

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 11 3321 2837

##### Email address

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

**City**

Tehran

**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

##### **Street address**

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

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##### **Phone**

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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

##### **Street address**

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

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##### **Phone**

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##### **Fax**

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##### **Email**

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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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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