Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 comittee 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
City
Tehran
Province
Tehran
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 begining of study and after 8 weeks
Method of measurement
EMG

2

Description
Level of activity of abdominal muscles
Timepoint
At the begining of study and after 8 weeks
Method of measurement
EMG

3

Description
Thickness of abdominal muscles
Timepoint
At the begining of study and after 8 weeks
Method of measurement
Ultrasonography

4

Description
Thickness of multifidus muscle
Timepoint
At the begining 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 selecte 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 Scien
Full name of responsible person
Seyedeh Hedieh Hoseini
Street address
Faculty of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences. Damavand St., Imam Hossein (AS) Square,
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hediehoseini68@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
Research and technology assistance, Shahid Beheshti University of medical sciences, Yaman St, Shahid Chamran highway,
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Fax
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Zarghi@sbmu.ac.ir
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.

Other areas of specialty/work

Physiotherapy

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Physiotherapy department, Rehabilitation Sciences Faculty, Shahid Beheshti University of Medical Science, In front of Bo Ali Hospital, Damavand St, Imam Hossein Sq,s,

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Position

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Latest degree

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Person responsible for updating data

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Position

professor

Latest degree

Master

Other areas of specialty/work

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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