Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of reactive – core training on pain, some functional characteristics and quality of life in male with non-specific low back pain

Protocol summary

Study aim
investigates the effects of reactive core stability training on pain, selected functional characteristics, and quality of life in patients with non-specific chronic low back pain

Design
This semi-experimental study uses a pre-test/post-test design with two groups. Participants are men and women aged 40–60 with chronic low back pain, recruited from orthopedic and neurology clinics in Meshkinshahr.

Settings and conduct
The study will take place at the University of Isfahan's Faculty of Physical Education. Sessions will be held indoors under professional supervision, three times per week for eight weeks, following standardized protocols.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1- Pain (2-5 based on the VAS scale) 2- Gender: Male and female, age range 40-60 3- Chronic back pain for more than three months 4- Ability to perform exercises (based on the opinion of a specialist) 5- Voluntary participation in the study Exclusion criteria will include patients with a history of spondylolisthesis, osteoporosis, inflammatory rheumatic diseases, acute disc herniation, any spinal surgery, irregular participation in training sessions (3 consecutive sessions - 5 alternating sessions), failure to complete research tests, any unforeseen problem that prevents the subject from participating in training, and voluntary withdrawal.

Intervention groups
Group 1: Reactive core stability exercises, 3 sessions/week for 8 weeks under supervision. Group 2: Conventional core stability exercises, same schedule, based on standard physiotherapy protocols for chronic low back pain.

Main outcome variables
In this study, the main outcome variables included pain intensity, functional disability, motor function, gait, muscle strength, muscle endurance, joint range of motion, fear of movement, and quality of life in patients with chronic nonspecific low back pain.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241128063883N1**
Registration date: **2025-10-31, 1404/08/09**
Registration timing: **prospective**

Last update: **2025-10-31, 1404/08/09**
Update count: **0**

Registration date
2025-10-31, 1404/08/09

Registrant information

Name
Vahid seyedazizi

Name of organization / entity
Esfahan univercity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-11, 1404/08/20

Expected recruitment end date
2026-01-21, 1404/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of reactive – core training on pain, some functional characteristics and quality of life in male with non-specific low back pain

Public title
reactive – core training for Reducing Chronic Low Back Pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having pain (2-5 based on the var scale) The gender of men and women in the age range of 40-60 Chronic back pain for more than three months The ability to do exercises (based on the opinion of a specialist doctor) Voluntary participation in the study

Exclusion criteria:
History of spondylolisthesis rheumatic inflammatory diseases acute disc herniation had any spinal surgery irregular participation in training sessions (3 consecutive sessions - 5 alternating sessions) failure to complete research tests any unpredictable problems that hinder The subject's presence in the training withdrawal will be voluntary

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Somewhere University of esfahan

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5661611453

Approval date
2024-12-07, 1403/09/17

Ethics committee reference number
IR.UI.REC.1403.134

Health conditions studied

1

Description of health condition studied
Non-specific low back pain

ICD-10 code
M54.9

ICD-10 code description
Dorsalgia, unspecified

Primary outcomes

1

Description
Low back pain

Timepoint
Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement
Pain assessment with VAS scale, fear of movement assessment with Tempa scale, quality of life assessment with SF36 test, functional disability assessment with ODI index, strength assessment with digital dynamometer, endurance assessment with McGill test, back flexibility assessment with Schuber test, motor performance assessment With Lomajuki test

Secondary outcomes

1

Description
Gait Performance

Timepoint
Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement
With foot scan device

2

Description
Pain intensity

Timepoint
Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-

week reactive–core stability exercise program

Method of measurement

Pain assessment with Vas scale

3

Description

Fear of movement

Timepoint

Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement

fear of movement assessment with Tempa scale

4

Description

Quality of life

Timepoint

Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement

quality of life assessment with SF36

5

Description

Functional disability

Timepoint

Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement

functional disability assessment with ODI index

6

Description

Core muscle strength

Timepoint

Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement

strength assessment with digital dynamometer

7

Description

Muscular endurance

Timepoint

Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement

endurance assessment with McGill test

8

Description

Lumbar flexibility

Timepoint

Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement

back flexibility assessment with Schuber test

9

Description

Motor performance

Timepoint

Outcome variables will be measured at two timepoints: > 1. Baseline – prior to the start of the intervention > 2. Post-intervention – immediately after completing the 8-week reactive–core stability exercise program

