

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of supervised rehabilitation on gait symmetry and regularity after acute ankle sprain

Protocol summary

Study aim

Determining the effect of supervised rehabilitation on gait symmetry and regularity after acute ankle sprain

Design

Quasi-experimental, pretest-posttest, single-group, non-randomized clinical trial, with a healthy reference group without intervention for comparison with normative values. On 16 patients, unblinded.

Settings and conduct

This study will be conducted on 16 patients with acute ankle sprain. This is a quasi-experimental clinical trial with a pre-post design; therefore, randomization or blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged between 18 and 50 years, Patients with Grade 1 or 2 ankle sprain, Patients with an acute ankle sprain, meaning the injury occurred between 7 days and 1 month ago, Presence of symptoms such as swelling or pain on the lateral side of the ankle, limited ankle range of motion, and tenderness over the lateral ligaments, Minimum literacy level, with the ability to read and write at least at a middle school level

Intervention groups

The intervention group will receive 10 supervised ankle rehabilitation sessions. Each intervention session, which includes electrotherapy and therapeutic exercises, will last between 1.5 to 2 hours. Overall, the therapeutic exercises will include strengthening, neuromuscular, range of motion, and balance exercises. The duration of electrotherapy in each session will be between 15 to 30 minutes, using TENS (Transcutaneous Electrical Nerve Stimulation). Strengthening exercises for the muscles around the ankle will be performed using resistance bands of varying levels. Balance and proprioception exercises will be conducted using a balance board and other related equipment.

Main outcome variables

step regularity; stride regularity; gait symmetry

General information

Reason for update

The inclusion age range was updated from 18–50 years to 18–55 years, as patients older than 50 years who met all other inclusion criteria (physician-diagnosed Grade I or II acute lateral ankle sprain) presented during the data collection period. In addition, the achieved sample size is being recorded as 15 participants per group (patient and healthy reference groups), reflecting attrition during study conduct.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250503065584N1**

Registration date: **2025-08-07, 1404/05/16**

Registration timing: **prospective**

Last update: **2026-08-22, 1405/05/31**

Update count: **2**

Registration date

2025-08-07, 1404/05/16

Registrant information

Name

Melika Shameli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3273 2021

Email address

shamelimelika@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-22, 1404/05/31

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

2025-08-11, 1404/05/20

Actual recruitment end date

2026-01-20, 1404/10/30

Trial completion date

2026-01-20, 1404/10/30

Scientific title

Investigating the effect of supervised rehabilitation on gait symmetry and regularity after acute ankle sprain

Public title

The effect of rehabilitation on gait symmetry and regularity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged between 18 and 55 years Patients with Grade 1 or 2 ankle sprain Patients with an acute ankle sprain, meaning the injury occurred between 7 days and 1 month ago Presence of symptoms such as swelling or pain on the lateral side of the ankle, limited ankle range of motion, and tenderness over the lateral ligaments Minimum literacy level, with the ability to read and write at least at a middle school level

Exclusion criteria:

Patients with syndesmotic injury in addition to the ankle sprain. Patients with a history of surgery or fracture in the lower limbs within the past year. Patients who had sustained an acute injury to the musculoskeletal structures of other lower limb joints within the past three months that affected joint integrity and function—such as a sprain or fracture—and had missed at least one day of their usual physical activity. Patients with neurological disorders such as stroke, multiple sclerosis (MS), or neuropathy. Individuals who had experienced an ankle sprain within the past 12 months. In the treatment of ankle sprains, initial protection is typically provided for one to two weeks, followed by the use of bandages or tape, which does not interfere with our study. However, patients using foot or ankle orthoses were excluded from the study.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Deputy of Research and Technology, Central Headquarters Building, Iran University of Medical Sciences, Hemmat Expressway, next to Milad Tower, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2025-05-14, 1404/02/24

Ethics committee reference number

IR.IUMS.REC.1404.159

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

Acute ankle sprain

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

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

Step regularity based on trunk acceleration

Timepoint

Before the intervention and immediately after the tenth session of supervised ankle rehabilitation.

Method of measurement

The Phyphox software installed on the mobile phone

2**Description**

Stride regularity based on trunk acceleration

Timepoint

Before the intervention and immediately after the tenth session of supervised ankle rehabilitation.

Method of measurement

The Phyphox software installed on the mobile phone

3

Description

Gait symmetry based on trunk acceleration

Timepoint

Before the intervention and immediately after the tenth session of supervised ankle rehabilitation.

Method of measurement

The Phyphox software installed on the mobile phone

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: In this study, the intervention consists of supervised ankle rehabilitation. Supervised ankle rehabilitation refers to the use of electrotherapy and exercise therapy based on current guidelines. The rehabilitation program will be conducted over 10 sessions (approximately 3 sessions per week). The duration of electrotherapy in each session will range from 15 to 30 minutes (using TENS current). Each intervention session, which includes both electrotherapy and exercise therapy, will last between 1.5 to 2 hours. In general, the exercise therapy includes strengthening, neuromuscular, range of motion, and balance exercises. Strengthening exercises for the muscles surrounding the ankle will be performed using resistance bands of varying levels. Balance and proprioception training will be carried out using a balance board and other equipment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar hospital

Full name of responsible person

Melika Shameli

Street address

Akhter Advanced Subspecialty Orthopedic Center, Azar Dead End, Sharifi Manesh Street, Pol-e Roomi Street, Shariati Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2200 1072

Email

shamelimelika@gmail.com

2

Recruitment center

Name of recruitment center

School of Rehabilitation, Iran University of Medical Sciences

Full name of responsible person

Melika Shameli

Street address

School of Rehabilitation Sciences, Madadkaran Street, Shah Nazari Street, Madar Square, Mirdamad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2225 6434

Email

shamelimelika@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Majid Safa

Street address

5th Floor, Central Headquarters, Iran University of Medical Sciences, Hemmat Expressway, Next to Milad Tower, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2503

Email

safa.m@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Melika Shameli
Position
Master's student in Physiotherapy
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Dormitory of Golestan, School of Rehabilitation
Sciences, Madadkaran Street, Shah Nazari Street,
Madar Square, Mirdamad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2225 6434
Email
shamelimelika@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sanjari
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Biomechanics
Street address
School of Rehabilitation Sciences, Madadkaran Street,
Shah Nazari Street, Madar Square, Mirdamad, Tehran,
Iran
City
Tehran

Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 2059
Email
sanjarima@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Melika Shameli
Position
Master's student in Physiotherapy
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Dormitory of Golestan, School of Rehabilitation
Sciences, Madadkaran Street, Shah Nazari Street,
Madar Square, Mirdamad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2225 6434
Email
shamelimelika@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We do not have ethical approval for this purpose.

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

Undecided - It is not yet known if there will be 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