Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of craniocervical flexion training on head and neck dynamic postural response during head perturbation in patients with chronic neck pain

Protocol summary

Study aim

The main objective is to evaluate the effect of craniocervical flexion training (CCFT) along with proprioception training (ProT) on head and neck postural control in patients with chronic neck pain, and to compare it with placebo group which perform only the (ProT). In addition, the effect of this training on pain intensity and neck disability index will be evaluated.

Design

Two groups, parallel, 30 samples, randomized controlled trial, randomized by blocked balanced randomization method, single blinded (participants blinding)

Settings and conduct

The postural stability test equipments place at an empty room separately from the intervention site. Trainings will be performed at exercise section of physical therapy clinic, with supervision of physical therapist. In this study participants are blinded. Grouping is done before study beginning and samples will not know about that. Explanation of treatment method to both groups will be similar. Also, participants perform their trainings separately.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18-55 years Neck pain with or without referral pain for at least 3 months Pain intensity of less than 60 millimeters, based on visual analog scale Neck disability index range of 5.5 to 15.5 Exclusion criteria: Any regular treatment in recent 3 months Cervical pathologies or obvious postural disorders Cervical myelopathy or radiculopathy History of head and neck trauma or surgery Tensional or cervicogenic headache

Intervention groups

Both group's participants perform cervical proprioception training. Intervention group perform craniocervical flexion training as well ,but placebo group do craniocervical flexion with the target pressure less than 15 mmHg (the minimal detectable change in pressure biofeedback).

Main outcome variables

Head and upper cervical spine postural angles Lower cervical spine postural angles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230620058545N1**
Registration date: **2023-07-08, 1402/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-08, 1402/04/17**
Update count: **0**

Registration date

2023-07-08, 1402/04/17

Registrant information

Name

Maryam Javani Vardin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 2059

Email address

javanimaryam97@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of craniocervical flexion training on head and neck dynamic postural response during head perturbation in patients with chronic neck pain

Public title
Effect of craniocervical flexion training on neck stability in patients with neck pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 18-55 years old, able to read and write Persian language Neck pain with or without referral pain to occiput, shoulder or upper limb for at least recent 3 months Pain intensity of less than 60 millimeters, based on visual analog scale Neck disability index range of 5.5 to 15.5
Exclusion criteria:
Regular exercise in recent 3 months Physical therapy or manual therapy in recent 3 months or regular antiinflammatory drugs consumption in recent 48 hours Cervical pathologies or obvious postural disorders Cervical disc herniation with radicular pain, myelopathy, radiculopathy, canal stenosis and progressive spondylosis History of surgery or trauma in head and neck Neurological, visual and vestibular disorders Tensional or cervicogenic headache Trigger points as the only pain source
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocked balanced randomization method, by using the generator's list website was applied. Randomized numbers were determined by 4-items blocks before the trial's beginning. Blocks contain 2 even and 2 odd numbers which each number represents each sample. Even numbers represents the samples of intervention group and odd numbers are counted as the samples of placebo group. Physical therapist conserved the results and samples will be uninformed.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this trial, participants will be uninformed about the group that they're belonged to. Both group's participants perform cervical proprioception training. Intervention group perform craniocervical flexion training as well ,but placebo group do craniocervical flexion until 15 mmHg (the minimal detectable change in pressure biofeedback). Participants of each group perform their training separately to remain unknowing about their groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of medical science
Street address
IUMS School of Rehabilitation Science, Madadkaran Ave., Shah-nazari Street, Madar Square, Mirdamad Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2023-06-24, 1402/04/03
Ethics committee reference number
IR.IUMS.REC.1401.065

Health conditions studied

1

Description of health condition studied
Cervical dynamic postural instability
ICD-10 code
M53.2X2
ICD-10 code description
Spinal instabilities, cervical region

Primary outcomes

1

Description
Upper and lower cervical postural angles
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
Dynamic postural angles are measured by quick release

system to apply perturbation, camera for recording slow motion videos and kinovea software in order to calculation of angles.

Secondary outcomes

1

Description
Pain intensity
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
It is measured by visual analogue scale.

2

Description
Neck disability index
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
It is measured by neck disability index questionnaire.

Intervention groups

1

Description
Intervention group: Intervention consists of 6 weeks training (12 sessions); proprioception and craniocervical flexion trainings. Proprioception trainings include cervical movement sense, cervical joint position sense, and oculomotor control which they are all performed in sitting position on chair, with a laser pointer on head, and 90 centimeters distance from the target on the wall. In order to do craniocervical flexion training, physiotherapist educates participants the appropriate performance first and then they are asked to perform it by a pressure sensor and gradually increase the range of craniocervical flexion motion from 20 mmHg to 30 mmHg as the target.
Category
Rehabilitation

2

Description
Control group: Control group: Intervention consists of 6 weeks training (12 sessions); proprioception and placebo craniocervical flexion trainings. Proprioception trainings are same as intervention group and include cervical movement sense, cervical joint position sense, and oculomotor control which they are all performed in sitting position on chair, with a laser pointer on head, and 90 centimeters distance from the target on the wall. Placebo craniocervical flexion training has same steps to the original training that consists educating participants about the appropriate performance and doing that by a pressure sensor; but physiotherapist ask them to begin with 8 mmHg and increase the range of craniocervical flexion motion to 10 or 12 mmHg (less than minimal detectable change in pressure biofeedback) as the target.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Sepanta physiotherapy clinic
Full name of responsible person
Maryam Javani Vardin
Street address
No. 98, Shahid Atayi (4th) Street, 1st square, Fardis town
City
Fardis
Province
Alborz
Postal code
3175796469
Phone
+98 26 3666 6675
Email
javanimaryam97@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Kazem Mousavizade
Street address
IUMS school of rehabilitation science, Madadkaran Ave., Shah-nazari Street, Madar Square, Mirdamad Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 2059
Email
javanimaryam97@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Maryam Javani Vardin
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
IUMS School of Rehabilitation Science, Madadkaran Ave., Shah-nazari Street, Madar Square, Mirdamad Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 2059
Fax
Email
javanimaryam97@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Maryam Javani Vardin
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
IUMS School of Rehabilitation Science, Madadkaran Ave., Shah-nazari Street, Madar Square, Mirdamad Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 2059
Fax
Email
javanimaryam97@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Maryam Javani Vardin
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
IUMS School of Rehabilitation Science, Madadkaran Ave., Shah-nazari Street, Madar Square, Mirdamad Blvd., Tehran
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Province
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Postal code
1545913487
Phone
+98 21 2222 2059
Fax
Email
javanimaryam97@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Title: Head and neck postural angles change Head and neck postural angles change as the primary outcome measurement, will be shared after individuals deidentification.
When the data will become available and for how long
Availability period will start after the end of sampling and data analysis, since 2024 and there will be no time limit.
To whom data/document is available
Study results data will be available for all patients, students and researchers work in academic institution or

businesses who apply.

Under which criteria data/document could be used

There are no limits to use the study results and applicants can take advantage of unidentified individuals data in other researches، health and medical usage.

From where data/document is obtainable

Applicants can get access to study data at rehabilitation school of IUMS and websites related to scientific journals, after publishing.

What processes are involved for a request to access data/document

Applicants must write the application letter to research office of rehabilitation faculty and after justification receipt, they can get access to the study. Also, after publishing in journals, study will be available after the journal approval.

Comments