

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of a multimodal intervention based on physical exercise, mindfulness, behavior change and education on pain, disability, kinesiophobia, movement patterns and trunk muscle endurance in employees with chronic non-specific low back pain

Protocol summary

Study aim

The main aim of the study is to determine the effect of a multifaceted intervention on pain, disability, kinesiophobia, movement patterns, and trunk muscle endurance in employees with non-specific chronic low back pain.

Design

The study design is a quasi-experimental clinical trial with a control group and two parallel groups. The sample size includes 48 male employees with chronic nonspecific low back pain, purposefully selected and then randomly assigned to intervention (24 participants) and control (24 participants) groups. Randomization is performed using the RAND function in Microsoft Excel. This study is in the intervention efficacy evaluation phase.

Settings and conduct

The study is conducted in a sports hall belonging to the Ministry of Education, and the interventions are delivered by myself, a corrective exercise student. Assessments are performed by evaluators blinded to group allocation.

Participants/Inclusion and exclusion criteria

Male employee with non-specific chronic low back pain (lasting more than 12 weeks), able to move independently, without serious structural spinal disorders, no acute or terminal illness, no recent physical injury or severe physical/mental disease, no concurrent treatment or regular exercise for low back pain, and providing informed consent.

Intervention groups

The intervention group (24 participants) receives an 8-week multifaceted program including 16 physical exercise sessions, 8 mindfulness sessions, a behavior change app program, and 5 pain neuroscience education sessions. The control group (24 participants) receives usual care with no specific intervention.

Main outcome variables

The primary outcomes of the study include pain intensity; degree of back disability; quality of life; lumbar range of motion; and participants' stress levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260703070057N1**

Registration date: **2026-07-10, 1405/04/19**

Registration timing: **prospective**

Last update: **2026-07-10, 1405/04/19**

Update count: **0**

Registration date

2026-07-10, 1405/04/19

Registrant information

Name

Mohammadamin Dadgar

Name of organization / entity

Buali Sina university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-09-01, 1405/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a multimodal intervention based on physical exercise, mindfulness, behavior change and education on pain, disability, kinesiophobia, movement patterns and trunk muscle endurance in employees with chronic non-specific low back pain

Public title

Effect of physical exercises and mindfulness on chronic low back pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Male employee. Diagnosed with non-specific chronic low back pain lasting more than 12 weeks. Provided written informed consent. Able to walk and move without external assistance.

Exclusion criteria:

Presence of serious structural spinal disorders such as spondylolysis, spondylolisthesis, spinal canal stenosis, degenerative disc disease, herniated disc, tumor, trauma, fracture, cauda equina syndrome, or radicular pain. Acute or terminal illness. Recent physical injury. Severe physical or psychiatric illness preventing participation in the study. Medical prescription contraindicating participation in the intervention.

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals were randomly assigned to the research groups. The randomization process was carried out using a Random Number Generator software. Specifically, a random number was generated for each participant, and based on the sequence of the generated numbers, the participants were assigned to the study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator responsible for recording and analyzing the data was not aware of the allocation of the participants to the experimental and control groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary ids**

empty

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

Ethics committee of Buali sina university

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Hamedan, Modarres Town, Abutaleb Street, Bu-Ali Sina University

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Approval date

2026-04-25, 1405/02/05

Ethics committee reference number

IR.BASU.REC.1405.003

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

Chronic nonspecific low back pain (CNSLBP)

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Kinesiophobia (fear of movement)

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Altered lumbar movement patterns

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

Reduced trunk muscle endurance

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Primary outcome variable 1: Pain intensity measured by the Numerical Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst possible pain). Primary outcome variable 2: Degree of back disability assessed by the Oswestry Disability Index (ODI), scored from 0 to 100. Primary outcome variable 3: Health-related quality of life measured by the SF-36 questionnaire, covering physical and mental health domains. Primary outcome variable 4: Lumbar range of motion measured with a goniometer in flexion and extension directions. Primary outcome variable 5: Participants' stress level assessed using the stress subscale of the DASS-21 questionnaire.

Timepoint

Before the intervention begins (pre-test) Immediately after the 8-week intervention period (post-test) One-month follow-up after the intervention completion

Method of measurement

Pain intensity is measured using the Numerical Rating Scale, which ranges from zero (no pain) to ten (worst possible pain). Degree of back disability is assessed by the Oswestry Disability Index questionnaire, scored from zero to one hundred. Kinesiophobia is evaluated using the Tampa Scale of Kinesiophobia, which includes questions about fear of movement. Lumbar movement patterns are measured by the Lumbar Motor Control Test, assessing controlled movement performance. Trunk muscle endurance is assessed by the Biering-Sorensen Test, which records the time a specific position is maintained.

minutes of light activity such as walking or stretching. Alerts are disabled during sleep and naps. Pain neuroscience education program: Five two-hour sessions every two weeks conducted by a specialized physiotherapist using slides, metaphors, images, and interactive discussions. Topics cover pain defense systems, neuroplasticity, maladaptive learning, and tools for reversing changes to enable sustainable pain self-management.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Education Department

Full name of responsible person

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Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The multimodal intervention consists of four main components delivered over eight weeks: Supervised physical exercise program: Sixteen sessions of 45 minutes each (two sessions per week) focusing on strengthening trunk core muscles. Each session includes 5 minutes of warm-up, 35 minutes of main strengthening exercises, and 5 minutes of cool-down with static stretching. Exercise intensity is regulated using the Rating of Perceived Exertion scale to avoid pain induction. Mindfulness-based stress reduction program: Eight weekly group sessions of 2.5 hours each using an adapted Mindfulness-Based Stress Reduction protocol by Kabat-Zinn. Sessions include practical exercises such as body scan, breathing meditation, gentle yoga, and compassion meditation, with daily home practice of 30 to 45 minutes. Continuous behavior change program: Use of free applications Google Fit, Samsung Health, or Apple Health to provide hourly inactivity alerts over 12 waking hours, prompting two

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Buali Sina University

Full name of responsible person

Farzaneh Saki

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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

Buali Sina University
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

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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