Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The comparison of trunk balance exercises and whole body vibration on the postural control of the patients with chronic non-specific low back pain.

Protocol summary

Study aim

The purpose of this study was to compare the effects of trunk balance exercises and whole body vibration on postural control in patients with chronic non-specific LBP.

Design

The Randomized Clinical Trial consisted of two groups of patients (balance training group and whole body vibration group) and consist of 50 patients. The study was single blind.

Settings and conduct

The study was performed at physiotherapy clinics of Shiraz University of Medical Sciences. both groups performed trunk balance training or whole body vibration. The randomization method was performed by a person who had no role in the evaluation and intervention.

Participants/Inclusion and exclusion criteria

Fifty patients aged 20–50 years were recruited. Individuals were included if they had local pain in the lumbar and sacroiliac joint regions of at least 4 months duration, pain severity according to a numerical rating scale (NRS) between 3 and 7, and functional disability with a score greater than 8 on the Persian version of the Roland–Morris Disability Questionnaire (PRMDQ). General exclusion criteria were any dysfunctional entrapment of the nerve roots or history of radicular pain, history of lower extremity orthopedic surgery, chronic ankle instability, any vestibular and neurological disease that could negatively influence postural stability.

Intervention groups

Patients were randomly allocated to either a trunk balance exercises or whole body vibration group. Both groups performed training three times a week for six weeks. At the beginning of each session, both groups received routine physical therapy. The trunk balance exercise group performed exercise protocol for 20 min in each session. The whole body vibration group performed static or dynamic training 5-10 min with whole body vibration device according to training stage.

Main outcome variables

static balance; Dynamic balance

General information

Reason for update

Having finished the study, the purpose of updating is to complete and edit the information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072229029N1**
Registration date: **2016-09-06, 1395/06/16**
Registration timing: **prospective**

Last update: **2020-12-04, 1399/09/14**
Update count: **1**

Registration date

2016-09-06, 1395/06/16

Registrant information

Name
Farahnaz Emami
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3627 1551
Email address
emamif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date
2017-10-22, 1396/07/30
Actual recruitment start date
2016-09-26, 1395/07/05
Actual recruitment end date
2017-10-12, 1396/07/20
Trial completion date
2017-10-12, 1396/07/20

Scientific title
The comparison of trunk balance exercises and whole body vibration on the postural control of the patients with chronic non-specific low back pain.

Public title
The effect of trunk balance exercises and whole body vibration on the low back pain.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic non-specific low back pain longer than four months duration Pain severity according to a numerical rating scale (NRS) between 3 and 7 Functional disability with a score greater than 8 on the Persian version of the Roland–Morris Disability Questionnaire (PRMDQ)
Exclusion criteria:
Any dysfunctional entrapment of the nerve roots or history of radicular pain Leg length discrepancy Añy history of hip or knee surgery Ankle or foot problems History of lower extremity orthopedic surgery Chronic ankle instability Vestibular and neurological disease Any uncorrected auditory or visual impairment
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the randomization with block size of four was used. One group was indicated with the letter A and the other with the letter B. Then different blocks of AABB was written. They were assigned the number of 1-6. For example(AABB=1,ABAB=2,BABA=3,BBAA=4,BAAB=5, ABBA=6 A number was randomly selected between 1-6 and the selected number indicated the pattern of assigning individuals to groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The assessment of ultrasound measurements(muscle thickness and cross sectional area) were conducted by an assessor who was blinded to interventions
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 St., Imam Hossein Square
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2016-07-17, 1395/04/27
Ethics committee reference number
IR.SUMS.REC.1395.72

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
Dynamic balance
Timepoint
Baseline, End of study
Method of measurement
Y- balance test

2

Description
Static balance
Timepoint
Baseline, End of study
Method of measurement

Single leg stance test

Secondary outcomes

1

Description
Differences of thickness of TrA, Internal oblique, External obliqe and multifidus muscles bilaterally
Timepoint
Baseline, End of study
Method of measurement
Rehabilitation Ultrasonography Imaging

2

Description
Pain intensity
Timepoint
Baseline, End of study, One month after the end of study
Method of measurement
Visual Analog Scale(VAS)

3

Description
Functional disability
Timepoint
Baseline, End of study, One month after the end of study
Method of measurement
Persian version of the Roland–Morris Disability Questionnaire (PRMDQ)

