

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of motor control exercises combined with self-compassion based on mindfulness training on pain, disability, psychological factors and lumbopelvic kinematic during lifting in patients with chronic nonspecific low back pain.

Protocol summary

Study aim

The effect of motor control exercise combined with self-compassion based on mindfulness training on pain, disability, psychological factors, and kinematic variables of the lumbopelvic in patients with non-specific chronic low back pain.

Design

A controlled clinical trial with parallel groups, single-blind, randomized, on 99 patients, using the instructions available on the website (<http://randomizer.org>) for randomization.

Settings and conduct

Assessments will be conducted 2 weeks before and after the intervention in Javad Mofavaghian's Clinical Movement Analysis Laboratory. The protocol will be implemented at the Dofika Health Center. In this study, patients are unaware of the randomization process.

Participants/Inclusion and exclusion criteria

The inclusion criteria: Persian-native female and male, primary complaint of low back pain (more than 3 months, experienced between L1 and the gluteal fold without pathoanatomical cause) confirmed by an orthopedic specialist; The exclusion criteria: previous spinal surgery and neurological signs, specific spinal pathology and Conditions that may be uncontrolled for self-compassion meditation (psychosis, major depression or anxiety), pregnancy.

Intervention groups

Group 1, Will receive motor control exercise 3 times a week (for 8 weeks). Group 2, Will receive motor control exercise (3 times a week) along with mindfulness-based self-compassion training (1 time a week) for 8 weeks.

Main outcome variables

Pain; disability; catastrophizing pain; fear avoidance beliefs; fear of movement; angular velocity of the lumbopelvic during lifting; range of motion (ROM) lumbar

flexion relative to the hip during lifting; ROM lumbar flexion relative to the pelvic during lifting; ROM pelvic relative to the hip during lifting.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240325061364N1**

Registration date: **2025-05-21, 1404/02/31**

Registration timing: **registered_while_recruiting**

Last update: **2025-05-21, 1404/02/31**

Update count: **0**

Registration date

2025-05-21, 1404/02/31

Registrant information

Name

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Name of organization / entity

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Kharazmi University

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-13, 1404/01/24

Expected recruitment end date

2025-06-09, 1404/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of motor control exercises combined with self-compassion based on mindfulness training on pain, disability, psychological factors and lumbopelvic kinematic during lifting in patients with chronic nonspecific low back pain.

Public title

Effect of self-compassion exercises combined with motor control exercises on chronic non-specific low back pain.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Persian-native (female and male) primary complaint backpain (more than 3 months, experienced between L1 and the gluteal fold without pathoanatomical cause) confirmed by an orthopedic specialist.

Exclusion criteria:

Previous spinal surgery and neurological signs Specific spinal pathology Conditions that may be uncontrolled for self-compassion meditation (psychosis, major depression or anxiety) pregnancy

AgeFrom **18 years** old to **69 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

Following the baseline examination, by using the method on the website <http://randomizer.org/> (Social Psychology Network, Connecticut, USA), participants are randomly assigned into the two experimental groups (motor control_ self-compassion and motor control) and control group. This site uses the random. Math method in the programming language, JavaScript is used as the main method for generating random numbers. The allocation concealment is done using a computer-generated block randomization table, where the number 1 will be defined for the motor control training group with self-compassion training, the number 2 for the motor control training group, and the number 3 for the control group. Then the random number sequence will be placed in opaque and sealed envelopes. Also, the treatment will be continued by the researcher according to the group assignment.

Finally, the results will be evaluated before the interventions and eight weeks after the interventions.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the patients was blind to the process of randomization and assignment of individuals into experimental and control groups. During the intervention, participants will only be familiar with the members of their own therapy group. Each group will receive the treatment at different times to prevent contact between participants from the two groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

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Approval date

2024-03-03, 1402/12/13

Ethics committee reference number

IR/SSRI.REC.2024.15963.2536

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**

Pain

Timepoint

2 weeks before intervention, 2 weeks after intervention

(12th week)

Method of measurement

Using a visual analog pain scale or pain ruler (scale 0 to 10)

Secondary outcomes

1

Description

disability

Timepoint

2 weeks before intervention, 2 weeks after intervention (12th week)

