

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of home exercise with and without weight loss program on pain, disability, fear of movement, and endurance of trunk muscles in people with non-specific chronic low back pain

#### Protocol summary

##### Study aim

Comparison of the effect of home exercise with and without weight loss program on pain, disability, fear of movement, and endurance of trunk muscles in people with non-specific chronic low back pain

##### Design

60 men and women with non-specific chronic low back pain were randomly divided into two groups (experimental = exercise at home with a weight loss program) and (control = exercise at home) according to inclusion criteria and random sampling method. They were exposed for six weeks.

##### Settings and conduct

The present study is an interventional and quasi-experimental and applied research. All participants in the two groups performed for 6 weeks under the online supervision of a correctional specialist.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female patients with nonspecific chronic low back pain The age of the domain is between 20 and 60 years Low back pain for more than 3 months Exclusion criteria: People who have had surgery on the intervertebral disc. People who are not able to walk and sit alone and control urination and defecation. People with uncontrolled heart disease. Spine pathology

##### Intervention groups

Home practice intervention: Exercises in this intervention included controlling the abdominal muscles and strengthening the thigh muscles. Weight loss intervention: In addition to receiving the exercise therapy protocol, the subjects in the combined group also received a weight loss program for 6 weeks, 3 sessions per week.

##### Main outcome variables

Reduce pain and mechanical loads Restore muscle balance by strengthening weakened muscles and

shortening muscle tension Stabilization of vertebrae with excessive mobility Improve body structure and increase mobility Reducing the mechanical load of spinal weight bearing structures Balance in lordotic curvature of the lumbar spine due to obesity.

#### General information

##### Reason for update

Revising the recruitment dates

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201030049193N4**

Registration date: **2022-06-29, 1401/04/08**

Registration timing: **retrospective**

Last update: **2024-04-30, 1403/02/11**

Update count: **1**

##### Registration date

2022-06-29, 1401/04/08

##### Registrant information

###### Name

Mahdi Hosseinzadeh

###### Name of organization / entity

Sport Sciences Research Institute of Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7714 6478

###### Email address

metti@ssrc.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-09, 1400/09/18

**Expected recruitment end date**

2022-03-09, 1400/12/18

**Actual recruitment start date**

2021-12-09, 1400/09/18

**Actual recruitment end date**

2022-03-16, 1400/12/25

**Trial completion date**

2022-06-15, 1401/03/25

**Scientific title**

Comparison of the effect of home exercise with and without weight loss program on pain, disability, fear of movement, and endurance of trunk muscles in people with non-specific chronic low back pain

**Public title**

Comparison of the effect of home exercise with and without weight loss program in people with chronic low back pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Male and female patients with nonspecific chronic low back pain Age range between 20 to 60 years Low back pain for more than 3 months

**Exclusion criteria:**

People who had intervertebral disc surgery. People whose back pain is caused by something else, such as a fracture, a cancerous tumor, a severe lumbar slip, and an infection. People with underlying mental illness People with suspected or corona virus People who are not able to walk and sit alone and control urination and defecation. People with uncontrolled heart disease. The need for spinal and disc herniation surgery Spine pathology Use any type of medication or pain reliever and treatment to relieve back pain

**Age**From **20 years** old to **60 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**Target sample size: **60**Actual sample size reached: **60****Randomization (investigator's opinion)**

Randomized

**Randomization description**

An uninvolved person in the study helped us via random number allocation software to randomly assign a number to each of the participants (60 participants for both the groups training at home n=30 and weight loss training n=30). Then after recording the pretest session measurements, the assigning group (assigned via SNOSE method) was considered for each of the participants.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In order for single blinding, some general information about how to perform the training and testing methods will be given to all the participants. However no information will be provided to the participants on which training group they will be placed in.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research ethic committees of sport sciences research institute (SSRI)

**Street address**

No. 24, Unit 2, Mehrnami St., Tehranpars First Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1651998816

**Approval date**

2021-10-20, 1400/07/28

**Ethics committee reference number**

IR.SSRC.REC.1400.101

**Health conditions studied****1****Description of health condition studied**

non-specific chronic low back pain

**ICD-10 code**

M95.5

**ICD-10 code description**

Acquired deformity of pelvis

**Primary outcomes****1****Description**

pain

**Timepoint**

Pre-test (before the start of the study) and post-test (at the end of the study)

**Method of measurement**

The pain variable was measured by a visual pain intensity scale.

## Secondary outcomes

### 1

#### Description

Disability

#### Timepoint

Pre-test (before the start of the study) and post-test (at the end of the study)

#### Method of measurement

The Oswestry questionnaire was used to assess functional impairment in daily activities.

### 2

#### Description

Fear of movement

#### Timepoint

Pre-test (before the start of the study) and post-test (at the end of the study)

#### Method of measurement

The fear of movement variable was examined according to the Tampa movement fear questionnaire.

### 3

#### Description

Endurance of trunk muscles

#### Timepoint

Pre-test (before the start of the study) and post-test (at the end of the study)

#### Method of measurement

Trunk muscles endurance was performed in two modes of flexion and extension.

## Intervention groups

### 1

#### Description

First intervention group: Practice at home: Exercises in this intervention included controlling the abdominal muscles and strengthening the thigh muscles. The exercises consisted of 5 movements for 6 weeks, 3 sessions per week, 3 sets per day, and each set of 10 repetitions for the subjects. Each session lasted 60 minutes, with the initial and final 10 minutes including warm-up and cooling, respectively. Progress in exercise was determined based on the pain intensity of each subject.

#### Category

Treatment - Other

### 2

#### Description

The second intervention group: Weight lose: In addition to receiving the exercise therapy protocol, the subjects in this group also received a weight loss program for 6 weeks, 3 sessions per week. If the subject had a treadmill, he could use it after complete training on how to work with the treadmill. Each training session

consisted of a 40-minute walk, which included 5 minutes of basic warm-up, 30 minutes of walking at a speed of your choice, progressing at a faster pace, and finally 5 minutes slower to cool down.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kharazmi University

##### Full name of responsible person

Amir Letafatkar

##### Street address

Kharazmi Faculty of Physical Education and Sports Sciences, at the end of Hesari Street, Mirdamad Boulevard

##### City

Tehran

##### Province

Tehran

##### Postal code

15875-4398

##### Phone

+98 21 2222 8001

##### Email

minaafshar.ma8@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kharazmi University

##### Full name of responsible person

Jamshid Shanbeh Zadeh

##### Street address

Kharazmi University, No. 43, Shahid Mofateh St, before the Enghelab Square

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Tehran

##### Province

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##### Postal code

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##### Phone

+98 21 8607 0779

##### Email

research@khu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kharazmi University

#### Proportion provided by this source

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Province**

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letafatkaramir@yahoo.com

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

Kharazmi University

**Full name of responsible person**

Mina Afshari

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Corrective Exercises

**Street address**

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**Other areas of specialty/work**

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

Kharazmi University

**Full name of responsible person**

Amir Letafatkar

**Position**

Professor Assistant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Corrective Exercises

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**City**

Tehran

**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