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

Protocol summary

Study aim

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@ymail.com

Recruitment status
recruiting

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
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 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
permutated 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

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

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
Basi 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
Assisstant 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
Person responsible for scientific 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
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

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

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Rasool Bagheri

Position
Assistatnt 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