Method of measurement

Using the Persian translation of the Roland Morris Disability Questionnaire

2

Description

Fear-avoidance beliefs

Timepoint

2 weeks before intervention, 2 weeks after intervention (12th week)

Method of measurement

Using the Persian translation of the 16-item Fear Avoidance Beliefs Questionnaire

3

Description

Catastrophic pain

Timepoint

2 weeks before intervention, 2 weeks after intervention (12th week)

Method of measurement

Using the Persian translation of the Catastrophizing Pain Scale

4

Description

Fear of movement

Timepoint

2 weeks before intervention, 2 weeks after intervention (12th week)

Method of measurement

Using the Persian translation of the Tampa Scale of Kinesiophobia

5

Description

Range of motion of the lumbar flexion relative to the pelvis during forward bending and lifting

Timepoint

2 weeks before intervention, 2 weeks after intervention (12th week)

Method of measurement

Using a 3D motion capture device while bending forward and lifting a load at their chosen speed for up to 5 repetitions.

6

Description

Range of motion of the lumbar flexion relative to the hip while bending forward and lifting a load

Timepoint

2 weeks before intervention, 2 weeks after intervention (12th week)

Method of measurement

Using a 3D motion capture device while bending forward and lifting a load at their chosen speed for up to 5 repetitions.

7

Description

Range of motion of hip flexion relative to the pelvis during forward bending and lifting

Timepoint

2 weeks before intervention, 2 weeks after intervention (12th week)

Method of measurement

Using a 3D motion capture device while bending forward and lifting a load at their chosen speed for up to 5 repetitions.

8

Description

Angular velocity of the lumbopelvic during forward bending and lifting of a load

Timepoint

2 weeks before intervention, 2 weeks after intervention (12th week)

Method of measurement

Using a 3D motion capture device while bending forward and lifting a load at their chosen speed for up to 5 repetitions.

Intervention groups

1

Description

Intervention group: Participants in this group will engage in 24 sessions of motor control exercises over 8 weeks, with each session lasting 30 minutes, supervised by two movement science specialists. This protocol is designed to facilitate patient rehabilitation by improving spinal and pelvic girdle control and coordination through motor learning principles such as segmentation and simplification. The first phase of treatment involves assessing posture, movement patterns, and muscle activation patterns based on symptoms (reduced activation of deep lumbopelvic muscles) to design personalized exercises tailored to each individual's needs. If therapeutic goals are achieved in the first phase, the second phase will incorporate more functional activities aimed at improving coordination in both static and dynamic conditions. As movement improves, the duration and number of repetitions will be gradually increased.

Category

Treatment - Other

2

Description

Intervention Group: Participants in this group will engage in 8 sessions of Mindfulness-Based Self-Compassion training over 8 weeks, facilitated by two clinical psychologists. Each session of the Mindfulness-Based Self-Compassion protocol focuses on a specific topic. The first session introduces and provides a general overview of self-compassion. The second session offers foundational information about mindfulness. In the third week, the application of self-compassion in various life aspects, including chronic pain, will be discussed. Week four helps participants develop a compassionate inner voice in various situations. The fifth week emphasizes living according to core values. In week six, coping skills for dealing with difficult emotions will be taught. Week seven focuses on managing and facing challenging interpersonal relationships. In the final session, the discussion will revolve around how to connect with one's positive aspects and life, accompanied by gratitude. Between the fourth and fifth sessions, a half-day session lasting 4 hours will be held, involving various types of meditation, restorative yoga, and mindful eating in complete silence. The self-compassion approach, which includes self-kindness during moments of pain and suffering, leads to improvements in pain-related functioning, disability, and increased brain awareness, altering the pain processing mechanism. It also enhances psychological variables (reducing stress, anxiety, pain catastrophizing, increasing self-efficacy, life satisfaction, and sleep quality) in patients with chronic low back pain.

Category

Behavior

3

Description

Control group: It does not receive any intervention and is evaluated to compare the changes made in the other two groups.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dofika health center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Kharazmi

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

No governmental fund has been received for this study, and it is conducted by researchers.

Proportion provided by this source

100

Public or private sector

Private

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

The University of Kharazmi

Full name of responsible person

Amir LetafatKar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Science

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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