Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 7714 6478

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

1

Sponsor
Name of organization / entity
Kharazmi University
Full name of responsible person
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Street address
Kharazmi University, No. 43, Shahid Mofateh St, before the Enghelab Square
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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

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
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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