

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The short-term effects of of stabilization Exercise on the stability index of Biodex system, abdominal and back muscle electromyography (EMG) and lumbar curvature in men with non-specific low back pain (NS.CLBP)

Protocol summary

Summary

This study investigated the effects of short-term training "drawing in or Abdominal Hollowing (AH)" and Abdominal Bracing (AB) techniques on the stability index of Biodex, abdominal and lumbar EMG muscle activity and lumbar curvature in men with Non-Specific Chronic Low Back Pain (NS-CLBP). Twenty male patients with NS-CLBP (as intervention group) and 10 matched patients (as control group) were enrolled. Participants were trained in a single day training session before the test session to become familiar with the equipment and exercises used in the study. The patients in the intervention group were randomly assigned in a cross-over manner into one of the above-mentioned exercises with a week washout period. Before and immediately after exercise, muscle EMG activity, lumbar curvature, and stability index by Biodex system were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711151637N1**

Registration date: **2010-12-11, 1389/09/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-11, 1389/09/20

Registrant information

Name

Sedighe Kahrizi

Name of organization / entity

Tarbiat Modares University

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University

Expected recruitment start date

2009-01-20, 1387/11/01

Expected recruitment end date

2009-08-06, 1388/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The short-term effects of of stabilization Exercise on the stability index of Biodex system, abdominal and back muscle electromyography (EMG) and lumbar curvature in men with non-specific low back pain (NS.CLBP)

Public title

Effect of stabilization Exercise on Low Back Pain (LBP) patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 25- 35 years, no history of exercise therapy (especially in the abdominal area) or professional exercise.; abdominal skin fold thickness no greater than 25 mm. Exclusion criteria: having history of major heart problem, cardiovascular, respiratory or neurological problems, having radicular pain in single or

both feet, pain exacerbation during the intervention process, history of major spinal surgery, using depression drug in the month prior to the study, addiction to drugs and alcohol

Age

From **25 years** old to **35 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tarbiat Modares University (T.M.U)

Street address

Medical Ethics Committee, Faculty of Medical Sciences, Tarbiat Modares University, Jalal Al Ahmad Highway

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Tehran

Postal code

1411713116

Approval date

2008-04-11, 1387/01/23

Ethics committee reference number

82852.150

Health conditions studied

1

Description of health condition studied

Non- Specific Chronic Low Back Pain

ICD-10 code

M40.4 ,M40

ICD-10 code description

Kyphosis and lordosis, Other deforming dorsopathies, Other intervertebral disc disorders, Other dorsopathies,

not elsewhere classified, Dorsalgia

Primary outcomes

1

Description

EMG of abdomen and back muscles

Timepoint

Before and immediately after interventions

Method of measurement

EMG muscle activity with electromyography system as Root Mean Square value or RMS and Intensity of muscle activity as microvolt value

2

Description

Lumbar Curve

Timepoint

Before and immediately after interventions

Method of measurement

by Inclinomometer system as degree value

3

Description

Biodex stability Indexes

Timepoint

Before and immediately after interventions

Method of measurement

By Biodex Stability System, as Anterior-posterior , Lateral stability and Limit of Stability indexes

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention: Abdominal Hollowing exercise "Drawing in" or "Abdominal Hollowing" training: The subject was placed in crock lying position and was taught special and isolate contraction of Transversus Abdominis muscle based on Richardson concepts. Training will continue until the patient was quite remembering the correct contraction. The subject was instructed to pull him navel in (toward spinal column) and up (less than 10 percent maximum voluntary contraction MVC). When ideal contraction of Transversus Abdominis was obtained (best activation with minimal other muscle activation), was asked them to hold contraction with breathing and Imprisonment not their breath. Pressure BoiFeedback Unit was used for control of muscle contraction. 3 set each one with 10 repetitions while 2 minutes as a rest period between each set and keeping contraction of muscle for 10 seconds was the ultimate goal. Time of training, depends on correct learning of Abdominal Hollowing and was different between

patients.
Category
Rehabilitation

2

Description

Second intervention: "Abdominal Bracing exercise "Co-contraction" or "Abdominal Bracing training. First, a natural waist position (slight lordosis) was investigated ,then subject must contract all muscles as 360° around the trunk(area of lumbar spine), such as someone pressure to his waist but he can resist while he had normal breathing , at beginning of this maneuvers ,therapist would give touch feedback with her hands to the patient and after learning, patients would do it himself Pressure Bio Feedback Unit Was used to control of correct contraction of abdominal wall muscle. Patient must reach a stage that can do this maneuvers simultaneously with normal breathing and maintain this state about 10 seconds. This exercise in supine crook lying mode is done. Like the first intervention, achieving to 3 set each one with10 repetitions while 2 minutes as a rest period between each set and keeping contraction of muscle for 10 seconds was the ultimate goal.

Category
Rehabilitation

3

Description

Control group: For subjects of this group was not performed any intervention and the mean duration of time equivalent to the intervention training group, were given to them instead of intervention period between data recording because for the real effects of the intervention in the treatment group is determined .

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Tarbiat Modares University (T.M.U)
Full name of responsible person
Zahra Yaghoubi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Deen for Research of Faculty of Basic of Medical Science of Tarbiat Modares University (TMU)

Full name of responsible person

Dr S. Mohammad Firoozabadi Pourmirjaafari

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Tehran

Grant name

ردیف پژوهشی دانشگاه

Grant code / Reference number

Masters Thesis

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Deen for Research of Faculty of Basic of Medical Science of Tarbiat Modares University (TMU)

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

Name of organization / entity

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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