

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Myofascial Release Technique on Lumbar Spine Kinematics in People with Non-Specific Chronic Low Back Pain

Protocol summary

Study aim

Evaluation of the effect of adding Myofascial Release technique to routine physiotherapy on lumbar spine kinematics, pain and disability in patients with non-specific chronic low back pain.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, permuted block randomization was used for randomization.

Settings and conduct

People with non-specific chronic low back pain will be included in the study voluntarily in the research center of Semnan University of Medical Sciences and will be randomly divided into two groups of control and intervention; Then the kinematics of their lumbar spine will be measured during physiological and functional movements and their pain and disability. Both groups will receive ten sessions of routine physiotherapy treatment (Tennessee, USA, Hot Pack), the intervention group will receive treatment in four sessions using myofascial release technique, and the control group will undergo four sessions of myofascial release technique without applying Will receive traction. After two weeks of kinematic intervention, the subjects in the study will be measured and the results will be compared.

Participants/Inclusion and exclusion criteria

People with non-specific chronic low back pain that lasts more than 12 weeks and who have a VAS of less than 3 per day will be included in the study, and people with a BMI above 25, with certain conditions, or those with myofascial release or rehabilitation treatment. Received two months ago will be excluded from the study.

Intervention groups

Each group will receive ten sessions of routine physiotherapy with four sessions (twice a week for two weeks) of myofascial treatment, but the myofascial control group will receive sham release.

Main outcome variables

Pain Disability Maximum angular displacement Angular

velocity Relative phase angle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029264N12**

Registration date: **2021-07-03, 1400/04/12**

Registration timing: **prospective**

Last update: **2021-07-03, 1400/04/12**

Update count: **0**

Registration date

2021-07-03, 1400/04/12

Registrant information

Name

Rasool Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 1022

Email address

rasool.bagheri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Myofascial Release Technique on Lumbar Spine Kinematics in People with Non-Specific Chronic Low Back Pain

Public title

The effect of myofascial release on lumbar kinematics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 55 years People with nonspecific chronic low back pain that lasts for more than 12 weeks VAS less than 3 per day of study

Exclusion criteria:

BMI above 25 Spinal cord tumor Infection Fracture Autoimmune disease Vascular disease Endocrine disease Metabolic disease Systemic neoplastic disease Fibromyalgia Cauda equina syndrome Previous spinal surgery Muscular injuries of the lower extremities Previous experience with myofascial History of rehabilitation treatment for low back pain over the past two months

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

permuted block randomization: 4 blocks are used for randomization. The intervention groups are called A and the control group is called B. Different 4 blocks including A, B are defined in different permutations. We will have 15 blocks of 4. Each block is assigned a number from 1 to 6. Using a random number generator, the blocks are selected from 6 selected blocks, respectively. Eligible individuals are assigned to either A or B in each block (from left to right) in a predetermined order.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not be aware of their group, nor will the data analyzer be aware of patients being assigned to groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Comitee of Semnan University of Medical Sciences

Street address

Basij Blvd., Semnan., Semnan Province

City

Semnan

Province

Semnan

Postal code

99951-35198

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.SEMUMS.REC.1400.073

Health conditions studied

1

Description of health condition studied

Non-specific chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Kinematic

Timepoint

The first session, last session

Method of measurement

3D motion analysis system

Secondary outcomes

1

Description

Pain

Timepoint

The first session, last session

Method of measurement

Visual Analogue Scale

2

Description

Disability

Timepoint

The first session, last session

Method of measurement

Oswestry checklist

Intervention groups

1

Description

Intervention group: Participants in this group will receive ten routine sessions of physiotherapy along with four sessions (twice a week for two weeks) of myofascial treatment. Routine physiotherapy includes 20 minutes of using TENS electric current with a frequency of 50 to 120 Hz, 1 MHz Ultrasound with an intensity of 1.5w / cm² for 5 minutes and a hot pack. Myofascial release protocol will include release of thoracolumbar fascia, paravertebral lumbar muscles, quadratus lumborum and seasickness.

Category

Rehabilitation

2

Description

Control group: Participants in this group will receive ten routine sessions of physiotherapy along with four sessions (twice a week for two weeks) of myofascial treatment. Routine physiotherapy includes 20 minutes of using TENS electric current with a frequency of 50 to 120 Hz, 1 MHz Ultrasound with an intensity of 1.5w / cm² for 5 minutes and a hot pack. The myofascial release protocol will include the release of the thoracolumbar fascia, the paravertebral lumbar muscles, the quadratus lumborum, and the seas, which the group will receive as sham.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center,
Semnan University of Medical Sciences., Semnan., Iran.

Full name of responsible person

Dr Rasool Bagheri

Street address

Basij Blvd., Semnan., Semnan Province

City

Semnan

Province

Semnan

Postal code

3513135111

Phone

+98 23 3336 4180

Email

rasool.bagheri@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Parviz Kokhaei

Street address

Semnan University of Medical Sciences, Basij Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Fax

Email

P_kokha@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Rasool Bagheri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Km 5 Damghan Road., Semnan University of Medical Sciences., School of Rehabilitation., Semnan town

City

Semnan

Province

Semnan

Postal code

3513135111

Phone

+98 23 3344 1022

Email

rasool.bagheri@ymail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Rasool Bagheri

Position

Assistant professor

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Person responsible for updating data

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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