Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect and Persistence Durability of Selected Functional Restoration Exercise and Pilates on Pain, Functional Disability, Proprioception and Quality Of Life In Female with Non-S Pecific Chronic Low Back Pain.

Protocol summary

Study aim

The main purpose of this research is to determine the effect and sustainability of functional rehabilitation exercises and pilates on pain, disability, proprioception and quality of life of women suffering from non-specific chronic back pain.

Design

According to the nature of the subject and the form of its implementation, the present research is semi-experimental, which will be carried out with the presence of two experimental groups and a control group, and performing the pre-test and post-test stages. and shelf life of one month

Settings and conduct

The statistical population of the current research is women aged 40 to 50 with non-specific chronic back pain in Isfahan. Among the clients with chronic back pain, 30 women were selected with the approval of an orthopedic specialist based on the criteria for entering the research in a purposeful and accessible manner and were placed in three groups: control (10 people), Pilates (10 people) and functional rehabilitation (10 people).

Participants/Inclusion and exclusion criteria

gender (female) The participants should participate in this study by signing the consent form and being aware of the research objectives and methods. People suffering from non-specific chronic back pain Body mass index between 18 and 25 Women with an age range of 40-50 years Not having any regular sports activity (at least two days a week) within the last 3 months before starting the protocol (3) Q not be an athlete 1- History of spine surgery 2- Disc 3- Osteoporosis 4- Autoimmune disorders 5-Pregnancy 6- Fracture 7- Diabetes

Intervention groups

Pilates group for functional rehabilitation of control

Main outcome variables

Pilates exercises and functional rehabilitation are likely to be effective in reducing pain, increasing proprioception, and range of motion

General information

Reason for update

The actual patient enrollment date has been entered.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250208064684N1**
Registration date: **2025-06-01, 1404/03/11**
Registration timing: **prospective**

Last update: **2026-10-27, 1405/08/05**
Update count: **1**

Registration date

2025-06-01, 1404/03/11

Registrant information

Name
Maral Amini
Name of organization / entity
The University of tehran
Country
Iran (Islamic Republic of)
Phone
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maral.am28@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-06, 1404/04/15

Expected recruitment end date

2025-11-08, 1404/08/17

Actual recruitment start date

2025-07-06, 1404/04/15

Actual recruitment end date

2025-11-08, 1404/08/17

Trial completion date

empty

Scientific title

Effect and Persistence Durability of Selected Functional Restoration Exercise and Pilates on Pain, Functional Disability, Proprioception and Quality Of Life In Female with Non-S Pecific Chronic Low Back Pain.

Public title

Effect and Persistence Durability of Selected Functional Restoration Exercise and Pilates on Pain, Functional Disability, Proprioception and Quality Of Life In Female with Non-S Pecific Chronic Low Back Pain.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gender (female) Participants participated in this study by signing a consent form and being aware of the research objectives and methods. Individuals suffering from chronic non-specific low back pain, body mass index between 18 and 25, women with an age range of 40-50 years, not having any regular exercise (at least two days a week) within the last 3 months before starting the protocol (3) History of low back pain for at least 12 weeks to diagnose chronicity of the disease

Exclusion criteria:

1- History of spinal surgery 2- Disc 3- Osteoporosis 4- Autoimmune disorders 5- Pregnancy 6- Fracture 7- Diabetes 8- Suffering from inflammatory spinal disease 9- People with any postural abnormalities 10- Absence of 3 sessions in training sessions (experimental group) 11- Participants' unwillingness to continue their activities at any stage of the research and voluntary withdrawal from participation and cooperation

Age

From **40 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Fifty-four women were selected purposively and conveniently with the approval of an orthopedic specialist based on the inclusion criteria and were placed in three groups and randomly and equally divided into two intervention groups and a control group. In order to randomly assign the subjects to the intervention and control groups, a number was assigned to each subject, and the numbers were randomly divided between the three groups using a random number table. In order to conceal the numbers in each group, they were written on paper, and each was kept in a separate opaque sealed envelope. Each subject was asked to choose one of the envelopes and was placed in one of the groups based on the number.

Blinding (investigator's opinion)

Single blinded

Blinding description

A blind strainIn order not to influence the test method and results, the experimenter was kept blind to which group (intervention or control) the subjects were in, and the subjects also expressed their consent to participate in a study by being fully informed about the research and filling out a consent form.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق درپژوهش دانشکده علوم ورزشی

Street address

west tehran univercity of tehran

City

tehran

Province

Tehran

Postal code

ethicsreserch.sport@

Approval date

2024-09-10, 1403/06/20

Ethics committee reference number

IR.UT.SPORT.REC.1403.072

Health conditions studied

1

Description of health condition studied

Non-SPecific Chronic Low Back Pain.

ICD-10 code

ICD-10 code description

M54.5 Low back pain

Primary outcomes

1

Description

The effect of Pilates exercises and functional

rehabilitation on pain, functional disability, range of motion, proprioception, and endurance in patients with non-specific chronic back pain.

Timepoint

Before the intervention, 2 days after the completion of eight weeks, then a shelf life of 1 month

Method of measurement

Goniometer - Schuber test meter - Lumbar extension test - Measuring proprioception with goniometer - Abdominal test - McGill test - Visual pain scale - Quality of life questionnaire and functional disability questionnaire Asustri Bering Sorensen test

Secondary outcomes

1

Description

pilates- functional restoratoin

Timepoint

2 months

Method of measurement

pilates- functional restoratoin

Intervention groups

1

Description

Intervention group: The intervention group did Pilates exercises and functional rehabilitation for 8 weeks, 3 sessions per week and each session lasted 45 to 60 minutes. Pilates - functional rehabilitation - controlThe control did not have any activity during this period and were engaged in daily activities

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

orthopedist

Full name of responsible person

orthopedist

Street address

esfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

university of tehran

Full name of responsible person

university of tehran

Street address

Tehran - Northern Kargar St. - above Jalal Al Ahmad Intersection - between 15th and 16th Streets - in front of Tehran University Koi

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Province

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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

university of tehran

Proportion provided by this source

50

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

university of tehran

Full name of responsible person

mohammad hosein alizadeh

Position

full professor

Latest degree

Ph.D.

Other areas of specialty/work

Sports pathology and corrective movements

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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

Not applicable

Title and more details about the data/document

Pre- and post-tests and durability

When the data will become available and for how long

1405

To whom data/document is available

Researchers and workers and other people

Under which criteria data/document could be used

Use for rehabilitation

From where data/document is obtainable

Research team maral.am28@gmail.com

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

email

Comments