

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

A comparative study of the sonographic, electromyographic and functional changes following 8 weeks dynamic neuromuscular stabilization (DNS) exercises between patients with non-specific low back pain and the control group.

Protocol summary

Study aim

Evaluating effect of dynamic neuromuscular stabilization on activity level and thickness of abdominal and multifidus muscle in postural task on patient with non specific low back pain

Design

Clinical trial with control group, triple blind with block randomization on 40 patients

Settings and conduct

Non-specific back pain patients are included in the study with informed consent of how to perform interventions in both groups, but without knowing how to group and with appropriate physical distance between the groups. The first group will perform dynamic neuromuscular stability exercises for 8 weeks, and the second group will perform the defined McGill exercises for 8 weeks. The exercises will be conducted at the research center of Shahid Beheshti Faculty of Rehabilitation of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients with chronic back pain in the area between the 12th rib and the buttock without referral to the lower limbs, whose pain has lasted for more than 6 weeks and has not subsided, and the criteria for not entering the study: history of trauma, recent fracture, The presence of nerve or spinal cord damage in the lumbar spine, Having a history of severe lumbar spine disorders such as disc herniation, rheumatic, inflammatory disease, peripheral nerve damage, severe mental illness, previous surgery in the lumbar region, spondylolisthesis or spondylolysis, neuromuscular or joint disease, systemic disease, organic and malignant diseases, pregnancy, Cardio-respiratory and metabolic disease, Also, patients who have exercised the muscles of the lower back during the last three months

Intervention groups

First intervention group: dynamic neuromuscular

stabilization exercises. Second intervention group: McGill exercise.

Main outcome variables

Thickness and activity of abdomen and multifidus muscle and disability and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220310054242N1**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **retrospective**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name

Seyedeh Hedieh Hosseini Makrani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3321 2837

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hediehoseini68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the sonographic, electromyographic and functional changes following 8 weeks dynamic neuromuscular stabilization (DNS) exercises between patients with non-specific low back pain and the control group.

Public title

A comparative study of the sonographic, electromyographic and functional changes following 8 weeks dynamic neuromuscular stabilization (DNS) exercises between patients with non-specific low back pain and the control group

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adults of both sexes with Non-specific low back pain that last more than 6 months Patients aged between 30 and 50 years Absence of referral pain Absence of disability. Absence of nerve or spinal damage in the lumbar spine No history of severe lumbar spine disorders such as disc herniation, rheumatic, inflammatory disease, peripheral nerve damage, severe mental illness, previous surgery in the lumbar region, spondylolisthesis or spondylolysis, neuromuscular or joint disease, systemic disease, organic and malignant diseases. , pregnancy, cardio-respiratory and metabolic disease

Exclusion criteria:

Patients who do not understand the technique used mobility disability The patient's unwillingness to continue the research process The patient's inability to perform exercises

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The Block Randomization method will be used to allocate

each participant to intervention groups using different block sizes. Excel software and function (rand) are used to prepare random sequences inside each block. After determining the type of intervention in each participant, a code is assigned to the individual. Codes assigned through a software are awarded to eligible candidates respectively.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participant and the researcher herself at the time of measuring and checking the data and the person who gives the exercises to the two groups are unaware of whether they are the control group or the main group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

ethic committee of shahid beheshti university of medical sciences

Street address

Building No. 2, 5th Floor, Shahid Beheshti University of Medical Sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway

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Province

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Postal code

4816987519

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.996

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

Low back pain

ICD-10 code

S34.1

ICD-10 code description

Other injury of lumbar spinal cord

Primary outcomes

1

Description

Level of activity of multifidus muscles

Timepoint

At the beginning of study and after 8 weeks

Method of measurement

EMG

2

Description

Level of activity of abdominal muscles

Timepoint

At the beginning of study and after 8 weeks

Method of measurement

EMG

3

Description

Thickness of abdominal muscles

Timepoint

At the beginning of study and after 8 weeks

Method of measurement

Ultrasonography

4

Description

Thickness of multifidus muscle

Timepoint

At the beginning of study and after 8 weeks

Method of measurement

Ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: dynamic neuromuscular stabilization exercises. In this group, patients will perform selected dynamic neuromuscular stabilization exercises for 8 weeks and three sessions a week

Category

Rehabilitation

2

Description

Intervention group: mcgill exercises. In this group, patients will perform selected McGill exercises for 8 weeks and three sessions a week

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Research Center, School of Rehabilitation, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyedeh Hedieh Hoseini

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Faculty of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences. Damavand St., Imam Hossein (AS) Square,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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Research and technology assistance, Shahid Beheshti University of medical sciences, Yaman St, Shahid Chamran highway,

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedigheh Sadat Naimi
Position
professor
Latest degree
Ph.D.
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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