Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effects of Weeks Core Stabilization on swissball and Suspended Exercises on Balance and Quality of Life in women with Non-Specific Chronic Low Back Pain

Protocol summary

Summary

Objective: The purpose of this study is to compare the effect of 8-week selected core stability exercise and suspension exercise on the balance and quality among women with non-specific low back pain. Design: 45 women with chronic non-specific low back pain will voluntarily participate in this study and will be randomly divided into three groups: Ball Exercise (BE) group, Suspension Exercise (SE) group and control group. Using random allocation law in a limited randomization method, the sample size of the selected will be randomly assigned to the three groups. Setting and conduct: The BE group and the SE group will participate in training sessions for 8 weeks (3 sessions per week, 45 minutes per session) while the control group will not receive none of the intervention. Major inclusion and exclusion criteria: Inclusion criteria: Female gender; having at least three months of Not specific low back pain history; Age between 29 to 45 years. Exclusion criteria from the study include: having a history of spinal surgery; underlying abnormalities causing back pain; having a regular exercise history; pregnancy; cancer; drug addiction; having History of using any drug or other therapies to relieve back pain. Interventions: Ball Exercise and Suspension Exercise. Main outcome variables: The core stability, static and dynamic balance, pain and quality of life (QOL) assessed using Biodex Balance System, Functional test, quality of life questionnaire (SF-36), Pain intensity measurement questionnaire (Quebec) respectively, Pre and Post intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061734594N1**

Registration date: **2017-10-26, 1396/08/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-26, 1396/08/04

Registrant information

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Name of organization / entity

Shahid Bahonar University of Kerman

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Recruitment status

Recruitment complete

Funding source

Researcher-Shahid Bahonar University of Kerman

Expected recruitment start date

2017-04-19, 1396/01/30

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Weeks Core Stabilization on swissball and Suspended Exercises on Balance and Quality of Life in women with Non-Specific Chronic Low Back Pain

Public title
The Effects of Core Stabilization on swissball and Suspended Exercises on Chronic Low Back Pain
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Female gender; having at least three months of low back pain history; Age between 29 to 45 years. Exclusion criteria: having a history of spinal surgery or spinal and pelvic fractures; having acute or semi-acute low back pain; underlying abnormalities causing back pain such as disk hernia, spondylolysis, vertebral canal stenosis; infection, cauda equina syndrome, sciatica; having a regular exercise history; pregnancy; cancer; rheumatoid arthritis; osteoporosis; drug addiction; having History of using any drug or other therapies to relieve back pain.
Age
From **29 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Participants will be allocated into 3 groups. In this method, randomized allocation law will be used. Randomized allocation law: in this method, researchers determine the total sample size and then allocate two groups of them to A & B groups randomly and allocate the rest to C group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Research Deputy, Tahmase Abad Crossroads, Ibn Sina Avenue
City
Kerman
Postal code
Approval date
2017-01-09, 1395/10/20
Ethics committee reference number
IR.KMU.REC.1395.180

Health conditions studied

1

Description of health condition studied
Non-Specific Low Back Pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Core Stability of Body
Timepoint
Befor and after intervention
Method of measurement
Hand Held Dynamometer & Chronometer

2

Description
Pain
Timepoint
Before and after intervention
Method of measurement
Pain intensity measurement questionnaire (Quebec)

3

Description
Static and Dynamic Balance
Timepoint
Befor and after intervention
Method of measurement
Biodex Balance System

4

Description
Quality of Life
Timepoint
Befor and after intervention
Method of measurement
SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The control group will not receive any intervention
Category
N/A

2

Description
Intervention group 2 (Suspension core stability exercise): This exercise group will participate in 45 minute training sessions, 3 sessions a week for 8 weeks. Their status will be evaluated before, during and after intervention. Exercise will be performed using a suspension device which is one form of CST with an unstable base. “core muscle activity during suspension exercises” consists of multi-planar and multi-jointmovements against gravity with body weight as resistance. During the exercise, one or both limbs are supported on handle straps (orcradles) at the end of a suspension cable with a single above-head(i.e., ceiling or wall) anchor point. The level of workout difficulty is adjusted by altering the “working angle” (i.e., inclination of the body from upright position) and/or adding balancing equipment. Suspension exercise has become a popular type of CST due to its versatility, with a simple set-up, low space occupancy, and large variety of workouts.
Category
Prevention

3

Description
Intervention group 1 (Core stability exercise on swiss ball): This exercise group will participate in 45 minute training sessions, 3 sessions a week for 8 weeks. Their status will be evaluated before, during and after intervention.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy and Rehabilitation, Sports Medicine and Orthopedics Clinics
Full name of responsible person
Street address
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shahid Bahonar University of Kerman
Full name of responsible person
Dr Maryam Ehtesham Zadeh
Street address
Shahid Bahonar University, Pajohesh Square, Kerman
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Shahid Bahonar University of Kerman
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty