

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of motor control, neurological and cognitive exercises on psychological and kinetic variables of gait in patients with chronic nonspecific low back pain

Protocol summary

Study aim

The aim of the present study is the effect of motor, neurological and cognitive control exercises on the psychological and kinetic variables of walking in patients with non-specific chronic back pain.

Design

Clinical trial, with factorial groups, double-blind, randomized, on 100 patients, Random Number Generator software was used for randomization.

Settings and conduct

The present research is conducted in the sports rehabilitation laboratory of Boali Sina University, Hamadan. In this study, the subjects and the examiner were blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women between the ages of 30 and 60 years old, diagnosis and confirmation of non-specific chronic back pain by a specialist doctor
Exclusion criteria: having a history of injury in the past year in the trunk and lower limbs, having a history of surgery in the back and lower limbs

Intervention groups

Individuals will be assigned to one of four groups: motor control exercises, motor control exercises combined with neurofeedback exercises, motor control exercises combined with cognitive exercises and a combined group (motor control exercises, neurofeedback exercises and cognitive exercises).

Main outcome variables

Measurement of pain, disability, fear of movement, muscle activity, vertical ground reaction force

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230430058033N1**

Registration date: **2023-05-04, 1402/02/14**

Registration timing: **prospective**

Last update: **2023-05-04, 1402/02/14**

Update count: **0**

Registration date

2023-05-04, 1402/02/14

Registrant information

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Name of organization / entity

The University of Bo Ali Sina Hamedan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-10, 1402/02/20

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of motor control, neurological and cognitive exercises on psychological and kinetic variables of gait in

patients with chronic nonspecific low back pain

Public title
Investigating the effect of motor control, neurological and cognitive exercises on non-specific chronic back pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women between the ages of 30 and 60
Diagnosis and confirmation of non-specific chronic back pain by a specialist doctor
Not participating in other sports activities
Presence of at least two movement control disorders in Lomajoki movement control tests
Exclusion criteria:
Having a history of injury in the past year in the trunk and lower limbs
A history of surgery in the back and lower limbs
People with back pain of non-mechanical origin
Participants if they have already experienced neurofeedback

Age
From **30 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomized based on Random Number Generator software. In addition to simple randomization, random sequence generation softwares are capable of generating random sequences by block method. Nowadays, due to its ease of use and saving time, this method has replaced other random sequence generation methods. And then, based on the concealment of the SNOSE method, the allocation is divided into one of four groups: motor control exercises, motor control exercises along with neurofeedback exercises, Movement control exercises along with cognitive exercises and combined group (motor control exercises, neurofeedback exercises and cognitive exercises) will be assigned. This method is one of the common methods of hiding random allocation. In this method, first, a random sequence is created by the Random Number Generator software, then, based on the sample size of the research, a number of envelopes with aluminum foil (for the lack of clarity of the contents of the envelopes), preparation and each of the random sequences created on A card is recorded and the cards are placed in the letter envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order. At the time of the registration of the participants,

according to the order of entry of the eligible participants into the study, one of the letter envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
During the initial test before the beginning of the training period and also the secondary test after the training, the researcher was not involved in the tests in any way and the tests were done by people who did not know about the plan. They were aware and acted completely anonymously according to the orders. The person who was in charge of analyzing the data did not know about the study and examined the data in general.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Bu Ali Sina Hamadan University
Street address
Pajohesh Intersection, Mahdiah Street
City
Hamedan
Province
Hamadan
Postal code
65178-38695
Approval date
2022-09-14, 1401/06/23
Ethics committee reference number
IR.BASU.REC.1401.026

Health conditions studied

1

Description of health condition studied

Chronic non-specific back pain

ICD-10 code

S30.0XXS

ICD-10 code description

Contusion of lower back and pelvis, sequela

Primary outcomes

1

Description

Muscle activity

Timepoint

At the beginning of the study before the interventions and 60 days after the exercises

Method of measurement

EMG A device for measuring muscle activity

2

Description

vertical earth reaction force

Timepoint

At the beginning of the study before the interventions and 60 days after the exercises

