Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Trunk Motor Control Exercises Along with Pain Neuroscience Education in Water and Land Environment on Disability, Psychological Variables and Postural Control of Patients with Non-Specific Chronic Low Back Pain: A Randomized Controlled Trial

Protocol summary

Study aim

The Effect of Trunk Motor Control Exercises Along with Pain Neuroscience Education in Water and Land Environment on Disability, Psychological Variables and Postural Control of Patients with Non-Specific Chronic Low Back Pain.

Design

This Clinical Trial as Parallel Design. The Patients will be Completely Randomly Assigned to two Experimental Groups and one Control Group, so that Random Codes by an Evaluator who is not Aware of the Study Design Deliver them to the Patients. The Experimental Group will Receive Rehabilitation Protocol for 4 and 8 Weeks, and the Control Group will not Receive any Intervention.

Settings and conduct

All Tests and Rehabilitation Protocol will be done in the Laboratory and Swimming Pool of Bu-Ali Sina University. Patients will be Randomly Assigned to Two Experimental Groups and one Control Group, so that Random Codes will be Delivered to Patients by an Evaluator who is not Aware of the Study Design. As a Result, Patients and Assessors will be Unaware of Group Allocation.

Participants/Inclusion and exclusion criteria

Pain in Other Joints Misalignment of Upper and Lower Limbs History of Surgery Use of Painkillers in the Past 6 Months Physiotherapy in the Last Year Participate in Sports Sciatica Pain Spondylolysis Neuromuscular Disorders Neurological Disorder Respiratory Disorders Muscle Spasm Vertebral Fractures.

Intervention groups

Two Experimental Groups will Receive the Combination of Motor Control Exercises with Pain Neuroscience Education in Water and Land to 4 and 8 Weeks. The Third Group, Which is the Control Group, will not Perform any Rehabilitation Exercises During this Period.

Main outcome variables

Pain, Disability, Fear of Movement, Stress, Anxiety, Depression, Pain Catastrophizing, Posture Control, Plantar Pressure Distribution, Vertical Ground Reaction Force

General information

Reason for update

Acronym

CNSLBP

IRCT registration information

IRCT registration number: **IRCT20240311061249N1**
Registration date: **2024-03-30, 1403/01/11**
Registration timing: **retrospective**

Last update: **2024-03-30, 1403/01/11**
Update count: **0**

Registration date

2024-03-30, 1403/01/11

Registrant information

Name

Fatemeh Sori

Name of organization / entity

Bu_Ali Sina University of Hamedan

Country

Iran (Islamic Republic of)

Phone

+98 81 3429 6149

Email address

fatemesori1862@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Trunk Motor Control Exercises Along with Pain Neuroscience Education in Water and Land Environment on Disability, Psychological Variables and Postural Control of Patients with Non-Specific Chronic Low Back Pain: A Randomized Controlled Trial

Public title

The Effect of Trunk Motor Control Exercises Along with Pain Neuroscience Education in Patients with Non-Specific Chronic Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from Chronic Low Back Pain for More than 3 Months The Cause of Low Back Pain is Unknown Age Range from 30 to 60 Years Pain Intensity more than 45 mm on the Visual Analog Scale Oswestrian Disability Index More than 25

Exclusion criteria:

Pain in other Joints Misalignment of Upper and Lower Limbs History of Surgery Use of Painkillers in the Past 6 Months Physiotherapy in the Last Year Participate in Sports Sciatica Pain Spondylolysis Neuromuscular Disorders Neurological Disorder Respiratory Disorders Muscle Spasm Vertebral Fractures

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

First, Random Codes will be Generated Using Random Allocation Software and then they will be Placed Inside Sealed Envelopes. An Evaluator who is not Aware of the Study Purpose will Randomly Deliver the Envelopes to the Patients. As a Result, Patients will be Assigned to Experimental and Control Groups (30 People in Each Group) with a 1:1:1 Allocation. Patients and Assessors will be Unaware of Group Allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

First, Random Codes will be Generated Using Random Allocation Software and then they will be Placed Inside Sealed Envelopes. An Evaluator who is not Aware of the Study Purpose will Randomly Deliver the Envelopes to the Patients. As a Result, Patients will be Assigned to Experimental and Control Groups (30 People in Each Group) with a 1:1:1 Allocation. Patients and Assessors will be Unaware of Group Allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه بوعلی سینا

