

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Effects of adding Cognitive-Behavioral Therapy (CBT) to stability exercises on Lumbo-Pelvic Rhythm during lifting in non-specific low back pain patients with high fear of movement

#### Protocol summary

##### Study aim

Evaluation of the effect of adding cognitive-behavioral therapy to stability exercises on lumbar-pelvic rhythm in nonspecific low back pain patients with high fear of movement during lifting.

##### Design

A randomized clinical trial study with three parallel groups including two intervention groups and a control group, not blinded on 51 patients. Randomization is done using the 3 and 6 permutation random block method.

##### Settings and conduct

This study is performed with the voluntary participation of patients with nonspecific low back pain after fulfilling the conditions for entry and exit from the study in the neuromuscular rehabilitation research center of Semnan University of Medical Sciences. Initially, the lumbo-pelvic rhythm of all patients will be evaluated and the first and second groups will be given 2 days a week of stabilization exercises and the second group will also be given 1 day a week of cognitive-behavioral therapy and the control group will be without treatment. Patients' pelvic lumbar rhythm will be measured after 8 weeks of treatment and also one month after the end of the study. In this study, researcher is blind.

##### Participants/Inclusion and exclusion criteria

Patients with nonspecific low back pain who are between 20 and 55 years old and have periodic low back pain for at least 12 weeks. Patients' pain on the study day should be less than 3 based on the VAS scale and Fear of movement score on the Tampa scale is greater than 40. Participants had no signs of specific pathology in the spine.

##### Intervention groups

The first and second groups are taught stability exercises, the second group is given cognitive-behavioral therapy too, and the control group is without treatment and will receive several sessions of treatment after

completing the study in order to observe ethical considerations.

##### Main outcome variables

Lumbo-pelvic rhythm, fear of movement, disability, pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210101049910N1**

Registration date: **2021-03-12, 1399/12/22**

Registration timing: **prospective**

Last update: **2021-03-12, 1399/12/22**

Update count: **0**

##### Registration date

2021-03-12, 1399/12/22

##### Registrant information

##### Name

Mahdie Ghasemian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3332 8502

##### Email address

mahdieghs21@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-03, 1400/01/14

##### Expected recruitment end date

2021-09-05, 1400/06/14

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Effects of adding Cognitive-Behavioral Therapy (CBT) to stability exercises on Lumbo-Pelvic Rhythm during lifting in non-specific low back pain patients with high fear of movement

**Public title**  
Effects of adding Cognitive-Behavioral Therapy (CBT) to stability exercises in low back pain patients

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Non-specific low back pain patients with high fear of movement At least 12 weeks have passed since the low back pain Having fear scores greater than 40 on the Tampa scale for kinesiophobia According to VAS on the day of the study the maximum pain intensity of each patient must be 3  
**Exclusion criteria:**  
Any signs of serious spinal involvement Having symptoms of cauda equina syndrome Having symptoms of sciatica Symptoms of spinal canal stenosis Symptoms of nerve root involvement History of spinal surgery Spinal fracture Structural abnormalities in the spine Swelling, inflammation and dryness of the lumbar joints Having a BMI of more than 25 kg per square meter Report of uncorrected visual impairment Severe cognitive and memory impairment Pregnancy

**Age**  
From **20 years** old to **55 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **51**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Blocks of 3 and 6 are used for randomization. The intervention groups are called A and B; the control group is called C. Different 3 blocks including A, B, C, and 6 different blocks with two A, B, C are defined in different permutations. We will have 3 blocks of 3 and 7 blocks of 6. Each block is assigned a number from 0 to 9. Using a random number generator, the blocks are selected from 10 designated blocks, respectively. Eligible individuals are assigned to one of three groups A, B, or C in each block (from left to right) in a predetermined order.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Semnan University of Medical Sciences  
**Street address**  
Semnan University of Medical Sciences, Basij Blvd, Semnan  
**City**  
Semnan  
**Province**  
Semnan  
**Postal code**  
3514799442

**Approval date**  
2020-12-22, 1399/10/02

**Ethics committee reference number**  
IR.SEMUMS.REC.1399.274

## Health conditions studied

**1**

**Description of health condition studied**  
Non-specific low back pain

**ICD-10 code**  
M54.5

**ICD-10 code description**  
Low back pain

## Primary outcomes

**1**

**Description**  
Lumbo-pelvic rhythm

**Timepoint**  
The first session, last session, and one month after the end of the sessions

**Method of measurement**  
3D motion analysis system

## Secondary outcomes

**1**

**Description**  
Fear of movement

**Timepoint**

The first session, last session and one month after the end of the sessions for the intervention and control groups

**Method of measurement**

Tampa scale for kinesiophobia

**2**

**Description**

Disability

**Timepoint**

The first session, last session and one month after the end of the sessions for the intervention and control groups

**Method of measurement**

Roland Morris disability questionnaire

**3**

**Description**

pain

**Timepoint**

The first session, last session and one month after the end of the sessions for the intervention and control groups

**Method of measurement**

Visual analog scale

**Intervention groups**

**1**

**Description**

First intervention group: Participants in this group will receive stabilization exercises that involve pulling the abdomen in 10 different positions for eight weeks, two days in a week. Patients will be taught how to do the exercises orally and using pictures. The abdominal inhalation practice is held for 10 seconds and is repeated 10 times with a pause of 3 seconds and the time interval of each Practice until the next exercise is 60 seconds. The exercises are progressive and the number of exercises increases over time.

**Category**

Rehabilitation

**2**

**Description**

Second intervention group: In addition to trunk stabilization exercises that will be given to the subjects for eight weeks and two sessions per week, cognitive behavioral therapy will also be given to the participants of this group. This treatment is based on problem solving, so in the first stage, the patient is evaluated by the therapist. Evaluation in this treatment aims to collect information that based on the cognitive model, determine how the disorder is formed and its continuation. The psychotherapist examines the patient's mood and asks him or her to make a list of his or her problems, write down his or her thoughts, identify abnormal behaviors, and try to control them. Each week, a treatment session is provided for patients in this group,

the first session will be 2 hours and the next sessions will be 30 minutes for 8 weeks. Except for the first session, which is more about introducing the patient to the treatment process, in the next sessions, the therapist and the patient review the previous week and both work together to determine the current agenda. In the treatment sessions, the treatment assignments are reviewed, the current agenda is executed, a new assignment is determined, and at the end of each session, the patient is asked to comment on the session.

**Category**

Rehabilitation

**3**

**Description**

Control group: This group will not receive treatment.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Neuromuscular Rehabilitation Research Center

**Full name of responsible person**

Mahdie Ghasemian

**Street address**

Neuromuscular Rehabilitation Research Center,  
Ghods Blvd

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mahdieghs21@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr Parviz Kokhaei

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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**

Rosita Hedayati

**Position**

Faculty member of the Faculty of Rehabilitation

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road

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**Full name of responsible person**

Rosita Hedayati

**Position**

Faculty member of the Faculty of the Rehabilitation

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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**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available