Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
Zanjan

Province
Zanjan

Postal code
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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
Street address
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
Dr. Samad Nadri
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Phone
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Email
Research@zums.ac.ir
Web page address
https://zums.ac.ir/
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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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