

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Isometric Exercises on Disability and Pain of Cervical Spondylosis

Protocol summary

Study aim

Determining the effectiveness of isometric neck exercises on pain and disability of cervical spondylosis

Design

Single-blind randomized clinical trial with a control group (1:1), parallel design of 24 patients with chronic neck pain, enrolled between January 2017 and March 2017, followed for 4 weeks. Excel software's rand function was used for randomization. Random allocation concealment was performed using sealed opaque envelopes.

Settings and conduct

The main location of the trial is the rheumatology clinic of Vali-e-Asr hospital, Zanjan, Iran. Intervention group performed neck isometric exercises 6 days a week for 4 weeks as 3 sets/day, each set consists of 6 movements, holding each movement for 10 seconds, and repeating each 5 times with a 5-second rest between them. Data analysts and the outcome assessor are masked.

Participants/Inclusion and exclusion criteria

Patients >18 years with chronic neck pain, clinical findings and signs on cervical magnetic resonance imaging compatible with cervical spondylosis, without acute cervical nerve root compression, without neck surgical indications, not receiving exercise therapy or physiotherapy during the 6 weeks prior to the study are included in the trial. A history of neck surgery over the past year, history of inflammatory diseases involving the neck joints, history of fractures or dislocations of the cervical vertebrae, pregnant women, either patients who did not have a good compliance with the intervention or had difficulty following the study and a history of myelopathy are excluded.

Intervention groups

1. Intervention group receiving home-based neck isometric strengthening exercises. 2. Control group receiving no intervention.

Main outcome variables

1. Cervical disability score on the Neck Disability Index 2. Neck Pain score on the Neck Pain and Disability Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220206053950N1**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **retrospective**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

Mina Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2017-02-03, 1395/11/15

Actual recruitment start date

2017-01-04, 1395/10/15

Actual recruitment end date

2017-02-09, 1395/11/21

Trial completion date

2017-03-11, 1395/12/21

Scientific title

Effectiveness of Isometric Exercises on Disability and Pain of Cervical Spondylosis

Public title

Effectiveness of Isometric Exercises on Disability and Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients >18 years Clinical findings of cervical spondylosis (mild to moderate) such as stiffness, chronic neck weakness, radicular or non-radicular neck pain Chronic pain (at least 3 months) Without acute cervical nerve root compression Without surgical indications With a physical examination compatible with cervical spondylosis and with signs on cervical magnetic resonance imaging (MRI) compatible with cervical spondylosis Not receiving exercise therapy or physiotherapy during the 6 weeks prior to the study

Exclusion criteria:

A history of neck surgery over the past year A history of inflammatory diseases involving the neck joints myelopathy A history of fractures or dislocations of the cervical vertebrae Pregnant women Either patients who did not have a good compliance with the intervention or had difficulty following the study A history of myelopathy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **22**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Microsoft Excel program was used to allocate participants randomly to each group using Blocked randomization with randomly varying blocks (block size 4 and 8). Concealed opaque envelopes identifying the assignments to each group were randomly chosen by participants.

Blinding (investigator's opinion)

Single blinded

Blinding description

Initially, the outcome assessor, who is blind to the allocation of the study groups, evaluated all study participants in terms of clinical outcomes. Participants then go to the therapist with an envelope containing their random allocation for intervention. The therapist is an experienced physiotherapist and exercise therapist who is not blind group allocations. The therapist is not involved in other parts of the study. Then, depending on the allocation of the participants, the therapist either

teaches them the exercises (intervention group) or does not teach them (control group). After four weeks, the clinical outcomes are re-evaluated by the same clinical outcome assessor and the data are collected and made available to data analysts who are blind to group allocations. It should be noted that, given the nature of the intervention, which is a type of exercise therapy, and the fact that the control group did not receive any intervention, it was naturally not possible to blind the participants and the therapist during the clinical trial.

Placebo

Not used

Assignment

Parallel

Other design features

Exercise therapy group performs home-based neck isometric strengthening exercises 6 days a week for 4 consecutive weeks as 3 sets/day (morning, afternoon, evening), Each set consists of 6 movements, holding each movement for 10 seconds, and repeating each 5 times with a 5-second rest between each of them.

Secondary Ids

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

Room No. 22, First Floor, Ethics Committee in Biomedical, Vice-Chancellor for Research and Technology, Azadi Blvd., Zanjan

City

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Province

Zanjan

Postal code

4515613191

Approval date

2016-12-20, 1395/09/30

Ethics committee reference number

ZUMS.REC.1395.222

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

Cervical spondylosis

ICD-10 code

M47.812

ICD-10 code description

Spondylosis without myelopathy or radiculopathy, cervical region

Primary outcomes

1

Description

Cervical disability score on the Neck Disability Index (NDI)

Timepoint

At the beginning of the study (before the intervention) and 4 weeks after the initiation of the exercise therapy

Method of measurement

Neck Disability Index (NDI) score

2

Description

Neck Pain score on the Neck Pain and Disability Scale (NPAD)

Timepoint

At the beginning of the study (before the intervention) and 4 weeks after the initiation of the exercise therapy

Method of measurement

The Neck Pain and Disability Scale (NPAD)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: received home-based neck isometric strengthening exercises 6 days a week for 4 consecutive weeks as 3 sets/day (morning, afternoon, evening), Each set consisted of 6 movements, holding each movement for 10 seconds, and repeating each 5 times with a 5-second rest between each of them.

Category

Rehabilitation

2

Description

Control group: did not receive the intervention during this period.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr Hospital, Zanjan University of Medical Sciences

Full name of responsible person

Alireza Sadeghi

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Vali-e-Asr Hospital, Vali-e-Asr square, Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mina Rostami

Position

General physician

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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

There is 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