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 envelops.

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 1017, 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 symptomes 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

+98 21 7753 3939

Email address

javaherian_m@razi.tums.ac.ir

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 commitee of Iran University of Medical Sciences
Street address
Next to Milad tower, Hemmat highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
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
Ostwestry Disability Index
Timepoint
Before intervention, 5 weeks after, and 2 months follow-up
Method of measurement
Ostwestry 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
Street address
School of Rehabilitation, Madadkaran Alley, Shah-Nazari street- Mirdamad Blvd.
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 7124
Email
sarrafzadeh.j@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyyed Kazem Malakouti
Street address
Next to Milad tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
kmalakouti@iums.ac.ir
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
Street address
School of Rehabilitation of Iran University of Medical Sciences, Madadkaran Alley, Shah-Nazari Street, Mirdamad Blvd,
City
Tehran
Province
Tehran
Postal code
15459113487
Phone
+98 21 2222 7124
Email
Koohestan_3000@yahoo.com

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
Physiotherapy
Street address
School of Rehabilitation of Iran University of Medical Sciences, Madadkaran Alley, Shah-Nazari Street, Mirdamad Blvd,
City
Tehran
Province
Tehran
Postal code
15459113487
Phone
+98 21 2222 7124
Email
amiri.alipt10@yahoo.com

Person responsible for updating data

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
Street address
School of Rehabilitation of Iran University of Medical Sciences, Madadkaran Alley, Shah-Nazari Street, Mirdamad Blvd,
City
Tehran
Province
Tehran
Postal code
15459113487
Phone
+98 21 2222 7124
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.alipt١٠@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