

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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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

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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

Goniometer

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 Sciences and the related hospitals

Full name of responsible person

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Recruitment center

Name of recruitment center

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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

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

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Person responsible for scientific inquiries

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PhD

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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

Person responsible for updating data

Contact

Name of organization / entity

University of Social welfare and Rehabilitation Sciences

Full name of responsible person

Dr. Leila Rahn timer

Position

PhD, Assistant Professor

Latest degree