

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of ankle and lumbopelvic manipulation with ankle manipulation alone on static and dynamic balance in people with chronic ankle instability

Protocol summary

Study aim

Comparison of the effect of ankle and lumbopelvic manipulation with ankle manipulation alone on static and dynamic balance in people with chronic ankle instability.

Design

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

Settings and conduct

In this study, patients aged 18-45 with chronic ankle instability who referred to orthopedic clinics in Shiraz city will be selected and will be divided into two intervention and control groups by simple randomization method. The intervention group will receive a combination of ankle manipulation and lumbopelvic manipulation along with exercise, and in the control group, ankle manipulation will be applied along with exercise. The present study will be conducted in the biomechanics laboratory of Shiraz Rehabilitation Faculty. This study will be conducted with blinding of the evaluator. 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.

Participants/Inclusion and exclusion criteria

Patients aged 18-45 years with a diagnosis of chronic ankle instability who referred to orthopedic clinics in Shiraz were included in the study, among them, patients who were athletes and had a history of surgery or fractures in the vertebrae and lower limbs and were prohibited from using manipulation. are excluded from the study.

Intervention groups

The intervention group receives lumbopelvic manipulation and ankle manipulation along with exercise, the control group receives ankle manipulation along with exercise.

Main outcome variables

Static balance dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230205057336N1**

Registration date: **2023-03-16, 1401/12/25**

Registration timing: **prospective**

Last update: **2023-03-16, 1401/12/25**

Update count: **0**

Registration date

2023-03-16, 1401/12/25

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

2023-04-15, 1402/01/26

Expected recruitment end date

2023-08-10, 1402/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of ankle and lumbopelvic manipulation with ankle manipulation alone on static and dynamic balance in people with chronic ankle instability

Public title

Assessment of lumbopelvic manipulation on balance in chronic ankle instability patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a report of chronic ankle instability according to the form announced by the International Ankle Association, in such a way that the person declares that they have a condition in which they feel the ankle is unstable during daily activities and sports activities, and usually with the fear of developing an acute sprain People who have a history of at least one ankle sprain in the last 12 months, which was accompanied by symptoms of inflammation and prevented them from doing their daily activities for at least one day At least 3 months have passed since the last injury People who have a feeling of instability or recurrent ankle sprains (2 or more cases in one ankle) or ankle sprains (at least two cases in the 6 months before the study) People who score less than 24 from the Cumberland ankle instability tools (CAIT) questionnaire. To investigate chronic ankle instability and the presence of instability, the Persian version of the CAIT questionnaire is used. This questionnaire consists of 9 questions, after completing it, a score between 0 and 30 is obtained. A score equal to and above 24 indicates stability, and a score below 24 indicates chronic instability. This questionnaire has been translated into Farsi, which has good validity and reliability People who score less than 90% for daily activities from the questionnaire (FAAM) foot and ankle ability measures. This questionnaire includes 21 items related to daily activities and 8 items related to sports. Each item is scored from zero to four, where zero means no ability to do it and 4 means no difficulty in doing it. ADL total score is from 0 to 84 and exercise score is from 0 to 32. Then these scores are calculated as a percentage. For instability, the ADL score should be less than 90% and the exercise score should be less than 80%. This questionnaire has been translated into Farsi and is a valid and reliable tool in determining the physical performance of people who have foot and ankle disorders People aged 18-45

Exclusion criteria:

Athletes (those who have special and regular sports training at least three times a week) Rheumatic diseases History of surgery or fracture on vertebrae and lower limb History of abdominal surgery Myelopathy, radiculopathy or nerve compression Taking similar treatments for ankle in the last 3 months Any neurological disease such as diabetic neuropathy or multiple sclerosis Chronic non-specific back pain Vestibular or balance disorders diagnosed by a physician History of damage to the central nervous system Taking

sleeping pills 12 hours before balance tests Uncorrected visual impairment Any contraindication to manipulation such as spine and ankle hypermobility History of taking corticosteroid drugs Osteopenia and osteoporosis following metabolic diseases Sacroiliac problems Measurements should not be taken during the monthly cycle

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done based on the Randomizer software. For input information in this software, the following must be entered: Number of groups: 2 Number of people in each group: 26 The total number of people studied: 52 After entering this information in the software, the software presents 26 numbers with a random order between 1 and 52 for the first group and 26 numbers with a random order between 1 and 52 for the second group. These numbers will be placed in each group. How to hide: based on the size of the research sample, a number of non-transparent envelopes are prepared (in order to make the content of the envelopes unclear) and each of the random sequences is recorded on a card and the cards are placed inside the envelope in order In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the envelope is glued and placed inside a box in order. Qualified to study, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

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

Abiverdi St 1, Chamran Blvd

City

Shiraz

Province

Fars

Postal code

71947-33669

Approval date

2022-12-20, 1401/09/29

Ethics committee reference number

IR.SUMS.REHAB.REC.1401.049

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

Static balance

Timepoint

Before the start of the intervention, immediately after the end of intervention, two weeks and one month after the end of intervention

Method of measurement

balance score static scale test, Biodex Balance machine

2

Description

Dynamic balance

Timepoint

Before the intervention, immediately after the end of the intervention, two weeks and one month after the intervention

Method of measurement

Y balance test, biodex balance machine

Secondary outcomes

1

Description

Pain

Timepoint

before the start of the intervention, immediately after

the end of the intervention, two weeks and one month after the intervention

Method of measurement

Visual analogue scale

2

Description

Ankle dorsiflexion rang of motion

Timepoint

Before the intervention, immediately after the end of the intervention, two weeks and one month after the intervention

Method of measurement

Goniometer

Intervention groups

1

Description

Intervention group: receive lumbopelvic manipulation and ankle manipulation along with exercise. In lumbopelvic manipulation, the patient lies supine on the bed. The therapist stands on the opposite side of the injured ankle. After locking the fingers behind the head by the patient, the therapist bends the patient's trunk towards the injured ankle and rotates it in the opposite direction. Then, a thrust with low intensity and high speed is applied to the anterior superior cruciate spine in the posterior and downward direction. Manipulation of the ankle is done while the person is lying in the arched position. The therapist's hands are wrapped proximal to the leg and fingers at the level of the neck of the talus. The therapist then applies a high-speed, low-intensity thrust in the downward direction. The exercise protocol includes mobilization exercises for the foot and ankle, mild strengthening exercises, strengthening exercises for the muscles around the ankle using theraband, strengthening exercises using body weight, standing on one leg, balance exercises on the balance board. Interventions will be conducted twice a week for 4 weeks.

Category

Treatment - Other

2

Description

Control group: they receive ankle manipulation along with exercise. The therapist's hands are wrapped proximal to the leg and fingers at the level of the neck of the talus. Then the therapist inserts a thrust with high speed and low intensity in the downward direction. The exercise protocol includes mobilization exercises for the foot and ankle, mild strengthening exercises, strengthening exercises for the muscles around the ankle using theraband, strengthening exercises using body weight, standing on one leg, balance exercises on the balance board. Interventions will be conducted twice a week for 4 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Rehabilitation Faculty Clinic

Full name of responsible person

Narges Meftahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempour

Street address

7th floor, Central building of Shiraz University of
Medical Sciences, next to the Red Crescent, Zand St.

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71348-14336

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+98 71 3235 7282

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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

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<https://scholar.google.com/citations?hl=en&user=0niDJBkAAAAJ>

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

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Person responsible for updating data

<https://scholar.google.com/citations?hl=en&user=0niDJBkAAAAJ>

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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Web page address

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