

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 receive 18 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

mozghan emami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3743 6244

Email address

emami.mozhgan73@gmail.com

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 follow 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 follow 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 Boulevard

City

Shiraz

Province

Fars

Postal code

71345-1733

Phone

+98 71 1626 1081

Email

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

City

Shiraz

Province

Fars

Postal code

71345-1974

Phone

+98 71 7282 3235

Email

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

Email

TaghizSh@Sums.ac.ir

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

Street address

Abiverdi 1 Avenue, Chamran Boulevard

City

Shiraz

Province

Fars

Postal code

71345-1733

Phone

+98 71 1626 1081

Email

TaghizSh@Sums.ac.ir

Person responsible for scientific 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

Street address

Abiverdi 1 Avenue, Chamran Boulevard

City

Shiraz

Province

Fars

Postal code

71345-1733

Phone

+98 71 1626 1081

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mozhgan Emami

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

No.7, floor 2, Hoomehr buliding, Niayesh Ave.,
Chamran Blvd.

City

Shiraz

Province

Fars

Postal code

84531-45641

Phone

+98 7198

Email

emami.mozhgan73@gmail.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

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