

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Treatment methods based on Strength-Endurance exercise with and with out Thoracic Manipulation to Improve the body Balance , Pain and Disability of patients with Non Specific chronic Neck pain

Protocol summary

Study aim

Comparison of Treatment methods based on Strength-Endurance exercise with and with out thoracic Manipulation to improve the body balance , pain and disability of patient with non specific chronic Neck pain

Design

Block Randomized Allocation with control group, parallel group Trial with Double blinded outcome assessment, with 40 participants

Settings and conduct

School of Rehabilitation Shiraz University sciences. All the patients are blinded and assessments in this study are done by trained physiotherapist who is unaware from patient classifications in two group. Intervention group will revive another intervention in addition of control group.

Participants/Inclusion and exclusion criteria

inclusion criteria: 18 - 60 yeaes old patient with the history of neck pain for more than 3 months, scoring 15_24 on neck disability index that shows moderate pain, scoring 31-69 millimeters on visual analouge scale, exclusion criteria: nerve injury or spinal cord compression, surgery, instability and whiplash injury, cancer, balance disturbance and dizziness,

Intervention groups

At the beginning, patients with non specific chronic neck pain fill out the personal information questionnaires, then their pain , disability and balance will be measured. after that in intervention and control group will be done strength-Endurance exercise for six weeks then we ask both group to do the exercise two times a day. these exercise include the progressive strength-Endurance training while the patient supine and prone lying with head support then bring up his head until the neck is bending. in intervention group manipulation must be done in 3 sessions every 4 days in supine position. after six weeks of doing these exercises patients pain, neck

disability and balance will be measured again.

Main outcome variables

Changes in Balance, Pain and Neck Disability Index after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181020041395N1**

Registration date: **2018-12-21, 1397/09/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-21, 1397/09/30**

Update count: **0**

Registration date

2018-12-21, 1397/09/30

Registrant information

Name

Amir Eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3233 4982

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Treatment methods based on Strength-Endurance exercise with and with out Thoracic Manipulation to Improve the body Balance , Pain and Disability of patients with Non Specific chronic Neck pain

Public title
Checking the effect of exercise in balance

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
the history of neck pain for more than 3 months Scoring 15 - 24 on Neck Disability Index Scoring 31-69millimeters on Visual Analoge Scale 18- 60 years old patient
Exclusion criteria:
Nerve injury or spinal cord compression Surgery , Instability , truma and Whiplash injury Cancer Sever osteoporosis history of Traumatic Brain Injury Increase pain as much as the patient would not cooperate with treatment Balance disturbance and dizziness

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Random Allocation In this case different situation that patient classify in 2 group will be written. then these six situation (ABAB, BABA , AABB, BBAA ,ABBA, BAAB) will be put in six sealed enveloped and patient will be divided by random withdrawal to put in 2 groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
All the patients are blinded and the assessments in this study are done by trained physiotherapist who is unaware from patients classifications in two group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central bulding of Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number

IR.SUMS.REC.1397.512

Health conditions studied

1

Description of health condition studied

Non specific chronic Neck pain

ICD-10 code

M62.9

ICD-10 code description

Disorder of muscle, unspecified

Primary outcomes

1

Description

Balance based on Balance Error Scoring System

Timepoint

Beginning of research and seven Weeks after started intervention

Method of measurement

Balance Error Scoring System

Secondary outcomes

1

Description

Pain based on Visual Analogue Scale

Timepoint

Beginning of research and seven weeks after started intervention

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention Group: At the beginning, patients with non specific chronic neck pain fill out the personal information questionnaires, then their pain , disability and balance will be measured. after that in intervention and control group will be done strength-Endurance exercise for six weeks then we ask Intervention group to do the exercise two times a day not more than 20 minutes.these exercise include the progressive strength-Endurance training while the patient supine and prone lying with head support then bring up his head until the neck is bending. in intervention group manipulation must be done in 3 sessions every 4 days in supine position.after six weeks of doing these exercises patients pain, neck disability and balance will be measured again.

Category

Rehabilitation

2

Description

Control group: At the beginning, patients with non specific chronic neck pain fill out the personal information questionnaires, then their pain , disability and balance will be measured. after that in control group will be done strength-Endurance exercise for six weeks then we ask control group to do the exercise two times a day not more than 20 minutes.these exercise include the progressive strength-Endurance training while the patient supine and prone lying with head support then bring up his head until the neck is bending. after six weeks of doing these exercises patients pain, neck disability and balance will be measured again.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz School of Rehabilitation Sciences

Full name of responsible person

Amir Eskandari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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Vice Chancellor of Research, Central bulding of Shiraz
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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Amir Eskandari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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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

No more information is 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