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 Mayofacial 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 myofacial release technique, and the control group will undergo four sessions of myofacial 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)

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+98 23 3344 1022

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rasool.bagheri@ymail.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 lumbarum 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 lumbarum, 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 Scinces., Semnan., Iran.
Full name of responsible person
Dr Rasool Bagheri
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Basij Blvd.,Semnan., Semnan Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Parviz Kokhaei
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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
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
Assisstant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
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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