people with peripheral neuropathy, MS, Parkinson's, migraine, radiculopathy and diseases related to the middle ear) Individuals who received physical therapy and dry needling for pain from their CAI in the past 6 months history of skeletal-muscular injuries in other joints of the lower limbs in the last three months
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the randomizer software, 40 numbers are considered for each case and the software creates 10 blocks of 4 using permutation randomization, of which 2 people enter the first group and 2 people enter the second group. and it will be done in this way until number 40.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the person who performs the evaluation is different from the person who performs the treatments. Also, data analysis is done by another person who is unaware of the evaluation and treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in shiraz faculty of rehabilitation sciences research
Street address
Sadra Shahr Road - Behind Amirul Mominin (AS) Burn Accident Hospital - Shahid Doran Campus - Faculty of Rehabilitation Sciences
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2023-11-01, 1402/08/10
Ethics committee reference number
IR.SUMS.REHAB.REC.1402.020

Health conditions studied

1

Description of health condition studied
Chronic Ankle Instability
ICD-10 code
M25.373
ICD-10 code description
Other instability, unspecified ankle

Primary outcomes

1

Description

Dynamic balance

Timepoint

Before, immediately after and four weeks after the end of the intervention

Method of measurement

Modified star excursion balance test

2

Description

Ankle dorsiflexion range of motion

Timepoint

Before, immediately after and four weeks after the end of the intervention

Method of measurement

weight bearing lung test

3

Description

Pain

Timepoint

Before, immediately after and four weeks after the end of the intervention

Method of measurement

Visual analogue scale

4

Description

Function

Timepoint

Before, immediately after and four weeks after the end of the intervention

Method of measurement

Foot and Ability Measure questionnaire

Secondary outcomes

1

Description

severity of functional ankle instability

Timepoint

Before, immediately after and four weeks after the end of the intervention

Method of measurement

Cumberland Ankle Instability Tool (CAIT)

Intervention groups

1

Description

Intervention group: Ankle mobilization group and dry needling exercise therapy: patients in this group, in addition to ankle mobilization treatment exactly the same as the first group, dry needling for four sessions and once a week, for at least one of the peroneus longus, peroneus muscles Brevis, gastrocnemius and tibialis anterior will receive.

Category

Treatment - Other

2

Description

Control group: Ankle mobilization group and therapeutic exercise: joint mobilization will be done when the patient is lying in an open arch and the ankle is out of the edge of the bed. Then the ankle is placed in 20 degrees of plantar flexion so that the talocrural joint is in a loose-packed position. The stabilizer hand is placed above the ankles (to stabilize the leg), while the mobilizer hand grabs the talus with the first web, then the talus is given a 4-grade glide with downward force. Mobilization for the relevant groups will be held for three sessions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Rehabilitation Faculty Clinic

Full name of responsible person

Narges Meftahi

Street address

Sadra Shahr Road - Behind Amirul Mominin (AS) Burn Accident Hospital - Shahid Doran Campus - Faculty of Rehabilitation Sciences

City

Shiraz

Province

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Postal code

7134814336

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Email

meftahin@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

Street address

Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences

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hashempurm@sums.ac.ir
Grant name
Grant code / Reference number
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
Narges Meftahi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Sadra Shahr Road - Behind Amirul Mominin (AS) Burn Accident Hospital - Shahid Doran Campus - Faculty of Rehabilitation Sciences
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Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Narges Meftahi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Narges Meftahi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Sadra Shahr Road - Behind Amirul Mominin (AS) Burn Accident Hospital - Shahid Doran Campus - Faculty of Rehabilitation Sciences
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7134814336
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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