4

Description
Differences of cross sectional area of multifidus muscle bilaterally
Timepoint
Baseline, End of study
Method of measurement
Rehabilitative Ultrasonography Imaging

Intervention groups

1

Description
In balance training group intervention consists of 18 sessions,3 times and 6 weeks. Modalities (TENS : low frequency=1-4 Hz, duration =100-400 micro sec, amplitude as tolerated, hot pack, US = 1 MHz ,intensity 1.5 w/cm2) are used. After that, patients execute trunk balance exercises in 5 levels. The levels of exercises are simple to difficult, and if his/her pain increases, the patient remains at the same level of exercises. The total duration of treatment is 6 weeks ,3 times per week .
Category
Treatment - Other

2

Description
For the whole body vibration group intervention consists of 18 sessions, 3 times and 6 weeks. Modalities (TENS : low frequency=1-4 Hz, duration =100-400 micro sec, amplitude as tolerated, hot pack, US = 1 MHz, intensity 1.5 w/cm2) are used. After that , whole body vibration device (sinusoidal mode, frequency= 20 Hz, amplitude= 4mm, a= 5.8 g) is used for them. The patients stands with 20 flexion of knee joints on plate form. 5 boot uses in each session with 1 minute rest between them. Duration of each boot in first 2 week is 30 seconds, in second 2 week 45 seconds and in the last 2 week is 1 minute. The total duration of intervention is the same as other group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Physical therapy clinics affiliated with Shiraz University of Medical Sciences
Full name of responsible person
Farahnaz Emami
Street address
Abivardi 1 str,Chamran Blvd.
City
Shiraz
Province
Fars
Postal code
71947-33669
Phone
+98 71 3628 9269
Email
emamif@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohsen Moghadami
Street address
Zand str.
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3233 2093
Email

moghadami@sums.ac.ir

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

Farahnaz Emami

Position

Instructor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Abivardi 1 str., Chamran Blvd.

City

Shiraz

Province

Fars

Postal code

71947-33669

Phone

+98 71 3628 9269

Fax

Email

emamif@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohsen Razeghi

Position

Full professor of Physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Abivardi 1 str., Chamran Blvd.

City

Shiraz

Province

Fars

Postal code

71947-33669

Phone

+98 71 3628 9269

Fax

Email

razeghm@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farahnaz Emami

Position

Instructor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Abivardi 1 str., Chamran Blvd.

City

Shiraz

Province

Fars

Postal code

71947-33669

Phone

+98 71 3628 9269

Fax

Email

emamif@sums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To fully protect the data of the participants

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary
Not applicable

Trial results

Please tick if results have been published
Yes
Summary result posting date
2020-12-04, 1399/09/14
Table of baseline comparison
Participant flow diagram

Table of variable outcomes' results
Table of adverse events
First publication date
2018-07-22, 1397/04/31
Abstract of published paper
Patients with low back pain (LBP) have reduced core muscle geometry and impaired postural balance. Impaired trunk control was shown to be associated with poor balance and limited functional mobility in these patients. However, the relationship between muscle geometry and postural balance is unclear. This study aimed to determine the correlation of core muscle geometry with pain intensity, functional disability and postural balance in patients with chronic nonspecific mechanical LBP. Thirty patients aged 20–50 years were enrolled. Ultrasound imaging was used to assess their muscle geometry. The participants completed a numerical rating scale (NRS) for pain severity, and the Persian version of the Roland–Morris Disability Questionnaire (PRMDQ). To estimate static balance, they were asked to perform the single leg stance test. Dynamic balance was assessed with the Y-balance test. Significant correlations were found between NRS scores and bilateral multifidus cross-sectional area during rest ($r \geq -0.31$, $P \leq 0.04$) and con- traction ($r \geq -0.37$, $P \leq 0.02$). NRS scores correlated significantly with bilateral multifidus thickness during rest ($r \geq -0.31$, $P \leq 0.04$) and contraction ($r \geq -0.28$, $P \leq 0.04$). Significant correlations were also observed for PRMDQ scores with thickness ($r \geq -0.35$, $P = 0.04$) and cross-sectional area of the multifidus muscles ($r \geq -0.33$, $P = 0.04$) bilaterally during contraction. A significant correlation was found between Y-balance scores and right abdominal muscle thickness during rest and contraction ($r \geq 0.34$, $P \leq 0.04$). Core muscle geometry correlated with pain, functional disability indices and dynamic balance in these patients.