

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The comparison of lumbosacral manipulation with and without pain neuroscience education method in treatment of nonspecific chronic low back pain in athlete with sacroiliac dysfunction

Protocol summary

Study aim

The comparison of lumbosacral manipulation with and without pain neuroscience education method in treatment of nonspecific chronic low back pain in athlete with sacroiliac dysfunction

Design

Randomised clinical trial with control group, sample size of 38 subjects, permutation block randomization In blocks 4-digit blocks, 2 groups of intervention and control with 19 subjects in each group

Settings and conduct

Athletes who are referred to Shiraz School of Rehabilitation Sciences by a physician with a diagnosis of chronic non-specific low back pain will enter the study after evaluating the entry criteria. The intervention group will receive sacroiliac and lumbar manipulation technique with pain neuroscience education technique during 3 sessions and the control group will receive only sacroiliac and lumbar manipulation technique during 3 sessions

Participants/Inclusion and exclusion criteria

Age range 18-32, Non-specific chronic low back pain, Individuals who performed specialized exercise at least three times a week for two hours each session, Pain based on the Numerical Rate Scale (NRS) between 3 and 6, Functional disability based on the Oswestry Disability Index (ODI) questionnaire between 20 and 40, Catastrophizing pain based on the Pain Catastrophizing Scale (PCS) questionnaire between 26 and 39

Intervention groups

Intervention group: sacroiliac and lumbar manipulation technique with pain neuroscience education technique (3 sessions) Control group: only sacroiliac and lumbar manipulation technique as a basic treatment (3 sessions)

Main outcome variables

Pain; functional disability; catastrophizing pain; balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200218046542N1**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **prospective**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

mahdi soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-04, 1399/03/15

Expected recruitment end date

2020-09-15, 1399/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of lumbosacral manipulation with and without pain neuroscience education method in treatment of nonspecific chronic low back pain in athlete with sacroiliac dysfunction

Public title

The effect of Pain Neuroscience Education technique on Nonspecific chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non-specific chronic low back pain Who performed specialized exercise at least three times a week for two hours each session Pain between 3 to 6 based on the NRS Functional disability between 20 to 40 based on the ODI questionnaire Catastrophizing pain between 26 and 39 based on the PCS questionnaire sacroiliac dysfunction

Exclusion criteria:

Patient dissatisfaction Do additional therapy in addition to the treatment specified in the study Patients who are included in one of the cases of absolute non-use of interventions such as Recent infections, cancer, use anticoagulants, lymphedema, etc. History of spine surgery Osteoporosis Leg length difference Use of painkillers and anti-inflammatory drugs over the past three months Recent physiotherapy in the past three months Spinal deformities including scoliosis Cauda equina syndrome Neurological symptoms from pressure on the nerve Disc herniation Pregnancy Inability to read and write Having medical or paramedical information (such as neuroanatomy-neurophysiology information)

Age

From **18 years** old to **32 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed by permutation block randomization method with 4-digit blocks (two groups of 19 subjects)

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher who will do the manipulation and assess the outcome measures, as well as the statistic specialist will be unaware of the control and intervention groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz university of Medical Sciences

Street address

Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-07-31, 1398/05/09

Ethics committee reference number

IR.SUMS.REHAB.REC.1398.023

Health conditions studied

1

Description of health condition studied

Chronic low back pain with sacroiliac dysfunction

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

pain intensity

Timepoint

Before, after 3 sessions and after one month

Method of measurement

Numerical rate scale

2

Description

Functional disabilities

Timepoint

Before, after 3 sessions and after one month

Method of measurement

Oswestry disability index

3

Description

Pain catastrophizing rate

Timepoint

Before, after 3 sessions and after one month

Method of measurement

pain catastrophizing scale questionnaire

4**Description**

Static balance with closed eyes

Timepoint

Before, after 3 sessions and after one month

Method of measurement

Single leg stance bilaterally with closed eyes

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Performing sacroiliac and lumbar manipulation similar to the control group with a pain neuroscience education technique that teaches about pain management and control it. This technique is performed in three sessions and each session is about 90 minutes before other interventions by PowerPoint and clip. And within a month, the taught material will be sent every week to remind them. In fact, PNE technique creates a new perception of the past and previous experience. Due to the lack of focus on the damaged tissue and Pain is taught simply in neurobiology and neurophysiology. In other words, the patient is informed about the mechanism of pain and neuroanatomy in practice. And this makes it possible to identify false pains of psychological origin and improve them.

Category

Rehabilitation

2**Description**

Control group: only perform lumbar and sacroiliac manipulation techniques as baseline treatment in three sessions

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz School of Rehabilitation Sciences

Full name of responsible person

Mohamad Mahdi Soltani

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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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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

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**

Shiraz University of Medical Sciences

Full name of responsible person

Mohamad Mahdi Soltani

Position

Student

Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

The results will be published as an article in the research international journals

When the data will become available and for how long

In the next 1 to 2 years

To whom data/document is available

Only people who ask the main investigator for the information

Under which criteria data/document could be used

With the permission through a written or oral request

From where data/document is obtainable

School of Rehabilitation Sciences. Shiraz University of Medical Sciences

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

School of Rehabilitation Sciences. Shiraz University of Medical Sciences

Comments