

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Investigation of the effects of myofascial release techniques on clinical findings and electroencephalography activities in patients with nonspecific chronic low back pain

Protocol summary

Study aim

The purpose of study is to investigate of the effects of myofascial release techniques on clinical findings and electroencephalography activities in patients with nonspecific chronic low back pain

Design

Randomized, controlled, single blinded trial

Settings and conduct

50 patients with NSCLBP participate in this research in physiotherapy clinic of School of Rehabilitation, Tehran University of Medical Sciences. After the randomization, patients are placed in one of the intervention or control groups. Physiotherapist performs myofascial release techniques and trains therapeutic exercises for three times a week for three weeks. Then, patients are asked to complete the pain and disability questionnaire, and they evaluate lumbar active range of motion and brain signals before and after the intervention. Evaluation of variables is performed before intervention, at the end of each week and one month after the third week of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Male patients with an average age between 20-40 years old 2-History of bilateral or unilateral lumbar pain, between the margins of the ribs to the inferior gluteal fold, without referral or radicular pain to the lower limbs and without any obvious cause in the patient's history 3-History of low back pain for at least 3 months 4-A maximum pain score 4 from 10 with using a Visual Analogue Scale (VAS) Exclusion criteria: 1-Inappropriate recording brain signals with electroencephalography 2-Unwillingness of subjects to continue testing

Intervention groups

There are two groups (Intervention group: myofascial release techniques with therapeutic exercises, and Control group: Only therapeutic exercises)

Main outcome variables

1-pain intensity 2-Functional disability index 3-Lumbar active flexion and extension range of motion 4-Brain signals and parameters

General information

Reason for update

Change recruitment dates

Acronym

MFR & CNSLBP

IRCT registration information

IRCT registration number: **IRCT20090301001722N24**

Registration date: **2020-04-18, 1399/01/30**

Registration timing: **prospective**

Last update: **2020-05-08, 1399/02/19**

Update count: **1**

Registration date

2020-04-18, 1399/01/30

Registrant information

Name

Samira Karimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

hadianrs@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-11-20, 1399/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the effects of myofascial release techniques on clinical findings and electroencephalography activities in patients with nonspecific chronic low back pain

Public title
effects of myofascial release techniques on patients with nonspecific chronic low back pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Male patients with an average age between 20-40 years old A Body Mass Index (BMI) between 25 and 30 History of bilateral or unilateral lumbar pain, between the margins of the ribs to the inferior gluteal fold, without referral or radicular pain to the lower limbs and without any obvious cause in the patient's history History of low back pain for at least 3 months A maximum pain score 4 from 10 with using a Visual Analogue Scale (VAS) Right-handed participants
Exclusion criteria:
Receiving physiotherapy programs (myofascial release, massage, therapeutic exercise, ...) two months ago A previous surgery for spinal and abdominal area, shoulder and pelvic girdles, lower extremities A previous history of medical diseases, and cardiovascular / respiratory diseases, neurological diseases Previous postural problems or muscle shortening A previous history of pain or disability in the upper and lower extremities A previous history of infection or vertebral fractures, and fibromyalgia A previous history of vestibular disorders, and balance and cognitive problems Inappropriate recording brain signals with electroencephalography Unwillingness of subjects to continue testing

Age
From **20 years** old to **40 years** old

Gender
Male

Phase
3

Groups that have been masked

- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomly divided into three groups by closed envelope method. The allocation of the subjects will be concealed by using sequentially numbered, sealed and opaque envelopes. On the first day of

treatment, the envelope allocated will be opened by participant.

Blinding (investigator's opinion)
Single blinded

Blinding description
Assessor Blind: Data safety will be ensured by assigning Specific Identity numbers and all consent, readings forms will be placed in locker to bind Assessors

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1148965111

Approval date

2020-03-10, 1398/12/20

Ethics committee reference number

IR.TUMS.VCR.REC.1398.1020

Health conditions studied

1

Description of health condition studied

Chronic Non-specific Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain intensity

Timepoint

before intervention, after each intervention session, and After one month follow up

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Pain intensity

Timepoint

before intervention, after three weeks, and After one month follow up

Method of measurement

Short Form McGill Pain Questionnaire

3

Description

Brian signals and parameters

Timepoint

before intervention, at the end of each week, and After one month follow up

Method of measurement

Electroencephalography

Secondary outcomes

1

Description

Functional disability index

Timepoint

before intervention, after three weeks, and After one month follow up

Method of measurement

Quebec Low Back Pain Disability Scale Questionnaire

2

Description

Functional disability index

Timepoint

before intervention, after three weeks, and After one month follow up

Method of measurement

The Oswestry Disability Questionnaire

3

Description

Lumbar active flexion and extension range of motion

Timepoint

before intervention, after each intervention session, and After one month follow up

Method of measurement

Inclinometer

Intervention groups

1

Description

Intervention group: myofascial release techniques with therapeutic exercises. These techniques are performed

three times a week for three weeks by a physiotherapist. These techniques include unloading techniques with low force and long duration for quadratus lumborum, psoas muscles, and thoracolumbar fascia.

Category

Rehabilitation

2

Description

Control group: Therapeutic exercises. These exercises are taught by a physiotherapist and performed for three weeks. These exercises include "single knee to chest", "double knee to chest", camel-cat, and knee rocking.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation of Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Hadian

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School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amir Ali Sohrabpour

Street address

The Seventh Floor- Main Building Tehran University of Medical Sciences-Ghods Str-Keshavarz Boulevard

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Hadian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Arsalan Ghorbanpour

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available