Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effect of multi segmental foot and ankle mobilization on pain, disability and lumbar and ankle flexion range of motion on patient with chronic mechanical low back pain (Randomized controlled trial)

Protocol summary

Study aim

Determining the effect of multi-segmental mobilization of the ankle and foot on pain, disability and range of motion(ROM) of the lumbar and ankle flexion in people with chronic mechanical low back pain.

Design

Clinical trials with two control and experimental groups, parallel, single-blind, randomized using a table of random numbers will be performed on 56 patients.

Settings and conduct

The researcher selects 56 women with chronic mechanical low back pain. All screening forms are numbered before classification and will be kept for analysis until the end of the study. After filling out the consent form, all assessments are performed by a therapist unaware of the plan and then the individuals are randomly placed in two control and experimental groups by using the table of random numbers by the student and the patients are unaware. These studies will be performed in Berjis physiotherapy.

Participants/Inclusion and exclusion criteria

inclusion: woman; age: 30-60 years old; VAS more than 3; chronic pain; BMI less than 30; navicular bone drop more than 10mm; ankle dorsiflexion less than 20; first metatarsophalangeal joint extension less than 65 exclusion:Absence of systemic diseases such as diabetes and rheumatoid arthritis; Fractures in the trunk and lower limbs; Infection; Pregnancy; Tumor; Acute ankle sprains; Ankle ankylosis; Open sores on the feet; have not medical insoles; Lack of use of physiotherapy, massage therapy and manipulation in the last month; Lack of permanent pain in the lower limbs especially below the knee, and positive straight leg raising(SLR) and well SLR

Intervention groups

Control group: Ten sessions of therapy including TENS, hot pack, exercise therapy and education Experimental group: In addition to the above, multi-segmental mobilization of the ankle and foot is also performed.

Main outcome variables

pain; disability; lumbar and ankle flexion ROM

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200318046813N1**
Registration date: **2021-08-21, 1400/05/30**
Registration timing: **retrospective**

Last update: **2021-08-21, 1400/05/30**
Update count: **0**

Registration date

2021-08-21, 1400/05/30

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of multi segmental foot and ankle mobilization on pain, disability and lumbar and ankle flexion range of motion on patient with chronic mechanical low back pain (Randomized controlled trial)

Public title

evaluation of the effect of ankle and foot mobilization on low back pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Sex: female Age: 30-60 years old Participants must be based on the Force Quebec Task classification in the chronic course. (At least 12 weeks have passed since the onset of symptoms.) VAS > 3 Navicular drop > 10 mm based on navicular drop test Ankle dorsiflexion range of motion must be less than 20 degrees and Metatarsophalyngeal (MTP) extension range of motion must be less than 65 degrees Females with BMI less than 30

Exclusion criteria:

Past surgical history of trunk and lower extremity, malignancy, infection, pregnancy, systemic disorder like diabetes and rheumatoid arthritis People who are currently using medical insoles People who underwent physiotherapy, massage therapy and manipulation a month before the study People with nervous system disorders and disc herniation with radicular pain. For example, if a person has persistent pain in the lower limbs, especially below the knee, and has a positive SLR and well-SLR test. All pathological disorders of the ankle and sole of the foot, such as acute ankle sprains in the last 6 weeks, ankle ankylosis, open sores on the feet and ankles

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use random block method to assign patients to two control and experimental groups. In this method, blocks of 4, 6 and 8 or blocks that have an even number can be used. In this study, we will use quadruple blocks in which two people will be assigned to the experimental group and two to the control group. A quadruple block can be formed into 6 possible states according to the laws of probability. First, we identify these 6 possible cases and assign them the number one to six. In the next step, we determine the required number of blocks, which because the number of samples is 56 people, it is necessary to define this number in the form of 14 blocks of 4 people.In other words, in order to assign patients to two groups of 28 people, 14 times must be selected from codes 1 to 6, which is for possible cases of block formation. To do this, with the eyes closed and the tip of the pencil in the table of random numbers, we select a one-digit number and move in one of four directions, and We will select only numbers from one to six. We will continue this process until we randomly select 14 times from the numbers 1 to 6. Next, we write the blocks on a piece of paper, and select them in order of selection, depending on which of the modes constitutes the 4-person block. For example, if the first selected number is code 5 and the fifth mode of formation of 4 blocks is ABBA mode, it means that the first person will be assigned to group A, the second to B, the third to B and the fourth to A. As patients enter the study, the selected blocks will determine which of the two experimental or control groups each individual should be placed in. Finally, 56 patients will be assigned to one of the two groups of intervention (n = 28) and control (n = 28) during the study according to 14 blocks of 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

