Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of a multimodal intervention based on physical exercise, mindfulness, behavior change andeducation on pain, disability, kinesiophobia, movement patterns and trunk muscle endurance in employeeswith 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
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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 andeducation on pain, disability, kinesiophobia, movement patterns and trunk muscle endurance in employeeswith 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
Street address
Hamedan, Modarres Town, Abutaleb Street, Bu-Ali Sina University
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Province
Hamadan
Postal code
3869565178
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.

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 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
MohammadAmin Dadgar

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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

Name of organization / entity
Bu-Ali Sina University.

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MohammadAmin Dadgar

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Sports Rehabilitation

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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