Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of diaphragmatic myofascial release on pain, balance and quality of life in patients with nonspecific chronic low back pain: A regional interdependence model

Protocol summary

Study aim

According to relative high prevalence of non specific chronic low back pain and the absence of conclusive treatment for this disorder, aim of this study is to provide an option in treatment of this disorder.

Design

A concealed, randomized with "Random allocation software", two parallel group trial with blinded participants and post intervention assessor.

Settings and conduct

The study would take place in a physiotherapy clinic; The first assessor is the therapist who would do intervention and sham intervention and the second assessor is another person who does not know about groups. Both group will receive analgesic treatment with electrical stimulations; Intervention group will receive diaphragm myofascial release and sham group will receive same hand placements by therapist but no release.

Participants/Inclusion and exclusion criteria

Participants of this study are patients with non specific chronic low back pain who do not receive concurrent treatment for their pain; Participants are aged between 18 - 40 years old. They lack history of surgery in thoracic and lumbar regions or infection and fracture in the region of treatment.

Intervention groups

In the intervention group which includes12 non specific low back pain patients the myofascial release of diaphragm will be done with two techniques. There will be three sessions of treatment and myofascial release of diaphragm will be done in every session. In the sham intervention group which includes12 non specific low back pain patients the same hand placements will take place but with no intention to release.

Main outcome variables

Pain, Low back pain induced disability, Chest expansion, Lumbopelvic mobility, Static balance, Dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221216056836N1**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **retrospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

Soheil Hejazi yekta

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3301 6644

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of diaphragmatic myofascial release on pain, balance and quality of life in patients with nonspecific chronic low back pain: A regional interdependence model

Public title
Effect of diaphragm myofascial release on non specific chronic low back pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with symptoms of non specific chronic low back pain (Have symptoms more than 3 months) Patients with consent Pain in the area between last rib and gluteal crease No radicular symptoms No nerve root compression symptoms No history of surgery in thoracic or lumbar regions

Exclusion criteria:
Pain below gluteal crease Infection or fracture in the particular region Neurologic disorders Receiving treatment for low back pain concurrent with this study

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of participants will be done with "Random allocation software" with 4 randomized blocks and 1:1 allocation ratio.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will be randomized in two intervention and sham groups. none of the participants know which group is he in so the participants would be blind to grouping. The intervention and sham intervention would get done by the same therapist that has assessed the baseline measurements; After the last session, another therapist would measure the outcomes without knowing which group each participant was in so the second assessor would be blind to the participants and grouping; Therefore it will be a two blinded RCT.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees of Tehran University of medical sciences

Street address
Room no. 604, 6th floor, Tehran university of medical sciences central building, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1769654649

Approval date
2022-12-11, 1401/09/20

Ethics committee reference number
IR.TUMS.FNM.REC.1401.119

Health conditions studied

1

Description of health condition studied
Non specific chronic low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain is an unpleasant emotional and sensory experience related to an injury or a potential injury.

Timepoint
First and last session of treatment

Method of measurement
Using Visual analogue scale

Secondary outcomes

1

Description
Disability is a prolonged dysfunction of body, mind, sensation or a complex of them which prevents individuals to participate efficiently in society.

Timepoint
First session of treatment and one week after the last session of treatment.

Method of measurement
Roland Morris low back pain questionnaire

2

Description
Mobility of lumbopelvic region with flexion of trunk and

pelvis.

Timepoint

First and last sessions of treatment

Method of measurement

Finger tip to floor distance test with measuring the distance between 3rd finger and the floor with the patient flexed fully from trunk and pelvis in standing position.

3

Description

Dynamic balance is the ability to maintain body line of gravity within base of support margins during extremities movements and weight shifting.

Timepoint

First and last sessions of treatment

Method of measurement

by measuring the maximal reaching by patient in standing position without lower extremity movement

4

Description

Static balance is the ability to maintain body line of gravity within base of support margins while standing still

Timepoint

First and last sessions of treatment

Method of measurement

By measuring the person's ability to maintain his/her balance during single leg stance.

5

Description

Chest expansion is the difference of thoracic level perimeter during maximal inhalation and exhalation.

Timepoint

First and last sessions of treatment

Method of measurement

By measuring the difference of thoracic level perimeter during maximal inhalation and exhalation.

Intervention groups

1

Description

Intervention group: In the intervention group which includes12 non specific low back pain patients the myofascial release of diaphragm will be done with two techniques. There will be three sessions of treatment and myofascial release of diaphragm will be done in every session.

Category

Rehabilitation

2

Description

Control group: In the sham intervention group which includes12 non specific low back pain patients the same hand placements will take place but with no intention to release.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Energy rehabilitation center

Full name of responsible person

Soheil hejazi yekta

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No. 67, Bustan 7 alley, Pasdaran Exp, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Hamid Dalvand

Street address

Piche shemiran, Enghelab Ave, Tehran

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1148965111

Phone

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Email

rehabilitation@tums.ac.ir

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

Soheil hejazi yekta

Position

Physiotherapist

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

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Person responsible for scientific inquiries

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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