Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of a workout with a pelvic clock tool on central muscle endurance, torso range of motion and pain intensity in middle-aged women with nonspecific chronic low back pain

Protocol summary

Study aim
The effect of a workout with a pelvic clock tool On endurance of central body muscles, torso range of motion and pain intensity in middle-aged women with non-specific chronic low back pain

Design
A randomized clinical trial with simple and available sampling was performed on 30 patients with nonspecific chronic low back pain.

Settings and conduct
This 1400 randomized clinical trial was performed in Tehran through simple and available sampling.

Participants/Inclusion and exclusion criteria
Inclusion criteria: nonspecific back pain that is at least 3 months old, more than 40 years old and less than 50 years old, no history of radicular pain and any neurological symptoms, systemic infection, cardiovascular disorders and balance, no pregnancy History of metabolic, systemic, inflammatory, rheumatic and malignant diseases. Exclusion criteria: Existence of a history of recent trauma and fracture and recent lower limb injury Existence of apparent instability in the lumbar region History of spinal surgery and deformity or severe spinal disease

Intervention groups
workout with a pelvic clock tool

Main outcome variables
endurance of central body muscles, torso range of motion، pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220117053752N1**
Registration date: **2022-06-05, 1401/03/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-05, 1401/03/15**
Update count: **0**

Registration date
2022-06-05, 1401/03/15

Registrant information

Name
Forough Sepiddar

Name of organization / entity
Islamic Azad University of Science and Research

Country
Iran (Islamic Republic of)

Phone
+98 21 4467 1640

Email address
forough.sepidar@srbiau.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-30, 1401/03/09

Expected recruitment end date
2022-06-14, 1401/03/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of a workout with a pelvic clock tool on central muscle endurance, torso range of motion and pain intensity in middle-aged women with nonspecific chronic low back pain

Public title
The effect of a workout with a pelvic clock tool on central muscle endurance, torso range of motion and pain intensity in middle-aged women with nonspecific chronic low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Nonspecific back pain that is at least 3 months old Age over 40 years and under 50 years No history of radicular pain and any neurological symptoms, systemic infection, cardiovascular and balance disorders Not pregnant No history of metabolic, systemic, inflammatory, rheumatic and malignant diseases
Exclusion criteria:
Existence of a history of recent trauma and fracture and recent lower limb injury Existence of obvious instability in the lumbar region History of spinal surgery and deformity or severe spinal disease
Age
From **40 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
RA simple randomization method was used to assign individuals to two groups, which was done by coin tossing method. This method is usually used to create a random sequence in two-group experiments in such a way that one of the study groups considers the lion and the other group the line, and based on the sample size, coins were tossed and Individuals are assigned to two random groups. In order to make it clear that before allocating people to two groups, it is not clear to which group individuals will be assigned, or in other words, hiding the random allocation (Allocation concealment) by the method of opaque envelopes sealed with sequentially randomized sequence (Sequentially numbered, sealed opaque envelopes) was used. This method is one of the common methods in concealing random allocation, which is abbreviated to SNOSE method. In this method, after a random sequence, a number of envelopes are prepared and each of the random sequences created is recorded on a card and the cards are placed in the envelopes respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened and the assigned group of the participant is revealed.
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
Research Ethics Committees of Islamic Azad University- Science and Research Branch
Street address
Tehran: Ekbatan Phase 2, Block 3, Entrance 6, Unit 122
City
Tehran
Province
Tehran
Postal code
1396948111
Approval date
2021-11-22, 1400/09/01
Ethics committee reference number
IR.IAU.SRB.REC.1400.278

Health conditions studied

1

Description of health condition studied
Chronic non-specific low back pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Endurance of the muscles of the central part of the body
Timepoint
Before and after interventions
Method of measurement
McGill Tests

2

Description
Range of motion of the trunk
Timepoint
Before and after interventions
Method of measurement
modified-modified Shober's technique

3

Description
Intensity of pain
Timepoint
Before and after interventions
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Muscular strength of torso extensions
Timepoint
Before and after interventions
Method of measurement
Nicholas handheld dynamometer

2

Description
Proprioception Functional
Timepoint
Before and after interventions
Method of measurement
Universal Goniometer in method Newcomer

3

Description
Movement Control Ability
Timepoint
Before and after interventions
Method of measurement
Luomajoki Motion Control Tests

4

Description
Static balance
Timepoint
Before and after interventions
Method of measurement
BESS test

5

Description
Dynamic balance
Timepoint
Before and after interventions
Method of measurement
Star test

Intervention groups

1

Description
Intervention group: The training protocol of the present study is derived from Pilates exercises, the movements of which are performed on a sports mat. The exercises include 18 movements of Pilates exercises (the protocol consists of three parts: 1- Ten stretching exercises for the pelvis and back 2- Two stretching exercises for the direction of the body 3- Six exercises for central body stability). Exercises are performed for eight weeks (3 sessions of 45 minutes per week) under the supervision of a doctor. The intensity of the exercises is based on increasing the subject's ability to perform the exercises while keeping the body in line and without feeling pain. The equipment used to perform the exercises includes a sports mat and a compressed foam.
Category
Rehabilitation

2

Description
Control group:
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr.Barati sports medicine clinic
Full name of responsible person
Amirhossein Barati
Street address
Unit 5, No 8, Nemati Alley, Ostad Hassan, Bana Ave.
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1667753316
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ahbarati20@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University, Science and Research Branch, Tehran
Full name of responsible person
Forough Sepiddar
Street address
Tehran: Ekbatan Phase 2, Block 3, Entrance 6, Unit, 122
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Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University, Science and Research Branch, Tehran

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
Shahid Beheshti University

Full name of responsible person
Amirhossein Barati

Position
Associated Professor

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

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Valenjac_ Daneshjou Blvd_ Shahid Beheshti University

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Person responsible for scientific inquiries

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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data can be shared after identifying individuals.

When the data will become available and for how long

All data can be shared after identifying individuals.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

After identifying the participants, all the data can be made available to researchers, and any other analysis of the data and any use for research and therapeutic purposes of this study is allowed

From where data/document is obtainable

Islamic Azad University, Research Sciences Branch, Department of Physical Education. Forough Sepiddar- Contact number 09195901181 Email: Sepidar1181@gmail.com

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

After receiving the message from the applicant and reviewing the application conditions, the required information will be sent to the person at the earliest opportunity.

Comments

I do not have