Street address

Madani Town, Azadegan Street, 2 Yas Alley, Azin Building, Unit 8

City

Hamedan

Province

Hamadan

Postal code

6513861328

Approval date

2024-03-09, 1402/12/19

Ethics committee reference number

IR.BASU.REC.1402.095

Health conditions studied

1

Description of health condition studied

Chronic Non-Specific Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low Back Pain

Primary outcomes

1

Description

Pain, Fear of Movement, Stress, Anxiety, Depression, Pain Catastrophizing

Timepoint

In this Clinical Trial, the Researcher Intends to Evaluate the Variables of Pain, Fear of Movement, Stress, Anxiety, Depression, Pain Catastrophizing in Two time Periods

Before the Intervention (Pre-Test) and After the Intervention (4 and 8 Weeks).

Method of measurement

Pain (Visual Analog Scale), Fear of Movement (Tampa Questionnaire), Stress, Anxiety and Depression (Stress, Anxiety and Depression Questionnaire), Pain Catastrophizing (Pain Catastrophizing Questionnaire)

Secondary outcomes

1

Description

Disability, Postural Control, Plantar Pressure Distribution, Vertical Ground Reaction Force

Timepoint

In this Clinical trial, the Researcher Intends to Evaluate Disability Variables, Posture Control, Plantar Pressure Distribution, Vertical Ground Reaction Force in two time Periods before the Intervention (Pre-Test) and after the Intervention (4 and 8 Weeks).

Method of measurement

Disability (Oswestory Questionnaire), Posture Control, Plantar Pressure Distribution and Vertical Ground Reaction Force (Foot Pressure)

Intervention groups

1

Description

Intervention Group: Motor Control Exercises in Four Weeks, 6 Sessions per Week (3 Sessions in the Swimming Pool of Bu-Ali Sina University and 3 Sessions in the Sports hall of Bu-Ali Sina University) Each Session will be done for 30 to 45 Minutes and the Neuroscience Education Includes 8 Topics Along with Verbal Explanations be Presented for 10 Minutes before the Beginning of the Treatment Sessions

Category

Rehabilitation

2

Description

Intervention Group: Motor Control Exercises will be done in Eight Weeks, (4 Weeks in Water and 4 Weeks on Land) Three Sessions per Week for 30 to 45 Minutes Each Session and Neuroscience Education Includes 8 Topics with Oral Explanations for 10 It will be Provided Minutes Before the Start of Treatment Sessions.

Category

Rehabilitation

3

Description

Control Group: They will not Receive any Intervention.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinics of Hamedan Province

Full name of responsible person

Fatemeh Sori

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Madani Town, Azadegan Street, 2 Yas Alley, Azin Building, Unit 8

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Phone

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Email

fatemesori1862@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bu-Ali Sina University, Hamedan

Full name of responsible person

Ali Yalfani

Street address

Madani Town, Azadegan Street, 2 Yas Alley, Azin Building, Unit 8

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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

There is no source of financial support.

Proportion provided by this source

1

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Bu-Ali Sina University, Hamedan

Full name of responsible person
Ali Yalfani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

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Madani Town, Azadegan Street, 2 Yas Alley, Azin Building, Unit 8

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All Data and Documents Can be Shared, but with the Non-Identification of People and the Preservation of Private Information of Subjects.

When the data will become available and for how long
The Results of this Study will be Available 3 Months after Publication in Journals.

To whom data/document is available
The Results of the Studies will be Accessible to all Members of the Society Without any Restrictions.

Under which criteria data/document could be used
The Presented Documentation Can be Used for the Treatment of Non-Specific Chronic Low Back Pain. These Interventions are Applicable if they are Prescribed and Supervised by a Physiotherapist.

From where data/document is obtainable
Fateme Soori's email Address is fatemesori1862@gmail.com

What processes are involved for a request to access data/document
When the Applicant Provides Documents for her Field of Work Related to the Subject of the Thesis and in Case of a Reasonable Request and a Commitment not to Misuse

the Data of This Research, the Data will be Sent to her for 1 Working Week.

Comments