Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The comparative effects of comprehensive protocol and routine physical therapy on pain, balance, disability and quality of life in patient with chronic ankle instability

Protocol summary

Study aim

To compare the effects of comprehensive physiotherapy protocol and conventional physiotherapy on pain, range of motion, balance, disability and activity level, and treatment effectiveness in patients with chronic ankle instability

Design

The clinical trial consists two arm parallel group, randomized trial with blinded postoperative care and outcome assessment. randomization was based on random numbers which was in sealed opaque.

Settings and conduct

This research project was conducted in two hospitals of Ghaem and Imam Reza in Mashhad. After evaluating the inclusion criteria by a specialist physician, patients were randomly assigned into two groups: comprehensive and conventional physiotherapy. Before starting the study, the outcome assessments were performed by a physiotherapist who was unaware of the study process. In the conventional physiotherapy protocol exercise and techniques were done for ankle joint specifically. In the comprehensive physiotherapy group, in addition to special ankle techniques and exercises, techniques and exercises were also prescribed to strengthen the hip muscles.

Participants/Inclusion and exclusion criteria

Patients aged between 18-68 years with a history of unilateral chronic ankle instability identified by a validated Persian version of the Ankle Instability Instrument (AII).

Intervention groups

1. Comprehensive physiotherapy 2. Conventional physiotherapy

Main outcome variables

Pain, disability, balance, range of motion, quality of life and treatment effectiveness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180109038285N2**
Registration date: **2022-05-01, 1401/02/11**
Registration timing: **retrospective**

Last update: **2022-05-01, 1401/02/11**
Update count: **0**

Registration date

2022-05-01, 1401/02/11

Registrant information

Name

Maryam Daghiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3752 9812

Email address

maryamdaghiyani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-01, 1397/04/10

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

2018-07-01, 1397/04/10

Actual recruitment end date

2020-06-30, 1399/04/10

Trial completion date

2020-07-31, 1399/05/10

Scientific title
The comparative effects of comprehensive protocol and routine physical therapy on pain, balance, disability and quality of life in patient with chronic ankle instability

Public title
The comparative effects of comprehensive protocol and routine physical therapy on pain, balance, disability and quality of life in patient with ankle sprain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
History of unilateral chronic ankle instability Answer "yes" to at least five Yes/No questions of 9 questions of Persian-version of ankle instability instrument Age between 18-68 year

Exclusion criteria:
severe or constant pain and swelling radicular pain from the lumbar or buttock region history of lower extremity surgery lower extremity fracture ankle fracture or surgery

Age
From **18 years** old to **68 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
in order to have equal number of participants, the random allocation of participants into two groups utilized the balanced block randomization method. In the present study, block randomization was run within blocks of four, there are six possible ways to equally assign participants to a block (A: intervention group; B: control group). All possible modes of the four blocks were written and numbered as follows: 1. AABB; 2. ABAB; 3. BBAA; 4. BABA; 5. ABBA; 6. BAAB. Consequently, in each block, two participants were assigned to the intervention group and two were assigned to the comparison group. The allocation sequence was prepared using the randomizer.org website before starting the study, with letter A for the intervention group and the letter B for the control group. The allocation sequence was prepared using the randomizer.org website before starting the study, with letter A for the intervention group and the letter B for the control group. In order to conceal the allocation sequence, 60 opaque envelopes were prepared.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study was performed in a double-blind manner so that the physiotherapist who performed the pre- and post-test was not involved in the treatment process, and in addition the person who analyzed the data was blind from the grouping allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
National Institute for medical research Development (NIMAD)

Secondary trial Id
IR.NIMAD.REC.1397.008

Registration date
2018-07-01, 1397/04/10

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of National Institute for Medical Research Development

Street address
West Fatemi Street

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۶۹۳۱۱۱

Approval date
2018-07-01, 1397/04/10

Ethics committee reference number
IR.NIMAD.REC.1397.008

Health conditions studied

1

Description of health condition studied
Chronic ankle instability

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Disability

Timepoint
Before starting physiotherapy and after completing physiotherapy sessions

Method of measurement
FAAM and FAOS questionnaires

Secondary outcomes

1

Description
Pain
Timepoint
Pre-intervention and immediately after finishing the physiotherapy sessions
Method of measurement
Visual Analog Scale

2

Description
Range of motion
Timepoint
Pre-intervention and immediately after physiotherapy sessions
Method of measurement
Calibrated goniometer

3

Description
Balance
Timepoint
Pre-intervention and immediately after physiotherapy sessions
Method of measurement
Star excursion balance test

4

Description
Treatment effectiveness
Timepoint
Immediately after the physiotherapy sessions
Method of measurement
Global rating of change

Intervention groups

1

Description
Intervention group: It involved up to twelve face-to-face sessions over four weeks and each session last for approximately 45 minutes. Patients in the comprehensive group, during the four-week program, received a combination of specific exercises modified from updated evidence-based randomized controlled trials and conventional physiotherapy protocol
Category
Rehabilitation

2

Description
Intervention group: It involved up to twelve face-to-face sessions over four weeks and each session last for approximately 45 minutes. Patients in the conventional group received exercises from standard physiotherapy which has been done in most randomized controlled trials elaborated in recent systematic reviews. Ankle strengthening (isometric, concentric, eccentric, weight bearing, and non-weight bearing), stretching, and retraining exercise and talocrural and subtalar mobilization were done each session.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Dr. Hossein Negahban
Street address
Ghaem hospital, Ahmad abad Ave, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9596126532
Phone
+98 51 3752 9810
Email
maryamdaghiani@yahoo.com

2

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Dr. Ahmad Ajvadi
Street address
Emam Reza squ
City
mashhad
Province
Razavi Khorasan
Postal code
9691236532
Phone
+98 51 3842 9092
Email
maryamdaghiyani@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Institute for Medical Research Development

Full name of responsible person
Hossein Negahban
Street address
No. 21, Beginning of Besat St., West Fatemi St., Tehran, Iran National Institute for Development of Medical Research (NIMAD)
City
Tehran
Province
Tehran
Postal code
99191-91778
Phone
+98 21 6693 8037
Email
NIMAD@RESEARCH.AC.IR

Grant name

Grant code / Reference number

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

Title of funding source
National Institute for Medical Research Development

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hossein Negahban
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Khorasan Razavi, Mashhad, Azadi Square, east door of the university campus
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2000
Email
honegahban@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hossein Negahban
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Khorasan Razavi, Mashhad, Azadi Square, east door of the university campus
City
ئشسااشی
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2000
Email
honegahban@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Maryam Daghiani
Position
MSc of physiotherapy
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
No 42, la'l Ave 4, Pardis Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3752 9812
Fax
Email
maryamdaghiyani@gmail.com

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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the assessed outcome after publishing the article, is available

When the data will become available and for how long

Start of access period 6 months after printing

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to find a better way to treat ankle sprains, the data will be used after the article is published.

From where data/document is obtainable

Dr. Hossein Neghaban honegahban@yahoo.com

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

If the applicant needs the data, he / she will receive the data after giving an electronic message to Dr. Hossein Neghaban, and at his / her discretion.

Comments