

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of the immediate effect of abdominal muscle massage with lumbar muscle massage in non-acute back pain patients

#### Protocol summary

##### Study aim

This study compares the immediate effect of abdominal and lumbar muscle massage on pain outcomes and range of motion in non-acute back pain patients.

##### Design

After finding the conditions to enter the study, this clinical trial of patients was done using the block randomization method. It was assigned to two parallel control and intervention groups with the closed envelope method. TA sample size of 37 people will be provided in each group. Phase three, during which the effectiveness of the intervention is evaluated.

##### Settings and conduct

This study was conducted at Mashhad University of Medical Sciences. The intervention consisted of a session of abdominal muscle massage for 15 to 30 minutes in an intervention group and a lumbar muscle massage in the control group with the same duration and number of sessions. The analyst was unaware of the intervention and control groups. The examiner was unaware of grouping before and after the treatment, and the participants were

##### Participants/Inclusion and exclusion criteria

Patients with non-acute mechanical back pain

##### Intervention groups

The intervention group received abdominal muscle massage, and the control group received lumbar muscle massage.

##### Main outcome variables

Pain and range of motion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230212057390N1**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **retrospective**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

##### Registration date

2023-05-13, 1402/02/23

##### Registrant information

###### Name

Majid Shahbazi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3884 6710

###### Email address

shahbazim2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-10, 1401/06/19

##### Expected recruitment end date

2022-12-21, 1401/09/30

##### Actual recruitment start date

2022-09-10, 1401/06/19

##### Actual recruitment end date

2022-12-21, 1401/09/30

##### Trial completion date

2022-12-21, 1401/09/30

##### Scientific title

Comparison of the immediate effect of abdominal muscle massage with lumbar muscle massage in non-acute back pain patients

##### Public title

Investigation of the immediate effect of abdominal muscle massage in non-acute back pain patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients with non-acute mechanical back pain Disability level greater than 15% based on Oswestry modified questionnaire Presence of pain during at least one physiological movement of the back

**Exclusion criteria:**

RED flag patients, including malignancy, infection, fracture Patients who need surgery Pregnant patients Skin problems in patients<sup>5</sup>. Patients who are prohibited from massaging the abdominal area for any reason, such as patients with a recent history of abdominal obstruction, radiotherapy, and recent abdominal surgery, inflammatory bowel disease, or irritable bowel syndrome. Patients with acute back pain they cannot stand and perform tests.

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **74**

Actual sample size reached: **74**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This study will use the block randomization method to generate a sequence of random numbers. In this method, 15 blocks of size 4 and 7 blocks of size two will be randomly selected from the combination of letters A and B with the table of random numbers. The list of blocks with size two are 1:AB, 2:BA and the list of blocks with size four are 1:AABB, 2:ABBA, 3:BBAA, 4:BAAB, 5:BABA, 6:ABAB To select blocks of size 2, 7 numbers randomly from the table of random numbers are selected; if this number is from 0 to 4, the first block, and if the number is from 5 to 9, the second block will be selected. To select blocks of size 4, randomly 15 numbers between 1 to 6 will be selected from the table of random numbers; then, if this number is one, the first block of size four, and if the selected number is 2, the second block of size four and ..., will form our random sequence. After determining the random sequence, each person's type of treatment is placed in sealed envelopes, and referring patients, if they meet the criteria for entering the study, will receive their type of treatment based on the sequence obtained.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی مشهد

**Street address**

Department of Physical Therapy-School of Paramedical and Rehabilitation Sciences-University campus-Azadi square-Mashhad-Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Approval date**

