Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of deep neck muscles specific training compared to general training on pain, disability, functional indices and neck muscles thicknesses in patients with chronic non-specific neck pain

Protocol summary

Study aim
The aims of the present study are to investigate and compare the effects of deep neck muscles specific exercises versus general exercises on pain, disability, functional indices, and neck muscles' thicknesses in patients with chronic non-specific neck pain.

Design
Single-blinded randomized control trial.

Settings and conduct
Participants will be assigned to one of the two exercise groups, specific neck exercises versus general exercises. specific neck exercises: nodding with and without eye movement, isometric head extension. General exercises: active range of motion of the neck and the shoulder joint.The primary outcomes: pain, disability, and neck muscles' thicknesses. The secondary outcomes: sleep quality, fear-avoidance, and quality of life. The day before starting the 8-week exercise program and the day after finalizing it the primary and secondary outcomes will be measured. participants will be blinded. None of the participants will be aware of the other training group

Participants/Inclusion and exclusion criteria
A total number of 64 patients with chronic non-specific neck will participate in this study. The inclusion criteria for this study include the presence of neck pain for at least 3 months in the past year with a pain intensity of 30 mm or more on the visual analog scale. Patients with acute neck pain or any history of spinal congenital deformity, trauma, surgery, and inflammatory diseases will be excluded.

Intervention groups
Two intervention groups including specific and general neck exercise groups. Deep neck muscles specific exercises: nodding with and without eye movement, isometric head extension. General exercises: active range of motion of the neck, shoulder joint, seated push-up, and shoulder shrugs.

Main outcome variables
pain, disability and neck muscles thicknesses, and cervical joint repositioning error (added in the amendment)

General information

Reason for update
To adapt the new version of IRCT software

Acronym

IRCT registration information
IRCT registration number: **IRCT2017091620787N2**
Registration date: **2017-11-11, 1396/08/20**
Registration timing: **prospective**

Last update: **2021-02-07, 1399/11/19**
Update count: **1**

Registration date
2017-11-11, 1396/08/20

Registrant information

Name
Leila Rahnama

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2218 0039

Email address
l.rahnama@uswr.ac.ir

Recruitment status
Recruitment complete

Funding source
University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2017-11-15, 1396/08/24

Expected recruitment end date

2019-03-18, 1397/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of deep neck muscles specific training compared to general training on pain, disability, functional indices and neck muscles thicknesses in patients with chronic non-specific neck pain

Public title

The effects of neck specific and general exercises on pain and functional indices in patients with neck pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A positive history of neck pain for at least three months in the past year Pain intensity of more than 30 mm on visual analogue scale Non-specific neck pain

Exclusion criteria:

Acute neck pain A positive history of spine surgery Cervical Fracture or tumor Discopathy or radicular pain distributed in to shoulder or presence of any neurogenic signs History of cervical trauma or car accident Congenital spinal abnormality Systemic inflammatory diseases Vertigo and vestibular disorders Diabetes Receiving any shoulder or neck muscles training , physiotherapy or manual therapy on the neck in the past 6 months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using sealed envelopes. Each participant will choose one of the sealed envelopes to be allocated to one of the exercise groups. The envelope will then be returned to the envelope box. Randomization will be carried out by someone who is not involved in evaluation or treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

None of the participants will be aware of the other training group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Board, University of Social Welfare and Rehabilitation Sciences

Street address

Velenjak, Koudakyar dead end

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2017-09-25, 1396/07/03

Ethics committee reference number

IR.USWR.REC.1396.194

Health conditions studied

1

Description of health condition studied

Chronic non-specific neck pain

ICD-10 code

R52.2

ICD-10 code description

Other Chronic Pain

Primary outcomes

1

Description

Pain

Timepoint

One day before the starting the exercise program and one day after finalizing the 8-week exercise program. Pain will also be measured before and immediately after each exercise session.

Method of measurement

visual analog scale

2

Description

Disability

Timepoint

One day before the starting the exercise program and one day after finalizing the 8-week exercise program.

Method of measurement
Neck disability index (NDI) questionnaire, Persian version

3

Description
Neck muscle thickness
Timepoint
One day before the starting the exercise program and one day after finalizing the 8-week exercise program.
Method of measurement
Ultrasound device with a 45-millimeter linear array probe and frequency of 12 MHz for neck flexor muscles and 6 MHz for neck extensor muscles.

