

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the Effect of Diaphragm Release on Posture, Pain and Function in Women with Forward Head Posture and Neck Pain

Protocol summary

Study aim

The Effect of Diaphragm Release on Posture, Pain and Function in Women with Forward Head Posture and Neck Pain

Design

A randomized, controlled, single blinded clinical trial

Settings and conduct

In this clinical trial study, 52 individuals with forward head posture and neck pain will be randomly divided into two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1_women between 18 and 45 years old
2_The craniovertebral angle less than 49 degrees.
3_Patients who have a primary complaint of neck pain (pain in the posterior part of the cervical spine and the inter scapula region). 4- The subjects who have the tenderness in diaphragm. exclusion criteria: 1_ History of neck surgery. 2_History of any trauma to the cervical spine such as wiplash. 3_History of fracture in the neck. 4_History of any fracture in clavicle and ribs. 5_ Congenital deformity in the neck such as torticollis. 6_Respiratory disease.

Intervention groups

Group1: Diaphragm release and corrective exercise of forward head posture. Group2: corrective exercise of forward head posture only.

Main outcome variables

Craniovertebral angle, The Copenhagen questionnaire related to functional neck pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191116045461N1**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-23, 1398/10/02**

Update count: **0**

Registration date

2019-12-23, 1398/10/02

Registrant information

Name

Farzaneh Haghighat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 5108

Email address

haghighatf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Diaphragm Release on Posture, Pain and Function in Women with Forward Head Posture and Neck Pain

Public title

Release of Diaphragm in Forward Head Posture and Neck Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

women between 18 and 45 years old The posterior part of the ear's lobe is 1 cm or more anterior than plumb line. The craniovertebral angle less than 49 degrees. Patients who have a primary complaint of neck pain (pain in the posterior part of the cervical spine and the inter scapula region). The subjects have tenderness in the diaphragm. Average usage of smart phone and computer is 4 hours or more in 24 hours.

Exclusion criteria:

Auditory or visual impairment. Neurological problem. Impairment in balance. History of neck surgery. History of any trauma to the cervical spine such as wiplash. Perceptual problems Inflammatory disease such as rheumatoid arthritis. History of any fracture in cervical region. History of any fracture in clavicle and ribs. Congenital deformity in the neck such as torticollis. Respiratory disease and Zona Whose who have had regular, scheduled workouts in the past 6 months. Professional athletes

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Volunteer patients are randomly assigned to one of two intervention or control groups with blocked randomization method. six blocks with the size of four were considered and 26 subjects were placed in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients become aware of the second group when filling out the informed consent form so they will not be blind to the groups. Therapists are also aware of both groups and types of treatment, But the patients examiner and analyzer are completely unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of research of Shiraz Faculty of Rehabilitation Sciences

Street address

Abivardi 1 Street., Chamran Blvd

City

Shiraz

Province

Fars

Postal code

۳۳۶۶۹_۷۱۹۴۷

Approval date

2019-03-18, 1397/12/27

Ethics committee reference number

IR.SUMS.REHAB.REC.1397.022

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

Forward head posture, Neck pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The extent of postural changes is determined by neck imaging and cranio-vertebral angle determination. Such a Copenhagen questionnaire on functional pain in the neck, whose validity and reliability of the Persian version has been confirmed, is completed by the patients.

Timepoint

Before the intervention and after the intervention

Method of measurement

The Craniovertebral angle (CVA) will be measured in order to assess the posture. The CVA is the angle made by the line that drawn from the seventh cervical spine to the tragus and the horizontal line of the seventh cervical spine, This angle represents the position of the head relative to the C7 vertebra, which is less than 49 degrees in people with forward head posture. The lowering this angle measured, the greater the forward head. In this research the CVA angle is measured by Left-sided profile photograph. For this purpose a camera with 35-70mm zoom lens is mounted on a tripod and loaded with slid film will be used. The lens aperture is set at F-stop 8, zooms to 70mm, and the camera is placed so that the center of the lens is 4m from the subject, with the subject in approximately the center of the lens so as to reduce lens error, and in order to observe this distance, At a distance of 4 meters from the camera, a line is drawn on the ground, and the person standing must make sure that the toe tip is on that line, ie the legs are completely behind the line. The front of the camera stand is located 120 cm from the wall, and the location of

