Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 gruops.

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 interventiont and after the intervention

Method of measurement
The Craniovertebral angle (CVA) will be measured in order to asses 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 7Omm, 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 subjec 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 re- corded 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 we 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.
ExerciseMeasuresStrengthen 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 repetitionsThree sets of 12 repetitionsStretch Cervical Extensors Chin drop Three repetitions with 30-sec holdStretch Pectoralis MuscleBilateral Pectoral stretchThree 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.
ExerciseMeasuresStrengthen 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 repetitionsThree sets of 12 repetitionsStretch Cervical Extensors Chin drop Three repetitions with 30-sec holdStretch Pectoralis MuscleBilateral Pectoral stretchThree 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
۱۴۳۳۶_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 Siences

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