# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

# The effectiveness of muscle energy techniques on some clinical signs in participants with myofascial trigger points related to chronic non-specific back pain: Study protocol for a double-blind randomized controlled trial

## Protocol summary

**Study aim**

to investigate The effectiveness of muscle energy techniques on some clinical signs in participants with myofascial trigger points related to chronic non-specific back pain

**Design**

The present study will be a randomized, double-blind, controlled trial.

**Settings and conduct**

After selecting people with non-specific chronic back pain using non-probability sampling method, the patients will be randomly divided into two groups of muscle energy techniques (first group) and placebo group of muscle energy techniques (second group). In both treatment groups, participants will undergo routine physical therapy (includes low-power laser and fixed exercises). Both groups will be treated for 9 sessions in 3 days. Also, this study is a double-blind study in which the participants, the one who evaluates the outcomes and the one who analyzes the characteristics of the patients will be treated in two groups. This study will be conducted in the Faculty of Rehabilitation Sciences of Iran University of Medical Sciences.

**Participants/Inclusion and exclusion criteria**

Patients aged between 20 to 50 years no referral pain to lower extremities Moderate pain intensity (between 3 to 6) based on Numerical Pain Rating Scale. no specific cause for a subject's chronic back pain. Patients with trigger points in the quadratus lumborum and erector spine muscles and gluteus medius muscle

**Intervention groups**

The treatments of the intervention group include muscle energy techniques and routine physiotherapy. The treatment of the control group includes sham muscle energy techniques along with routine physiotherapy.

**Main outcome variables**

a)Pain intensity measurement based on Numerical Pain Rating Scale b) functional disability based on oswestry disability index c) lumbar ROM d) pain pressure threshold

## General information

**Reason for update**

The edited items include change the word "clinical signs" to "some clinical signs" due to more explanation in the title. In this study, some clinical symptoms were investigated and not all symptoms. Another case is the change of the word "individuals" to "participants". In the text of the article, an attempt has been made to use the same words for the participants, so this change was made in order to unify the text and the title. The final change is apdate the word "trigger points" to "myofascial trigger points". In other studies , myofascial trigger points were used and the word "myofascial" was added to specify the nature of trigger points. Another apdate is the change of the primary outcomes, which was reduced from two variables "pain intensity" and "functional disability" to one "pain intensity". With the consultation with statistician and methodologist and considering the determination of the sample size based on the variable of pain intensity and also considering the past studies that only considered pain as the primary outcome and also emphasizing the fact that pain is a primary factor that affects othervariables, we decided to mention only "pain intensity" as the primary variable.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20191208045652N6**
Registration date: **2022-12-07, 1401/09/16**
Registration timing: **prospective**

Last update: **2024-07-09, 1403/04/19**
Update count: **1**

**Registration date**

2022-12-07, 1401/09/16

**Registrant information**

**Name**

marzieh Yassin

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-01-20, 1401/10/30

**Expected recruitment end date**

2023-06-20, 1402/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of muscle energy techniques on some clinical signs in participants with myofascial trigger points related to chronic non-specific back pain: Study protocol for a double-blind randomized controlled trial

**Public title**

The effectiveness of a type of manual therapy on clinical sign in individuals with low back pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients aged between 20 to 50 years No referral pain to lower extremities Moderate pain intensity (between 3 to 6) based on Numerical Pain Rating Scale Patients with trigger points in the quadratus lumborum and erector spine muscles and gluteus medius muscle

**Exclusion criteria:**

History of lumbar surgery Complications that affect the treatment process such as systemic diseases, neurological disorders, inflammatory conditions, infectious conditions, structural and degenerative changes, metabolic bone diseases and bleeding disorder. Fracture People who have received exercise therapy or manual treatments or dry needling for the lumbar region in past month. Active cancer Pregnancy Long history of steroid use

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **33**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All eligible chronic non-specific low back pain patients will be randomized to an intervention group ( muscle energy techniques and routine physical therapy) and a control group (sham muscle energy techniques and routine physical therapy) with a ratio of 1:1. Randomized allocation will be performed by using permuted block randomization method, which consists of four-letter blocks made of letters A and B. Then, the random treatment list that will be obtained at the end of the random allocation task will be placed in letters A and B inside the sealed and numbered envelopes (muscle energy techniques and letter B indicates sham muscle energy techniques). The random assignment process will be performed by someone outside the research team before the study begins. After the initial evaluation of the patient by the examiner, the numbered envelopes will be presented to him/her according to the ordinal number of each person admitted to the study. Finally, after each patient enters the treatment sessions, the therapist will adjust the treatment interventions based on the letters in the envelope. Patients are asked not to provide their grouping information to the assessor to prevent data contamination.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, participants, outcome assessor and data analyzer will be kept blind to being assigned to the study groups. Blinding method: A) Participants: Participants will not have information about which treatment group they have entered, and also in each treatment group, people will receive a real treatment in addition to sham of the real treatment in the other group (the first group includes muscle energy techniques and the second group includes sham muscle energy techniques ) were used so the participants could not guess which treatment group they have entered. B) Outcome assessor: Outcome assessment will be performed by a person who does not know the grouping of the individuals and the treatments performed in each treatment group. C) Data analyzer: Data analysis will be performed by a person who does not know the grouping of individuals and the treatments performed in each treatment group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Iran University of Medical Sciences
**Street address**
Dormitory of the school of Rehabilitation of Iran University of Medical Sciences, Shah nazari Ave., Madar square, Mirdamad Blvd
**City**
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**Province**
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**Postal code**
1545913487
**Approval date**
2022-05-31, 1401/03/10
**Ethics committee reference number**
IR.IUMS.REC.1401.189