2022-05-29, 1401/03/08

**Ethics committee reference number**

IR.MUMS.FHMPM.REC.1401.032

**Health conditions studied****1****Description of health condition studied**

non acute mechanical low back pain

**ICD-10 code**

M51.2

**ICD-10 code description**

due to intervertebral disc displacement

**Primary outcomes****1****Description**

Pain with the visual analog scale during back movements

**Timepoint**

Immediately before and after the intervention

**Method of measurement**

Visual Analog Scale

**Secondary outcomes****1****Description**

range of motion lumbar

**Timepoint**

Immediately before and after the intervention

**Method of measurement**

With two bubble inclinometer

**Intervention groups****1****Description**

Intervention group: In this study, the abdominal muscles

include rectus abdominis, paramedialis, and oblique abdominal muscles. The mentioned techniques are performed in the posture of archer and palmer. The treated muscles for the lumbar region are Quadratus Lumborum, Erector Spinae, Multifidus, and Rotators. The patient sleeps in a supine position in the abdominal muscle massage group. He is lying on his back. The therapist stands next to the client in the hip area. Place one hand flat on the upper abdomen near the chest, pass the other hand over the first hand, and place it on the lower abdomen on the other side (fingers on the ASIS). Let the hands sink into the tissue until they are involved with the superficial fascia of the abdomen. Separate the hands without letting them slide over the skin. Hold for release. Repeat on the opposite side. 3 minutes 3) The patient is lying on his back. The therapist stands next to the client in the pelvic area. Fingertips were placed on one side of the rectus abdominis muscle just above the pubic bone. Pressing firmly into the tissue, pull the fingertips upwards along the muscle towards the rib attachment. Repeat the same procedure on the other side. 3) The client is lying on his back. The therapist stands next to the client in the pelvic area. Place the supported thumb on the lateral border of the rectus abdominis muscle. Above the genital area, by pressing firmly on the tissue, slide the thumb along the muscle towards the upper joints on the muscle. Repeat the same procedure on the other side. 5 minutes 4) The client is lying on his back. The therapist stands next to the chest. Place the supported thumb at the junction of the ventral line with the pubis on the side closest to the therapist. Press the muscle firmly against the bone and look for tender points. Hold for freedom. Move the hand towards the middle to the next point and repeat this until the hand reaches the line in the center. Repeat this procedure on the other side. 5) The client is lying on his back. The therapist stands next to the lumbar region. Place the thumb tip on the rectus abdominis in the midline (middle line) just above the pubic area. Pushing firmly into the tissue, slide the thumb tip laterally toward the fingertips and prick. Repeat this procedure, starting just above the previous point. Repeat the same procedure along the abdominal line until reaching the chest. Repeat this procedure on the other side. 6) The patient sleeps prone. We stand next to the patient's chest. We repeat this technique on the opposite side until it covers the entire surface of the abdomen.

**Category**

Rehabilitation

**2**

**Description**

Control group: In the posterior muscle massage, first, the patient lies on his back for three minutes, and 3 bilateral superficial strokes are performed in the warm-up phase. 2) The therapist stands next to the participant's chest. Place the lumbar region next to the vertebrae on the iliac crest next to the sacrum bone. Pass the other hand over or under the first hand, placing it flat on the chest area over the lower three or four ribs, letting the hands sink into the tissue until it felt contact with the superficial fascia. Press in the opposite direction, with enough

downward pressure to stretch the superficial fascia. The therapist maintained the pressure until it felt the release of the fascia. Place both hands one hand's width apart for three minutes, and this technique 3) The patient sleeps prone, and the therapist stands next to the hip (to work in the upward direction). Place the heel of the hand on the erector spinae muscle bundle near the sacrum. By pressing firmly on the tissue, slide along the entire length of the muscle 3) The patient lies prone. The therapist stands next to the client's chest. We press the tips of the fingers or the supported thumb in the upper part of the sacrum and the lateral vertebrae firmly downward and outward inside the tissue and let it slide. Repeat this technique on the other side as well. For 5 minutes 4) The patient sleeps on his back. The therapist stands next to the client's back. Place the thumb or the tip of the finger (with or without support) on the space between the L5 vertebra and the sacrum. Apply lateral pressure (away from you); push the superficial muscles aside to reach the internal muscles. If the patient reports tenderness, hold the pressure to release. The therapist moved the hand and applied the technique between the upper two vertebrae. Repeat for three minutes until the 12th thoracic vertebra and the first lumbar vertebra. 5) Ischemic compression in painful points. Ischemic compression is applied in different ways to release trigger points and relax hypertonic areas. The thumb is used in the quadratus lumborum and around the sacroiliac joint. The quadratus lumborum is also pressed by the elbow.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Comprehensive Rehabilitation Center

**Full name of responsible person**

Majid Shahbazi

**Street address**

Department of Physical Therapy-School of Paramedical and Rehabilitation Sciences-University campus-Azadi square-Mashhad-Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

:9177948964

**Phone**

+98 51 3884 6710

**Fax**

+98 51 3884 6728

**Email**

shahbazim2@mums.ac.ir

**Web page address**

<https://sps.mums.ac.ir/>

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Shahbazi

**Street address**

Department of Physical Therapy-School of  
Paramedical and Rehabilitation Sciences-University  
campus-Azadi square-Mashhad-Iran

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Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3884 6710

**Email**

shahbazim2@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Shahbazi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Department of Physical Therapy-School of  
Paramedical and Rehabilitation Sciences-University  
campus-Azadi square-Mashhad-Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3884 6710

**Fax**

**Email**

shahbazim2@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Shahbazi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Department of Physical Therapy-School of  
Paramedical and Rehabilitation Sciences-University  
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**Postal code**

9177948964

**Phone**

+98 51 3884 6710

**Fax**

**Email**

shahbazim2@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Shahbazi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Department of Physical Therapy-School of  
Paramedical and Rehabilitation Sciences-University  
campus-Azadi square-Mashhad-Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177978131

**Phone**

+98 51 3884 6710

**Fax****Email**

shahbazim2@mums.ac.ir

**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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals

**When the data will become available and for how long**

After the article is published

**To whom data/document is available**

Journal, related researchers

**Under which criteria data/document could be used**

For further studies

**From where data/document is obtainable**

Mashhad University of Medical Sciences - Department of Physiotherapy

**What processes are involved for a request to access data/document**

Apply in writing to Mashhad University of Medical Sciences. shahbazim2@mums.ac.ir Majid Shahbazi

**Comments**