4

Description
Cervical Joint Position Error
Timepoint
One day before the starting the exercise program and one day after finalizing the 8-week exercise program.
Method of measurement
Subjects had to rotate their head from a relaxed position, turn to one direction and return to the original position. A laser pointer was used to measure the cervical joint repositioning error. The angle between the target and reference point in degrees will be defined as the joint position error. This variable has been added to the trial when IRB approval was received for the additions to the main protocol.

Secondary outcomes

1

Description
Sleep quality
Timepoint
One day before the starting the exercise program and one day after finalizing the 8-week exercise program.
Method of measurement
Pittsburgh Sleep Quality Index, Persian version

2

Description
Neck range of motion
Timepoint
One day before the starting the exercise program and one day after finalizing the 8-week exercise program.
Method of measurement
Goniameter

3

Description
Neck Muscles Maximum Isometric Voluntary Contraction
Timepoint
One day before the starting the exercise program and one day after finalizing the 8-week exercise program.
Method of measurement
Tensiometer unit for extensor muscles and Pressure Biofeedback Unit for flexor muscles

4

Description
Quality of life
Timepoint
One day before the starting the exercise program and one day after finalizing the 8-week exercise program.
Method of measurement
Sf-36 questionnaire, Persian version

5

Description
Fear avoidance
Timepoint
One day before the starting the exercise program and one day after finalizing the 8-week exercise program.
Method of measurement
Tampa Scale of Kinesiophobia, Persian version

Intervention groups

1

Description
Deep neck muscles specific exercises: 1) IN the supine position, the participant moves his/her eyes upward without any movement on the head and neck as much as possible and holds it for 5 seconds. Then the participant moves his/her eyes downward as much as possible and holds it for 5 seconds. 2) In the supine position the participant performs a light isometric nodding along with moving his/her eyes from forward to downward. A gentle pressure will be applied to the participant’s chin with his/her own hand. This exercise will be held for 5 seconds. 3) In the supine position the participant presses his/her occiput area with submaximal pressure to the bed and holds it for 5 seconds. 4) In the supine position the participant performs the nodding exercise by closing his/her chin to the sternum and holds it for 5 seconds. All exercises will be performed three times a week, three trials in a day, and five repetitions in each trial. One trial will be performed under the examiner supervision and the other two trials will be performed by the participants themselves. The aim is to improve the exercises to 20 repetitions in each trial.
Category
Rehabilitation

2

Description
General exercises: 1) Neck active free range of motion in flexion, extension, bilateral side flexion and bilateral rotation while the participant is seated. 2) Shoulder active free range of motion in flexion, extension, abduction, adduction and internal and external rotation while the participant is seated. 3) Seated push-ups. 4) Seated shoulder shrug exercise while the participant holds a one Kg weight in his/her hands. All exercises will be performed three times a week, three trials in a day,

and five repetitions in each trial. One trial will be performed under the examiner supervision and the other two trials will be performed by the participants themselves. The aim is to improve the exercises to 20 repetitions in each trial.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
University of Social Welfare and Rehabilitation Scienses and the related hospitals

Full name of responsible person
Pegah Kashfi

Street address
velenjak, koudakyar dead end

City
Tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 2218 0083

Email
pegah.kashfi@yahoo.com

2

Recruitment center

Name of recruitment center
Shahid Beheshti University of Medical Sciences and its related hospitals

Full name of responsible person
Pegah Kashfi

Street address
Velenjak, Koudakyar dead end

City
Tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 2218 0083

Email
pegah.kashfi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Dr. Hamid-Reza Khankeh

Street address
Velenjak, Koudakyar dead end

City
Tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 2218 0083

Email
pegah.kashfi@yahoo.com

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
Pegah Kashfi

Position
Physiotherapy MSc student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
velengak, koudakyar dead end

City
Tehran

Province
Tehran

Postal code
۱۹۸۵۷۱۳۸۳۴

Phone
+98 22180084

Fax

Email
pegah.kashfi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Social Welfare and Rehabilitation Scienses

Full name of responsible person
Dr. Leila Rahnama

Position
PhD

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
velenjak, koudakyar dead end

City
Tehran

Province
Tehran

Postal code
۱۹۸۵۷۱۳۸۳۴

Phone
+98 22180084

Fax

Email
l.rahnama@uswr.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
University of Social welfare and Rehabilitation Sciences

Full name of responsible person
Dr. Leila Rahnama

Position
PhD, Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
velenjak, Koudakyar dead end

City
Tehran

Province
Tehran

Postal code
۱۹۸۵۷۱۳۸۳۴

Phone
+98 21 2218 0085

Fax

Email
lrahnama@gmail.com

Web page address

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
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
Undecided - It is not yet known if there will be 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