

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Effect of core stability and massage training and maintenance on plantar peressure amplitude in low back pain individual during runnig

Protocol summary

Study aim

To investigate the effect of central stability exercises and massage on the range of plantar pressure variables of people with back pain during running.

Design

A clinical trial with a control group, with parallel groups, a blind strain, on 36 back pain patients.

Settings and conduct

The location of the study was the health center and physical training hall of Mohaghegh Ardabili University. Subjects were purposefully divided into three groups of 12 people.

Participants/Inclusion and exclusion criteria

The criteria for entering the study included female gender, age range of 18-35 years, and a pain index higher than 4 in the lower back area, and a history of lower back pain longer than 6 months. No history of rheumatic and inflammatory diseases, peripheral nerve lesions, severe lumbar spine disorders, severe mental illnesses, previous surgery in the back area, neuro-muscular or joint disease, systemic disease, pregnancy, cardio-respiratory and metabolic disease, among the exclusion criteria. It was from study.

Intervention groups

The study was conducted in 3 groups, one group of central stabilization exercises and massage, one group received only massage and one group was a control group that had back pain only.

Main outcome variables

The effect of central stability exercises and massage on the range of plantar pressure variables and plantar variables and muscle electrical activity in people with back pain during running

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240109060659N1**

Registration date: **2024-01-17, 1402/10/27**

Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**

Update count: **0**

Registration date

2024-01-17, 1402/10/27

Registrant information

Name

Fatemeh Mehralian

Name of organization / entity

Mohagheghe ardabili univercity

Country

Iran (Islamic Republic of)

Phone

+98 31 3773 4649

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-09, 1402/11/20

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of core stability and massage training and maintenance on plantar peressure amplitude in low back pain individual during runnig

Public title

Investigating the effect of central body muscle exercises and massage and its durability on biomechanical variables in people with back pain during running

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

female gender age range of 18 to 35 years, pain index higher than 4 in the lower back area presence of lower back pain for more than 6 months

Exclusion criteria:

No history of rheumatic and inflammatory diseases, peripheral nerve lesions, severe lumbar spine disorders, severe mental illnesses, previous surgery in the back area, neuro-muscular or joint disease, systemic disease, pregnancy, cardio-respiratory and metabolic disease.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was designed as a double-blinded randomized controlled trial An envelope concealment method was used to allocate study participants. Participants and examiners were unaware of group allocation. In other words, participants and assessors were blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National system of ethics in biomedical research

Street address

daneshgah st

City

ardabil

Province

Ardabil

Postal code

5619913131

Approval date

2023-12-12, 1402/09/21

Ethics committee reference number

IR.UMA.REC.1402.064

Health conditions studied

1

Description of health condition studied

chronic nonspecific low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of central stability exercises and massage on the range of plantar pressure variables and plantar variables and muscle electrical activity

Timepoint

Pre-test before exercises and massage and post-test six weeks after exercises and massage and durability after 4 weeks

Method of measurement

Variables were measured using electromyography, foot scan and force plate.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: central stabilization exercises and Swedish massage for 6 weeks and 3 sessions per week, each session includes 10 minutes of warm-up, 30 minutes of exercises and 20 minutes of massage.

Category

Treatment - Other

2

Description

Intervention group: Intervention group: Swedish massage group for 6 weeks, 3 sessions per week for 20 minutes of massage of the lower back with warm stroking movements and rubbing and kneading techniques.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Mohaghegh Ardabili Health Center

Full name of responsible person

Fatemeh Mehralian

Street address

Daneshgah st

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mohaghegh Ardabili university

Full name of responsible person

Fateme Mehralian

Street address

University of Mohaghegh Ardabili, daneshgah St,
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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

Mohaghegh Ardabili university

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

Mohaghegh ardabili university

Full name of responsible person

Fatemeh Mehralian

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Mohaghegh Ardabili University

Full name of responsible person

Gabriel Razmjoo

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Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

treatment

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

mean of ground reaction forces

When the data will become available and for how long

When publishing an article

To whom data/document is available

All people

Under which criteria data/document could be used

it is free.

From where data/document is obtainable

The journal in which the article will publish.

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

Journal Process and Rules

Comments

Null