

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of myofascial release of psoas major muscle on lumbar spine kinematic and disability in the subjects with non-specific chronic low back pain

#### Protocol summary

##### Study aim

The aim of this study was to evaluate The effect of myofascial release of psoas major muscle on lumbar spine kinematic and disability in the subjects with non-specific chronic low back pain

##### Design

30 Individuals with non-specific chronic low back pain participate in this Double blind study, which is randomly divided into two groups of intervention and control using four random blocks.

##### Settings and conduct

Volunteer participants with non-specific chronic low back pain referred to the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences are included in the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria in this study Complete satisfaction to participate in this study, chronic non-specific low back pain with a minimum period of three months, age between 20-45, pain intensity 3-6, bilateral shortening of psoas major muscle, degree of disability 6-18 (from 24 points). Non-inclusion criteria include pregnancy, having systemic fibromyalgia, Cauda equina syndrome, spinal tumor, having autoimmune, infectious, vascular, endocrine, metabolic and neoplastic diseases, having previous experience of myofascial treatment or history of low back pain rehabilitation treatment Over the past two months, there has been a history of spinal surgery and other contraindications to myofascial therapy.

##### Intervention groups

The intervention group receives the technique of releasing the myofascia of psoas major muscle for four periods in two weeks (twice a week) for forty minutes on both sides. The control group symbolically receives the technique of releasing the myofascia of the Psoas major muscle in four periods of two weeks and for forty minutes on both sides.

##### Main outcome variables

Angular velocity, Angular displacement, Maximum range of motion, Relative phase, Maximum and minimum angular phase and time to reach them, Disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150602022539N12**

Registration date: **2022-04-19, 1401/01/30**

Registration timing: **prospective**

Last update: **2022-04-19, 1401/01/30**

Update count: **0**

##### Registration date

2022-04-19, 1401/01/30

##### Registrant information

##### Name

Ziaeddin Safavi Farokhi

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4180

##### Email address

zsafavi@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-29, 1401/02/09

##### Expected recruitment end date

2022-06-25, 1401/04/04

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of myofascial release of psoas major muscle on lumbar spine kinematic and disability in the subjects with non-specific chronic low back pain

**Public title**

The effect of myofascial release of psoas major muscle on lumbar spine kinematic and disability in the subjects with non-specific chronic low back pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Complete satisfaction to participate in this study  
People with nonspecific chronic low back pain with a minimum period of three months  
Age between 20-45  
Pain intensity 3-6  
Bilateral shortening of psoas major muscle  
Disability grade 6-18 (from 24 points)

**Exclusion criteria:**

Pregnancy  
Having systemic fibromyalgia, Cauda equina syndrome, spinal tumor  
Having autoimmune, infectious, vascular, endocrine, metabolic and neoplastic diseases  
History of spinal surgery and other criteria  
Contra-indicating use of myofascial therapy  
Have previous experience in myofascial treatment or a history of low back pain rehabilitation treatment in the last two months

**Age**

From **20 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyst

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, Permuted block randomization will be used for randomization, which includes 4 blocks (2 participants in the intervention group and 2 participants in the control group). Random allocation software is also used for randomization tools. In order to create an allocation concealment, each random sequence created is recorded on a card and the cards are placed in sealed opaque envelopes, respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. At the beginning of the registration of participants, according to the order of arrival, one of the envelopes is opened in order and the

assigned group of that participant is identified.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, blindness will be done in the participants. Participants from both groups will be admitted at different times for evaluation and intervention and will not be aware of the type of intervention of the other group. The implementation phase of this research is performed by another physiotherapist who is skilled in the field of manual therapies and the researcher who evaluates the outcome and Data analysis is involved. It is unaware of the grouping of participants and receives the data without knowing the grouping.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Semnan University of Medical Sciences

**Street address**

Semnan, km 5 of Damghan road, Semnan University of Medical Sciences

**City**

semnan

**Province**

Semnan

**Postal code**

3519899951

**Approval date**

2022-03-14, 1400/12/23

**Ethics committee reference number**

IR.SEMUMS.REC.1400.339

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

Non specific chronic low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

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

Angular velocity during stand to sit and sit to stand

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Motion analysis device

**2**

**Description**

Angular displacement during stand to sit and sit to stand

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Motion analysis device

**3**

**Description**

Maximum range of motion during stand to sit and sit to stand

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Motion analysis device

**4**

**Description**

Disability

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Ronald-Morris Questionnaire

**5**

**Description**

Relative phase during stand to sit and sit to stand

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Motion analysis device

**Secondary outcomes**

**1**

**Description**

Minimum phase angle during stand to sit and sit to stand

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Motion analysis device

**2**

**Description**

maximum phase angle during stand to sit and sit to stand

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Motion analysis device

**3**

**Description**

Time to reach the maximum phase angle during stand to sit and sit to stand

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Motion analysis device

**4**

**Description**

Time to reach the minimum phase angle during stand to sit and sit to stand

**Timepoint**

Before and immediately after the two-week intervention and one month after the intervention

**Method of measurement**

Motion analysis device

**Intervention groups**

**1**

**Description**

Control group: Symbolically receives the technique of releasing the myofascia of the Psoas major muscle in four periods of two weeks and for forty minutes on both sides

**Category**

Rehabilitation

**2**

**Description**

Intervention group: receives the technique of releasing the myofascia of psoas major muscle for four periods in two weeks (twice a week) for forty minutes on both sides.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

**Full name of responsible person**

Ziaeddin Safavi Farokhi

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Parviz Kookhaei

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Semnan, Mashahir Square, in front of the Red Crescent Center of Semnan

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p-kokha@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Ziaeddin Safavi Farokhi

**Position**

Ph.D, Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

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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