# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 Catasrophizing 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**

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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 catasrophizing rate

**Timepoint**
Before, after 3 sessions and after one month
**Method of measurement**
pain catastrophizing scale questionnare

**4**

**Description**
Static balance with closed eyes
**Timepoint**
Before,after 3 sessions and after one month
**Method of measurement**
Single leg stance bilateraly 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**
Shiraz University of Medical Sciences
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Younes Ghasemi
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vcrdep@sums.ac.ir
**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
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Physiotherapy
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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**
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**