Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of motor control exercises with and without McKenzie exercises on Kinesiophobia and pain self-efficacy in chronic low back pain patients

Protocol summary

Study aim
Effect of motor control exercises with and without McKenzie therapy on kinesiophobia and pain self-efficacy in chronic low back pain patients

Design
A single-blind, controlled clinical trial with parallel groups, block-randomized (block size = 6), conducted on 48 patients with low back pain (24 per group).

Settings and conduct
Patients with chronic low back pain referred to the Mashhad Comprehensive Rehabilitation Center will be evaluated using the McKenzie method. Those with a directional preference for extension or lateral flexion will be randomly assigned to receive either electrotherapy with motor control exercises or the same program plus McKenzie exercises. Treatments will be provided three times per week for ten sessions, with reassessment at the end. Home exercises will be monitored, and the outcome assessor will be blinded to group allocation.

Participants/Inclusion and exclusion criteria
This single-blind, parallel, randomized controlled trial includes patients aged 20–50 years with chronic low back pain who show a directional preference for extension or lateral movements, moderate to severe kinesiophobia, and pain intensity above 3. Exclusion criteria include prior lumbar surgery or fracture, spinal malignancy or infection, pregnancy, spondylolisthesis, previous McKenzie therapy, lack of directional preference, sequestrated disc, contraindications to exercise, or poor compliance with home exercises.

Intervention groups
The intervention group will receive 10 sessions of electrotherapy plus motor control and McKenzie exercises, while the control group will receive electrotherapy and motor control exercises only.

Main outcome variables
Kinesiophobia and Pain self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251029067812N1**
Registration date: **2025-11-05, 1404/08/14**
Registration timing: **prospective**

Last update: **2025-11-05, 1404/08/14**
Update count: **0**

Registration date
2025-11-05, 1404/08/14

Registrant information

Name
Tahere Seyedhoseinpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3219 4641

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01

Expected recruitment end date
2026-05-22, 1405/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of motor control exercises with and without McKenzie exercises on Kinesiophobia and pain self-efficacy in chronic low back pain patients

Public title
Effect of motor control exercises with and without McKenzie exercises on Kinesiophobia and pain self-efficacy in chronic low back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged between 20 and 50 years. Patients experiencing unilateral or bilateral pain extending from the T12 vertebra downward to the gluteal fold, with or without lower limb pain. Patients with chronic low back pain (lasting more than three months). Patients with chronic low back pain who, based on the McKenzie assessment, demonstrate a directional preference for extension or lateral movements Patients who score moderate to severe levels of kinesiophobia on the Fear-Avoidance Beliefs Questionnaire (score greater than 48). Patients reporting pain intensity greater than 3

Exclusion criteria:
History of lumbar spine fracture or spinal surgery Presence of progressive malignant disease Cauda equina syndrome Cancer or other neoplastic conditions Spinal tumors Inflammatory or infectious diseases of the spine Pregnancy Spondylolisthesis Patients who have previously undergone McKenzie therapy Patients for whom no directional preference can be identified Patients with a sequestrated disc, confirmed by MRI In general, any individual with contraindications to exercise therapy or repetitive movements (with or without therapist-applied pressure) Lack of compliance in performing prescribed home exercises

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

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
In this parallel randomized controlled trial, since participants do not enter the study simultaneously and the investigators cannot predict which treatment group each patient will be assigned to, the block randomization method will be employed. In order to ensure an equal number of patients with different directional preferences (extension and lateral flexion, according to the McKenzie approach) in the two study groups, stratified sampling will be conducted using two strata. In this study, eligible participants who provide informed consent will be randomly assigned to either the intervention group or the control group in a 1:1 ratio, using a block randomization procedure (blocks of six) generated by the Random Allocation Software. The allocation process is designed to ensure that the investigators cannot predict the group assignment of the next participant. The randomization codes will be sequentially placed in opaque sealed envelopes, and as each new participant is enrolled, the clinic secretary will open the next envelope to determine the participant's group assignment.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blind trial. The outcome assessor, who is responsible for evaluating the study outcomes, will be blinded to the participants' group allocation and will operate independently from the physiotherapist responsible for administering the interventions in each group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganj Afrooz St, Kargar Sq, Babol, Mazandaran

City
Babol

Province
Mazandaran

Postal code
47745-47176

Approval date
2025-10-13, 1404/07/21

Ethics committee reference number
IR.MUBABOL.REC.1404.142

Health conditions studied

1

Description of health condition studied
Chronic low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Kineziophobia
Timepoint
Before Intervention and after completing 10 sessions of intervention
Method of measurement
Kineziophobia will be assessed using the persion version of the Fear-Avoidance Beliefs Questionnaire.

2

Description
Pain self-efficacy
Timepoint
Before Intervention and after completing 10 sessions of intervention
Method of measurement
Pain self-efficacy will be measured using the Persian version of Pain Self-Efficacy Scale.

Secondary outcomes

1

Description
Pain intensity
Timepoint
Before intervention and after completing 10 sessions of intervention
Method of measurement
Pain intensity will be measured using the Visual Analogue Scale.

2

Description
Functional disability
Timepoint
Before intervention and after completing 10 sessions of intervention
Method of measurement
The level of functional disability will be assessed using the Persian version of the Roland-Morris Disability Questionnaire.

Intervention groups

1

Description
The intervention group will receive ten sessions of electrotherapy combined with motor control exercises and McKenzie exercises.
Category
Rehabilitation

2

Description
The control group will receive ten sessions of electrotherapy combined with motor control exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Comprehensive Rehabilitation Center
Full name of responsible person
Tahere Seyedhoseinnpoor
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Babol University of Medical Sciences, Ganj Afrooz St, Kargar Sq, Babol, Mazandaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Reza Ghadimi
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Tahere Seyedhoseinpoor
Position
Assistant Professor
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
An Excel file containing data related to the primary and secondary outcomes will be shared.
When the data will become available and for how long
Access will be granted after the publication of the study results.
To whom data/document is available
The data will be available to researchers affiliated with academic and scientific institutions.
Under which criteria data/document could be used
ChatGPT said: The Excel data file will be available solely for academic use upon request.
From where data/document is obtainable
Via Email: t.seyedhoseinpoor@mubabol.ac.ir

What processes are involved for a request to access data/document	Request via email
Comments	