the camera stand on the ground is marked, as well as the location of the rear camera stand on each test run. and with the camera perpendicular to the ground, parallel to the facing plane of the subject, and approximately level with the subject's pelvis to minimize parallax error. (Gonia is used to determine the camera frame, which is plotted 90 degrees on the wall using a Gonia angle, and the angles are colored on the wall), to ensure that the head does not rotate. A circular frame, parallel to the patient's eye, is mounted on the wall in front of the patient and the patient is asked to look at it. The patient's neck and upper thoracic area will be naked and will be photographed from the same range. The same conditions will apply to everyone taking photos. To commence, Bony landmarks are palpated and marked with adhesive skin markers that will be visible in photographs. Subjects stand in comfortable erect standing, the instructions being to place their weight evenly on both feet, with knees straight, hands at their sides, and with their eyes looking forward. For to touch the C7 bends the head forward, in which case the C7 vertebrae can be touched, and the patient is then asked to bring his head back, in which case the C7 vertebrae should not disappear underneath. The palpation and marking is carried out in the same standing position as the subject will later adopt for the photographs, to reduce any error that might have occurred from skin movement. If clothing is overlying a bony landmark it is moved aside Until Landmark is clear. White adhesive dots of 14mm diameter are used as skin markers. Since marking the subjects required them to stand still, they are encouraged to walk around after the markers are applied, to prevent them from feeling uncomfortable or becoming faint. In order to be photographed, the subjects are next instructed to stand comfortably, in their "normal, loose, or habitual" posture for two photographs, with their weight evenly on both feet and looking straight ahead. They are asked not to stand erect, or in a "best posture," because the purpose of the photograph is to capture their habitual or usual standing posture. Subjects are given time to adopt a relaxed, comfortable posture, and then photograph is taken from the left side. The Persian version of the Copenhagen Scale is used to assess the severity of functional neck pain.

Secondary outcomes

1

Description

chest expansion

Timepoint

Before the intervention and after the intervention

Method of measurement

Chest expansion: Chest expansion is measured with the subject standing, hands on head and the tape is placed circumferentially over the xiphoid. The subject is inhaled maximally, then exhaled, and a value is recorded; the subject then is inhaled maximally and a second value is recorded. Total change is recorded as the value at maximum inspiration minus the value at maximum

expiration.

Intervention groups

1

Description

Intervention group: Diaphragm release technique will be done in the interventional group in the following way: Each subject is positioned seated erect. The therapist stands behind the patient and passes his hands around the thoracic cage, carefully introducing fingers under the costal margin. The patient slightly rounds the trunk in order to relax rectus abdominis. As the patient exhales the therapist grasps the lower ribs and costal margin and eases their hand caudally. This traction is maintained during 5 to 7min. This techniques will only once a week completed once a week and each session will be held once. (during this 4 weeks, diaphragm release technique will be performed once a week for four weeks). Also Patient in this group receive a specific exercise program for 3session a week for 4 weeks. This exercise program include strengthening of deep cervical flexor and shoulder retractor muscle and stretching of cervical extensor and pectoral muscles.

Exercise Measures Strengthen Deep Cervical Flexors Lying chin tuck Lying chin tuck with head lift(4s) Three sets of 12 repetitions Three sets of 12 repetitions Strengthen Shoulder Retractors Standing shoulder pull back with elastic resistance Shoulder pull back with weight (2 lb) Three sets of 12 repetitions Three sets of 12 repetitions Stretch Cervical Extensors Chin drop Three repetitions with 30-sec hold Stretch Pectoralis Muscle Bilateral Pectoral stretch Three repetitions with 30-sec hold

Category

Rehabilitation

2

Description

Control group: Patient in this group receive a specific exercise program for 3session a week for 4 weeks. This exercise program include strengthening of deep cervical flexor and shoulder retractor muscle and stretching of cervical extensor and pectoral muscles.

Exercise Measures Strengthen Deep Cervical Flexors Lying chin tuck Lying chin tuck with head lift(4s) Three sets of 12 repetitions Three sets of 12 repetitions Strengthen Shoulder Retractors Standing shoulder pull back with elastic resistance Shoulder pull back with weight (2 lb) Three sets of 12 repetitions Three sets of 12 repetitions Stretch Cervical Extensors Chin drop Three repetitions with 30-sec hold Stretch Pectoralis Muscle Bilateral Pectoral stretch Three repetitions with 30-sec hold

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz School of Rehabilitation

Full name of responsible person

Farahnaz Ghafari Nejad

Street address

Abivard1 Street., Chamran Blvd

City

Shiraz

Province

Fars

Postal code

۳۳۶۶۹_۷۱۹۴۷

Phone

+98 71 3627 1551

Fax

+98 71 3627 2495

Email

fghafarinejad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farahnaz Ghaffarnejad

Street address

Zand Street, opposite Palestine Street, Central
Building of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

۱۳۳۳۶_۷۱۳۴۸

Phone

+98 71 3230 5410

Fax

+98 71 3235 9317

Email

vcrdep@sums.ac.ir

Web page address

<http://www.sums.ac.ir>

Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Farahnaz Ghaffarnejad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Abivardi 1 st, chamran Blvd

City

Shiraz

Province

Fars

Postal code

۳۳۶۶۹_۷۱۳۴۸

Phone

+98 71 3627 1551

Fax

+98 71 3627 2495

Email

ghafarif@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farahnaz Ghaffarnejad

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Faculty of Rehabilitation, chamran Boulevard, 1
Abivardi Ave.

City

Shiraz

Province

Fars

Postal code

۳۳۶۶۹_۷۱۹۴۷

Phone

+98 71 3627 1551

Fax

+98 71 3627 2495

Email

haghighatf@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farahnaz Ghaffarnejad

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Abivardi 1 St, Chamran Blvd

City

Shiraz

Province

Fars

Postal code

۳۳۶۶۹_۷۱۹۴۷

Phone

+98 71 3627 1551

Fax

+98 71 3627 2495

Email

fghafarinejad@yahoo.com

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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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