Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of diaphragm myofascial release on pain, disability, range of motion, kinesiophobia and quality of life in patients with chronic shoulder pain

Protocol summary

Study aim

The aim of this study is to determine the effects of myofascial release of the diaphragm muscle in patients with chronic shoulder pain on pain, disability, range of motion, chest expansion, quality of life, and kinesiophobia

Design

The clinical trial has two experimental and control groups. Double-blind, randomized by block randomization software

Settings and conduct

The treatment in both groups will be done one day in between (3 days a week) and six sessions in total. The place of research will be in the physiotherapy clinic located in the east of Tehran. Diaphragm myofascial release treatment will be performed by the physiotherapist for the treatment group, which is a type of manual treatment and does not require tools. The evaluator of the variables before and after the treatment and the patients do not know which group each person is in.

Participants/Inclusion and exclusion criteria

inclusion criteria: women and men with chronic shoulder pain in the age range of 25 to 45 years with moderate pain intensity. exclusion criteria: having diseases and special conditions that disturb the results of the study.

Intervention groups

Both groups will receive routine physical therapy, with the difference that in the intervention group, in addition to routine physical therapy, manual therapy of myofascial release of the diaphragm muscle is performed, and in the control group, sham techniques are performed in addition to routine physical therapy. Routine physical therapy includes the use of TENS, hot pack and exercise therapy.

Main outcome variables

Dependent variables that are measured before and after the study in both groups include the following: pain, shoulder range of motion, chest expansion rate, disability, quality of life, kinesiophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240201060879N1**
Registration date: **2024-05-11, 1403/02/22**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-11, 1403/02/22**
Update count: **0**

Registration date

2024-05-11, 1403/02/22

Registrant information

Name

Fateme Ghaderi Varkani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-09, 1402/11/20

Expected recruitment end date

2024-08-10, 1403/05/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of diaphragm myofascial release on pain, disability, range of motion, kinesiophobia and quality of life in patients with chronic shoulder pain

Public title
Effects of diaphragm myofascial release on pain, disability, range of motion, kinesiophobia and quality of life in patients with chronic shoulder pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients suffering from chronic shoulder pain(More than three months have passed since the onset of symptoms) and with a referral from the specialist doctor Age range from 25 to 45 years both genders Has not received physiotherapy treatment in the last two months. Pain during activity or rest should be between 3 and 7 on the VAS scale. Having informed consent
Exclusion criteria:
Neurological problems (such as multiple sclerosis, stroke, etc.) Systemic diseases (such as rheumatism, fibromyalgia, etc.) History of previous surgery, fracture, shoulder dislocation A professional athlete who has intense upper limb activity during exercise. If, according to clinical examinations and joint play, it is determined that the pain is of capsular origin (such as a frozen shoulder) If clinical tests show that the pain has a neck origin (cervical radiculopathy). Osteoporosis, cancer Reluctance to continue treatment If it is found in the MRI image that the patient has a complete tendon rupture of even one of the rotator cuff muscles, or in clinical tests such as the drop arm test, it is found that one of the tendons of the shoulder is torn. BMI above 30 (obese people)
Age
From **25 years** old to **45 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 will be done using random allocation software and based on the random block method with a block size of 4 and with an allocation ratio of 1:1, and patients will be divided into intervention and control groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Patients in each group do not know about the other group. (Patients are blinded to study groups) The evaluator of variables before and after treatment is another physiotherapist who is blinded to the type of treatment and patients. (Assessor is blinded to study groups)
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 science
Street address
Tehran University of Medical Sciences Central Building, Qods St. intersection, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1416633591
Approval date
2024-02-09, 1402/11/20
Ethics committee reference number
IR.TUMS.FNM.REC.1402.201

Health conditions studied

1

Description of health condition studied
chronic shoulder pain
ICD-10 code
M25-9
ICD-10 code description
M25-5

Primary outcomes

1

Description
pain
Timepoint
Before starting the intervention and after completing 6 sessions of physiotherapy
Method of measurement
using VAS scale

2

Description
disability
Timepoint
Before starting the intervention and after completing 6 sessions of physiotherapy
Method of measurement
Using the SPADI questionnaire

3

Description
chest expansion
Timepoint
Before starting the intervention and after completing 6 sessions of physiotherapy
Method of measurement
Using a tape measure

4

Description
shoulder range of motion(flexion, abduction, external rotation)
Timepoint
Before starting the intervention and after completing 6 sessions of physiotherapy
Method of measurement
using a goniometer

5

Description
quality of life
Timepoint
before the intervention and one month after the completion of 6 physiotherapy sessions
Method of measurement
Using the SF-12 questionnaire

6

Description
kinesiophobia
Timepoint
Before starting the intervention and after completing 6 sessions of physiotherapy
Method of measurement
Using the tampa questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diaphragm myofascial release. In this group, in addition to routine physiotherapy, which includes the use of low-frequency TENS, IR (infrared) and therapeutic exercises at home and in the clinic, a type of manual therapy called myofascial release is also used for the diaphragm muscle. This manual therapy is considered as an effective technique to reduce pain and disability, which aims to restore the optimal length of fascial tissue. The treatment in this group lasts six sessions requiting the patient to be visited every other day. The diaphragm myofascial release technique is performed in two ways. In the first method, the patient is lying in supine postion and the therapist is placed on top of the patient's head, and the hypothenar area of both hands is located under the lower ribs, and the patient is asked to inhale and exhale. During inhalation, a force is applied in the direction of raising and pulling out the lower ribs, and during exhalation, manual resistance is applied. This technique is done in two sets with ten repetitions. In the next method, the patient lies prone. one hand of the therapist is placed on the popliteal area and the other hand is placed on the edge of the lower ribs on the same side. The patient performs inhalation and exhalation and both hands move away from each other during exhalation. After ten repetitions, this treatment is repeated for the other side as well.
Category
Rehabilitation

2

Description
Control group: Sham myofascial diaphragm release treatment. In this group, patients receive routine physical therapy that includes the use of low-frequency TENS, IR (infrared) and therapeutic exercises at home and in the clinic. The treatment in this group lasts six sessions requiting the patient to be visited every other day. Diaphragm myofascial release treatment in this group is sham. In this way, the hands are similar to the intervention group, but no effective force is applied to the person's body.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
rehabilitation school of Tehran university of medical science
Full name of responsible person
Fateme Ghaderi Varkani
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Tehran University of Medical Sciences, Ghods St., Enghelab 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

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

Fateme Ghaderi Varkani

Position

student of master

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Other areas of specialty/work

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Person responsible for updating data

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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
After analyzing the data, raw data are published in general.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
It will be published as an article and thesis file.
When the data will become available and for how long
After completing the study
To whom data/document is available
Students, professors and professionals
Under which criteria data/document could be used
Article
From where data/document is obtainable
People can refer to the first or responsible author to receive the study documentation after analyzing the data and writing the thesis. The access ways in order of priority are as follows: Fateme Ghaderi Varkani Email: Fateme1ghaderi@gmail.com Contact number: +989931496749 Address: Department of Physiotherapy, Rehabilitation Faculty of Tehran University of Medical Sciences, Enghelab St. Postal code: 1148965111
What processes are involved for a request to access data/document
Email to the responsible or first author
Comments