Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of exercise on stable surface versus unstable surface on cross section area of lumbar stabilizer muscle, pain, disability index, static and dynamic balance in patients with chronic low back pain

Protocol summary

Study aim

Comparison of the effect of exercise on stable surface versus unstable surface on cross section area of lumbar stabilizer muscle, pain, disability index, static and dynamic balance in patients with chronic low back pain(LBP)

Design

two arm parallel group randomized trial. participants and outcome assessor will be blind. 40 participants will be randomly allocated to the 2 groups via permuted block randomization with block of size 2.

Settings and conduct

This study will be done in Rehabilitation Sciences Research Center and Clinic, Shiraz University of Medical Sciences, Shiraz, Iran on 40 individual with chronic LBP. The individuals will be assessed by a blind assessor and allocated randomly into the 2 groups: treatment on stable and unstable surface.They will receive18 sessions of treatment during 6 weeks and will be followed up after 1 month.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mechanical LBP without radicular symptoms such as radiating pain below the knee, loss of sensation, or loss of reflex; pain intensity of 3–6 in the VAS; 18-40 years old. Non-inclusion criteria: Pregnancy; Spinal fractures; Herniated discs; Acute LBP; spondylolisthesis and spondylolysis; lower limb length discrepancy; previous surgery on vertebral column; specific diseases causing back pain such as malignancy, rheumatologic conditions; severe osteoporosis; stabilization exercise performance within last 6 weeks; Athletes; Neurological diseases; BMI above 26; Disability more than 60% in the oswestry Disability index; Uncontrolled disorders of the liver, kidney and thyroid

Intervention groups

Intervention group 1: common physical therapy treatment group and exercise on unstable surface.

Intervention group 2: common physical therapy treatment group and exercise on stable surface.

Main outcome variables

Thickness of lumbar stabilizer muscle,balance, pain, disability index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190527043730N1**
Registration date: **2019-07-16, 1398/04/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-16, 1398/04/25**
Update count: **0**

Registration date

2019-07-16, 1398/04/25

Registrant information

Name

mozhgan emami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3743 6244

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of exercise on stable surface versus unstable surface on cross section area of lumbar stabilizer muscle, pain, disability index, static and dynamic balance in patients with chronic low back pain

Public title
Effect of lumbar stabilization exercise performed on stable versus unstable surfaces in chronic low back pain patient
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 40 years mechanical low back pain(LBP) but no radicular symptoms such as radiating pain below the knee, loss of sensation, or loss of reflex pain intensity of 3–6 in the Visual Analogue Scale (VAS)
Exclusion criteria:
Pregnancy Spinal fractures Herniated discs Acute low back pain spondylolisthesis and spondylolysis lower limb length discrepancy previous surgery on vertebral column specific diseases causing back pain such as malignancy, rheumatologic conditions severe osteoporosis recent stabilization exercise performance (within last 6 weeks) Athletes Neurological diseases body mass index(BMI) above 26 Disability more than 60% in the oswestry Disability index Uncontrolled disorders of the liver, kidney and thyroid
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals with block randomization and sealed opaque envelopes concealment take place in two groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
in this study evaluations and intervention are performed by two different physiotherapists.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee of Shiraz School of Rehabilitation sciences
Street address
School of Rehabilitation Sciences, Abiverdi 1 st., Chamran Blvd., Shiraz,Iran
City
Shiraz
Province
Fars
Postal code
71345-1978
Approval date
2019-02-27, 1397/12/08
Ethics committee reference number
IR.SUMS.REHAB.REC.1397.025

Health conditions studied

1

Description of health condition studied
Chronic low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Thickness of lumbar stabilizer muscle
Timepoint
Pre and post intervention (after 6 weeks)
Method of measurement
ultrasound device

Secondary outcomes

1

Description
pain
Timepoint
pre and post intervention (after 6 weeks) and fallow up (after 10 weeks)
Method of measurement
visual analogue scale

2

Description
static balance
Timepoint
pre and post intervention (after 6 weeks)
Method of measurement
open and close eye single leg stance

3

Description
dynamic balance
Timepoint
pre and post intervention (after 6 weeks)
Method of measurement
modified star excursion balance test

4

Description
disability
Timepoint
pre and post intervention (after 6 weeks) and fallow up (after 10 weeks)
Method of measurement
oswestry disability index

Intervention groups

1

Description
Intervention group 1: This group will receive the common physical therapy treatment and exercise on unstable surface for 18 session during a period of 6 weeks. lumbar stabilization exercise program progressively increase during the 6-week exercise program. The subjects will ask to perform three sets of 10 repetitions during the first and second week, progress to three sets of 15 repetitions during each session in the third and fourth weeks, and three sets of 20 repetitions during the fifth and sixth weeks.
Category
Treatment - Devices

2

Description
Intervention group 2: This group will receive the common physical therapy treatment and exercise on stable surface for 18 session during a period of 6 weeks. lumbar stabilization exercise program progressively increase during the 6-week exercise program. The subjects will ask to perform three sets of 10 repetitions during the first and second week, progress to three sets of 15 repetitions during each session in the third and fourth weeks, and three sets of 20 repetitions during the fifth and sixth weeks.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy Clinics in Shiraz city
Full name of responsible person
Shohreh Taghizadeh
Street address
School of Rehabilitation Sciences, Abiverdi 1 Avenue, Chamran Boulvard
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71345-1733
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taghizsh@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ghasemi Unes
Street address
Floor 7, Center bilding of Shiraz Univercity of Medical Science, Zand street
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71345-1974
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+98 71 7282 3235
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vcrdep@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
Dr. Shohreh Taghizadeh

Position
Assistant Professor, PT, PhD

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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Full name of responsible person
Mozhgan Emami

Position
Student

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Bachelor

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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
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
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