Method of measurement

motor performance assessment With Lomajuki test

Intervention groups

1

Description

Intervention group: Participants in the intervention group performed a combined reactive–core stability exercise program for eight weeks, consisting of three sessions per week, each lasting approximately 60 minutes.Each session included three phases:1. Warm-up (10 min): Walking, dynamic and stretching exercises, followed by 5 minutes of moderate-intensity cycling on a stationary bike.2. Main exercises (40 min): The core program included reactive–core stability exercises such as abdominal vacuum on a ball, bridge with resistance band, bird-dog on a ball, isometric and balance exercises in unstable positions. Exercise intensity was progressively increased from week 1 to week 8 (holding time from 12 to 30 seconds). Swiss ball and elastic bands were used as auxiliary tools. Exercise load was adjusted based on each participant’s pain tolerance, and movements were modified if discomfort occurred.3. Cool-down (5 min): Light walking and gentle stretching to return the body to the initial state.All sessions were supervised by the researcher and assisted by a nurse. The training aimed to improve motor control, enhance core stability, and activate deep lumbar–pelvic muscles (multifidus and transversus abdominis).

Category

Rehabilitation

2

Description

Control Group: Participants in the control group engaged in a conventional core stability exercise program for eight weeks, with three sessions per week (each lasting approximately 60 minutes). Each session consisted of three parts:1. Warm-up (10 minutes): Light walking,

general stretching exercises, and basic mobility drills to prepare the body for training.2. Main phase (40 minutes): Standard core stability exercises such as basic glute bridges, abdominal and lumbar strengthening routines performed in stable positions, and isometric holds without the use of unstable surfaces. Exercise intensity remained consistent throughout the program and followed standard rehabilitation protocols. No reactive or instability-based movements were included. Exercises were adjusted based on each participant's pain tolerance.3. Cool-down (10 minutes): Gentle stretching and slow walking to return the body to its resting state.All sessions were supervised by the researcher and conducted in the presence of a nurse. The aim of this program was to maintain and enhance basic core function without incorporating reactive or instability-focused components.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Vice Presidency For Research and Technology, University Of Isfahan

Grant code / Reference number
Not applicable

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

Title of funding source
University Of Isfahan – Physical Education Department Of The University Of Isfahan

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
Isfehan Univercity

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Vahid Seyedazizi

Position
Ph. D. Candidate

Latest degree
Master

Other areas of specialty/work
Corrective Exercise And Sport Injury

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Effect of reactive – core training on pain, some functional characteristics and quality of life in patiant with non-specific low back pain

When the data will become available and for how long
The data will become available after the publication of the article derived from this thesis and will remain accessible for at least five years for academic and research purposes.

To whom data/document is available
For all students of Physical Education, Physiotherapy, and Occupational Therapy

Under which criteria data/document could be used
The data and documents may be used for academic and research purposes upon request and with proper citation. Use is permitted for students, educators, and researchers in fields related to physical education, physiotherapy, and rehabilitation. Commercial use or redistribution is not allowed without written permission from the principal investigator.

From where data/document is obtainable
The data and documents will be obtainable from the principal investigator upon request, and after the publication of the article derived from this thesis. The study is affiliated with the University of Isfahan – Faculty of Physical Education and Sport Sciences.

What processes are involved for a request to access data/document
Interested researchers or academic users must submit a formal request to the principal investigator via email. The request should include the purpose of data use, institutional affiliation, and a commitment to proper citation. Access will be granted after the publication of the article derived from this thesis, and only for non-commercial academic or research purposes.

Comments
This study is part of a doctoral thesis conducted at the University of Isfahan – Faculty of Physical Education and Sport Sciences. The data will be available after the publication of the derived article and may be used for academic purposes upon request. The intervention protocol is designed to benefit students in Physical Education, Physiotherapy, and Occupational Therapy.