

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

#### **Street address**

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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1148965111

#### **Phone**

+98 21 7753 6586

#### **Email**

hadianrs@sina.tums.ac.ir

## **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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1417653761

#### **Phone**

+98 21 6649 2271

**Email**

aasohrabpour@tums.ac.ir

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

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

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Hadian

**Position**

Professor

**Latest degree**

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**Other areas of specialty/work**

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

Tehran University of Medical Sciences

**Full name of responsible person**

Arsalan Ghorbanpour

**Position**

PhD candidate

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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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