

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of lumbopelvic fascial release alone with lumbopelvic and cervical fascial release on pain intensity, functional disability, pressure pain threshold, quality of life and sonoelastography indices of the fascia in both regions in non-specific chronic low back pain patients associated with neck pain

Protocol summary

Study aim

Due to the connection of the fascias of different parts of the spine, in this study it is possible to examine the effect of releasing the fascia in one area on areas far away from applying the technique.

Design

The present study is a randomized clinical trial with two parallel groups. The sample size was based on similar studies, using G-power software and considering the average pain index with 95% confidence and 80% power. Patients will be assigned to two groups based on the random block method (block size of 4 and allocation ratio 1:1) using the website www.randomization.com.

Settings and conduct

In Tehran's private physiotherapy clinic, after completing the informed consent form and background information and measuring primary and secondary outcomes, patients will receive treatment for two consecutive weeks and will be followed up for two weeks. The outcome assessor and the person performing the analysis will be blinded.

Participants/Inclusion and exclusion criteria

People with the simultaneous complication of non-specific chronic back pain and neck pain, where the severity of back pain is greater compared to the neck
Age between 20 and 55 years
Not having back pain and neck pain caused by specific pathologies
Not being pregnant
Not receiving painkillers and anti-inflammatory drugs during the last 3 to 7 days
Not currently receiving physical therapy or other treatment
Attending therapy sessions regularly
Willingness to continue participating in the study
Absence of contracting or developing cases (after the start of the study) that for any reason violates the criteria for entering the study

Intervention groups

Group A: they receive lumbopelvic fascial release. Group B: they receive lumbopelvic and cervical fascial release.

Main outcome variables

Primary outcomes are pain and disability, and secondary outcomes are pressure pain threshold, quality of life, and fascial elasticity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230502058059N1**

Registration date: **2023-07-09, 1402/04/18**

Registration timing: **prospective**

Last update: **2023-07-09, 1402/04/18**

Update count: **0**

Registration date

2023-07-09, 1402/04/18

Registrant information

Name

Soodeh Zandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 6911

Email address

soodeh.zandi@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-15, 1402/04/24

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of lumbopelvic fascial release alone with lumbopelvic and cervical fascial release on pain intensity, functional disability, pressure pain threshold, quality of life and sonoelastography indices of the fascia in both regions in non-specific chronic low back pain patients associated with neck pain

Public title

Evaluation of the effect of lumbopelvic fascial release alone with lumbopelvic and cervical fascial release on pain intensity, functional disability, pressure pain threshold, quality of life and sonoelastography indices of the fascia in both regions in non-specific chronic low back pain patients associated with neck pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with the simultaneous complication of non-specific chronic low back pain and neck pain, where the intensity of low back pain is greater compared to the neck pain Age between 20 and 55 years Not having low back pain and neck pain caused by specific pathologies Not receiving painkillers and anti-inflammatory drugs in the last 3-7 days Not currently receiving physical therapy or other treatment

Exclusion criteria:

pregnancy Not attending regular therapy sessions Unwillingness to continue participating in the study Infecting or developing cases (after the start of the study) that violates the criteria for entering the study for any reason

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be assigned to two groups based on

the random block method (block size of 4 and allocation ratio 1:1) using the website www.randomization.com. To conceal the sequence of random allocation, numbered sealed envelopes containing group A or group B contents will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, the outcome evaluator and the person who analyzes the results will be blind to the study conditions. In this way, the questionnaires are taken by another person and the sonoelastography is performed by a radiologist and the results are analyzed by a statistician. In this study, the patients are blinded in terms of placement in the groups, but they are not blinded in terms of the type and place of treatment they receive, because the treatment process is explained to the patient. Also, the therapist is not blind and a trained and skilled physiotherapist (myself) performs fascia release.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of University of Social Welfare and Rehabilitation Sciences

Street address

First bell, No. 42, Dolatshad West St., Farid Afshar St., Zafar St

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Postal code

1916615463

Approval date

2023-03-15, 1401/12/24

Ethics committee reference number

IR.USWR.REC.1401.250

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

Low back pain

ICD-10 code

M95.9-M99.

ICD-10 code description

XIII Diseases of the musculoskeletal system and

connective tissue

2

Description of health condition studied

Neck pain

ICD-10 code

M95.9-M99.

ICD-10 code description

XIII Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description

Pain score on Visual Analog Scale

Timepoint

Before the start of the intervention, at the end of the intervention and after the two-week follow-up

Method of measurement

Visual Analog Scale

2

Description

Back disability score in back disability questionnaire

Timepoint

Before the start of the intervention, at the end of the intervention and after the two-week follow-up

Method of measurement

Oswestry Disability Index

3

Description

Neck disability score in neck disability questionnaire

Timepoint

Before the start of the intervention, at the end of the intervention and after the two-week follow-up

Method of measurement

Neck Disability Index

Secondary outcomes

1

Description

Pressure pain threshold score

Timepoint

Before the start of the intervention, at the end of the intervention and after the two-week follow-up

Method of measurement

Algometer tool

2

Description

Quality of life score

Timepoint

Before the start of the intervention, at the end of the

intervention and after the two-week follow-up

Method of measurement

Short form health survey

3

Description

Fascia elasticity

Timepoint

Before the start of the intervention, at the end of the intervention and after the two-week follow-up

Method of measurement

Sonoelastography

Intervention groups

1

Description

The first intervention group: they receive lumbo-pelvic fascial release.

Category

Rehabilitation

2

Description

The second intervention group: they receive lumbo-pelvic and cervical fascial release.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Rehabilitation Center of Medico Plus Center Complex

Full name of responsible person

Soodeh Zandi

Street address

unit 502, 5th floor, Medico Plus Center complex, Bakhshgandan Alley, not far from Tavanir, Valiasr St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Vice President of Research and Technology University of Welfare and Rehabilitation Sciences

Street address

University of Welfare and Rehabilitation Sciences, Chibiyar St., Student Blvd., Valenjek St.

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Soodeh Zandi

Position

Phd candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Considering that in the ethical considerations section, we said that we do not publish the information, the data of the participants will not be published and there is no more information regarding the non-identification of individual data.

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

No - There is not 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