

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison the Craniosacral Therapy, Sensorimotor Training and Muscle Energy Technique on Postural control, pain, Functional Disability, Depression and Quality of Life in Low Back Pain Patients and with Malalignment of the Pelvis

#### Protocol summary

##### Study aim

The aim of this study is to compare the effects of Craniosacral therapy, Sensorimotor training and Muscle energy technique in patients Low back pain (LBP) patients with pelvic malalignment.

##### Design

A three parallel, Randomized, clinical trial. All patients were assessed before, immediately after and 2 months after study. After allocation of 46 participants to study, they were randomized into Craniosacral therapy (n= 16), Sensorimotor training (n=15) and Muscle energy techniques (n=15) using random numbers in the sealed envelopes.

##### Settings and conduct

All patients with non-specific chronic low back pain with pelvic malalignment were allocated to study at physiotherapy clinic of School of Rehabilitation of Iran University of Medical Sciences from 2016, July to 2017, August. All patients received information about the trial and informed consent was received from each participant.

##### Participants/Inclusion and exclusion criteria

Patients with ages 20 to 40 years with history of more than 3 months LBP and pain intensity between 4 and 6 (based on Visual Analogue Scale) were included. Also, Patients with history of spinal surgery, neurologic symptoms and non-mechanical pain were excluded.

##### Intervention groups

All patients received 10 therapeutic sessions in 5 weeks. In the Craniosacral therapy group, the therapist tried sensing and following cerebrospinal fluid and craniosacral movement in 4 positions. In sensorimotor training group, patients were progressed the ability in static, dynamic and functional tasks respectively. In Muscle energy technique group, the therapist tried finding the direction of rotational and upslip pelvic

malalignment and then correct them with muscle energy techniques.

##### Main outcome variables

Center of pressure displacement; Anterior-posterior center of pressure location; -lateral center of pressure location; Center of pressure displacement velocity using force platform.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170117032020N3**

Registration date: **2018-12-10, 1397/09/19**

Registration timing: **retrospective**

Last update: **2018-12-10, 1397/09/19**

Update count: **0**

##### Registration date

2018-12-10, 1397/09/19

##### Registrant information

##### Name

Mohammad Javaherian

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2016-08-22, 1395/06/01

**Expected recruitment end date**

2017-09-22, 1396/06/31

**Actual recruitment start date**

2016-08-22, 1395/06/01

**Actual recruitment end date**

2017-09-22, 1396/06/31

**Trial completion date**

2017-09-22, 1396/06/31

**Scientific title**

Comparison the Craniosacral Therapy, Sensorimotor Training and Muscle Energy Technique on Postural control, pain, Functional Disability, Depression and Quality of Life in Low Back Pain Patients and with Malalignment of the Pelvis

**Public title**

Comparison Two Manual Therapy Techniques and Balance Training in Patients with Low Back Pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Presence of back pain (from below the costal margin to inferior gluteal folds) for more than 3 months Pain intensity between 3 and 6 based on visual analogue scale Pain reduction through reduce the strain on affected segment

**Exclusion criteria:**

Presence of symptoms such as Neurological pain, Non-mechanical pain, and General Pain Severe muscle weakness Presence of significant scoliosis History of Spinal surgery Pregnancy during study spondylolisthesis Inflammatory diseases

**Age**

From **20 years** old to **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

Actual sample size reached: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants were divided into treatment groups using simple randomization. Initially, random numbers were identified through Excel software. A researcher who no participate in sampling, treatment, and assessment, put random numbers into sealed envelopes. The therapist opened envelopes immediately before first treatment session, therefore allocations were concealed.

