Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Comparing the effectiveness of two isometric and isotonic core stability exercise methods on pain and performance in people with non-specific chronic back pain

Protocol summary

Study aim

The purpose of the present study is to compare two isometric and isotonic stability training methods on pain and performance of people with non-specific chronic back pain.

Design

In this research, patients in two training groups will receive therapeutic exercises for 8 weeks, and the control group will not receive any intervention. For the randomization process, each patient will choose a number in a closed envelope. For the convenience of calculation, the website program "Research Randomize" will be used. The groups included isometric stability training, isotonic stability training and control. G*Power 3.1 was used to calculate the sample size with an alpha of 0.05, a power (90%) and an effect size (0.5). A total of 36 patients (12 in each group) were required for the study. For this reason, in order to avoid the possible drop rate of participants, the number of 15 people (45 people in total) will be allocated in the groups.

Settings and conduct

These people will be identified by an orthopedic doctor and referred to the sports science laboratory of Shahid Beheshti University to perform exercises (subject courses and evaluators).

Participants/Inclusion and exclusion criteria

Research entry criteria: the subjects of this study include people with chronic back pain. The subjects of this study will not participate in any other sports activities or therapeutic interventions during the research. Exclusion criteria from the research: having symptoms such as: fever, cough, weakness, and in general suspected people with the corona virus; bone diseases; mental disorders; neurological and muscular disorders; congenital abnormalities; any trauma; history of spinal surgery and In general; having any other disease except non-specific chronic back pain.

Intervention groups

1- Exercise therapy group, 2- Exercise therapy group, 3- Control group.

Main outcome variables

Pain and disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180727040609N2**
Registration date: **2023-05-01, 1402/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-01, 1402/02/11**
Update count: **0**

Registration date

2023-05-01, 1402/02/11

Registrant information

Name

Arash Khaledi

Name of organization / entity

University of Tehran

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of two isometric and isotonic core stability exercise methods on pain and performance in people with non-specific chronic back pain

Public title

Comparison of two methods of core stability exercises to improve chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with non-specific chronic back pain Absence of any history of spine surgery Absence of pathological records (disease) of the spine Absence of orthopedic and neurological injuries Absence of structural or functional shortness of more than 2 cm in one of the lower limbs

Exclusion criteria:

The presence of the lumbar disc herniation The presence of the acute stage of lumbar disc protrusion The presence of the systematic diseases (such as cardiovascular) Spine surgery in the past Having a fracture or inflammatory diseases of the spine Having any therapeutic intervention in the last two months Taking medical drugs Failure to participate in the treatment sessions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **45**

Three groups including two experimental groups and one control group (15 people for each group)

Randomization (investigator's opinion)

Randomized

Randomization description

For the randomization process, each patient will choose a number in a sealed envelope. For the convenience of calculation, the website program "Research Randomizer" will be used. Therefore, these patients were equally divided into the following three groups: isometric stability training group (n=15), isotonic stability training group (n=15) and control group (n=15).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, after the subjects were referred to the exercise therapy department by the doctor, they will go through a complete treatment process and will not be informed that they are included in a research. On the other hand, in order to examine dependent variables before and after therapeutic exercise, we have considered experts who will be unaware of the research process. Therefore, our study will involve blinding of patients and assessors (double-blind).

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee at the Institute of Physical Education and Sports Science

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran. Research Institute of Physical Education and Sports Sciences

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Approval date

2023-03-08, 1401/12/17

Ethics committee reference number

IR.SSRC.REC.1401.155

Health conditions studied

1

Description of health condition studied

Chronic non-specific back pain

ICD-10 code

M54.5

ICD-10 code description

Back pain

Primary outcomes

1

Description

Pain

Timepoint

8 weeks. The pain variable will be evaluated one day before the start and one day after the end of the research/treatment period.

Method of measurement

Pain (Using Visual Analog Scale; VAS).

2

Description

Functional disability.

Timepoint

8 weeks. The functional disability variable will be evaluated one day before the start and one day after the end of the research/treatment period.

Method of measurement

Functional disability (Using Oswestry questionnaire)

Secondary outcomes

1

Description

Pain

Timepoint

8 weeks. The pain variable will be evaluated one day before the start and one day after the end of the research/treatment period

Method of measurement

The visual analogue scale (VAS)

2

Description

Functional disability.

Timepoint

En 8 weeks. The functional disability variable will be evaluated one day before the start and one day after the end of the research/treatment period.

Method of measurement

Functional disability (Using Oswestry questionnaire)

Intervention groups

1

Description

Intervention group: Isometric core stability exercises. In this group, the training intervention only includes training movements that are performed in a static position with isometric contractions. Patients in this group will exercise for 8 weeks (three sessions, 45-60 minutes per week) under the direct supervision of a specialist, using equipment such as Swiss ball, Theraband and light weights. The number of movements is from 6 to 12 in each session, which will be progressed from the beginning to the end of the treatment based on the patient's level of adaptation.

Category

Treatment - Other

2

Description

Intervention group: Isotonic core stability exercises. In this group, the exercise intervention only includes exercise movements that are performed in a dynamic position with isotonic contractions (without maintaining a constant contraction). Patients in this group will exercise for 8 weeks (three sessions of 45-60 minutes per week) under the direct supervision of a specialist, using equipment such as Swiss ball, Theraband and light weights. The number of movements is from 6 to 12 in each session, which will be progressed from the beginning to the end of the treatment based on the patient's level of adaptation.

Category

Treatment - Other

3

Description

Control group: (no intervention). During the entire research period, the control group will be under simple supervision and will not receive any therapeutic intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University Faculty of Physical Education laboratory

Full name of responsible person

Mehdi Ghitasi

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Sponsors / Funding sources

1

Sponsor
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Grant name
Shahid Beheshti University
Grant code / Reference number
دانشگاه شهید بهشتی
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University
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

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Shahid Beheshti University
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

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Person responsible for updating data

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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

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

Title and more details about the data/document

All the above information will be made available in the format of university plan and research articles

When the data will become available and for how long

6 to 15 months after the completion of the research plan

To whom data/document is available

All researchers, therapists and specialists

Under which criteria data/document could be used

In order to help therapists, researchers and specialists to promote academic research and treatment of patients

From where data/document is obtainable

Dr. Arash Khaledi, contact number: 09120078615, email address: arashkhaledi@ut.ac.ir

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

As soon as possible and after the publication of scientific articles, everything that can help the scientific and therapeutic process will be available.

Comments