Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effects of Iliopsoas Strain-Counterstrain Technique and McKenzie Exercise Therapy on Directional Preference in Patients with Chronic Non-Specific Low Back Pain

Protocol summary

Study aim

The main objective of this study is to compare the effect of iliopsoas Strain Counterstrain technique with McKenzie exercise therapy on directional preference in patients with chronic non specific low back pain.

Design

Randomized controlled clinical trial, parallel groups, single-blind (assessor-blinded), on 100 patients with chronic non-specific low back pain; randomization in a 1:1 ratio using a randomization website.

Settings and conduct

This study will be conducted at the physiotherapy clinic of School of Rehabilitation Sciences, Tehran University of Medical Sciences and Rofideh Rehabilitation Hospital. Eligible patients will be randomly allocated to two treatment groups after baseline assessment and informed consent. Both groups will receive 3 treatment sessions (approximately 30 minutes each) within a maximum of one week. Pre- and post-intervention assessments will be performed by a blinded evaluator.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18-70 years, non-specific low back pain for more than three months, presence of iliopsoas tender point, and mechanical low back dysfunction. Exclusion Criteria: Red flags (fracture, tumor, infection), history of lumbar or pelvic surgery, pregnancy, radiculopathy, acute iliopsoas injury, and unwillingness to participate.

Intervention groups

Strain Counterstrain group: Participants receive the Strain Counterstrain technique on iliopsoas tender points (position of comfort held for 90 seconds per point). McKenzie group: Participants are assessed using the McKenzie method and perform repeated movements in their identified directional preference. Both groups will receive 3 treatment sessions (approximately 30 minutes each) over a maximum of one week.

Main outcome variables

Directional preference status (stable, changed, or newly developed) measured before and after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260206068774N1**
Registration date: **2026-05-17, 1405/02/27**
Registration timing: **prospective**

Last update: **2026-05-17, 1405/02/27**
Update count: **0**

Registration date

2026-05-17, 1405/02/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-19, 1405/02/29

Expected recruitment end date

2026-07-21, 1405/04/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Iliopsoas Strain-Counterstrain Technique and McKenzie Exercise Therapy on Directional Preference in Patients with Chronic Non-Specific Low Back Pain

Public title
Effect of Iliopsoas Muscle Treatment Combined with the McKenzie Method in Chronic Low Back Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with non-specific chronic low back pain (NSCLBP) with duration of more than 3 months (≥12 weeks). Age between 18 and 70 years. Presence of mechanical low back dysfunction based on clinical assessment. Presence of at least one tender point in the iliopsoas muscle (unilateral or bilateral). Absence of relevant lateral shift.
Exclusion criteria:
Loss or absence of Directional Preference (DP) in the initial assessment Skin infection in the groin area. Acute iliopsoas injury (hematoma or acute strain). History of inguinal hernia repair with mesh. Pelvic visceral disorders. History of pelvic surgery. Pregnancy at the time of the study. Fracture, tumor, inflammatory or infectious diseases of the spine. Evidence of nerve root involvement (radiculopathy) such as muscle weakness, reflex changes, or sensory deficits in the lower extremities. History of lumbar spine surgery. Lumbar spinal fusion. Bowel or bladder incontinence, or saddle anesthesia (symptoms of Cauda Equina Syndrome). Cognitive impairment or inability to communicate effectively. Unwillingness to continue participation in the study. Inability to read and write.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a parallel-group, single-blind randomized clinical trial. Eligible participants will be randomly allocated to one of the two study groups (Strain-Counterstrain or McKenzie) in a 1:1 ratio using blocked randomization with randomly permuted blocks of size 4. The randomization sequence will be generated by an independent person not involved in the study using the website Randomization.com. To ensure allocation concealment, the randomization codes will be placed in sequentially numbered, opaque, sealed envelopes. Envelopes will be opened only after the participant has been recruited and has completed the baseline assessment
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the interventions (manual therapy technique versus exercise therapy), it is not possible to blind the therapists or participants. However, this study is designed as single-blind. The outcome assessor (evaluator) who performs the pre- and post-intervention assessments (including MDT evaluation, Directional Preference determination, range of motion, and pain assessment) will be blinded to group allocation. In addition, the statistician who performs the data analysis will also be blinded to group assignment. All data will be coded (e.g., Group A and Group B) before being provided to the statistician.
Placebo
Not used
Assignment
Parallel
Other design features
This is a parallel-group, single-blind randomized clinical trial. Participants will be randomly assigned (1:1 ratio) using blocked randomization with blocks of 4 to either the Iliopsoas Strain-Counterstrain group or the McKenzie Method group. Both groups will receive 3 treatment sessions (approximately 30 minutes each) over a maximum of one week. Pre- and post-intervention assessments will be performed by a blinded evaluator. The primary outcome is Directional Preference status (categorized as Stable, Changed, or Newly Developed). Data analysis will be conducted based on the Intention-to-Treat principle. This is a non-pharmacological interventional study

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Rooms 604-605, 6th Floor, Central Office Building, Tehran University of Medical Sciences, Keshavarz Boulevard, at the corner of Ghods Street, Tehran, Iran
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Approval date

2025-12-24, 1404/10/03

Ethics committee reference number

IR.TUMS.FNM.REC.1404.208

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

Directional Preference status, Directional Preference status is categorized into three groups: stable (direction remains the same before and after treatment), changed (direction changes after treatment), or newly developed (directional preference appears after treatment).

Timepoint

before the intervention (baseline) and after completion of three treatment sessions (post-intervention).

Method of measurement

Assessed using the standards McKenzie Lumbar Assessment Form by a certified McKenzie therapist. Directional preference is determined based on the patient's response to repeated movements in different directions.

Secondary outcomes

1

Description

Intensity and quality of pain

Timepoint

Before intervention and after three treatment sessions

Method of measurement

Short-Form McGill Pain Questionnaire (SF-MPQ)

2

Description

Flexion and extension range of motion of the lumbar spine

Timepoint

Before intervention and after three treatment sessions

Method of measurement

Using TiltMeter smartphone application installed on an iPhone

Intervention groups

1

Description

Intervention group: Strain Counterstrain technique applied to tender points of the iliopsoas muscle. The therapist identifies tender points and places the limb in a position of comfort (at least 70% pain reduction at the tender point), which is held for 90 seconds. A maximum of 1 to 2 tender points per side are treated. This intervention is performed in 3 treatment sessions (approximately 30 minutes each) over a maximum of one week.

Category

Treatment - Other

2

Description

Control group: Mechanical Diagnosis and Therapy (McKenzie Method). Participants are first assessed using the standard McKenzie lumbar assessment form to determine directional preference. They then perform repeated movements in the identified directional preference (flexion, extension, or lateral) with loading progression. This intervention is also delivered in 3 treatment sessions (approximately 30 minutes each) over a maximum of one week.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh Rehabilitation hospital

Full name of responsible person

Amirhossein Kahlaee

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2

Recruitment center

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Sponsors / Funding sources

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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

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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