Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of balance, lumbar stability, and combined exercise protocols on improving motor function, core muscle strength, postural instability, and quality of life in men with chronic nonspecific low back pain

Protocol summary

Study aim

The aim of the study was to investigate the effect of balance, lumbar stability, and combined exercise protocols on motor function, core muscle strength, pain, postural instability, and quality of life in men with chronic non-specific low back pain.

Design

A controlled clinical trial with factorial groups, single-blind, randomized, phase 1 on 60 patients. The rand function of Excel and SPSS software is used for randomization.

Settings and conduct

This study is related to men with chronic non-specific back pain, which is conducted at a sports clinic in Isfahan. To select the samples, the research design is first explained to the patients and written consent and personal information are obtained from those who wish to participate in the study. Also, single-sided blinding is performed only for the study participants, and each person receives and performs their exercises separately.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men with chronic non-specific low back pain with a history of at least three months Age range 25-50 years؛ No structural disorders in the spine and lower limbs؛ Score above 2 on the Visual Analogue Scale (VAS)؛ Having two defects in performing the diagnostic test for movement control disorders Exclusion criteria: Absence of more than three sessions during the training period؛ Having excessive pain and stiffness when performing the movements

Intervention groups

4 groups including: 1- Balance termination group (15) people 2- Stability termination group (15) people 3- Combined termination group (15) people 4- Control group (15) people. The protocol of balance exercises, stability exercises and combined exercises is implemented for 8 weeks and 3 sessions per week and after 8 weeks the parameters are measured for the first time.

Main outcome variables

Improved motor function; improved quality of life; no chronic pain throughout life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250915067250N1**
Registration date: **2025-10-25, 1404/08/03**
Registration timing: **prospective**

Last update: **2025-10-25, 1404/08/03**
Update count: **0**

Registration date

2025-10-25, 1404/08/03

Registrant information

Name

Amir hosein Rafiei

Name of organization / entity

University of physical education of tehran

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-11-21, 1404/08/30
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
Investigating the effect of balance, lumbar stability, and combined exercise protocols on improving motor function, core muscle strength, postural instability, and quality of life in men with chronic nonspecific low back pain

Public title
"Investigating the effect of balance, lumbar stability, and combined exercise protocols on improving motor function, core muscle strength, postural instability, and quality of life in men with chronic nonspecific low back pain"
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Men with chronic non-specific low back pain with a history of at least three months Getting a score above 2 on the Visual Analogue Scale (VAS) for measuring pain intensity Having two deficits in performing a diagnostic test for movement control disorder
Exclusion criteria:
Back pain in people under 18 years of age Having surgery within 1 month
Age
From **25 years** old to **50 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **65**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization was used, each participant is randomly assigned to one of the groups. And it is done using a lottery. Its unit is the choice (individual). It is done using the statistical software spss with analysis of covariance. The groups participating in the research each attend the clinic at a separate time so that each group's exercises remain hidden.
Blinding (investigator's opinion)
Single blinded
Blinding description
All research participants are blinded and do not know about their treatment exercises, but all research steps are fully explained to them. Only the relevant doctor and the examiners know about the process and type of exercises. Therefore, the study is single-blind.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of sport Sciences
Street address
No. 64, West Ashrafi Ave, Vali Asr Street.
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Tehran
Province
Tehran
Postal code
۱۴۱۷۹۳۵۸۴۰
Approval date
2025-10-19, 1404/07/27
Ethics committee reference number
IR.UT.SPORT.REC.1404.170

Health conditions studied

1

Description of health condition studied
Low back pain chronic
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Visual analogue scale
Timepoint
8 weeks
Method of measurement
To measure pain, a visual analog scale (VAS) was used. This scale was drawn and graded as a 10-cm line, which was used to measure the intensity of perceived pain in this study.

2

Description

Roland Morris Questionnaire.

Timepoint

8 Weeks.

Method of measurement

The standard Roland Morris questionnaire is used to measure the level of disability. This questionnaire consists of 24 questions, each question has one point. Subjects who score less than 4 are excluded from the study.

3

Description

Quality of life questionnaire.

Timepoint

8 weeks.

Method of measurement

The SF-36 Quality of Life Questionnaire is a self-report questionnaire that is mainly used to assess quality of life and health. This scale consists of 36 items divided into 8 subscales: physical functioning, role limitation due to problems, physical pain, physical general health, role limitation due to emotional problems, social functioning, vitality, and emotional well-being.

4

Description

Measuring postural oscillation.

Timepoint

8 weeks.

Method of measurement

The subject's postural fluctuation is measured by a plantar pressure distribution device. The distance of the body's center of pressure fluctuation in millimeters and the area of the body's center of pressure fluctuation range in square millimeters are displayed on the computer screen and recorded as indicators of the amount of postural fluctuation for each subject.

5

Description

Measuring core muscle endurance.

Timepoint

8 weeks.

Method of measurement

The McGill test is used to measure core muscle endurance. This test is performed in 4 positions, including the anterior trunk flexor test, right and left lateral plank, and trunk extensor test. The subjects practiced each position once to learn the correct movement and for a maximum of 5 seconds to prevent fatigue, and then for the main test, they were asked to maintain each position for as long as possible. The longest time that the subjects were able to maintain the correct position was recorded.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: "Balance exercises for eight weeks, three sessions per week, 3 sets, 15 repetitions per set."

Category

Rehabilitation

2

Description

Intervention group 2: "Stability exercises for eight weeks, three sessions per week, 3 sets, 15 repetitions per set."

Category

Rehabilitation

3

Description

Intervention group 3: "Combined exercises that include balance and stability exercises, which are eight weeks, three sessions per week, 3 sets, and 15 repetitions per set."

Category

Rehabilitation

4

Description

Control group: "They do not do any exercise activities and just do their daily tasks."

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran sport science university

Full name of responsible person

Amir hosein Rafiei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Physical education and science

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
Tehran University of Sport 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
Tehran University of Physical education and science

Full name of responsible person
Amir hosein rafiei

Position
phd candidate

Latest degree
Master

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Sport Medicine

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Access period starts 5 months after results are published.

To whom data/document is available

It will be available to researchers working in academic and scientific institutions and students.

Under which criteria data/document could be used

Data access is limited only to the participants themselves and they cannot learn about each other's information.

From where data/document is obtainable

Please contact Mr. Amirhossein Rafiei at 09356792816 and address: Faculty of Sport Sciences, University of Tehran.

What processes are involved for a request to access data/document

After the request letter, each participant is required to submit a report within one week.

Comments