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

City

Semnan

Province

Semnan

Postal code

3519698375

Phone

+98 23 3332 8502

Email

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

Street address

Semnan University of Medical Sciences, Basij Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email
P_kokha@yahoo.com
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
Street address
Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3365 4180
Email
rosehed@yahoo.com

Person responsible for scientific 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 the Rehabilitation
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3365 4180
Email
rosehed@yahoo.com

Person responsible for updating data

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
Street address
Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3365 4180
Email
rosehed@yahoo.com

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