**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**

Ethical committee of Iran University of Medical Sciences

**Street address**

Next to Milad tower, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Approval date**

2016-12-11, 1395/09/21

**Ethics committee reference number**

IR.IUMS.REC.139509211342216

**Health conditions studied****1****Description of health condition studied**

Low Back Pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

**Primary outcomes****1****Description**

Center of pressure displacement

**Timepoint**

Before intervention, 5 weeks after, and 2 months follow-up

**Method of measurement**

Force Platform

**2****Description**

mean of Anterior-posterior Center of pressure location

**Timepoint**

Before intervention, 5 weeks after, and 2 months follow-up

**Method of measurement**

Force Platform

### 3

#### **Description**

mean of medial-lateral Center of pressure location

#### **Timepoint**

Before intervention, 5 weeks after, and 2 months follow-up

#### **Method of measurement**

Force Platform

### 4

#### **Description**

Center of pressure displacement velocity

#### **Timepoint**

Before intervention, 5 weeks after, and 2 months follow-up

#### **Method of measurement**

Force Platform

## **Secondary outcomes**

### 1

#### **Description**

Pain

#### **Timepoint**

Before intervention, 5 weeks after, and 2 months follow-up

#### **Method of measurement**

Visual Analogue Scale

### 2

#### **Description**

Oswestry Disability Index

#### **Timepoint**

Before intervention, 5 weeks after, and 2 months follow-up

#### **Method of measurement**

Oswestry Disability Questionnaire

### 3

#### **Description**

Depression Score

#### **Timepoint**

Before intervention, 5 weeks after, and 2 months follow-up

#### **Method of measurement**

Beck Depression Inventory-II

### 4

#### **Description**

Quality of Life score

#### **Timepoint**

Before intervention, 5 weeks after, and 2 months follow-up

#### **Method of measurement**

Short-form 36 Questionnaire of Quality of Life

## **Intervention groups**

### 1

#### **Description**

Intervention group: Craniosacral therapy (CST); Craniosacral therapy was performed during 10 sessions for 5 weeks. One CST session last about 45 minutes which separates into 4 phase. In each phase, patients were in a specific position for 10 minutes. These phases are 1)Prone position; dominant hand on lower lumbar which moves slightly toward the thoracic and cervical spine and occipital bone; non-dominant hand on the sacrum.2)Side-lying position (behind of therapist) with slightly hip and knee flexion; dominant hand on the occipital bone; non-dominant hand on sacrum.3)Side-lying (in front of the therapist); dominant hand on the frontal bone; non-dominant hand on sacrum 4)Supine position; both hands of temporal and parietal bones of two sides these positions, both the therapist and patient should be relaxed to sense rhythmic CSF and craniosacral movements.

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group: Sensorimotor training, patients receive 10 sessions of balance training during 5 weeks. Patients were progressed through three stage during sessions including static, dynamic and functional. In each stage, patients experience different postures and base of support and their center of gravity is being challenged.

#### **Category**

Treatment - Other

### 3

#### **Description**

Intervention group: Muscle energy technique, In this group, therapist try finding pelvis rotational and upslip malalignment dysfunctions and then correct them using muscle energy techniques during 10 sessions. to find pelvis malalignment, Standing flexion test, Sitting flexion test, Gillet test, Long to sit test, and location of bony landmarks are used. during performing techniques, shortened muscles contract in a sub-maximal isometric form and then therapist try to move lower limb passively to opposite side in order to correct pelvic dysfunction. The patient can help therapist in this movement.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Physiotherapy clinic of Rehabilitation School of Iran University of Medical Sciences

**Full name of responsible person**

Javvad Sarrafzadeh

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School of Rehabilitation, Madadkaran Alley, Shah-Nazari street- Mirdamad Blvd.

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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Kobra Ghasemi

**Position**

PhD candidate

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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School of Rehabilitation of Iran University of Medical Sciences, Madadkaran Alley, Shah-Nazari Street, Mirdamad Blvd,

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Ali Amiri

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Latest degree**

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**Other areas of specialty/work**

Physiotherapy

**Street address**

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**Email**

Koohestan\_3000@yahoo.com

**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**

No - There is not 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**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not 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**

It is not possible to share all data of the study. we can share demographic information of participants and results of outcome measures.

**When the data will become available and for how long**

starting 1 year after publication

**To whom data/document is available**

All academic researchers can apply to receive data.

**Under which criteria data/document could be used**

Researchers can use data only for comparing them with their samples and do not have permission to publish them in any form. They should send us reasons for applying data and personal information.

**From where data/document is obtainable**

Applicants can send request to E-mail address: amiri.alipt1@yahoo.com.

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

After reviewing the reason of request and information of the applicant, data will be shared after 1 month.

**Comments**