Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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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
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Province
Tehran
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
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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?
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
Iran University of Medical Sciences

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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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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