Subjects are randomly assigned to treatment and control groups by researchers and are aware of the study and the type of treatment they receive. However, the evaluator is unaware of the groups being treated and the type of treatment in each group. Therefore, the study is a single-blind type. The tests are then taken and recorded by the evaluator unaware to the groups and treatment. After treatment, the tests are repeated by the same evaluator and the results are recorded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs -Medical University of Isfahan

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Hezar Jerib street

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Isfehan
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Approval date
2019-08-26, 1398/06/04
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.332

Health conditions studied

1

Description of health condition studied
chronic mechanical low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain score on Visual analog scale
Timepoint
Measurement of pain is performed at the beginning of the study (before the intervention) and 4 weeks after the start of physiotherapy treatment.
Method of measurement
Visual analog scale

2

Description
disability score on Oswestry questionnaire
Timepoint
At the beginning of the study (before the start of the intervention) and 4 weeks after the start of physiotherapy treatment
Method of measurement
Oswestry questionnaire

3

Description
Measure lumbar flexion range of motion using a tape measure
Timepoint
At the beginning of the study (before the start of the intervention) and 4 weeks after the start of physiotherapy treatment
Method of measurement
tape measurement

4

Description
Measurement of the ankle dorsiflexion range of motion using a goniometer
Timepoint
At the beginning of the study (before the start of the intervention) and 4 weeks after the start of physiotherapy treatment
Method of measurement
Goniometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ten sessions of physiotherapy including 30 minutes of electrotherapy using TENS acupuncture wave with a frequency of 10 Hz and a wavelength of 200 microseconds, 15 minutes of hot packs, exercises includes: abdominal muscle strengthening, iliopsoas, back and gastrosoleous muscle stretching . Each exercise should be repeated in 3 sets, each set has 3 repetition, each repetition should be holded 30 seconds . In each session, the experimental group, after training and electrotherapy, received the mobilization treatment as 4 sets of two-minute Maitland Grade III techniques (1 minute break between each set) for each part of the foot. It includes the ankle, first tarsometamatars, the calcaneutalus or sublatar and the first metatarsophalangeal joint.Ankle joint mobilization: The tibia and fibula are fixed with one hand and the talus is moved anteroposterior with the other hand. First tarsometatarsal joint: by grasping the first Quneiform bone with the index finger and thumb of the proximal hand and with the other hand moving the base of the first metatarsus towards the dorsal with high amplitude and frequency once per second. Calcanotealus or subtalar joint: As the patient lies on his side, the talus is fixed with one hand and the calcaneus is inverted with the other hand. First metatarsophalangeal joint: The person lies on his back and a pillow is placed under the knee that is flexing, then with one hand hold the first metatarsal fixed and with the other hand move the first thumb in the posteroanterior direction with the same criteria as We were told to move for the ankle.
Category
Rehabilitation

2

Description
Control group: Ten sessions of physiotherapy including 30 minutes of electrotherapy using TENS acupuncture wave with a frequency of 10 Hz and a wavelength of 200 microseconds, 15 minutes of hot packs, exercises includes: abdominal muscle strengthening, iliopsoas, back and gastrosoleous muscle stretching . Each exercise should be repeated in 3 sets, each set has 3 repetition, each repetition should be holded 30 seconds.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Berjis physiotherapy

Full name of responsible person
Mahnaz Rezaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Nafiseh Ghanbari Riseh

Position
student

Latest degree
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Other areas of specialty/work
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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