

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### comparison between effects of core stabilization and Mckenzie exercises in mechanical low back pain

#### Protocol summary

##### Study aim

this study will compare effects of Mckenzie exercises and core stability exercises in pain based on VAS scale, range of motion of flexion in standing based on FTF, disability based on ODI questionnaire and their function based on unilateral single limb stance

##### Design

randomized clinical parallel group trial with double blinded via dice on 44 patients will be done and even dedicating to Mckenzie exercises group and odd dedicating to core stability exercises group

##### Settings and conduct

this study conducts in non invasive low back pain treatment field with exercise therapy. blinding occurs with giving each participant a code and not naming exercises for patients. Range of motion will be measured with a ruler measuring tip of fingers to floor in flexion in standing position also ODI questionnaire will be used for disability, VAS for pain and unilateral single limb stance for function

##### Participants/Inclusion and exclusion criteria

patients with mechanical low back pain with or without radiculopathy which does not have red flags and not have any surgeries in Lumbar vertebrae region and also have age between 30 to 70 with BMI lower than 30 will be eligible to participate in this study

##### Intervention groups

in Mckenzie exercises group according to assessment done, one of these three exercises will be prescribed and progressed respectively if the patients did not get worse: prone lying, prone lying on elbow, extension in lying. In core stability exercises after mechanical assessment done three types of exercises will be prescribed: bridging, unilateral prone leg extension, abdominal drawing in

##### Main outcome variables

changes in pain of patients; changes in range of motion; changes in function; changes in disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230806059059N1**

Registration date: **2023-08-23, 1402/06/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-23, 1402/06/01**

Update count: **0**

##### Registration date

2023-08-23, 1402/06/01

##### Registrant information

##### Name

Hamidreza Nemati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3448 0756

##### Email address

hmdreza9898@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-16, 1402/05/25

##### Expected recruitment end date

2023-09-15, 1402/06/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparison between effects of core stabilization and Mckenzie exercises in mechanical low back pain

#### Public title

exercise therapy in lowback pain

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Lowback pain with or without radiculopathy Having a defined baseline for painful positions Having at least pain level of 2 based on VAS BMI lower than 30

##### Exclusion criteria:

history of any surgeries in Lumbar vertebrae including laminectomy or etc History of tumor or possibility of it History of trauma or possibility of infection or fracture Unwillingness to continue at any stages Urinary or fecal incontinence Pregnancy Hamstring shortness brain injuries Vestibular disorders, alcohol or drug abuse and psychotropic drugs

#### Age

From **30 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Investigator

#### Sample size

Target sample size: **44**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

participants will fill their demographic and personal data. Their pain based on VAS, range of motion based on FTF, disability based on ODI questionnaire and functional status based on unilateral single limb stance will be measured. All participants will be assessed via mechanical assessment form (mechanical diagnosis and therapy from Mckenzie institute) and then we will use a dice, even puts them in Mckenzie exercises group and odd puts them in core stability exercises group

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

all procedures except name of groups will be described to patients so that they will perform exercises according to the educations without knowing their group name. Each participant will be paired by a code to their names in a separate paper from their files so the final assessor would be blind of the groups.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

in this study we do not use any type of modalities or drugs and all participants will only do the prescribed exercises at the time of study Furthermore; all of them will be assessed via mechanical assessment form

introduced by Mckenzie institute before grouping

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of shahid beheshti university of medical sciences

##### Street address

No 16, Arghavan street, west mahan Blvd

##### City

Karaj

##### Province

Alborz

##### Postal code

3145944516

#### Approval date

2023-05-30, 1402/03/09

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1402.093

## Health conditions studied

### 1

#### Description of health condition studied

Mechanical low back pain

#### ICD-10 code

M54.5

#### ICD-10 code description

Low Back Pain

## Primary outcomes

### 1

#### Description

flexion in standing range of motion

#### Timepoint

before study and after 8 sessions therapy

#### Method of measurement

ruler

### 2

#### Description

pain intensity

#### Timepoint

before study and after 8 sessions therapy

#### Method of measurement

visual analogous scale

### 3

#### Description

disability

## Timepoint

before study and after 8 sessions of therapy

## Method of measurement

oswetry disability index

## 4

### Description

function and balance

### Timepoint

before study and after 8 session therapy

### Method of measurement

using a striated curtain with 1 meters away from patient. Test if positive if any compensatory movement or deviation occurs that does not turn back to the starting position immediately

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: core stability group in this group patients after mechanical assessment with mechanical assessment form will be educated to perform abdominal drawing in, unilateral prone leg extension and bridging in two sets and each set 5 seconds holding contraction and 5 minutes rest between each set.

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Mckenzie exercises in this group after assessment with mechanical assessment form patients will first do prone lying for 5 minutes, if symptoms does not get worse they will be progressed to prone on elbow position for 5 minutes. again if symptoms does not get worse they will perform extension in lying to end range and hold it for 2 seconds and 10 repetition then they will rest for 5 minutes and repeat for 10 times.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iranmehr physiotherapy clinic

##### Full name of responsible person

Mehdi Nikzad

##### Street address

Rose dead end, Eram Blvd, Mehrshahr

##### City

Karaj

## Province

Alborz

## Postal code

3186656825

## Phone

+98 26 3332 4230

## Email

mnj57@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Hoda Niknam

##### Street address

Damavand st, Emam ali Exp. way

##### City

Tehran

##### Province

Tehran

##### Postal code

1616913111

##### Phone

+98 21 7754 2057

##### Email

info@sbmu.ac.ir

#### 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

Hamidreza Nemati

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Physiotherapy

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**City**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Email**

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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**

All data related to pain,disability,range of motion,balance and function can be reported.Other data including demographic features can also be reported but they are not the purpose of this study

**When the data will become available and for how long**

start of publishing data:3 months after conclusions reported

**To whom data/document is available**

All of physiotherapist are allowed

**Under which criteria data/document could be used**

for the data mentioned above, no other permissions are required and all of physiotherapist are allowed to use these data.

**From where data/document is obtainable**

Just email of Hamidreza Nemati,Conductor of study is available Hmdrea9898@gmail.com

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

The detail of data asked should be emailed in one mail and after about one to two weeks the data will be send for them

**Comments**