

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effects of Diaphragmatic Breathing Exercise on Pain, Balance and Function in athletes with Chronic Non-specific Low Back Pain

Protocol summary

Study aim

The aim of this study was to investigate the effect of progressive diaphragmatic breathing exercises on reducing pain, improving function and balance in the population of non-specific low back pain patients.

Design

Phase 3 clinical trial with control group, with parallel group, one-way blind, randomized, 10 patients in each group, simple random sampling with papers written by control or intervention group.

Settings and conduct

20 patients were selected from 26 patients referred to Ramten and Hiran private clinics, then were randomly divided into control and intervention groups. Preliminary assessments were evaluated by a co-worker physiotherapist, including pain measurement based on visual analogue scale, static balance based on unilateral hip bridge test, and dynamic balance based on star test, and data were recorded. The examiner started treatment based on a sheet selected by the patient. In control group patients were received TENS and interferential modalities for 4 weeks and every other day. The intervention group were received breathing exercises in addition to modalities. At the end of 4 weeks, the outcomes were measured again and the person measuring the outcomes was not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with nonspecific back pain
Patients 20 to 50 years
People who exercise at least 3 times a week for a total of 6 hours
History of back pain for more than 12 weeks (chronic back pain)
Patients with VAS low back pain have less than 7 and more than 3
Exclusion criteria: Having any musculoskeletal disease or neurology
Pregnancy

Intervention groups

Control group received TENS and interferential modalities
intervention group received breathing exercises in addition to TENS and interferential, for 4

weeks

Main outcome variables

Pain, Static balance, Dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090228001719N8**

Registration date: **2020-09-10, 1399/06/20**

Registration timing: **retrospective**

Last update: **2020-09-10, 1399/06/20**

Update count: **0**

Registration date

2020-09-10, 1399/06/20

Registrant information

Name

khadije Otadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-20, 1398/02/30

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

2019-06-10, 1398/03/20

Actual recruitment end date

2019-11-21, 1398/08/30

Trial completion date

2019-11-21, 1398/08/30

Scientific title

Effects of Diaphragmatic Breathing Exercise on Pain, Balance and Function in athletes with Chronic Non-specific Low Back Pain

Public title

Effects of Diaphragmatic Breathing Exercise on improving of Chronic Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with nonspecific low back pain Age between 20 to 50 Training at least 3 times a week for a total of 6 hours History of back pain for more than 12 weeks (chronic back pain) Pain between 3 to 7 based on VAS(visual analogue scale)

Exclusion criteria:

Other musculoskeletal or neurological disorders
Pregnancy

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **10**

Actual sample size reached: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected by simple randomization from athletes with low back pain based on inclusion criteria, then samples were asked randomly select a piece of paper among 20 papers that was written on control group or breathing exercise group (10 control group and 10 breathing exercise group).

Blinding (investigator's opinion)

Single blinded

Blinding description

The person evaluating the outcome measures did not know the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

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1419934146

Approval date

2019-12-06, 1398/09/15

Ethics committee reference number

IR.TUMS.FNM.REC.1398.138

Health conditions studied**1****Description of health condition studied**

Non specific low back pain

ICD-10 code

G89.4

ICD-10 code description

Chronic pain syndrome

Primary outcomes**1****Description**

Pain

Timepoint

Before and after 4 weeks of treatment

Method of measurement

Visual Analogue Scale

2**Description**

Static balance

Timepoint

Before and after 4 weeks of treatment

Method of measurement

Unilateral Hip Bridge Endurance

3**Description**

Dynamic balance

Timepoint

Before and after 4 weeks of treatment

Method of measurement

Star balance test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients in the breathing exercise group also came on the clinic three days a week for four weeks. In each session, the patients received electrotherapy treatment same as control group. In addition to patients were required to perform two types of breathing exercises daily for 4 weeks. These breathing exercises were taught to the patient at the beginning of each week by the physiotherapist and practiced with him to ensure that the exercise was performed correctly. It lasted 5 minutes and was done twice a day, and considering that there were two types of exercises per day (days and times that did not go to the clinic at home), a total of 20 minutes a day. When patients went to the physiotherapy clinic, one set of these breathing exercises was performed with the therapist after electrotherapy. Exercises for each week are as follows: First week: Supine breathing+ Crocodile breathing Second week: Supine breathing+ Crocodile breathing with Theraband Third week: Seated Breathing+ 90/90/90 Breathing Forth week: Seated Breathing+ 90/90/90 Breathing with Theraband. Outcomes were measured before treatment and after 4 weeks of treatment. They received a total of 12 sessions of physiotherapy.

Category

Rehabilitation

2

Description

Control group: In this group, the patients came on the clinic 4 weeks , every weeks 3 days with every other day and received TENS and Interferential. In each session the patients received 30 minutes of conventional TENS with a pulse duration of 100 microseconds and 20 minutes of Interferential with a base frequency of 4000 Hz and a variable frequency of 50 to 100 Hertz . Outcomes were measured before treatment and after 4 weeks of treatment. There was no exercise therapy in this group. They received a total of 12 sessions of physiotherapy.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Private physiotherapy clinics

Full name of responsible person

Shariar Sharify

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Khadijeh Otadi

Position

Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only information about the effect of treatment on outcomes will be made available to faculty and students through the publication of articles and dissertations.

When the data will become available and for how long

After paper publishing

To whom data/document is available

Teachers, students, patients

Under which criteria data/document could be used

No condition

From where data/document is obtainable

My e-mail

What processes are involved for a request to access data/document

Sending message to my e-mail with specific cause of request

Comments