

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of effect of strengthening exercises and core stability exercises on lumbopelvic kinematic and disability while lifting among patients with non-specific chronic low back pain

Protocol summary

Study aim

The aim of this study was to compare the effect of strengthening exercises and stabilization exercises on disability and lumbopelvic rhythm in patients with chronic non-specific low back pain.

Design

Randomized controlled trial, 2 parallel intervention groups and a control group, single blinded, including 60 patients, randomization will be done by the random blocks.

Settings and conduct

The place of accuring the study is the Neuromuscular Rehabilitation Research Center of medical university of Semnan. The patients will be assessed by the Oswestry questionnaire and motion analysis device at the beginning and the end of the study. intervention will be done as strengthening and core stability exercise therapy in two groups. The assessor and the analyzer are blinded and the analysis and the assessment will be done without bias.

Participants/Inclusion and exclusion criteria

Including criteria contains at least 18 years and at most 45 years old for paitients, chronic low back pain (at least 12 weeks long) and visual analogue scale of at most 3 units. Excluding criteria contains any exercise therapy contraindications, neoropathic lesions, acute and subacute involvements, fractures, surgeries, cancers and pregnancy.

Intervention groups

This study has two groups of intervention and a group of control. One group receives strengthening exercises, the other receives core stability exercises and the control group doesn't receive interventions. After warming up using stretching exercises, each patient receives 8 exercises during 3 sets and 10 repetitions. At the end patient does the cool down exercises. Exercises result in increasing strength or stability in abdominal or lumbar

region. Each treatment session lasts about one hour and each patient has 18 sessions of exercise therapy .The duration is six weeks and the interval is one day.

Main outcome variables

Disability, kinematic of lumbopelvic rhythm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241110063656N1**

Registration date: **2025-01-11, 1403/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-11, 1403/10/22**

Update count: **0**

Registration date

2025-01-11, 1403/10/22

Registrant information

Name

Tara Kesvat Ara

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 918 371 1532

Email address

tkesvatara@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-30, 1403/09/10

Expected recruitment end date

2025-06-20, 1404/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of strengthening exercises and core stability exercises on lumbopelvic kinematic and disability while lifting among patients with non-specific chronic low back pain

Public title

Comparison of effect of strengthening exercises and core stability exercises on lumbopelvic rhythm and disability among patients with low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients should be at least 18 and at most 45 years old. The low back pain should have lasted for 12 weeks
The patients should experience at most 3 degrees of visual analogue scale of pain

Exclusion criteria:

existing any medical situation that has contraindication with exercise therapy
If the patient experiences radicular symptoms while walking or everyday activities
If the patient's BMI is over 25
If the patient experiences Sciatic nerve block, below knee and leg pain, feet paresthesia, movement loss or motor lesions in upper or lower extremities
If patient has acute disk hernia (according to MRI), surgery, spinal fracture or cancer
If the patient is pregnant

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The study will be conducted randomly using block randomization method. Steps of block randomization: 1- Block Design: First, the blocks are designed. For each block size (in this study we have 3 groups and we consider the block size to be 3) we create all possible states. Initially, random blocks consisting of 3 groups are designed in different allocation orders, which include 6 different modes: {Control, Stability, Strengthening} {Control, Strengthening, Stability} {Stability, Control, Strengthening} {Stability, Strengthening, Control} {Strengthening, Control, Stability} {Strengthening,

Stability, Control} 2. Allocation of participants: Then, one of the above blocks will be randomly selected by lottery. We then determine the allocation of the intervention or treatment to the groups based on the order in that block. For example, if your chosen block is {Control, Stability, Strengthening}, then the first participant will be assigned to the control group, the next two participants will be assigned to the stability and strengthening group, and this will continue until all the people are assigned to the groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is single-blinded. The assessor which in this study is the researcher, does the assessment of patients before and after the intervention. She's not aware of the group that each patient is in. Also the data will be given to the analyzer as first, second and third group and she is not informed which groups are the intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Semnan University of Medical Sciences and Health Services

Street address

Semnan university of medical sciences, Basij Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2024-11-11, 1403/08/21

Ethics committee reference number

IR.SEMUMS.REC.1403.166

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

Non-specific chronic low back pain

ICD-10 code

M99.9

ICD-10 code description

Biomechanical lesion, unspecified

Primary outcomes

1

Description

Disability scale from Oswestry questionnaire

Timepoint

Before the intervention and six weeks after the beginning of intervention

Method of measurement

Oswestry Disability Index

2

Description

Lumbopelvic kinematic

Timepoint

Before the intervention and six weeks after the beginning of intervention

Method of measurement

Qualysis motion analysis

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Eight exercises will be done to increase strength, with a frequency of three sets of exercises per session and eighteen sessions under the supervision of a physiotherapist. These exercises are performed to increase the strength of the superficial muscles of the trunk and abdomen. To prevent injury, stretching exercises are performed before and after strength exercises for warming up and cooling down. Each session lasts one hour, every other day, and lasts for six weeks.

Category

Treatment - Other

2

Description

Second intervention group: Eight exercises to increase core stability will be done, with a frequency of three sets of exercises per session and eighteen sessions under the supervision of a physiotherapist. These exercises are performed to increase the stability of the deep muscles of the trunk and abdomen. To prevent injury, stretching exercises are performed before and after strength exercises for warming up and cooling down. Each session lasts one hour, every other day, and lasts for six weeks.

Category

Treatment - Other

3

Description

Control group: does not receive any interventions

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Dr. Banafshe Mansuri

Street address

Neuromuscular Rehabilitation Research Center, Tabatabaee clinic, Qods Blvd.,

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nmrrc@semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

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?

Yes

Title of funding source

Semnan University of Medical 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

Semnan University of Medical Sciences

Full name of responsible person

Tara Kesvat Ara

Position

Msc. Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Data related to the main outcome such as tables of
before and after of variables can be shared.

When the data will become available and for how long

Beginning of the access period will be six months after
the results are published

To whom data/document is available

The data will be available to both researchers working in
universities and people working in physiotherapy clinics.

Under which criteria data/document could be used

Those conducting studies on the same topic, including
systematic reviews, are allowed to request non-
personally identifiable information.

From where data/document is obtainable

Applicants can refer to the researcher, Tara Kasvatara,
and tkesvatara@gmail.com address to receive the
documents.

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

The applicant can receive the information after verifying his/her identity and description of his/her study and

providing valid academic documents about his/her study, one week after submitting the application.

Comments