Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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-Brian 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)

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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 techniqes 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Mohammad Reza Hadian
Position
Professor
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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