

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3243 0715

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-04, 1402/01/15

##### Expected recruitment end date

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| <div>2023-05-05, 1402/02/15</div> <div><b>Actual recruitment start date</b></div> <div>empty</div> <div><b>Actual recruitment end date</b></div> <div>empty</div> <div><b>Trial completion date</b></div> <div>empty</div> <div><b>Scientific title</b></div> <div>Comparing the effectiveness of two isometric and isotonic core stability exercise methods on pain and performance in people with non-specific chronic back pain</div> <div><b>Public title</b></div> <div>Comparison of two methods of core stability exercises to improve chronic low back pain</div> <div><b>Purpose</b></div> <div>Treatment</div> <div><b>Inclusion/Exclusion criteria</b></div> <div><b>Inclusion criteria:</b></div> <div>People with non-specific chronic back pain<br/>Absence of any history of spine surgery<br/>Absence of pathological records (disease) of the spine<br/>Absence of orthopedic and neurological injuries<br/>Absence of structural or functional shortness of more than 2 cm in one of the lower limbs</div> <div><b>Exclusion criteria:</b></div> <div>The presence of the lumbar disc herniation<br/>The presence of the acute stage of lumbar disc protrusion<br/>The presence of the systematic diseases (such as cardiovascular)<br/>Spine surgery in the past<br/>Having a fracture or inflammatory diseases of the spine<br/>Having any therapeutic intervention in the last two months<br/>Taking medical drugs<br/>Failure to participate in the treatment sessions</div> <div><b>Age</b></div> <div>No age limit</div> <div><b>Gender</b></div> <div>Both</div> <div><b>Phase</b></div> <div>N/A</div> <div><b>Groups that have been masked</b></div> <div> <ul style="list-style-type: none"> <li>Participant</li> <li>Outcome assessor</li> </ul> </div> <div><b>Sample size</b></div> <div>Target sample size: <b>45</b></div> <div>More than 1 sample in each individual</div> <div>Number of samples in each individual: <b>45</b></div> <div>Three groups including two experimental groups and one control group (15 people for each group)</div> <div><b>Randomization (investigator's opinion)</b></div> <div>Randomized</div> <div><b>Randomization description</b></div> <div>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).</div> <div><b>Blinding (investigator's opinion)</b></div> | <div>Double blinded</div> <div><b>Blinding description</b></div> <div>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).</div> <div><b>Placebo</b></div> <div>Not used</div> <div><b>Assignment</b></div> <div>Other</div> <div><b>Other design features</b></div> <div><b>Secondary Ids</b></div> <div>empty</div> <div><b>Ethics committees</b></div> <div><b>1</b></div> <div><b>Ethics committee</b></div> <div><b>Name of ethics committee</b></div> <div>Ethics Committee at the Institute of Physical Education and Sports Science</div> <div><b>Street address</b></div> <div>No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran. Research Institute of Physical Education and Sports Sciences</div> <div><b>City</b></div> <div>Tehran</div> <div><b>Province</b></div> <div>Tehran</div> <div><b>Postal code</b></div> <div>1587958711</div> <div><b>Approval date</b></div> <div>2023-03-08, 1401/12/17</div> <div><b>Ethics committee reference number</b></div> <div>IR.SSRC.REC.1401.155</div> <div><b>Health conditions studied</b></div> <div><b>1</b></div> <div><b>Description of health condition studied</b></div> <div>Chronic non-specific back pain</div> <div><b>ICD-10 code</b></div> <div>M54.5</div> <div><b>ICD-10 code description</b></div> <div>Back pain</div> <div><b>Primary outcomes</b></div> <div><b>1</b></div> <div><b>Description</b></div> <div>Pain</div> <div><b>Timepoint</b></div> |
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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

**Street address**

Tehran-Evin-Shahid Beheshti University-in front of the Vice-Chancellor of Information and Communication Technology-Faculty of Sports and Health Sciences-Building No. 2

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**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University

**Full name of responsible person**

Mehdi Gheitasi

**Street address**

Department of Health and Sports Rehabilitation,  
Shahid Beheshti University, Shahid Shahriari Square,  
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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

## 2

### Sponsor

**Name of organization / entity**

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**Full name of responsible person**

Behrooz Abtahi

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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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

University of Tehran

**Full name of responsible person**

Arash Khaledi

**Position**

Specialist in rehabilitation and corrective exercises

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

### Contact

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 Mehdi Gheitasi  
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**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
 Shahid Beheshti University  
**Full name of responsible person**  
 Mehdi Gheitasi  
**Position**  
 Assistant professor  
**Latest degree**  
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**Other areas of specialty/work**  
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[https://www.sbu.ac.ir/web/sport/%D8%AF%DA%A9%D8%AA%D8%B1-%D9%85%D9%87%D8%AF%DB%8C-%D9%82%DB%8C%D8%B7%D8%A7%D8%B3%DB%8C?p\\_l\\_back\\_url=%2Fgroup%2Fsport%2F%7E%2Fcontr ol\\_panel%2Fmanage%3Fp\\_p\\_id%3Dcom\\_liferay\\_layou t\\_admin\\_web\\_portlet\\_GroupPagesPortlet%26p\\_p\\_lifec ycle%3D0%26p\\_p\\_state%3Dmaximized%26p\\_p\\_mode %3Dview%26\\_com\\_liferay\\_layout\\_admin\\_web\\_portlet \\_GroupPagesPortlet\\_tabs1%3Dpages%26\\_com\\_liferay \\_layout\\_admin\\_web\\_portlet\\_GroupPagesPortlet\\_privat eLayout%3Dfalse%26\\_com\\_liferay\\_layout\\_admin\\_web \\_portlet\\_GroupPagesPortlet\\_displayStyle%3Dmiller- columns%26\\_com\\_liferay\\_layout\\_admin\\_web\\_portlet\\_ GroupPagesPortlet\\_selPlid%3D24540%26p\\_r\\_p\\_layout SetBranchId%3D0%26p\\_p\\_auth%3DUMPM1GOV](https://www.sbu.ac.ir/web/sport/%D8%AF%DA%A9%D8%AA%D8%B1-%D9%85%D9%87%D8%AF%DB%8C-%D9%82%DB%8C%D8%B7%D8%A7%D8%B3%DB%8C?p_l_back_url=%2Fgroup%2Fsport%2F%7E%2Fcontr ol_panel%2Fmanage%3Fp_p_id%3Dcom_liferay_layou t_admin_web_portlet_GroupPagesPortlet%26p_p_lifec ycle%3D0%26p_p_state%3Dmaximized%26p_p_mode %3Dview%26_com_liferay_layout_admin_web_portlet _GroupPagesPortlet_tabs1%3Dpages%26_com_liferay _layout_admin_web_portlet_GroupPagesPortlet_privat eLayout%3Dfalse%26_com_liferay_layout_admin_web _portlet_GroupPagesPortlet_displayStyle%3Dmiller- columns%26_com_liferay_layout_admin_web_portlet_ GroupPagesPortlet_selPlid%3D24540%26p_r_p_layout SetBranchId%3D0%26p_p_auth%3DUMPM1GOV)

## 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