

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, sequestered 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)

Phone

+98 11 3219 4641

Email address

t.seyedhoseinpoor@mubabol.ac.ir

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 sequestered 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 Afroz 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 Persian 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 Seyedhoseinpoor

Street address

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

City

Babol

Province

Mazandaran

Postal code

47745-47176

Phone

+98 11 3219 4641

Email

t.seyedhoseinpoor@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

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

City

Babol

Province

Mazandaran

Postal code

47745-47176

Phone

+98 11 3219 7667

Email

r.ghadimi@mubabol.ac.ir

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

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Babol University of Medical Sciences, Ganj Afroz St,
Kargar Sq, Babol, Mazandaran

City

Babol

Province

Mazandaran

Postal code

47745-47176

Phone

+98 11 3219 4641

Email

t.seyedhoseinpoor@mubabol.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Tahere Seyedhoseinpoor

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Babol University of Medical Sciences, Ganj Afroz St,
Kargar Sq, Babol, Mazandaran

City

Babol

Province

Mazandaran

Postal code

47745-47176

Phone

+98 11 3219 4641

Email

t.seyedhoseinpoor@mubabol.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Tahere Seyedhoseinpoor

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Babol University of Medical Sciences, Ganj Afroz St,
Kargar Sq, Babol, Mazandaran

City

Babol

Province

Mazandaran

Postal code

47745-47176

Phone

+98 11 3219 4641

Email

t.seyedhoseinpoor@mubabol.ac.ir

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