## Health conditions studied

**1**

**Description of health condition studied**
chronic nonspecific low back pain
**ICD-10 code**
M54.5
**ICD-10 code description**
low back pain

## Primary outcomes

**1**

**Description**
Pain intensity based on Numerical Pain Rating Scale
**Timepoint**
Pain intensity measurement before intervention and after intervention
**Method of measurement**
numerical pain rating scale

## Secondary outcomes

**1**

**Description**
Range of motion
**Timepoint**
Before intervention and after intervention
**Method of measurement**
goniameter

**2**

**Description**
Pain pressure threshold
**Timepoint**
before and after intervention
**Method of measurement**
algometer

**3**

**Description**
functional disability
**Timepoint**
before and after intervention
**Method of measurement**
oswestry disability index questionnaire

## Intervention groups

**1**

**Description**
Intervention group:The treatments of this group include muscle energy techniques and routine physiotherapy: a) Muscle energy techniques: This technique is performed for the quadratus lumborum, erector spinae and gluteus medius muscles. To perform this technique after being in the treatment position The patient is asked to contract the muscle with a low power and a maximum of 20-35% of his power. After 5 to 7 seconds, the patient is asked to relax completely, then the therapist takes the muscle to a stretched position and maintains the stretched position for 30 seconds. After 2 to 3 seconds of rest, the above steps will be repeated 3 times.b)Routine physiotherapy includes a low-power diode laser (LAS-Expert, physiomed, made in Germany - with 14 diodes), wavelength 785 nm, output power 700 mW, with a frequency of 50 to 60 Hz, 50 J/cm2, as a pulse frequency With 80% duty cycle = 1.5 to 2 cm outside the spines of the lumbar vertebrae, it will be used for approximately 20 minutes.Core stability exercises will consist of three stages of exercises, The first week will include the exercises of the first stage, the second weeks include the first and second stage exercises, and the third week will include all of the exercises. The first stage exercises will include: abdominal drawing, abdominal bracing lift and alternative arm and leg lift, the second stage exercises will include: unilateral bridging, sideway bridging, quadruped contralateral arm and leg lift, curl up, diagonal curl up, sit back and the third stage exercises will include: bridging on swiss ball, diagonal curl up with elastic band, trunk extension on swiss ball, unilateral bridging with weight cuff and forward step up. Each exercise will be repeated 10 times and each repetition will last 10 seconds and there will be one minute break between each exercise. This group will be treated for 9 sessions over 3 weeks
**Category**
Rehabilitation

**2**

**Description**
Control group:The treatments of this group include sham muscle energy techniques and routine physiotherapy: a) Sham muscle energy techniques are performed for the quadratus lumborum, erector spinae and gluteus medius muscles. In this way, the muscle is brought to the

position of performing the technique, but no technique is performed.The treatment time will be the same in both groups. b)Routine physiotherapy includes a low-power diode laser (LAS-Expert, physiomed, made in Germany - with 14 diodes), wavelength 785 nm, output power 700 mW, with a frequency of 50 to 60 Hz, 50 J/cm2, as a pulse frequency With 80% duty cycle = 1.5 to 2 cm outside the spines of the lumbar vertebrae, it will be used for approximately 20 minutes.Core stability exercises will consist of three stages of exercises, The first week will include the exercises of the first stage, the second weeks include the first and second stage exercises, and the third week will include all of the exercises. The first stage exercises will include: abdominal drawing, abdominal bracing lift and alternative arm and leg lift, the second stage exercises will include: unilateral bridging, sideway bridging, quadruped contralateral arm and leg lift, curl up, diagonal curl up, sit back and the third stage exercises will include: bridging on swiss ball, diagonal curl up with elastic band, trunk extension on swiss ball, unilateral bridging with weight cuff and forward step up. Each exercise will be repeated 10 times and each repetition will last 10 seconds and there will be one minute break between each exercise. This group will be treated for 9 sessions over 3 weeks.

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Rehabilitation school of Iran university of medical science

**Full name of responsible person**
Marzieh yassin

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## Sponsors / Funding sources

**1**

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**Name of organization / entity**
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**Full name of responsible person**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
Iran 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**
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**Position**
Student

**Latest degree**
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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