Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of combining diaphragmatic exercises and physiotherapy treatment with physiotherapy treatment alone in patients with chronic neck pain

Protocol summary

Study aim

The aim of this study was to compare the effect of combining diaphragmatic exercises and physiotherapy treatment with physiotherapy treatment alone on pain, disability, neck range of motion, chest movement during maximal inhalation and exhalation, forward head posture and upper thoracic angles in patients with chronic neck pain.

Design

A clinical trial with a control group, with parallel, double-blind, randomized groups, conducted a study on 30 patients, the site http://www.graphpad.com/ quickcalcs / index.cfm is used for randomization.

Settings and conduct

The study will be performed using the selection of patients referred to the clinic, based on admission criteria. Patients will be blinded by not knowing the type of treatment in the other group and the evaluator will be blinded by not knowing the grouping of patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women between the ages of 20 and 35 who have chronic neck pain without headache for at least three months, with forward head posture (CVA angle less than 49 degrees), paradoxical breathing, rated 3 or higher on visual analogue scales. Non-inclusion criteria: Cancellation by the patient for any reason, discomfort and intolerance of treatment by the patient, history of heart disease and heart surgery and pregnancy.

Intervention groups

Intervention group: They receive the usual treatment with diaphragmatic exercises, preferably 5 days a week for 10 sessions. Control group: They receive only the usual treatment.

Main outcome variables

Examination of these variables in the first session including age, height, weight, BMI and duration of disease Examining the following variables in the first, tenth and two weeks later sessions, including: Pain intensity Disability Active and passive neck range of motion Chest movement during maximal inhalation and exhalation Forward head posture and upper thoracic angles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210223050476N1**
Registration date: **2021-03-28, 1400/01/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-28, 1400/01/08**
Update count: **0**

Registration date

2021-03-28, 1400/01/08

Registrant information

Name

Sima mosallaiezadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of combining diaphragmatic exercises and physiotherapy treatment with physiotherapy treatment alone in patients with chronic neck pain

Public title

The effect of diaphragmatic exercises and physiotherapy on chronic neck pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with chronic neck pain without headache who have pain and discomfort in the back of the neck for at least three months Have forward head posture (CVA angle less than 49 degrees) Breathe paradoxically. Have a rating of 3 or higher in the visual analogue scales Have not undergone physiotherapy in the past three months to treat neck pain Be 20 to 35 years old. Have expressed their informed consent to participate in the research project.

Exclusion criteria:

Discontinuation of cooperation by the patient for any reason Feeling uncomfortable and intolerant of treatment by the patient History of heart disease and heart surgery Spine and chest surgeries History of smoking Traumatic neck injuries BMI > 40 Diabetes Acute neuromuscular pain and cervical disc prolapse with neurological symptoms Congenital malformations Cancer or tumor in the last 5 years Patients with sensory impairment Pregnancy

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The second therapist obtains a random sequence through http://www.graphpad.com/ quickcalcs / index.cfm which contains the number with the name of one of the groups (group A or B). Then each person with their eyes closed takes a number from the basket containing numbers from 1 to 30 to be placed in the group specified by the site. To maintain confidentiality, the type of group will not be known before assigning the person in each group. To make the type of treatment random in groups A and B, the second therapist rewrites the type of treatment on two separate cards and puts it in opaque sealed envelopes with a random sequence and then removes one of the envelopes with his eyes closed. The envelope that we will get first will be the type of group A treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be blinded to the type of intervention and the people in each group will not know about the other group. Variables are evaluated by the outcome assessor who is not aware of the grouping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research School of Nursing and Midwifery and School of Rehabilitation - Tehran U

Street address

Block A, 13th floor, Iran TV St, Between South Flamek and Zarafshan, Ghods Town (West), Tehran

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Province

Tehran

Postal code

1419733171

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.TUMS.FNM.REC.1399.114

Health conditions studied

1

Description of health condition studied

Study condition: Women with chronic neck pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity

Timepoint
The first, tenth and two weeks later
Method of measurement
Visual Analogue Scales

2

Description
Disability
Timepoint
The first, tenth and two weeks later
Method of measurement
Neck Disability Index

