Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of postural restoration institute (PRI) training on pain, disability and selected biomechanical variables during walking in middle-aged men with and without nonspecific chronic low back pain with emphasis on modeling

Protocol summary

Study aim
Clinical trial of eight weeks of (PRI) training on pain, disability, kinematics (coordination and variability) and kinetics (joint power) during walking in middle-aged men with and without chronic nonspecific low back pain with emphasis on modeling.

Design
A clinical trial of Postural restoration Institute exercises with two control groups (healthy 14 and low back pain 14), with Parallel groups, not blinded, quasi-experimental grouping on 14 low back pain patients

Settings and conduct
The intervention group performed (PRI) exercise at the Behbood Center of Corrective Movement and Health for eight weeks, three sessions per week and each session for about 1 hour. This research is semi-experimental. There were 42 participants and they were divided into three groups: healthy (n = 14), control (n = 14) and intervention (14). Data were collected based on Visual Analogue Scale (VAS) and Roland Morris Disability Questionnaire (RMDQ) as well as biomechanical variabilitys before and after the intervention. The intervention group participated in a three-hour training session on the research process and how to perform the Training of the Posture Restoration Institute (PRI).

Participants/Inclusion and exclusion criteria
Having nonspecific chronic low back pain; Having pain in the lower back and buttocks; No severe injuries to the upper and lower limbs; Being in the age range of 30 to 50 years; Absent of any major orthopedic or neuromuscular surgery; No disc herniation and spinal canal stenosis

Intervention groups
Intervention group: A group of people with chronic non-specific low back pain to whom the exercises of the Posture restoration Institute are applied. Control group: Tow groups of healthy people and low back pain patient to compare the biomechanical variables of the intervention group with them.

Main outcome variables
Pain; disability; joints range of motion.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211127053189N1**
Registration date: **2021-12-15, 1400/09/24**
Registration timing: **retrospective**

Last update: **2021-12-15, 1400/09/24**
Update count: **0**

Registration date
2021-12-15, 1400/09/24

Registrant information

Name
Ali Salimi

Name of organization / entity
The University of Kharazmi

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

2021-05-10, 1400/02/20

Actual recruitment end date

2021-06-05, 1400/03/15

Trial completion date

2021-08-24, 1400/06/02

Scientific title

Clinical trial of postural restoration institute (PRI) training on pain, disability and selected biomechanical variables during walking in middle-aged men with and without nonspecific chronic low back pain with emphasis on modeling

Public title

Clinical trial of postural restoration institute (PRI) training on pain, disability and selected biomechanical variables

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

No medical prohibition to participate in the training program ability and opportunity to study no moral prohibition to participate no upper and lower limb injuries no visible deformity being in the age range of 30 to 50 years filling satisfaction Conscious no injury from injury or load on the lumbar region, disc herniation or spinal canal stenosis

Exclusion criteria:

Reluctance to participate for any reason A history of dangerous symptoms related to specific low back pain Observe signs of neurological problems that include weakness or numbness in the lower extremities Any lower limb changes that potentially alter trunk movement while standing (For example leg fractures) Vestibular disorder (balance problem) is observed in the person The person has severe mental health problems Roland Morris Low Back Disability Questionnaire scores less than 5

Age

From **30 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Kharazmi University Ethics Committee

Street address

Faculty of physical education; South Razan; Mirdamad;Tehran

City

Tehran

Province

Tehran

Postal code

Iran

Approval date

2019-12-09, 1398/09/18

Ethics committee reference number

IR.KHU.REC.1399.024

Health conditions studied

1

Description of health condition studied

Nonspecific chronic low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain (based on visual analog scale, Score between 3 and 6)

Timepoint

Before and after exercise

Method of measurement

Visual analog scale, Score between 3 and 6

2

Description

disability

Timepoint

Before and after exercise

Method of measurement

Roland Morris Disability Questionnaire, Score more than 5

3

Description

Range of motion

Timepoint
Before and after exercise

Method of measurement
Inclinometer

Secondary outcomes

1

Description
kinematic variables of gait

Timepoint
Before and after exercise

Method of measurement
Qualisys motion capture system

2

Description
kinetic variables of gait

Timepoint
Before and after exercise

Method of measurement
kistler force platform

Intervention groups

1

Description
Intervention group: The intervention group performed (PRI) exercise at the Behbood Center of Corrective Movement and Health for eight weeks, three sessions per week and each session for about 1 hour.

Category
Rehabilitation

2

Description
Control group: Healthy group to compare with the intervention group who did not do any exercise program.

Category
Other

3

Description
Control group: Low back pain control group without exercise to neutralize the effect of time on the desired variables.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Center of Behbood health and corrective movements

Full name of responsible person
Fatemeh Fazel Najafabadi

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
researchist

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
The University of Kharazmi

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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