Method of measurement

Foot pressure measuring device

3

Description

Brain Waves

Timepoint

At the beginning of the study before the interventions and 60 days after the exercises

Method of measurement

Neurofeedback device

4

Description

Cognitive function

Timepoint

At the beginning of the study before the interventions and 60 days after the exercises

Method of measurement

Fully listening to the patient in order to widely identify multidimensional stimuli that can change pain and disability (cognitive behaviors that trigger pain, movement, and lifestyle)

Secondary outcomes

1

Description

Visual measurement of pain

Timepoint

At the beginning of the study before the interventions and 60 days after the exercises

Method of measurement

Use the Visual Analogue Scale

2

Description

Disability

Timepoint

At the beginning of the study before the interventions and 60 days after the exercises

Method of measurement

Oswestry Disability Questionnaire

3

Description

Quality of Life

Timepoint

At the beginning of the study before the interventions and 60 days after the exercises

Method of measurement

Sherborn SF36 Questionnaire

Intervention groups

1

Description

Intervention group: Movement control exercises in eight weeks, three sessions a week and each session about 60 minutes (n=25). Movement control exercises will be performed in eight weeks, three sessions a week and each session will last about 60 minutes under the supervision of the researcher for all four exercise groups in the same way. This part will include about 10 minutes of general warm-up, about 40 minutes of movement control exercises and 10 minutes of cooling exercises in the form of stretching exercises. The movement control exercise program is based on the treatment program of Hodges et al. (2007). The primary goal of these exercises is to enable the patient to achieve control and coordination of the spine and pelvis using the principles of motor learning.

Category

Rehabilitation

2

Description

Intervention group: The group of motor control and neurofeedback exercises is a combination of two motor control and neurofeedback approaches. (n=25). Neurofeedback exercises will be conducted individually in the psychology laboratory of Bo Ali Sina University, Hamedan, 3 times a week for 30 minutes during eight weeks. The selected protocol for neurofeedback exercises will be in accordance with previous studies in the form of increasing the sensorimotor rhythm and decreasing beta and theta in the CZ region. Brain waves are processed by an amplifier and a computer device and provide appropriate feedback. The feedback process is like a person playing a computer game on his monitor. Unlike common games, a person does not use his hand to control the game, but does it through his brain waves

Category

Rehabilitation

3

Description

Intervention group: The group of motor and cognitive control exercises is a combination of two motor and cognitive control approaches (n= 25). Cognitive exercises will be done individually for eight weeks, 3 sessions a week for 30 minutes in the psychology

laboratory of Bo Ali Sina University, Hamedan. It will include listening to the patient's full story about their pain. This careful examination is essential in order to broadly identify modifiable multidimensional drivers of pain and disability (pain-triggering cognitive behaviors, movement, and lifestyle) for each participant. Each patient receives an individual targeted intervention aimed at changing individual cognitive, motor and lifestyle behaviors.

Category

Rehabilitation

4

Description

Intervention group: the combined group of motor control and neurocognitive exercises (n=25). In this way, movement control exercises will be performed on even days and neurological and cognitive exercises will be performed on odd days.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baath Hospital

Full name of responsible person

Ali Yalfani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

The University of Bu Ali Sina

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

The University of Bu Ali Sina

Full name of responsible person

Arash Ghorbani

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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

The University of Bu Ali Sina

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

The University of Bu Ali Sina

Full name of responsible person

Azadeh Asgarpoor

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Corrective Exercise and Sports Injuries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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

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

No - There is not a plan to make this available

Title and more details about the data/document

All data and documentation can be shared, but with the unidentifiable of people and private information for subjects

When the data will become available and for how long

Starting Data access 1 year after printing results

To whom data/document is available

Researchers who conduct research in this direction are allowed to take action to receive documents

Under which criteria data/document could be used

Only the type of analysis that can be done in the research can be redefined. It can also use the training protocol. Obligation not to misuse research data

From where data/document is obtainable

azadehasgarpoor@gmail.com

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

When the applicant submits a documents for her/his work area in relation to the subject matter of the thesis and if the request is reasonable and the commitment not to misuse the data of this research, the data will be sent to him within 1 week of work

Comments