3

Description
Active and passive neck range of motion
Timepoint
The first, tenth and two weeks later
Method of measurement
Goniometer

4

Description
Chest movement during maximal inhalation and exhalation
Timepoint
The first, tenth and two weeks later
Method of measurement
Tape meter

5

Description
Forward Head Posture
Timepoint
The first, tenth and two weeks later
Method of measurement
Samsung Galaxy Tab A SM-T355 camera

6

Description
Upper Thoracic Angle
Timepoint
The first, tenth and two weeks later
Method of measurement
Samsung Galaxy Tab A SM-T355 camera

7

Description
Age
Timepoint
Before starting the intervention
Method of measurement
ID card or national card

8

Description
Height
Timepoint
Before starting the intervention
Method of measurement
Tape meter

9

Description
Weight
Timepoint
Before starting the intervention
Method of measurement
Digital bathroom scale

10

Description
Body Mass Index
Timepoint
Before starting the intervention
Method of measurement
Ratio of weight to height squared

11

Description
Duration of chronic neck pain
Timepoint
Before starting the intervention
Method of measurement
Question from the person

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: includes a combination of diaphragmatic exercises and physiotherapy treatment (TENS, IR and Exercise). Diaphragmatic exercises: In the first session, the subjects of the experimental group will be trained in diaphragmatic breathing. In the supine position, the trunk is in a position of 30-50 degrees of flexion and the knees are in a comfortable position of flexion. The person is asked to place their hands on the abdomen and breathe slowly and deeply using the nose for 10 seconds. The subjects held the diaphragmatic exercise while holding the 2.5 kg weight in the first 5 sessions and the 5 kg weight on the abdomen in the second 5 sessions, in three sets with ten repetitions in the ratio of one second to two seconds of exhalation, three The next set consists of 15 repetitions with a two-second to four-second exhalation ratio, and the final three sets consist of 20 repetitions with a three-second to six-second exhalation ratio. A period of 60 seconds is rested between sets. These exercises are done 5 days a week in 10 sessions. Electrical stimulation of TENS: TENS is made by Novin Multistimulator735X made in Iran for 30 minutes (four electrodes on painful areas around the

patient's neck with a frequency of 80 Hz, square pulse, duration of each pulse is less than 150 microseconds and the intensity is increased to the point of contraction. Not seen) is used. Infrared rays (IR): The IR of the Tavanbakhsh Novin made in Iran is placed on the neck and back for 20 minutes. Exercise: The Sternocleidomastoid and Upper Trapezious muscles stretching exercises are performed on both sides for 30 seconds with two to three repetitions in each session while sitting on a chair with the soles of the feet on the floor. Chin tuck head lift exercise with Hold and Rest for 10 and 15 seconds, respectively, in the first 5 sessions of each person on the bed with the angle of the head of the bed with the horizon line 60 degrees, and in each session, after each ten-second hold, we reduce the inclination of the head of the bed by ten degrees to apply a load, so that at the end this angle reaches a slope of 30 degrees, and in the second 5 sessions, to apply more load, each person on the bed has an angle. The head of the bed is placed with a horizon line of 30 degrees. And again in each session after each hold for ten seconds, we reduce the inclination of the head of the bed ten degrees until the end of the head of the bed is completely flat (the angle of the head of the bed with the horizon line reaches zero degrees) and each session of this exercise It is repeated ten times in all 4 types of head angle. The duration of each session is 60 to 70 minutes.

Category

Rehabilitation

2

Description

Control group: In the control group, only physiotherapy treatment (TENS, IR and Exercise) similar to the experimental group is used. The duration of each session is 60 to 70 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation of Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyed Mohsen Mir

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Pich Shemiran, Enghelab St., District 12, Tehran

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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

50

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

Sima Mosallaiezadeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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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

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

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

Title and more details about the data/document

Treatment is done in ten sessions and evaluation of variables in the first, tenth and two weeks later.

When the data will become available and for how long

Start of access period: 8 months after printing the results

To whom data/document is available

I and my advisor professors

Under which criteria data/document could be used

Under the supervision of me and my advisor professors

From where data/document is obtainable

Come to me. Email address: ptsimaa@gmail.com

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

Start of access period: 8 months after printing the results

Comments