

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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###### Email address

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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**

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**

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

Pegah Kashfi

##### Street address

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### 2

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti University of Medical Sciences and its related hospitals

##### Full name of responsible person

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## 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

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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

### Contact

**Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences

**Full name of responsible person**

Dr. Leila Rahnama

**Position**

PhD

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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**

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 Rahnama

**Position**

PhD, Assistant Professor

**Latest degree**