Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

The effect of neuromuscular exercises plus traditional exercise therapy on muscle morphology, dynamic balance and functional disability indices in people with chronic ankle instability: “A randomised controlled trial”

Protocol summary

Study aim

The effect of neuromuscular exercises plus common exercise therapy on muscle morphology, dynamic balance &functional disability indices in people with chronic ankle instability.

Design

Single blind and block randomised trial with two parallel groups.The first group is the control group which is a common physiotherapy treatment, second group is the intervention group, which is a series of neuromuscular exercises associated with the common physiotherapy treatment.

Settings and conduct

In initiation, the end of treatment& follow-up(1 month),outcomes are evaluated by sonography,Y balance test& questionnaire.According to subject's group,common physiotherapy/common physiotherapy with neuromuscular exercise are performed at the Physical Therapy Clinic of Ahvaz Rehabilitation School for 12 sessions for 4 weeks & Data analyzer will be blind of intervention type and grouping.

Participants/Inclusion and exclusion criteria

Inclusion:1.18-40 years, 2. Ability of weight bearing on the injury leg, 3.At least one inversion ankle sprain with pain/ edema& temporary loss of ankle function at 1-6 months ago, 4. Twice ankle giving way during functional activity at 6 months ago, 5.Cumberland questionnaire score <= 28, 6.Fear of ankle instability.Exclusion:1.Neurological impairments, 2.Vestibular impairments, 3.Head trauma during 3 months ago,4.Pregnancy, 5.Lower limb fracture, 6.Ankle muscle or ligament rupture, 7.Ankle surgery, 8.Musculoskeletal impairments in Lower limb joints during 3 months ago

Intervention groups

Control group:Common physical therapy exercises (resistance exercises of Tibialis anterior& Peroneus longus& balance exercises on the tilt board). Intervention group: Control group exercises plus a series of neuromuscular exercises according to Lephart protocol. 12 treatment sessions(3 sessions per week for 4 weeks).

Main outcome variables

Function;Muscle thickness;Dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181216042008N1**
Registration date: **2019-02-15, 1397/11/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-15, 1397/11/26**
Update count: **0**

Registration date

2019-02-15, 1397/11/26

Registrant information

Name

Khadijeh Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 4426 1551

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of neuromuscular exercises plus traditional exercise therapy on muscle morphology, dynamic balance and functional disability indices in people with chronic ankle instability: “A randomised controlled trial”

Public title

The effect of neuromuscular exercises plus traditional exercise therapy in people with chronic ankle instability:

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inversion ankle sprain during 1-6 months ago Giving way of ankle during 6 months ago Fear of ankle instability Cumberland questionnaire score <= 28 Ability of weight bearing on the involved leg

Exclusion criteria:

Neurological impairments Vestibular impairments Head trauma during 3 months ago Pregnancy Lower limb fracture Ankle muscle or ligament rupture Ankle surgery Musculoskeletal impairments in Lower limb joints during 3 months ago

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is a block randomization method. The tool used in this method is Random allocation software. In this software; random sequence is determined by specifying the number of groups(2 groups), the type of groups (intervention and control) and the sample size .

Blinding (investigator's opinion)

Single blinded

Blinding description

After data collection& entry of them in SPSS software, data file that don't contain of patient names, available to the data analyzer.The data analyzer will not be aware of the type of intervention, participants grouping& researcher hypothesis to don't create bias in statistical results interpretation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Physiotherapy Department, Rehabilitation School, Ahvaz Jundishapur University of Medical Sciences, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.AJUMS.REC.1397.530

Health conditions studied

1

Description of health condition studied

sprain of ankle

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes

1

Description

Function

Timepoint

At the beginning of the treatment and after the 12 intervention sessions

Method of measurement

Foot and Ankle Outcome Score questionnaire

Secondary outcomes

1

Description

Dynamic balance

Timepoint

Before initiation of treatment, after the intervention

sessions and one month after the end of the intervention sessions

Method of measurement

Y balance test

2

Description

Muscle thickness

Timepoint

Before initiation of treatment, after the intervention sessions(12 sessions) and one month after the end of the intervention sessions

Method of measurement

By Sonography Device

Intervention groups

1

Description

Intervention group: Common physiotherapy (Ultrasound, Infra-Red, Trans-cutaneous Electrical nerve Stimulation, Tibialis Anterior& Peroneus longus muscles Resistance exercise by Elastic band and balance exercise by tilt board) with neuromuscular exercises taken from Lephart protocol for 12 sessions,3 times a week for 4 weeks, any session time: 1h, 20 min.

Category

Rehabilitation

2

Description

Control group: Common physiotherapy (Ultrasound, Infra-Red, Trans-cutaneous Electrical nerve Stimulation, Tibialis Anterior& Peroneus longus muscles muscles Resistance exercise by Elastic band and balance exercise by tilt board) for 12 sessions,3 times a week for 4 weeks, any session time: 1h.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic of Rehabilitation School

Full name of responsible person

Gholamhossein Nassadj

Street address

Rehabilitation school, Ahvaz Jundishapur university of medical sciences, Golestan Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Gholamhossein Nassadj

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only part of the data, such as the original outcome information, the study protocol and statistical analysis can be shared.
When the data will become available and for how long
6 months after results publish
To whom data/document is available
Data will only be available to researchers working in academic and scientific institutes.
Under which criteria data/document could be used
If the research plan is intended to apply the therapeutic exercises used or the variables studied are similar to this study.
From where data/document is obtainable
executor of plan: Dr.Gholamhossein nassadj E-mail: nassadj@yahoo.com
What processes are involved for a request to access data/document
By sending an email with a full explanation of the reason for requesting the documentation and the purpose of having it.
Comments